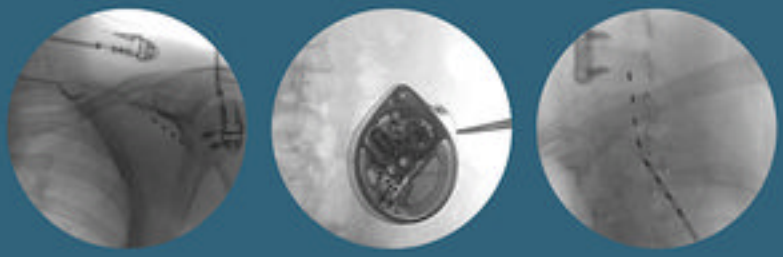

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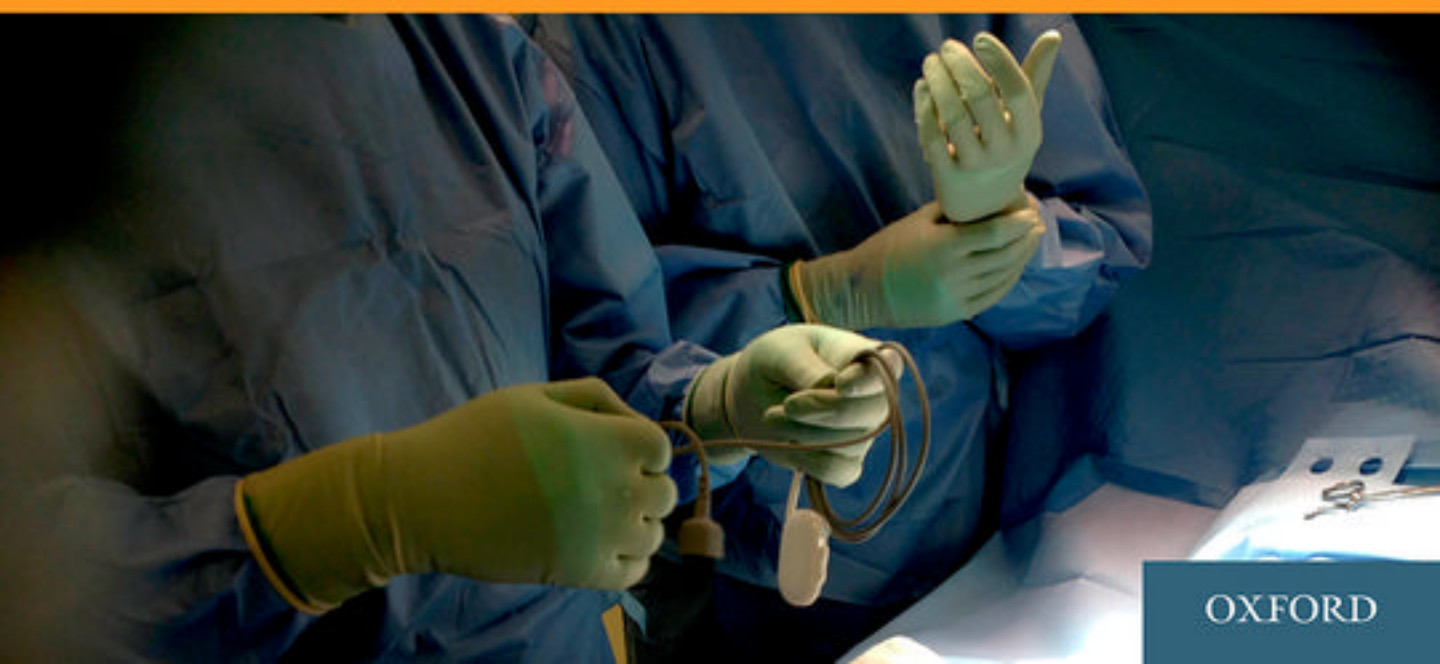
Surgical Pain Management

A Complete Guide to Implantable and Interventional Pain Therapies



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A Complete Guide to Implantable and Interventional Pain Therapies

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We dedicate this book to our patients and families.
Pain can destroy lives as readily as any objectively measurable disease. It is our patients that motivate and drive us to improve care and teach the next generation of pain doctors.
It is our families that permit and support us in our life's work

—Sanjeet, Alison, and Edgar

Foreword

Chronic pain remains a prominent problem in our society and there are no universally effective treatments. In recent decades, many minimally invasive surgical techniques have come in to common use and shown great promise in reducing pain for carefully selected patients. These modalities, most notably spinal drug delivery and spinal cord stimulation, have helped innumerable people with chronic pain to regain some semblance of normal life. Yet, there remains no comprehensive source of information about how to select appropriate patients to receive these treatments or how to assemble the extensive support network necessary to effectively incorporate these treatments in to a comprehensive pain treatment program. In this new textbook, Narang, Weisheipl, Ross and their colleagues at the Brigham and Women's Center for Pain Management in Boston share their collective wisdom with other practitioners.

Understanding the intricacies of patient screening and appropriate selection as well as mastering the technical aspects of device placement are difficult and good educational materials are lacking. The subspecialty-training program in pain medicine at Brigham and Women's has gained an international reputation as one of the leading centers where physicians can learn the practicalities of interventional pain treatment. Here, for the first time, these experts share more than 20 years of experience in teaching others interventional pain treatment techniques in one compendium.

The authors have focused on surgical and invasive treatment of pain and begin by telling us that these are advanced and expensive treatments reserved for those who fail to respond to more conservative measures. Staff and consultants from the Center for Pain Management have come together to offer their unique views—views that have allowed them to incorporate these invasive treatments as part of comprehensive pain management plans for their own patients. It is refreshing to see pain physicians and collaborating surgeons come together with their nursing, psychiatry and palliative care colleagues to offer lessons-learned in the course of patient care that will allow others to apply these therapies to better the lives of those suffering with chronic pain.

Like many evolving areas in medical and surgical treatment, there are too few data to use a rigorous evidence-based approach to selecting and treating patients with these invasive therapies. But, here in one place, practitioners will now have a close glimpse at how one leading academic medical center is adopting and rationally applying these treatments. From these careful descriptions, many can learn and continue the hard work of refining interventional pain treatments to deliver more effective pain relief.

James P. Rathmell, M.D.
Boston, Massachusetts, USA
September 2015

Preface

Chronic pain remains the number one public health problem in most of the developed world today. One out of three Americans suffers from chronic pain, with the cost to the health-care system exceeding that of heart disease, diabetes, and cancer combined (1). As the understanding of pain mechanisms has improved, our therapies have become more specific and effective. Yet significant numbers of our patients still continue to have chronic disabling pain. Implantable therapies are often used as a last resort. This is because of the significant upfront cost, the difficult to prove efficacy, and the bias of selection criteria toward end-stage patients who would prove an impossible challenge for almost any therapy. Concurrent with the growing realization that chronic pain is widespread has been the enormous increase in opioid prescribing. This has led to another and largely predictable healthcare crisis: the wide-spread misuse and diversion of opioids, leading to the conclusion that opioids should not be the mainstay of chronic pain therapy. Implantable therapies can only be part of the answer to treating complex patients. The growing sophistication of stimulators and the continued advancement in the understanding of intrathecal pharmacology for pain and many other neurodegenerative disorders has led to significant increase in FDA-approved indications, flexibility in tailoring therapies to individual patients' clinical conditions, and improvement in outcomes. Implantable therapies are now viable alternatives for many indications in terms of both long-term therapy costs and efficacy.

The key success criterion for a successful implantable program is an interdisciplinary team, which is essential for a comprehensive pain management program. Gone are the days when a surgeon could implant a device and leave the postoperative care to an ill-defined system of care for maintenance and optimization of therapy. This book covers in detail each and every aspect of care, and Chapter 1 should be considered a guide to the development of a team that will optimize care for some of the most difficult to treat chronic pain patients.

Patients who are candidates for these therapies have multiple medical problems, and the anesthetic considerations are vital in providing optimal surgical care. Chapter 2 reviews these considerations, along with important controversies in approaches for both intrathecal and spinal cord stimulation implants.

The psychological review of a patient prior to an implant is not only considered a standard of care but is required for reimbursement by most payers. The psychological clearance for implantation should be tailored to each patient's clinical need and his or her disease course.

A terminally ill patient is very different from a patient with persistent pain and a history of multiple spine surgeries. Little attention has been paid to these differences, and Chapter 3 discusses the varying individual patient selection criteria and the required treatment approaches for patients who do not meet the selection criteria.

Patient education is one of the key variables to successful patient outcomes. Many patients can express a complete understanding of their device, yet repeatedly fail to be compliant with pump refills or successful stimulator use, including recharging. Chapter 4 presents a primer in healthcare education for patients with these devices. Device selection and therapy should be based on the comprehension of either the patient or the patient's support system. Patients who are candidates for these therapies often consume a substantial amount of healthcare resources, and the complexity of their treatment plans can overwhelm even the most resourceful practitioner. Improvements in devices have, to some extent, simplified aspects of therapy for patients. Examples include automated stimulation adaption, with position-sensing capabilities and MRI compatibility, which is a very important consideration for many patients. These improvements can serve to improve patient understanding and compliance with implantable devices.

Chapters 5 through 16 discuss the field of neuraxial drug delivery, electrical stimulation of the peripheral and central nervous system, and a variety of invasive procedures for chronic and cancer pain. The surgical management of a patient is reviewed, along with the needed resources to organize an implant service. The approaches detailed within this book range from basic implant therapies to more advanced therapies. Many of the procedures discussed are off-label, yet the growing body of literature and practical experience suggest that these novel applications of existing technology have significant clinical potential. The intended purpose of these chapters is as a companion to an advanced training program in interventional pain management. A single weekend training course can no longer be used as evidence of competence and certification. In fact, implantable therapies should be considered a subspecialty in a physician's advanced training program for pain management.

The appendices provide supplemental information regarding guidelines, physiology, technologies available, troubleshooting, and the documentation required to organize an interventional service.

At its best, an interdisciplinary team can help patients with pain overcome even the most overwhelming psychosocial and medical history. When used as part of an overall treatment plan, implantable and interventional therapies are capable of changing lives for the most difficult to treat conditions. With this book as a companion, interested healthcare professionals can organized the needed resources to maximize the opportunity these treatments offer while experiencing the joy of changing a patient's life.

Edgar L. Ross

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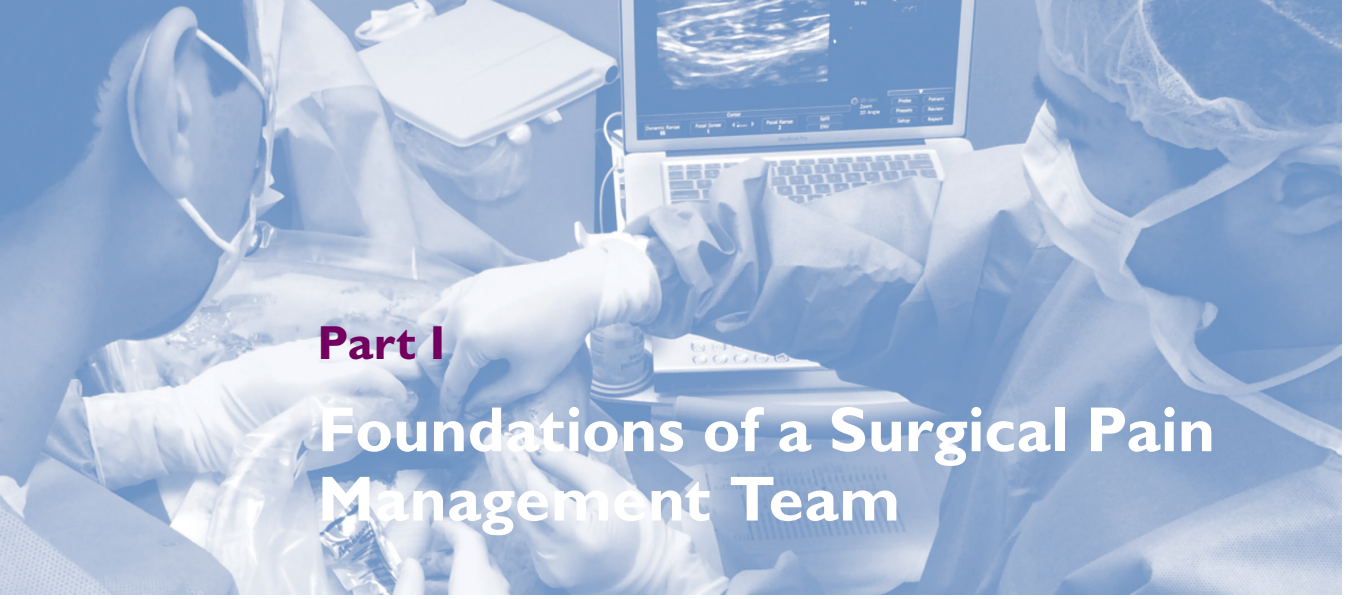


Part I

Foundations of a Surgical Pain Management Team

Chapter 1

Organization of an Implant Service

Daniel Vardeh and Diane Palombi

Introduction

Spinal cord stimulation and implantable infusion pump placements are invasive, interventional surgical procedures that have been proven to be useful in refractory chronic pain syndromes, including malignant and non-malignant pain. This chapter summarizes the administrative framework as well as the steps necessary to manage a safe and efficient implant service, guiding clinicians from patient selection to postoperative care.

The Interdisciplinary Team

An interdisciplinary pain program ideally consists of professionals with various training backgrounds who work closely together with the joint goal of providing the best possible care. This group typically consists of the primary care physician, a surgically trained pain specialist, a psychiatrist or psychologist, physical and occupational therapists, the device company representative, nursing and support staff. A multidisciplinary, well-coordinated approach becomes particularly important for patients who receive elective invasive procedures, since both proper pre-selection of the appropriate patient population and post-surgical follow-up are critical to the therapeutic success of the intervention. Patients who are under consideration to receive advanced pain therapies should be evaluated by the team for the following criteria:

- The diagnosis must be amenable to this therapy.
- The patient's quality of life is significantly impaired by the pain.
- Less invasive/conservative therapy has failed.
- Significant psychiatric comorbidities have been ruled out or are adequately treated, and the patient is deemed cooperative and compliant.
- The patient is free from drug misuse or drug-seeking behavior.
- There are no absolute contraindications to hardware implantation.
- The patient has undergone a successful trial.
- The patient has appropriate expectations of the procedure's benefit and is aware of the long-term risks associated with the therapy.

The importance of proper selection of candidates for implantable devices cannot be overstated and is crucial for the therapeutic efficacy. Clarity of diagnosis and nature of pain being treated is essential. A stable pain syndrome should be present, and all or a large portion of it should be amenable to the planned therapy. A successful trial is predictive of success, and results in fewer problems in future management. Psychiatric comorbidities, if severe, can significantly decrease the chances of good outcome.

Outcomes of interdisciplinary pain programs have shown superiority in the degree of pain relief, reduction of opiate use, and increase in physical activity compared to conventionally treated patients (1).

The Administrative Support System and Work Flow

The administrative apparatus typically consists first of a medical director, who oversees the various team members and provides overall vision to the implant service. There must be a functioning established pain management center, preferably with a multidisciplinary composition at least within the same geographic area if not under the same roof. Surgical privileges at the inpatient hospital are crucial, and a supportive relationship with a spine surgeon is very important as a source of referrals, assistance and guidance in complex surgery, and in case of complications. Any program that does not have adequately trained pain physicians (regardless of primary specialty), who are comfortable with the technical and surgical aspects of implantable therapy, is likely to fail. Support from device companies, cadaver workshops at national meetings, mentoring from nearby active implanting pain programs, and training courses for novice implanters are all resources that must be utilized by fledgling programs during early phase of development. If implantable drug delivery therapies are planned, it is critical to have a safe and responsive compounding pharmacy that has been vetted and approved by the parent organization where the implanting program is to start. The purchase personnel at the hospital should have coordinated and arranged with the preferred vendor to ensure stable and cost-effective supply of hardware needed for the variety of operations.

Patient Education

Patients with chronic pain often experience a large disease burden with a high incidence of psychiatric comorbidities, significant functional impairment, and in many cases a frustrating odyssey through the healthcare system in order to find adequate pain relief. Patient education in this scenario is of paramount importance in order to improve understanding of the anatomy and pathophysiology of the pain problem, clarify the logic of therapy, enlist the patient's cooperation toward the common goal, and ultimately improve therapeutic outcome. Appreciating the difference between the passive medical model and the chronic pain paradigm, where the patient's active involvement is necessary, is important for the patient to understand and absorb. Evaluation by a pain psychologist for appropriateness for implantable therapy must be done prior to any intervention.

Trial for Implantable Therapy

Once the patient has been selected and psychologically screened, and is adequately educated about and amenable to the procedure, a therapeutic trial is scheduled. This establishes the efficacy of the device and allows the patient to experience first-hand the potential therapeutic benefit and to make an informed decision about accepting the implant. It is an opportunity to educate and expose the patient to the physical reality and lifestyle adjustments that are included in having implantable pain therapies. The purpose of a trial for intrathecal therapy is twofold: the efficacy of the therapy needs to be proven, and an appropriate intrathecal dose is to be estimated. In the case of stimulation therapy, again, efficacy is to be established, and suitable location of leads and programming parameters are to be determined. Sometimes one trial may not be enough, and treatment failures can result, despite a satisfactory trial. Additionally, a successful trial is often a mandatory requirement of insurance providers in order to cover the permanent device implant. In general, trials can be of various types; these are discussed in later chapters. In brief, the trial can be outpatient or inpatient, and the timing of the permanent implant to follow can be concurrent or staggered to a later date.

In a large retrospective study including over 21000 patients, the US average conversion rate from trial lead to permanent system placement has been found to be just above 40%. Factors associated with higher rates included having commercial insurance, younger age and absence

of previous percutaneous trials (2). This relatively low average conversion rate indicates the strong need for better patient selection. As a consequence, providers with conversion rates below 50% have recently undergone increased scrutiny by insurance companies.

Planning for Permanent Implantation

Once the decision for permanent implantation is made, based on satisfactory therapeutic effect and minimal side effects, certain steps are followed to ensure a smooth and safe process for the surgery. Box 1.1 provides an example of the steps followed once the decision is made to proceed with an implant.

BOX 1.1 IMPLANT SERVICE WORKFLOW FOR PERMANENT IMPLANTATION

Decision for Surgery

- Information about procedure is given to patient and documented in patient's chart.
- OR booking form is filled out with implant equipment requested.
- OR booking form is submitted, given to scheduler for OR booking.
- If intrathecal or epidural drug is needed, place prescription.
- Preoperative anesthesia visit is scheduled.
- Surgery date and postoperative visit is scheduled.
- OR booking form faxed to device representative
- Ensure that equipment is available in the implant room at your facility.
- Psychological evaluation is completed.

Pre-anesthesia Evaluation

- Surgical and anesthesia history and physical are completed.
- Consent form for anesthesia and surgery are completed.
- Ensure that allergies and anticoagulation are entered into patient's chart.
- Medications are updated and correct doses are entered into patient's chart.
- Appropriate labs are ordered if needed.
- EKG is ordered if needed.
- Preoperative X-rays are ordered if needed.
- NPO guidelines are explained to patient.
- All forms are scanned into patient's chart.

Day Before Surgery

- Ensure that patients are called regarding preoperative instructions (time of surgery, time of arrival, directions, etc.).
- Chart of patient is reviewed and determined to be complete, including all labs by designated personnel at the clinic.
- Ensure chart arrival to OR site (if paper), or ensure availability of patient chart if there is an electronic medical record.
- Allergies to antibiotics are reviewed.
- Presence of intrathecal or epidural drug is confirmed in OR pharmacy.
- Surgical team members are determined.
- OR start time is confirmed with device representative.
- OR permission is obtained for device representative.

(*continued*)

BOX 1.1 CONTINUED

Day of Surgery: Preoperative Period

- Pre-procedure checklist is completed.
- Site verification is completed.
- Antibiotic prophylaxis is to be started 30 min prior to incision.
- OR setup is discussed with operating room personnel, configuration reviewed along with confirmation of appropriate instruments and equipment.
- Ensure correct sterile glove and gown size.
- If intrathecal pump or epidural placement: obtain drug from pharmacy.
- Ensure that X-ray equipment is available for case.

Day of Surgery: Patient in Operating Room

- Surgical pause completed.
- Induction of anesthesia requires surgical team presence.
- Patient is positioned with surgical team presence.
- Antibiotic prophylaxis completion is confirmed.
- Prepare surgical area.
- Use X-ray to find appropriate landmarks for procedure and ensure clearance of fluoroscopy.
- If pump replacement, confirm who will prepare pump with device representative.

Day of Surgery: Immediate Postop Period

- Postoperative orders are placed.
- Plan to admit to observation, if formal admission is required.
- Abdominal binder or soft collar is ordered.
- Brief written OP Note and/or Day of Procedure Reassessment (per institution protocol).
- Surgical dictation is completed.

Discharge Day

- Follow-up appointment scheduled for one week postop and coordinated with device representative.
- Postoperative instructions, including wound care, are given to patient.
- Patient training for device use, if required, is completed by device representative or appropriate clinic personnel.
- Dictate discharge summary if patient was admitted. This is not needed if patient was admitted only for observation.

Decision for Surgery

When the patient has completed the appropriate trial, a follow-up visit is planned, during which the decision is made to proceed with surgery. At this visit, various aspects of the trial are discussed, the expectations of relief are clarified, and the "dos and don'ts" for the postoperative period are reinforced; the patient should fully understand the device being placed and its potential complications, and the necessity of close and frequent post-procedure follow-up is explained. The natural course of events is clearly reiterated, that is, pain from surgical incisions, the necessity of keeping wounds dry, restrictions on activity, when the device will be

turned on, and when expectation of relief is to be entertained. Decisions regarding date of surgery and whether it will be performed as an outpatient or inpatient; site and side of incisions and placement of device should be discussed. Surgical consent should be obtained at about this time or during the pre-anesthesia visit, as limits exist on its validity, usually one month. If intrathecal or epidural medications are needed, the prescription is created at this time so that the drug can be ordered from the compounding pharmacy when needed.

A pre-anesthesia evaluation should be scheduled within 30 days of the scheduled implant. We use a standardized operating room (OR) booking form, which is submitted to our designated OR scheduler. Figure 1.1 is an example of an OR booking form. The form includes

Pain Management Center OR Booking Form

To be completed and signed by Physician and discussed with patient:

Physician _____ Date of request _____ Surgery Date _____

Expected Hospital Length of Stay _____ Days Sex M ☐ F☐

Procedure setting: ☐ Main OR ☐ Interventional Radiology Suite ☐ MRT

Do you wish use standard pre-operative antibiotic guidelines? ☐ Yes ☐ No Plastic surgery needed? ☐ Yes ☐ No

Admit status: ☐Outpatient ☐Same day admit ☐ Inpatient ☐Admission pre-Op ☐ Admit to Observation

DIAGNOSIS: _____

Anesthesia Requested: ☐ MAC ☐ General ☐ MAC/General ☐ Conscious Sedation

PROCEDURE: _____

Needs Rehabilitation Hospital admission? ☐ Yes, if so contact Inpatient Rehabilitation for Eval

Lab tests: ☐ ECG (Age > 50) ☐ CBC (Age > 60) ☐ Type and Screen Other labs _____

Position: ☐ Right lateral decubitus ☐ Left lateral decubitus ☐Prone ☐supine
(If change in position will be needed, number in order of position)

Is procedure unilateral ☐ Yes ☐ No If unilateral: ☐ Right side ☐ Left side

Procedure – Spinal Cord Stimulation

Short – 1-2 hours	Medium 2-4 hours	Long 4-6 hours
☐ IPG change (attach old IPG settings)	☐ SCS single or dual lead insertion	☐ Revision of entire SCS system
☐ Conversion to Restore System	☐ Revision of SCS leads	☐
☐ Removal of SCS	☐ Insertion of Peripheral Nerve or Field Stimulator	☐

Procedure – Neuraxial Infusion

Very Short- 30 minutes- 1 hour	Short – 1-2 hours	**Medium 2-4 hours**
☐ Epidural catheter insertion for Intrathecal pump trial	☐ Pump change (obtain old pump settings)	☐ Pump implant
☐ Celiac plexus block	☐ Pump pocket revision	☐ Catheter revision
☐ Nerve block	☐ Removal of pump	☐ Porta cath revision
☐ Epidural Blood patch	☐ Porta cath/Dupens catheter implant	☐ Repair CSF leak
☐ Other procedures_____	☐ Other procedures_____	☐ Other procedures_____

Equipment Needed for SCS

Electrodes	Extensions	Generator	Other equipment

Figure 1.1 Pain Management Center OR Booking Form.

Equipment Needed for Neuraxial Infusion

Pump/Portacath	Catheters	Other equipment

The prescription for the intrathecal medication must be ordered at least 2 days ahead of time.

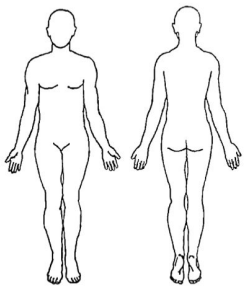
Rx completed? ☐ Yes ☐No **Rx must be submitted with this form for transmission to the OR preoperative process**

Emergency IT Drug Combinations (using manufacturer available products; no raw powder used; or have been micro/pyrogen pre-tested): These are the exact formulations that will be used in these situations.

Hydromorphone 10 mg/mL	Baclofen 2000 mcg/mL	Infumorph 25 mg/mL
Fentanyl 50 mcg/ml	Baclofen 500 mcg/ml	Baclofen 1000 mcg/ml

Operating Room Setup

C-Arm ☐ **Yes** ☐ No If the C-Arm is needed please fill in the area that will be required to be viewed



OR Table Needed

☐ Check if weight of patient great than 350 pounds

Table type	☐ Jackson	☐ Skytron	☐ Amsco
Description and use	Complete open for whole body visualization fluoroscopy	Electric bed, used for regional fluoroscopy	Mechanical bed, limited fluoroscopy area, or when no x-ray is needed
Table picture			

Follow-up appointment date _____

Fax form to:

1. Pre-op anesthesia clinic
2. Vendor representative

Figure 1.1 (Continued).

information on which implant devices will be needed, special instruments or equipment and specific operating tables required, need for fluoroscopy, and postoperative rehabilitation facilities, among other information, such as pharmacy details and phone numbers of essential personnel. Once the procedure is scheduled, and pre-anesthesia testing is arranged, information is relayed to the device representative to ensure they will be available during the placement, and post-operatively.

Pre-anesthesia Evaluation

The pre-anesthesia evaluation is important in order to identify any significant patient comorbidities that could present an increased risk to the patient while undergoing the procedure. Chapter 2 discusses these aspects in greater detail. From the perspective of running an implant service, it is important to ensure that there is a system in place that allows this visit to occur within 30 days of the surgery (consult your institutional guidelines), and to ensure that all institutional policies (medication reconciliation, NPO guidelines) are documented and explained to the patient to limit any issues that may arise on the day of surgery. Anticoagulation concerns should also be addressed among the anesthesiologist, the surgeon, and the patient's prescriber or primary care provider. Finally, it is also important to note that surgical history, physical examination, and consent should coincide with the anesthetic evaluation, and should also be done within 30 days of the planned procedure. The patient should be given clear information about the necessity of fasting and the medications to be taken or avoided. The general course of the operation and the sections that will be under conscious sedation and those that will be under general or spinal anesthesia should be clearly explained and the patient given opportunity to ask questions and form reasonable expectations of the process.

Day Before Surgery

On the day prior to the scheduled implantation, the patient should be aware of the finalized time and location of the surgery. Clinic personnel ensure that the surgical history and physical examination, consents, and anesthetic paperwork and orders are complete prior to the day of surgery. For intrathecal pump implants, the surgical consent should include the surgical risks and benefits as well as the pump refill process. See Figure 1.2 for an example of our institution's consent for intrathecal device implantation and refill. These documents should be placed in the patient's chart and should arrive at the procedure site (if paper charts are used) or should be updated in the electronic medical record. Confirmation of the availability of the epidural or intrathecal drug should be arranged. Finally, the device representative should be contacted to ensure availability.

Day of Surgery

Once the patient arrives at the preoperative area, consents for surgery and anesthesia should be reviewed. At this time, the anesthesiologist will complete his or her review of the patient and will identify any relevant changes in patient-related concerns or comorbid conditions. The surgeon and anesthesiologist should discuss the anesthetic requirements of the anticipated procedure to remove any ambiguity, especially if personnel are unfamiliar. The patient should be reassured, and any last minute questions of patient and family should be answered. Patients may need repetition of matters previously discussed. The surgeon should mark the correct side and site of implantation, and ensure that the site of the pump or implantable pulse generator (IPG) is in a comfortable and accessible position for the patient. Outlining the pump or IPG on the patient's skin in the preoperative area before any sedation has been given and allowing the patient to move to various positions (sitting, standing, lying) helps to ensure that the marked area is an acceptable place. Once the patient is placed under sedation or given general anesthesia and positioned, the position can vary widely, and incorrect placement of the pump or IPG can occur if it has not been previously marked.

Prior to bringing the patient to the operating room it is vital to ensure the presence of the intrathecal or epidural drug the proper implantable hardware and kits, and X-ray fluoroscopy. Antibiotic prophylaxis should be given within 30 minutes of incision or per institutional guidelines.

BRIGHAM AND WOMEN'S HOSPITAL

DANA-FARBER CANCER INSTITUTE

TEACHING AFFILIATES OF HARVARD MEDICAL SCHOOL

PATIENT IDENTIFICATION AREA

CONSENT FOR PROCEDURES: INTRATHECAL INFUSION DEVICE IMPLANTATION, INTRATHECAL INFUSION DEVICE MEDICATION REFILL AND INTRASPINAL MEDICATION ADMINISTRATION

An intrathecal infusion device (currently Medtronic SynchroMed II) will be implanted in my abdominal area. The device delivers continuous intraspinal medication for treatment of my intractable pain, but will not cure the primary source of my pain or eliminate my pain. A catheter will deliver the medication from the device to my spinal cord. Successful therapy generally means at least a 50% reduction of my pain, as well as improvements in my ability to function. Even when good pain relief is initially achieved, I may have increased pain over time that may or may not respond to increased medication doses, as tolerance may develop. I may also need to be involved in additional therapies, such as physical therapy and psychotherapy, to treat my pain. The device has a battery. The expected battery life is presently around seven years but may be sooner. The device must be surgically replaced at the end of the battery life. The device will require periodic medication refills. Each medication refill will require a procedure to access the device and must be performed at the BWH Pain Management Center.

I understand that the medical treatment for my condition may involve the participation of resident physicians, fellows, and/or nurse practitioners, physician assistants, pharmacists, nurses and other ancillary staff. My attending pain management physician performing the procedure today is _____, M.D. and will determine when it is appropriate for others to participate in my care. The attending pain management physician performing repeat medication refill procedures on subsequent visits to the BWH Pain Management Center may be different. My attending pain management physician may terminate treatment if I am not benefiting from treatment or if I am unable to be compliant with the treatment plan.

I understand the nature of my condition, the nature of the procedures being prescribed, and the benefits to be reasonably expected as compared with alternative approaches, as has been explained to me. I understand that I am free to refuse any treatment. I have had adequate opportunity to ask questions about the risks and benefits of treatments for my condition, including the risk(s) of no treatment, the risks and benefits of the treatments that are currently being prescribed, and the risks and benefits of any alternatives to these treatments. I understand that my intraspinal medication treatment will last an indefinite period of time and I consent to periodic medication refills of my device. I may also stop treatment at anytime. If treatment is stopped for any reason, I understand the device may need to be removed.

I understand that there is a chance that major risks or complications of the treatments may occur, including, but not limited to: life-threatening infection; hemorrhage (excessive blood loss); drug reactions (allergic or other); blood clotting disorders; nerve damage, such as loss of sensation, loss of limb function, paralysis, brain damage; and loss of life. I may also experience an unexpected complication that has not been previously seen, and no guarantees or promises have been made to me concerning the safety or results of any treatment. There will be a transitional phase after the intrathecal infusion device is implanted. I will have other medications gradually reduced so that the appropriate dose levels of the intraspinal drug(s) can be determined. I may not have maximum pain relief during this transition.

Specific additional risks for intrathecal infusion device implantation and medication refill may include, but are not limited to: Accumulation of fluid in the device site, hematomas (bruises), and spinal headaches. Patients often experience pain and tenderness in the incision sites until healing occurs. Long-term therapy of spinal infusion systems has been associated rarely with catheter granulomas that may cause temporary or permanent neurological damage up to and including paralysis. Mechanical complications associated with device may include dislodgement or kinking of the intraspinal catheter, pocket problems and device mechanical problems.

My physician will give me instructions regarding how to care for intrathecal infusion device after it is implanted. I will avoid physical activities that may damage the implant site or the device. I will avoid certain medical procedures/devices that may damage my device (unless approved by my physician) such as diathermy, ultrasound, lithotripsy, or focused radiation therapy over the device. I will have my device telemetry checked within 24 hours after having an MRI. In the event that I die, I agree to have the device removed prior to cremation.

Specific additional risks for and adverse effects of intraspinal medication administration may include, but are not limited to: Itching, urinary retention, constipation, nausea, vomiting, dizziness, anxiety, depression and edema. I will use caution when operating a motor vehicle. It is my responsibility not to drive if I am experiencing any side effects or feel impaired in any way. I will avoid alcohol, drugs of abuse or any other mood altering drugs (not prescribed by my pain

Figure 1.2 Consent for intrathecal infusion implant, which also includes consent for intrathecal infusion device medication refill, renewed annually.

BRIGHAM AND WOMEN'S HOSPITAL

DANA-FARBER CANCER INSTITUTE

TEACHING AFFILIATES OF HARVARD MEDICAL SCHOOL

PATIENT IDENTIFICATION AREA

CONSENT FOR PROCEDURES: INTRATHECAL INFUSION DEVICE IMPLANTATION, INTRATHECAL INFUSION DEVICE MEDICATION REFILL AND INTRASPINAL MEDICATION ADMINISTRATION

doctor) while receiving this therapy. I will not allow the device to run out of medication as this may cause severe harm from abrupt medication withdrawal. I will schedule my pump refill appointments in a timely manner. At a minimum, pump refills need to be scheduled three weeks in advance. I will attend my pump refill appointments in a timely manner or I may need to be rescheduled. I will inform my physician if I plan to be away for an extended period of time so the Pain Management Center can attempt to make arrangements for medication refill by an outside provider.

I understand that it is possible that one or more healthcare industry professionals (technical representatives for medical equipment and device companies) may be present during these procedures for advisory purposes only.

I understand that blood or other specimens removed for necessary diagnostic or therapeutic reasons may later be disposed of by the hospital. These materials also may be used by BWH / FH / DFCI, or other academic or commercial entities, for research, educational purposes (including photographing), or other activity, if in furtherance of the Hospital's missions.

Since aspects of this procedure may have educational value, data, video or photographs may be obtained for teaching purposes, presentations at medical/scientific meetings or publications in medical scientific journals. All such recordings used for teaching purposes will be de-identified.

CONSENT FOR THE USE OF BLOOD PRODUCTS: I understand that there is sometimes a need for blood products before, during or after the procedure, and that the benefits from receiving blood products outweigh the associated risks. I have had an opportunity for my questions about blood transfusion to be answered. I DO NOT CONSENT TO THE USE OF BLOOD PRODUCTS _____ (patient initials)

❒ YES _____ (clinician initials) PROCEDURAL SEDATION IS PLANNED TO BE USED AND/OR MAY POTENTIALLY BE USED FOR THIS PROCEDURE; My physician has discussed the use of Procedural Sedation. The risks include but are not limited to slower breathing and low blood pressure that may require treatment, and occasionally incomplete pain relief.

Additional comments (if any):

The above risks and benefits have been explained to me. I have had an opportunity to fully inquire about the risks and benefits of intrathecal infusion device implantation, device medication refills and intraspinal medication administration for my condition, alternatives to device implantation, device medication refills and intraspinal medication administration and the risks and benefits of the alternatives. All my questions were answered to my satisfaction and I consent to the procedures.

Date _____ Time _____ AM/PM _____
Signature (Healthcare Agent)

Date _____ Time _____ AM/PM _____
MD Signature

IF SIGNATURE CANNOT BE OBTAINED, INDICATE REASON IN COMMENTS SECTION

MEDICAL RECORDS COPY

Figure 1.2 (Continued).

Patient in Operating Room

Once the patient arrives at the operating room, the anesthesia and surgical safety pauses should be performed. A member of the surgical team should be present for transport, transfer to OR table, anesthesia induction, and patient positioning. Ensure that antibiotic prophylaxis has been given. Once the surgical site has been prepared and draped, confirm appropriate landmarks for procedure with fluoroscopic guidance and proceed with the implant. If a pump is being placed, it is important to identify a provider from the surgical team to prepare the pump with the device representative. This will allow parallel processing—as one person is preparing to implant the device, the other can work on preparing the pump at the same time.

Immediate Postoperative Period

Once the surgery is completed and the patient has awakened from sedation or general anesthesia, postoperative orders should be placed. Some patients are admitted to observation overnight or, if there are significant comorbidities, are admitted for longer periods. Thus, postoperative orders should be placed with consideration being made for fluids, postoperative pain and emesis control, antibiotic doses, and home medications. Before the patient leaves the operating room, an abdominal binder or soft collar should be placed, depending on the site of the pump or IPG. All appropriate documentation (surgical dictation, billing forms) for the procedure should take place at this time.

Prior to Discharge

Before the patient is discharged to home or a rehabilitation facility, appropriate follow-up should be scheduled and documented on the patient's discharge instructions. We arrange for postoperative visits at approximately one week; at that time a wound check is performed, and if appropriate healing has occurred, the dressings are removed. In the interim the patient is advised to keep the wound area dry and not remove the dressing. If a stimulation device has been placed, we wait until the postoperative visit to initiate stimulation to allow time for the incisional pain to subside. If an intrathecal pump or epidural is placed, further medication titration is performed at the postoperative visit.

In addition to scheduling a postoperative visit, wound care and activity restrictions should be included on the discharge paperwork. If the device requires specific training, a device representative or clinic representative should be available to impart this training to the patient.

Keeping Track of Patients With Implantable Devices

As the varying needs and demands of an implant program can be vast and complex, it is wise to designate an implant coordinator. This is typically a registered nurse (RN) who can field clinical questions and has working knowledge of the implantable devices in addition to organizational skills and attention to detail. The role of the implant coordinator includes but is not limited to the following:

1. Keeping track of all implantable devices and any complications,
2. Ordering medications for pump refills,
3. Serving as liaison to a home care company if used for pump refills,
4. Working with the facility and compounding pharmacies,
5. Ensuring that needed supplies are on the premises,
6. Providing patient education, and
7. Triaging calls for the implantable device patients.

It is important to keep all the paperwork in the proper place and to have a mechanism for tracking all aspects of the program.

Implantable Device Tracking Log

The implantable device tracking log is an Excel spreadsheet with fields that allow you to collect and sort data for a variety conditions (see Table 1.1):

- Inventory of all patients surgically implanted in the practice
- Tracking of cases done by procedure type—including revisions
- Surgeon-specific data
- Tracking infections/complications
- Data for retrospective studies.

Table 1.1 Implantable Device Tracking Log

Last Name	First Name	Medical Record Number	Date Implanted	Device	Complication	Attending	Comments

Pump Refill

In setting up an implanting program for targeted drug delivery, one of the first questions a practice must address is which medication(s) will be used in the intrathecal pump. The only medications approved by the FDA for intrathecal use in implantable pumps for pain are preservative-free morphine sulfate or ziconotide. Baclofen is approved for spasticity.

As these medications do not need to be compounded, they can generally be drawn up under the proper conditions at the inpatient facility pharmacy, provided one is able to work with the concentrations that are available as a direct draw from off-the-shelf, factory-prepared products. If medications other than those that are FDA approved are used or a combination product is clinically required, this will generally require outsourcing to a qualified compounding pharmacy that meets US Pharmacopeia (UE) guidelines (specifically, USP chapter 797) for compounding preparations. This has to be coordinated closely with the pharmacy of the parent inpatient facility the pain practice is associated with. Appendix 3 further discusses FDA-approved intrathecal medications.

Once a compounding pharmacy is chosen, a formulary needs to be developed (See Figure 1.3 for our formulary). The problems of dose calculation and titration, the issues of the side-effect profile of each drug as the concentration is changed, and the physical chemistry of the compounded product and its compatibility with CSF increase logarithmically with every drug added. It is a good rule to limit polypharmacy, and in our practice we have limited ourselves to a maximum of three drugs in any one compounded mixture. The compounder must produce evidence that the requested compounded medications have been tested for stability and sterility (confirmed by an outside laboratory) for the time the medication is likely to stay in the pump, typically up to 6 months. The next step is to determine how the billing will be designed, if through the pain practice, or through the inpatient facility's pharmacy, or if the outside pharmacy will bill the patient's insurer directly for the medication. If this format is used, patient profiles will need to be set up with the compounder, who will then keep an inventory of the patients in the practice and their refill needs. The pharmacy would need notification if new patients are added, or if a patient's refill interval, demographics, or insurance have changed. Patients may also be charged a copayment by the pharmacy.

If the parent facility is billing for the medication, a system needs to be set up to ensure that the medication is available at the time of the refill appointment. Box 1.2 is a flow chart that illustrates the process of obtaining compounded intrathecal medication from the compounding pharmacy. If the numbers of patients implanted are small, this may be accomplished by simply reviewing the schedule in advance and ordering the medications based on the lead time needed by the compounding pharmacy. Stocking standard mixes for emergent implants should also be considered.

Alarm Date Log

In a larger, more complex practice, the use of an alarm date log may be used in conjunction with the practice schedule to ascertain which prescriptions need to be ordered from the compounder. Table 1.2 is an example of a sample alarm date log. It can also help to ensure that an adequate supply of manufactured drug is on hand. The log is maintained by the implant coordinator, who reviews and inputs all telemetries from the practice on a daily basis. If a practice has multiple locations in which telemetry is performed, all telemetries should be faxed to the coordinator. A dedicated fax server is recommended to reduce the risk of lost telemetries. The refill coordinator may also serve as a liaison upon patient demise to ensure that the family and funeral home are aware of need to explant the pump if cremation is planned.

The information in the alarm date log can serve many purposes.

- Alarm Date Column: This provides the ability to sort patients based on their alarm date. This will reveal who needs to be filled regardless of whether or not an appointment has been made. If a patient's alarm date exceeds the maximum refill interval for that drug, the

Formulary of Available Intrathecal Medications at BWH

Routine use (pre-ordered from off-site Compounding Pharmacy)

- The following combinations may be ordered to refill pumps.
- The listed concentrations are the maximum concentrations that may be used.**

1. Baclofen 5000 mcg/mL
2. Baclofen 2000 mcg/mL; Clonidine 2000 mcg/mL

3. Bupivacaine 40 mg/mL
4. Bupivacaine 40 mg/mL; Clonidine 2000 mcg/mL
5. Bupivacaine 40 mg/mL; Baclofen 2000 mcg/mL
6. Bupivacaine 40 mg/mL; Baclofen 2000 mcg/mL; Clonidine 2000 mcg/mL

7. Hydromorphone 50 mg/mL
8. Hydromorphone 50 mg/mL; Bupivacaine 35 mg/mL; Clonidine 1000 mcg/mL
9. Hydromorphone 50 mg/mL; Bupivacaine 35 mg/mL: Baclofen 2000 mcg/mL (90 days)
10. Hydromorphone 50 mg/mL; Bupivacaine 40 mg/mL
11. Hydromorphone 50 mg/mL; Baclofen 2000 mcg/mL
12. Hydromorphone 50 mg/mL; Clonidine 2000 mcg/mL
13. Hydromorphone 50 mg/mL; Clonidine 2000 mcg/mL; Baclofen 2000 mcg/mL

14. Morphine 50 mg/mL
15. Morphine 70 mg/mL; Bupivacaine 30 mg/mL; Clonidine 1000 mcg/mL
16. Morphine 50 mg/mL; Baclofen 2000 mcg/ml
17. Morphine 50 mg/mL; Bupivacaine 40 mg/mL
18. Morphine 50 mg/mL; Clonidine 2000 mcg/mL
19. Morphine 50 mg/mL; Clonidine 2000 mcg/mL; Baclofen 2000 mcg/mL

20. Fentanyl 1000 mcg/mL; Baclofen 2000 mcg/mL; Clonidine 2000 mcg/ml
21. Fentanyl 1000 mcg/mL; Bupivacaine 35 mg/mL; Clonidine 1200 mcg/mL
22. Fentanyl 1000 mcg/mL; Bupivacaine 35 mg/mL; Clonidine 2000 mcg/ml
23. Sufentanil 500 mcg/mL; Bupivacaine 35 mg/mL; Clonidine 1200 mcg/mL
24. Sufentanil 500 mcg/mL; Bupivacaine 35 mg/mL; Clonidine 2000 mcg/ml

25. Ziconotide (Prialt) 25 mcg/ml in 20 mL (also 100 mcg/mL in 1 mL and 5 mL)

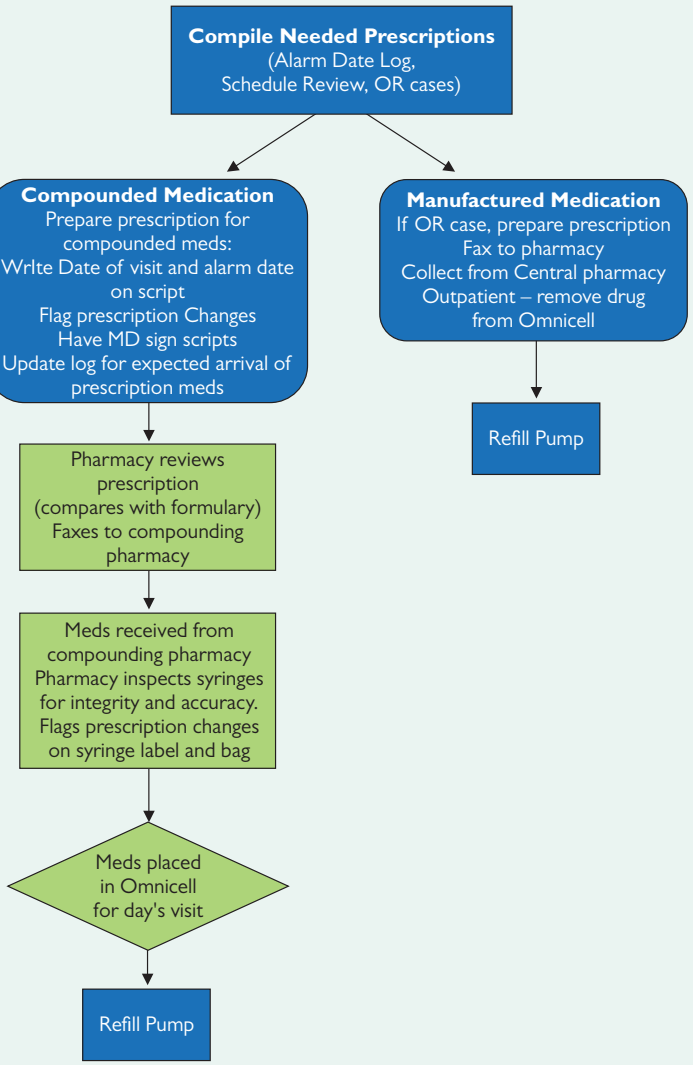
Emergency use (from Hospital Pharmacy)

1. Hydromorphone 10 mg/mL
2. Infumorph 25 mg/ml
3. Fentanyl 50 mcg/ml
4. Baclofen 500 mcg/ml
5. Baclofen 1000 mcg/ml
6. Baclofen 2000 mcg/mL

Figure 1.3 Formulary of available intrathecal medications at Brigham and Women's Hospital.

**Our current practice eschews some of the higher concentrations of opioid and local anesthetic to avoid risk of intrathecal granuloma –Editor's Note.

BOX 1.2 THIS FLOW CHART DEMONSTRATES THE PROCESS OF OBTAINING COMPOUNDED INTRATHECAL MEDICATION FOR OFFICE REFILLS AND OR CASES.



recommended refill interval is entered here and the true alarm date is entered into comments. A plan will need to be made by the practice for scheduling patients with Personal Therapy Managers or Patient Controlled Intrathecal Analgesia (PCIA), as use of this modality makes the alarm date variable.

- Flow Rate: This lists the daily dose of the primary drug in the pump.

Table 1.2 Intrathecal Pump Alarm Date Log

Last Name	First Name	MRN	Alarm Date	Flow Rate	Drug/ Availability	Refill Interval	Comments	ERI

- Drug Availability: This column allows an MD or administrative assistant to know if the drug is available or if it has been ordered and is being processed. The dates the drug is ordered, expected, and received from compounder are entered. The drug is colored in red when it is ordered and changed to black when the drug arrives and is inspected, and then deleted upon use. If a patient uses a stock drug, the drug may be noted here. One can also see by sorting this column if a patient did not come in for a refill after the drug was ordered.
- Refill Interval: This aspect adds another layer of safety. If the refill interval varies unexpectedly, a thorough review of the telemetry is in order, along with comparison to previous telemetry. Unfortunately, if a patient has adjustments between fills, the value of this column is lost.
- Comments: This allows some flexibility for special situations, particularly when the actual alarm date varies from the recommended refill date. This is also used to note patients whose needs are filled by a home-care company, or who may not get the next refill at the parent facility for any reason.
- Elective Replacement Indicator (ERI): The ERI instructs the patient and practitioner when the pump will reach the end of battery life. If the list is sorted by ERI, the practice can identify those patients in need of replacement prior to their next pump refill. Appropriate arrangements can then be made for surgical planning. This may also be helpful if a patient calls stating that the pump alarm has begun.

Any prescription changes should be made known to the refill coordinator so that the prescription can be flagged as a prescription change for the compounder. In turn, the new medication syringe is labeled or flagged as a prescription change. This can help to reduce the chance of a medication change not being inputted into the programmer and leading to a potentially fatal error. The size of the pump used and the amount of medication ordered should also match; this is not so much of a problem if more medication is ordered for a smaller pump, but when the converse occurs there is room for a major error.

If a shared drive is an option, the log should be saved to this. All members of the care team should have view access to the shared drive. This allows schedulers to see when a patient's medication needs to be refilled, as well as if the drug is available. Providers at off-site locations or during off hours should also be able to access the log.

Home Management Options

In some parts of the United States the option of a home-care company which provides registered nurses trained in assessing patients, and adjusting and refilling intrathecal pumps under remote medical direction may be available. Patients may or may not be eligible for this option based on their insurance. In fact, Medicare does not presently cover this service at our location. A patient may become eligible once entered into hospice care. Generally, if the patient requires this service, a referral is submitted by the implant coordinator. The home-care company will then review the referral and verify insurance eligibility. If accepted, the company will then contact the patient and set up an intake visit.

The referring provider is still ultimately responsible for the patient. All pump refill prescriptions and changes to the patient's orders are made by the referring provider after a discussion with the home management nurse. The implant coordinator can serve as liaison. The patient should be seen by the referring provider at least every 3–6 months. Video conferencing with the home nurse, MD, and patient may be considered when other methods of communication are not adequate. In our practice we generally refer patients to home management companies when they have severe mobility issues or extreme commutes, or if they are at end of life and regular doctor visits become a hardship.

Spinal Cord Stimulators

Patient education and coordination of care are the primary roles of the implant coordinator for spinal cord stimulators (SCS). Some of the duties may include maintaining/ensuring an inventory of patient education materials for the devices, meeting with patients to assist in educating, reviewing antibiotic allergies prior to a trial, ensuring needed electrode leads are available, and coordinating with the representative for the device to confirm their availability for trials and programming visits. Often, the device company representative becomes the closest to the patient by default, especially if repeated programming or education is required. The implanting physician must initiate and supervise application of therapy, however a skilled and experienced device programmer is indispensable and often of great assistance in continuing care of the implanted patient.

Inventory

Inventory for SCS and intrathecal pump operations will be needed in the outpatient practice for trials as well as in the operating room for permanent implants. Supplies may be purchased on consignment or brought to each case as needed by the vendor. An agreement between the institution and the vendor will define which of these or combination of these will be put in place.

Triaging Phone Calls

The implant coordinator is an important first-line person for fielding calls on implantable device patients. The calls may be from the patients themselves, with questions about their device or about symptoms they are now having. These calls may be of an urgent nature if, for example, there are signs of baclofen withdrawal, a critical pump alarm, or signs of an infection. The patient may also just need to be reminded how to use the device or when the alarm date is. Phone calls may also arrive from a Visiting Nurse Association or hospice, facilities with recent admission of a patient from the practice who has an implantable device, or from a radiology site that has questions about the implant before they provide imaging. Timely and accurate responses are crucial and obtaining physician input appropriately is critical.

Placement of Interventional Therapy in a Treatment Continuum

In general, patients who are considered to undergo device implantation procedures will likely have exhausted other more conventional pain treatment options, as outlined by the traditional World Health Organization (WHO) pain ladder (3). This traditional approach was initially developed for cancer-related pain, but has been widely adapted for non-malignant pain and includes medication escalation from non-opioid analgesics and weak opioids to strong opioids, with the option of adding adjuvant medication at each step. This regimen has been estimated to provide pain relief for pain in about 70%–90% of cancer pain (4), leaving a significant number of chronic pain patients without good analgesic control. Therefore, a fourth step has been introduced to include invasive pain procedures such as nerve blocks, radiofrequency ablation, SCS, and intrathecal pump implantation. Figure 1.4 identifies the four-step pain ladder, including interventional therapies. While this stepwise approach should be followed in the majority of cases, certain situations like acute pain crises in patients with chronic non-malignant pain or patients with cancer pain with limited life expectancy require a more aggressive approach, with skipping of the initial steps or even starting at the top and gradually moving down the ladder as analgesic control is achieved (5).In previous years, a trial of chronic oral opioids titrated to effect might precede offering an implantable device in the patient care algorithm; unfortunately with the national crisis of opioid diversion and abuse among the general populace, nowadays such implants are being offered earlier in the natural history of disease, prior to high dose opioid therapy and development of tolerance.

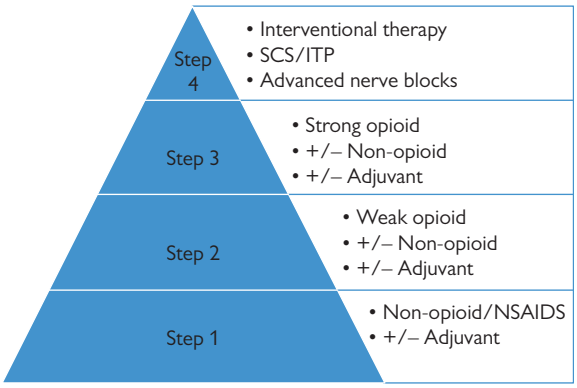


Figure 1.4 Four-step pain ladder, including invasive pain procedures.

Complications With Implantable Devices

Given a 30% device complication rate within the first year of implantation, it is worth discussing and developing systems to deal with possible complications after SCS implantation (6). In descending frequency, complications are related to lead migration, infection, pain at the stimulator site, or loss of therapeutic effect (6). For consecutive years 3–5, the annual complication risk has been estimated at 5%, with the majority of complications being related to stimulator replacement due to expired battery life (7). When thinking about developing an implant service, it is important to consider the possible complications and subsequent therapies needed. For example, if infection of a device is suspected, it is important to not only have appropriate resources available (laboratory for culturing, infectious disease consultation, OR availability for revision, spine surgeon support), but to also document and track these cases. By tracking these cases, a practitioner can assess for patterns such as organisms cultured, techniques used for those cases, and personnel involved with the case. Using this data, the service can work to decrease complications and improve outcomes with their device implants.

As with SCS, there are other considerations and complications to implantable drug delivery systems. These include the need for a complex procedure, the need for regular medication refills, and the risk of both hardware and human error regarding delivery of an improper dose of medication. A major risk of intrathecal pump therapy includes increased mortality, especially in the first few days after implantation, which is most often related or contributed to by inappropriately high starting rates of intrathecal opioid delivery (8). In addition, granuloma formation at the tip of the catheter can occur in as many as 3% of patients, which might be directly related to intrathecal (IT) opiate therapy and often resolves after IT opiates are weaned, therefore making surgical intervention rare. Other complications include catheter kinking, fracture, and migration, as well as pump erosion through the skin or local infection (8). As with SCS implants, it is important to have a system in place to evaluate for potential complications. Nurses or mid-level practitioners should be readily available and trained to either program pumps or double-check dosing changes. As described above, it is paramount to have a system in place to enable tracking of possible complications, end-of-battery life replacements, refill dates, timely orders for refill medication, and triaging of patient questions or problems with the hardware.

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Chapter 2

Anesthetic Management for Chronic Pain Surgery

Josemaria Paterno and Jason Stewart

Introduction

As pain procedures become more widely applied to various pain states, it is important for the anesthetist to be cognizant of how the intricacies of the procedures themselves and the comorbidities of the patients may affect the anesthetic plan. This chapter describes both the anesthetic management for pain surgical procedures as well as the anesthetic management for patient comorbidities in the pain patient.

In theory, every procedure in this text may be performed without general anesthesia. For some of these procedures, a cooperative awake patient, lightly sedated and capable of active feedback, is the preferred or only choice. Otherwise, the anesthetic planning for these interventions is guided by patient comorbidities and preference, implanter skill and technique, and anesthetist comfort level.

For all of these procedures, IV access is required for the administration of medications and possibly antibiotics. Standard American Society of Anesthesiology (ASA) monitors, consisting of pulse oximetry, blood pressure monitoring, electrocardiography, capnograpy, and temperature, are always indicated. Supplemental oxygen should be provided whenever sedation is administered. Patients should be comfortably sedated, though monitored closely for signs of hemodynamic instability, anaphylaxis, or vasovagal episodes that are sometimes, though rarely, produced by these procedures. If the patient is awake, verbal reassurance and communication from both the anesthetist and implanter ensure a smoother course for the patient.

Anesthetic Concerns for Specific Pain Procedures

In this section, we discuss the various surgeries in pain management and how these surgeries affect anesthetic care. First, implantable drug delivery systems (IDDS) are discussed, followed by a description of stimulation devices. The anesthetic concerns differ greatly based on the type of procedure being performed. Tables 2.1, 2.2, and 2.3, which appear in this section, review the pertinent anesthetic concerns for each of these procedures.

Anesthesia for Implantable Drug Delivery Systems: Intrathecal Pumps and Tunneled Epidural Port-A-Caths

Whether for cancer pain, chronic non-cancer pain, or refractory spasticity, implantation of an intrathecal drug delivery system (IDDS) entails placement of an intrathecal catheter connected to a drug reservoir system. Such systems also include a rotor pump and battery source that must be implanted subcutaneously. The most frequent site of pump placement is the abdominal subcostal region on the side least preferred for sleeping. Some implanters automatically favor left side placement because some of the more common abdominal surgical procedures that a patient may need in the future (e.g., laparascopic or open appendectomies and cholecystectomies) require incisions on the right side. However, some patients may require future procedures on the left side of the abdomen (such as a colostomy), so the pump reservoir location should be tailored to the individual patient and expected oncologic course. For those patients with terminal cancer with an expected prognosis of < 3 months to live, however, a tunneled epidural port-a-cath is the preferred option for neuraxial drug delivery The procedure is very similar to the intrathecal pump placement, except rather than

Table 2.1 Anesthetic Concerns for Placement of Drug Delivery Systems

Procedure	Tunneled Epidural Port-a-Cath	Intrathecal Pump System
Anesthetic Choice	(1) Local anesthesia + MAC (2) Neuraxial/Epidural anesthetic (3) General anesthesia	(1) General anesthesia (2) Neuraxial/Spinal anesthetic (3) Local anesthetic + MAC
Patient Positioning	Lateral decubitus	Lateral decubitus
Time	60–90 minutes	75–120 minutes
EBL	Minimal	Minimal

Table 2.2 Anesthetic Concerns for Neuromodulation Procedures

Procedure	SCS/PNS Trial	SCS/PNS Implant
Anesthetic Choice	None or light sedation	(1) MAC with light sedation (lead placement) followed by deeper sedation (generator implant) (2) MAC followed by general anesthesia
Patient Positioning		
SCS	Prone	Prone, or prone and then lateral decubitus
PNS	Site dependent	Site dependent
Time	45–90 minutes	75–120 minutes
EBL	Minimal	Minimal

Table 2.3 Anesthetic Concerns for Revision of SCS or Intrathecal Pump Systems

Procedure	SCS Revision	Intrathecal Pump System Revision
Anesthetic Choice	(1) MAC + general (2) General anesthesia	(1) General anesthesia (preferred) (2) Neuraxial/Spinal
Patient Positioning		
SCS	Prone	Lateral decubitus
PNS	Site dependent	
Time	120–180 minutes	120–180 minutes
EBL	Minimal	Minimal

an implantable drug reservoir system, a port-a-cath is secured under the subcutaneous tissue of the chest wall and is connected to an external drug reservoir and pump system.

All anesthetic modalities, such as general anesthesia, regional/neuraxial anesthesia, or monitored anesthetic care (MAC), are possible. General anesthesia is often preferred, depending upon surgical skill and speed, anesthetic comorbidities, and patient tolerance for the procedure. When this is the case, it is important to provide controlled respiration. The practice of surgical pain medicine has experienced significant growth, especially with the needs of the cancer pain population. As oncological therapies have afforded patients many years of extended life, the quality of those last few years and months are often hampered by painful metastatic disease. Indeed, cancer pain patients are often quite ill at the time they need implantable intrathecal therapy, with an overall prognosis that could be as short as several months. Relevant anesthetic considerations relate to nutritional status, cachexia, and the location and extent of primary and metastatic disease.

In some instances, general anesthesia is to be avoided. For example, patients may have had prior lung resection and extensive pulmonary metastatic disease, and now bear an existing oxygen requirement. Extubation may be challenging or even impossible. Thus, a neuraxial technique may be employed by the surgical team, with the patient in the lateral decubitus position after the intrathecal space is accessed but prior to tunneling and abdominal pocket creation for the pump. In our experience, 0.5–1.5 ml of 0.5% isobaric bupivacaine (2.5–7.5 mg) administered through the intrathecal catheter at the T10 thoracic level provides more than adequate anesthesia and time (45–90 minutes) for the tunneling and pocket creation. With a skilled implanter, 1 cc of 0.5% isobaric bupivacaine is more than sufficient. Isobaric bupivacaine is preferred over hyperbaric bupivacaine, as the hyperbaric solution may not provide sufficient regional anesthesia for the "up" or non-dependent lateral side where tunneling and pocket creation are performed. The anesthetist must, of course, pay careful attention to the hemodynamics as the spinal anesthesia is administered and takes effect, especially with cancer patients who have many comorbid conditions and may be sensitive to the hypotensive effects of a spinal anesthesia.

Additionally, the procedure may also be done under IV sedation, with local anesthetic administered by the implanter along the incision sites and tunneling path. Local anesthetic is administered in 3 areas: (1) the midline lumbar incision for catheter placement and anchoring at the thoracolumbar junction, (2) the tunneling path for the catheter, and (3) the pocket site for the drug reservoir pump. Constant communication between the anesthetist and implanter must be maintained to note the total local anesthetic dose administered to the patient and thus avoid local anesthetic toxicity. We often use alternating administration of 2% lidocaine with 1:200,000 epinephrine followed by 0.5% bupivacaine with 1:200,000 epinephrine in

order to safeguard against single agent toxicity and to provide a balance between onset and duration of effective pain relief.

Patient positioning is an often overlooked but critically important aspect of the procedure. Often the neuraxial catheter must be guided under live fluoroscopy to a mid-thoracic or higher level. In the lateral decubitus position, the arms should be positioned at or slightly above the shoulder level, depending on patient tolerance and comfort, such that a clear fluoroscopic view of the spine is obtained. A lateral armrest for the "up" or non-dependent arm aids in maximizing space for the fluoroscopy machine to obtain anterior-posterior thoracic images. Additionally, gastrointestinal or pelvic cancer patients may have stomas and ostomy bags, which must be carefully secured and protected in the "down" or dependent side, away from the sterile abdominal field where the pocket will be created. In either case, the pain surgeon may administer an intrathecal bolus to initiate therapy immediately after the operation or for postoperative pain relief; care should be taken to avoid additional opioids or sedatives and make the recovery room staff aware of the potential consequences of this potent neuraxial dose of medication.

Special anesthetic consideration is required for spasticity-related pain requiring intrathecal baclofen therapy. The main indications for implantable intrathecal baclofen therapy include intractable spasticity due to cerebral palsy, stroke, or spinal cord lesions resulting from multiple sclerosis or spinal cord injury. Patients referred for intrathecal baclofen have painful spasticity refractory to increasing doses of oral baclofen and other muscle relaxants.

For anesthetic planning, anesthetists must be vigilant of issues such as functional status and mobility. Some patients may be wheelchair bound or may have very limited use of one or more extremities. We encourage patients to take their morning oral dose of baclofen or muscle relaxant to avoid perioperative spasticity exacerbations. Careful attention should be paid to positioning, which may be difficult in the spastic patient. In these situations, general anesthesia may be preferred and frequently facilitates positioning.

Patients with cerebral palsy specifically are known to have a higher incidence of gastroesophageal reflux disease (1). Laryngeal Mask Airways (LMA) should be used with caution, if at all, especially for the prone position. Shorter acting muscle relaxant may be helpful for both airway management and positioning under general anesthesia. If paralytic is needed for airway management, however, succinylcholine may be contraindicated for spastic patients who are essentially immobile or have limited functional use of one or more extremities. Even disuse atrophy of one extremity is enough to generate a dangerous hyperkalemia from upregulation of extra junctional succinylcholine receptors and has been reported in the literature (2). Table 2.1 summarizes the anesthetic considerations for patients undergoing implantable drug delivery systems.

Anesthesia for Neuromodulation: Spinal Cord Stimulation, Peripheral Nerve Stimulation, and Field Stimulation Trials and Implants

Trialing of Stimulation Devices

Neuromodulation trials, whether for spinal cord stimulation (SCS) or peripheral nerve stimulation (PNS), may be performed in the office or hospital OR setting. These are ambulatory procedures for which general anesthesia is not utilized. Minimal sedation should be used as the patient must be alert and communicative during intraoperative stimulation testing to ensure optimum lead position and correct paresthesia coverage over the painful area. IV access is required because IV antibiotics are also administered prior to the procedure. Additionally, stimulation trials may sometimes provoke anxiety attacks or vasovagal episodes once the trial leads are activated. Airway equipment, resuscitation drugs, and supplemental

oxygen should therefore be readily available. Fluids should be restricted unless the urinary bladder has been catheterized; the trial may have to be aborted if the patient has to void midway through the procedure.

Permanent Placement of Stimulation Devices

Anesthetic planning for the SCS or PNS implant is determined by implanter skill and technique, anesthetist comfort level, and patient preference and comorbidities. SCS implantation is frequently a same-day procedure and does not require overnight stay unless patient comorbidities dictate otherwise. Unlike intrathecal pump placement, where a regional/spinal anesthetic can be used early in the surgery, a spinal anesthetic is usually avoided since intraoperative patient feedback is required for stimulation testing. Regardless of the anesthetic plan chosen (sedation vs. GA, or a combination of both), immediate incisional postoperative pain should be minimal if local anesthetic is administered properly in the subcutaneous tissues. The implantable pulse generator (IPG) battery is smaller than the intrathecal pump device, thus requiring a slightly smaller incision, and is often easily placed in the upper outer buttock or postero-lateral flank. Some implanters choose the lower quadrant of the abdomen for the IPG site, necessitating a change from prone to lateral mid-procedure. At this time, general anesthesia often is used for the second stage.

Before the surgery, the implanter and anesthetist must discuss the different phases of the procedure and the varying sedation requirements that will be necessary for each phase. Sedation should ideally be minimized during the initial phase of lead placement to ensure optimal lead positioning and to prevent excessive somnolence, which may cause patient disinhibition and unwanted movement during the lead positioning and testing. Once the leads are appropriately positioned, however, heavier sedation can be provided to facilitate lead anchoring and tunneling.

For SCS patients who cannot tolerate prone positioning with sedation, general anesthesia with endotracheal intubation may be provided from the start of the case. This option is less preferable, as the implanter loses valuable patient feedback and relies on adequate fluoroscopic images of the specific level and position of the trial leads as a guide for exact placement for the permanent leads. This is also the case when paddle leads are placed, which require a laminectomy and are difficult to accomplish with local anesthesia and sedation alone.

In the absence of general anesthesia, as with intrathecal pump placement, appropriate local anesthetic is required to maintain patient comfort for the tunneling and generator pocket creation. The implanter and anesthetist should be in communication regarding the total amount, type, and timeline of local anesthetic used in order to avoid local anesthetic toxicity.

Careful patient positioning is crucial for successful SCS/PNS implantation because of the need for an awake, comfortable, and cooperative patient and to minimize interference with the dynamic fluoroscopic imaging needs. For targeting chronic pain in the lower extremities and lower back, the stimulator leads are inserted at the high lumbar levels and are guided in the epidural space to the mid-low thoracic levels. The pulse generator is placed in the posterior flank above the iliac crest, the upper buttock, or in the lateral abdominal area. For SCS, the patient initially lies prone on the fluoroscopic table. One or two pillows placed under the patient's lower abdomen helps minimize lumbar lordosis. All pressure points should be padded. For female patients, the breasts should not have significant body weight or pressure. Arm boards should be positioned in a way that does not impede lateral fluoroscopic views. Extra time spent in positioning will allow the patient to lie still and to participate in the procedure without distraction.

For targeting chronic pain in the neck and upper extremities, the stimulator leads are inserted at the high thoracic levels/upper back, and the pulse generator is often placed in the

axillary region under the armpit or again in the posterior flank or upper buttock. The patient lies prone on the fluoroscopy table. The patient's head should be in normal anatomical position, with the neck flexed forward, and supported by a gel pad under the forehead. Excessive extension will make the approach to the epidural lead manipulation more difficult. One or two pillows under the patient's chest will promote slight cervical flexion, and all the pressure points should be padded. It is preferable to have the shoulders relaxed and the arms tucked at the patient's side to avoid interference with lateral and contralateral oblique fluoroscopic cervical imaging. If the arm boards are present, they should again be positioned so as not to impede target fluoroscopic views.

Regarding permanent implantation for peripheral nerve stimulation, the anatomic site guides the choice of anesthetic and the patient positioning. Avoiding general anesthesia with generous local anesthetic and sedation is often successful for lower extremity, abdominal, and low back peripheral stimulation. However, occipital and craniofacial stimulation involve sensitive areas of the head and face, so for patient comfort, general anesthesia and a secure airway are often preferred. The implanter is guided by marking and reproducing the placement of the superficial peripheral leads used during the trial. Table 2.2 summarizes the anesthetic considerations for stimulation devices.

Revision and Explant of Implantable Drug Delivery Systems and Stimulation Devices

A more challenging subset of cases related to chronic pain surgery involves revisions and explants of implanted systems, including both implantable drug delivery systems and neuromodulation. Over time, both spinal cord and peripheral nerve stimulation leads may migrate or fracture, or individual electrodes may stop functioning, resulting in ineffective neuromodulation and a need to modify the implanted system. Similarly, with implantable drug delivery systems, the catheter can become dislodged from the pump reservoir, can become kinked at the anchor site or other sites, or the catheter can develop granulomas.

For the implanter, the challenge demands careful dissection of the leads or catheter, intraoperative examination and testing of the defective system, and replacement and testing with a new system. Such cases can take anywhere from 2 to 4 hours. For revisions of spinal cord, peripheral nerve, and field stimulation, the revision often requires sedation. For the anesthetist, the challenge requires longer bouts of alternating light and heavier sedation with a prone patient. Patient communication and feedback during intraoperative stimulation testing is still necessary. Titration of sedation without a secure airway in the prone position is always challenging, especially in those with chronic pain, anxiety, larger habitus, or airway conditions such as obstructive sleep apnea (OSA). In longer cases, dexmedetomidine infusions may be effective, with their anxiolytic effects and minimal respiratory depression. For revisions of implantable drug delivery systems, general anesthesia is often the anesthetic of choice.

For an explant procedure (i.e., for device infection or system malfunction) without planned replacement, the anesthetic may be much simpler, and general anesthesia may be preferable for both anesthetist and patient if not otherwise contraindicated. Table 2.3 summarizes the various anesthetic considerations for revision procedures.

Spinal Interventions for Structural Back Pain

For spinal interventions related to structural back pain, such as disc herniations, discogenic pain, spinal stenosis, and vertebral compression fractures, the therapeutic procedures

include percutaneous discectomy, discography, minimally invasive lumbar decompressions (MILD), vertebroplasty, and kyphoplasty. These interventions are preferentially, if not always, performed with an awake and cooperative patient in order to maximize the safety of the procedure. Continuous patient feedback is essential in order to avoid serious neurological injury if a needle, trochar, or probe contacts neural elements not appreciated on fluoroscopy. Generous local anesthetic may be employed for procedures like vertebroplasty or minimally invasive lumbar decompression (MILD), which require larger instruments. General anesthesia is employed in specific circumstances for vertebroplasty or kyphoplasty if indicated by patient intolerance or expected length of procedure.

Anesthetic Concerns for Co-morbid Conditions Common in Patients With Chronic Pain or Spasticity

Chronic Opioid States

The anesthetic management of patients who are opioid dependent and/or opioid tolerant can be extremely challenging. The dosages and dosing intervals that many chronic pain patients utilize at baseline are often far above the range encountered in the care of the average patient. By far, one of the most important points in the care of chronic pain patients is the continuation of their home or inpatient opioid regimen in the immediate perioperative period. Long-acting opiate formulations should be taken as scheduled, and breakthrough medications cautiously continued in order to meet the patient's basal opioid requirements. It is not uncommon, however, to induce significant respiratory depression when additional sedatives, such as benzodiazepines, and GABA-acting agents are administered by the anesthetist. As a result, the consideration of alternative agents that provide hypnosis without additional respiratory depression is recommended. Dexmedetomidine (an alpha-2 receptor agonist) can be extremely useful in providing potent hypnosis while maintaining spontaneous ventilation in the sedated patient. In addition, ketamine (an NMDA antagonist) can be useful in providing pain relief while maintaining spontaneous ventilation, though its intraoperative use is cautioned against due to its propensity for altering cognition, especially in operations requiring feedback from the patient.

Polypharmacy

The use of adjuvant medications in the regimens of chronic pain patients has been shown to improve patient pain relief and to reduce the incidence of opiate-induced side effects. Common examples include antiepileptic medications, antidepressants, nonsteroidal anti-inflammatory drugs (NSAIDs), and benzodiazepines. These medications may pose a challenge to the anesthetist, given the pharmacodynamic changes they induce, which can affect the metabolism of routine medications given during a typical anesthetic. Many antiepileptics, for example, upregulate the P450 system in the liver and cause rapid metabolism of non-depolarizing muscle relaxants, resulting in the need for more frequent dosing intervals during the intraoperative period. In addition, benzodiazepines commonly prescribed for patients with severe spasticity can often make it difficult to achieve satisfactory anxiolysis in anxious and benzodiazepine-tolerant patients. As a result, careful consideration of patients' use of these classes of medications is warranted when formulating an appropriate anesthetic plan.

Patients With Chronic Spasticity

The care of patients with neuromuscular diseases that result in chronic spasticity can prove to be especially difficult for a number of reasons. First, these patients often have limited mobility and often present with chronic decubitus ulcers, recurrent urinary tract infections secondary to chronic indwelling Foley catheters, and marginal pulmonary reserves. The preoperative interview should therefore pay special attention to the possible presence of any such infection. Special attention should also be paid to the positioning of the patient for the procedure itself, as severe spasticity may make it difficult or, in some instances, impossible to complete without general anesthesia. These concerns should be thoroughly discussed with the patient, the implanter, and the anesthetist when formulating an appropriate anesthetic plan.

Second, patients with high or mid-thoracic spinal cord lesions undergoing pump implantation for intrathecal baclofen delivery may be at high risk for autonomic hyperreflexia due to the surgical stimulation associated with pocket creation. The anesthetist should therefore

be prepared to treat for episodic bradycardia and hypertension with anticholinergic and vasodilating medications. The use of succinylcholine in these patients may be relatively contraindicated due to the potential for hyperkalemia.

Patients at End of Life

The use of chronic pain procedures for the terminally ill patient is a rapidly expanding segment of the pain management specialty and has resulted in a number of unusual challenges for the anesthetist. For these patients, the procedures to be performed are purely palliative, as their life expectancy is projected to be so limited that they are often not candidates for device implantation. They are often at the end of their disease course and have evidence of end-organ dysfunction extending beyond their primary pathology. The health of these patients is often tenuous and may not tolerate even the minor hemodynamic changes that may occur in the course of a standard anesthetic. A patient with malignant mesothelioma who has undergone a penumonectomy, for example, may not be able to tolerate periods of apnea inadvertently caused by excessive sedation, or may not tolerate the lateral decubitus positioning necessary for placing an epidural port-a-cath or intrathecal pump. These patient-specific factors must be accounted for when formulating an appropriate anesthetic plan and should be discussed with the patient, the primary oncologist, and the implanting pain physician. It is also important to clarify the patient's DNR/DNI status prior to the procedure so that the care provided is commensurate with the patient's wishes.

Special Note on Neuromodulation Implantation and the Cardiovascular Population With Existing Implanted Cardiac Devices

The past decade has witnessed incredible growth of neuromodulation technology and increasing evidence of efficacy for the chronic pain population. Because the use of neuromodulation has expanded into patient populations with increasing severity of illness, such as those with extensive cardiovascular comorbidities, anesthetists may face unique intraoperative challenges. Strong evidence supports the use of SCS for peripheral vascular disease and refractory angina, both currently well-accepted indications for neuromodulation in Europe (3). Though rare, the anesthetist may encounter a situation where a patient scheduled for implant of an SCS system has a pre-existing implantable cardiac device (ICD), such as a pacemaker or defibrillator. The combination of SCS and ICD is controversial and has traditionally been contraindicated, although evidence suggests that it is possible to successfully use these devices in unison (4–6). Indeed, the successful use of SCS in this particular patient group is of paramount importance since the volume of patients with refractory cardiac ischemic pain, peripheral vascular disease, diabetic peripheral neuropathy, failed back surgery, complex regional pain syndrome (CRPS), or other pain disorders will likely grow over time, and these patients may benefit from neuromodulation therapy.

Spinal cord stimulators may indeed interfere with the operation of implanted sensing stimulators such as pacemakers or defibrillators. The life-saving function of the ICD naturally takes precedence over the function of the SCS system. Advanced coordination and planning are essential with the patient's cardiologist, the SCS company representative, and the ICD technician during the trial and implantation perioperative period. Regardless of device manufacturer, the anesthetist, implanter, and ICD and SCS representatives should all understand the critical steps involved for intraoperative evaluation of interference between the SCS and the ICD.

The concern for interaction between SCS and ICDs are mainly twofold: (1) for pacemakers, the loss of ability to pace; and (2) for defibrillators, failure to shock when indicated or propensity to shock inappropriately Specifically, with pacemaker-dependent patients (such as 3rd-degree heart block) who have demand-type cardiac pacemakers, SCS output may theoretically be misconstrued as native/intrinsic beats, resulting in the pacemaker failing to pace appropriately. To minimize this interaction, the SCS is set to a bipolar configuration that causes less intereference and is less likely to be misinterpreted as intrinsic cardiac activity. During intraoperative patient feedback testing, the anesthetist and pacemaker technician must be vigilant of the integrity of pacemaker function while the SCS parameters (voltage or current, frequency) are adjusted and finalized. Furthermore, because of the dynamic and positional nature of thoracic impedances with SCS, the anesthetist may coax the patient into breathing maneuvers while also adjusting the table angle to more closely simulate a standing/seated position. With each of these combinations, ICD function is tested with the active SCS system. One publication demonstrated no sensed artifact at maximum sensitivity from concomitant SCS, even at high output energy levels well above normal settings used for pain relief (6V pulse output with 450 microsecond pulse duration; normal settings 2–2.5V output with 200 microsecond pulse duration) (4).

With implanted defibrillators, whether placed for primary prevention or for a known history of malignant tachyarrhythmias (ventricular tachycardia [VT] or ventricular fibrillation [VF]), the intraoperative testing is more complex and requires two testing phases. The implanted defibrillator is turned off preoperatively, and external defibrillator pads are placed

on the patient. Once the SCS leads are correctly placed in the usual fashion, the SCS parameter settings are adjusted and finalized.

In the first testing phase, the implanted defibrillator is turned on and monitored. Theoretically, inappropriate shock should be rare because the vertebral column acts as an insulator to prevent the transmission of current and because the electrical signatures of VF and VT have dissimilarities to the stimulation parameters of the SCS system. SCS bipolar output, as opposed to monopolar, is especially preferred because bipolar output is less likely to be interpreted as intrinsic cardiac activity. The patient's level of sedation should be deepened at this point in the event that the ICD fires inappropriately. Both the SCS representative and the ICD representative may need to make quick adjustments if such a problem arises.

The second phase of testing involves the induction of a malignant tachyarrhythmia by the ICD technician. The implanted defibrillator is then observed to ensure that it detects and properly interrupts the arrhythmia in the setting of the active SCS system. For example, VF presents as a high rate (100–150 ms cycle length) and very low amplitude signal (0.3 mV), which must be adequately sensed by the ICD to provide safe and correct therapy. The ICD technician should be ready to activate the device if it fails to deliver correct shock therapy. Nevertheless, the anesthetist must also be ready to activate the external defibrillator pads as a backup in case the implanted device fails. And again, different patient positions, different phases of the respiratory cycle, and higher output SCS stimulation settings should all be tested to assess the full scope of compatibility with the ICD, as well as to create a range of acceptable stimulation parameter changes for the future. After defibrillation, the function and parameters of both ICD and SCS devices are checked. It is important to ensure that the function and impedance of the SCS system does not show any changes related to ICD discharge.

In sum, although these devices may be used in combination without problems (7, 8), the official position of the three major manufacturers of neuromodulation systems is one of caution (9–11). Thus, it is up to the implanting pain physician to determine if the risk of ICD or pacemaker malfunction is worth the benefit of improved pain relief. In addition, the patient must understand the risks and must determine if the potential benefits of improved pain relief outweigh the risks. Additionally, each case is unique, considering the manufacturer, number of leads used, stimulation settings required, anatomic lead location, and corresponding make, model, and settings of the cardiac device.

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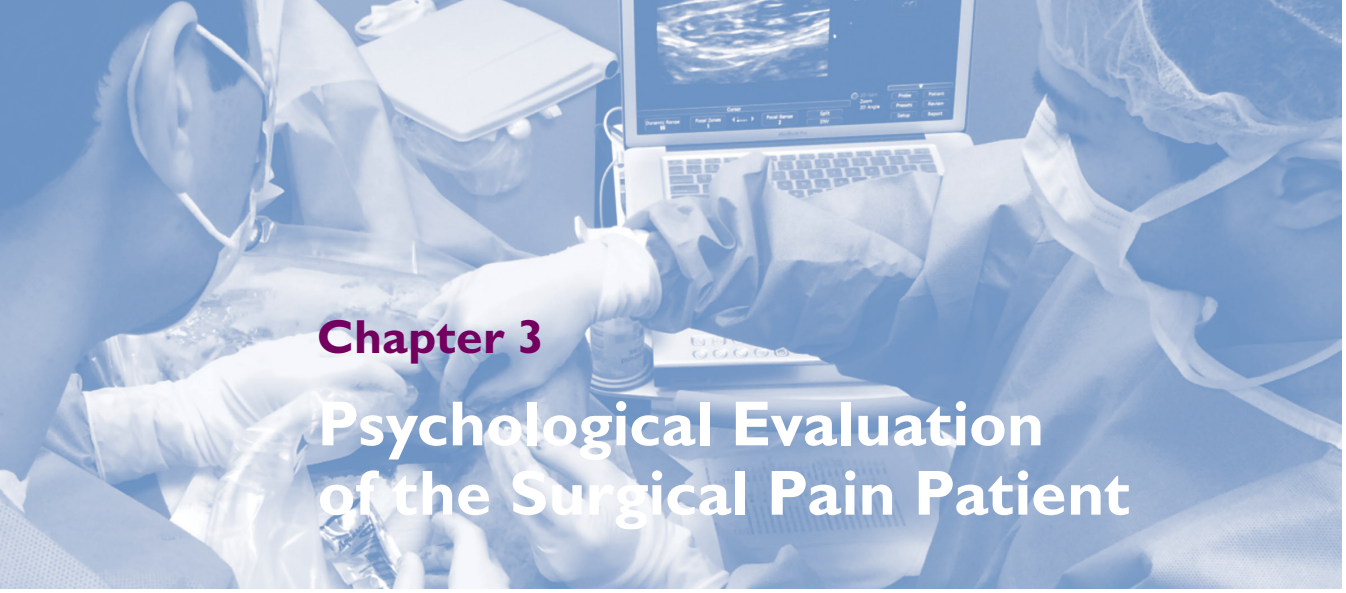

Chapter 3

Psychological Evaluation of the Surgical Pain Patient

Mohammed A. Issa

Introduction

Chronic pain affects every aspect of a person's life, including his or her social functioning, employment, hobbies, and activities of daily living. Patients with chronic pain often report associated psychiatric comorbidities such as depression, anxiety, irritability, anger, sleep disorders, and substance use disorders. Optimal care of patients, including their psychological and social well-being, are important determinants of pain and its response to treatment. Psychological and social issues, if not appropriately identified and managed, often result in intractability and poor response to available pain treatments, including surgical procedures (1).

Implantation of a pain control device is not without risks, which may include infection, nerve injury, bleeding, granulomas, or mechanical complications (2). Risks also include exacerbated psychological symptoms such as depression and anxiety if the device is ineffective (3). Substantial variation exists in the degree of benefit from implantable devices. As a result of the risks and substantial costs associated with the implantation of these devices, there has been increased emphasis on proper patient selection. Although practitioners will agree that proper selection of patients for implantable pain devices is essential to successful treatment outcome, there is nevertheless substantial variation in the methods that are used to select potential candidates. Originally, recommended selection criteria for implantable devices have included some psychosocial criteria, such as emotional stability, absence of depression, good compliance, and cooperation with a rehabilitation program. Thus, psychological evaluation has become a mandatory portion of the prescreening process when considering implantable pain devices (4, 5).

Psychological evaluation is designed to identify comorbid psychiatric, social, and behavioral factors that contribute to pain and disability. Studies have shown that almost 50%–80% of patients with chronic pain have associated psychiatric disorders, making this the most prevalent comorbidity among these patients (6). The most commonly identified psychological comorbidities in chronic pain patients are depression, anxiety, somatization, substance use, and personality disorders. Once these comorbidities are identified, treatment of the chronic pain patient can be tailored to address these challenges, thus increasing the likelihood of response to treatment and prevention of future exacerbations of the chronic pain condition. In this chapter, we will review the available strategies needed to assess psychological, social, and behavioral factors that may help predict the outcome from an implantable pain control device, such as a spinal cord stimulator or an intrathecal pump.

Role of Psychological Risk Factors

Psychological factors intermingle with physical characteristics to influence the overall experience of pain. Numerous factors have been identified that can likely play a role in predicting long-term treatment outcomes after surgical interventions. However, it is still unclear which precise factors are best predictive of treatment outcome. Relative risk factors that have been identified to correlate with poorer outcomes include variables of psychological distress, poor social support, history of childhood abuse or trauma, significant cognitive deficits, and chronicity of the pain condition (7). Psychopathology, extreme emotionality, maladaptive coping skills, and unrealistic expectations have been particularly associated with increased likelihood of developing chronic pain and with poorer response to treatment (8, 9). In addition, older age and longer duration of pain have also been identified to correlate with poor outcome from surgical interventions. Several studies have indicated that younger patients benefit the most when treated with dorsal column stimulation (SCS) earlier in the course of their pain condition, suggesting that SCS should not be considered solely as a last resort (10).

In a previous systemic review by Celestin et al., it was observed that depression, anxiety, somatization, and poor coping skills had a strong association with functional outcomes from back surgery and SCS (11). Even though the review determined that there was insufficient empirical evidence to suggest that presurgical psychological screening improved treatment outcomes, the results of the review still suggested that psychological factors were predictive of treatment outcome. A similar review by Sparkes et al. (12) determined that depression was strongly linked to reduced efficacy of SCS. On the contrary, other studies have suggested that successful SCS implantation (associated with 50% reduction of pain) can help improve symptoms of depression and quality of life associated with chronic pain (13, 14). Doleys and Brown demonstrated that patients with mildly abnormal Minnesota Multiphasic Personality Inventory-2 (MMPI-2) personality profiles reported a higher percentage of improvement in pain after 4 years of intrathecal therapy compared with patients with a more "normal" MMPI (5). Thus, patients should not be excluded based solely on predictive factors without considering other aspects of the psychological evaluation.

In addition to the identified psychological factors, several social factors may also be influential in patient selection for implantable devices. Patients experiencing social distress as a direct or indirect result of the pain condition (e.g., financial distress, family or relationship problems, unemployment or isolation from the community) are likely to experience higher levels of pain, increased physical disability after surgical interventions, and increased demands on the healthcare system. On the other hand, the presence of a supportive social environment is associated with decreased pain and disability after surgical interventions (15).

Strategies for a Psychological Evaluation

In clinical practice, a psychological assessment is an essential part of the evaluation process for patients being considered for implantable pain control devices. The role of a psychological evaluation is to help identify the patient for whom an implantable device would provide the maximum effect. Most health insurance companies now require pain implant candidates to undergo a psychological evaluation before considering approval for a device.

Components of a psychological evaluation should include the following (16):

1. Patient education regarding
   - Implantable device, its limitations, and mechanism of action. A model of the device can be shown to facilitate the patient's understanding of its size and properties.
   - Procedure, including the trial, as well as the potential risks and benefits of the device.
   - Potential complications of implanting a device, and the possibility of having future revisions or explants if complications develop.
2. Assess
   - Realistic expectations, pain beliefs, and coping skills;
   - Ability to understand the benefits of the treatment modality;
   - Ability to prepare for, commit to, and subjectively assess therapeutic benefits;
   - Motivation to receive an implantable device.
3. Assess different components of pain, including the sensory, affective, behavioral, and cognitive components:
   - Physical characteristics of pain (onset, course, location, quality, severity, radiation, aggravating and relieving factors);
   - Emotional characteristics and response to pain and related disability;
   - Cognitive distortions regarding pain experience and coping skills;
   - Behavioral component including interference with daily activities and nonverbal behaviors.
4. Identify psychosocial or personality factors that may exacerbate the experience of pain and impair the patient's ability to cope appropriately with his or her condition. Personality disorders may be difficult to diagnose during a single interview; however, they are more likely to be revealed over time in the course of the doctor-patient relationship. Psychological testing may also be beneficial. If intrathecal ziconotide is to be used, appropriate assessment of psychiatric comorbidities is critical given its potential for worsening such symptoms. In general, the following should be considered when assessing for psychosocial factors:
   - Psychiatric comorbidities: depression, anxiety, fear, substance use, and personality disorders;
   - Social stressors (employment, family, relationship, financial);
   - Supportive social environment (15);
   - Family socialization and support;
   - Ethnic and cultural variation, and family history of managing pain and illness (17);
   - History of managing and coping with pain.
5. Assess patient's ability to participate in concomitant behavioral/cognitive therapy to help improve function and maximize quality of life if needed.
6. Assess patient's cognitive functioning. Patients with cognitive impairment, such as those with dementia or traumatic brain injury (TBI), may have difficulty in the following areas: identifying and communicating changes in pain; fully understanding the goals,

expectations, and rationale for treatment; and appropriately expressing their perception of the treatment outcome. In addition, patients need good cognitive functioning to appropriately maintain their devices (e.g., remembering to charge their spinal cord stimulator).

7. Assess patient's compliance and adherence to treatment. This is especially important in patients considered for intrathecal pump placement, since regular visits for pump refills will be needed.
8. Identify possible secondary gain issues, such as litigation and worker's compensation.
9. Obtain collateral information from family members and significant others to help provide an alternative perspective to the patient-provided information regarding the patient's perception of the treatment outcome.
10. Open discussion of any other concerns.

Patient beliefs and coping strategies will influence treatment outcomes, either positively or negatively, by revealing the level of vulnerability to external influences on the pain condition. Patients with good insight into the multifactorial aspects of pain and its vulnerability to their own attitudes and behaviors, who are actively involved in treatment decisions, and who are willing to accept their pain condition and cope with it usually show more favorable treatment results. In contrast, those who restrict the pain experience to its physical characteristics and minimize the role of present psychosocial factors are more likely to experience negative outcomes.

Psychological Measures

Validated and reliable measures to assess the following categories should be incorporated into a psychological evaluation:

1. Pain characteristics

   Since pain control is the primary goal of an implantable device, it is important to assess pain intensity before and throughout the course of a device trial. The following measures may be used to assess the pain characteristics:

   - Visual Analogue Scales (18)
   - Electronic Pain Ratings (obtain multiple assessments of pain in the patient's natural environment) (19)
   - Verbal Scales (that describe the quality of pain) (20).

2. Psychiatric disorders

   Psychiatric and personality disorders are the most prevalent comorbidities among patients with chronic pain conditions. Patients with chronic pain often report depression, anxiety, fear, sleep disturbances, or a history of abuse (21, 22). Several measures are available to assess for emotional and personality problems, including the following:

   - Minnesota Multiphasic Personality Inventory-2 (MMPI) (23)
   - Beck Depression and Anxiety Inventories
   - Symptom Checklist-90-Revised (24).

3. Substance use disorders

   Substance use disorders are highly prevalent in patients with chronic pain, the commonest of which are alcohol and opioids. Patients with an active substance use disorder are generally considered poor candidates for implantable devices given the likelihood of the following: having associated withdrawal symptoms that may worsen pain tolerability and treatment outcome; potential for poor compliance and adherence to recommended treatment; impaired cognitive functioning; and higher rate of comorbid psychiatric disorders. In addition to urine toxicology screening, the following measures can be used to assess for substance use disorders:

   - CAGE questionnaire
   - Short Michigan Alcoholism Screening Test
   - Current Opioid Misuse Measure (COMM)
   - Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)
   - Substance Use Questionnaire.

4. Activity level

   Any treatment that targets pain should result in the improvement of functional capacity to be considered successful. Measures that can be used to assess activity level and functional capacity include the following:

   - Short-form Health Survey (25)
   - West Haven-Yale Multidimensional Pain Inventory (26)
   - Pain Disability Index (27).

5. Pain attitude and catastrophizing

   It is well-known that negative attitude and unrealistic expectations are associated with increased pain experience, worsened psychological problems, decreased level of activity and disability, and poor outcome to treatment, including implantable devices. Several self-report measures are available to assess pain beliefs and coping mechanisms:

- Coping Strategies Questionnaire (28)
- Pain Management Inventory
- Pain Self-Efficacy Questionnaire
- Survey of Pain Attitudes
- Inventory of Negative Thoughts in Response to Pain
- Pain Catastrophizing Scale (29).

6. Quantitative sensory testing

   This involves the administration of standardized noxious stimuli and measuring different parameters of pain sensitivity such as pain threshold and tolerance. This may be a useful adjunct to psychological evaluations in predicting treatment outcome to implantable devices; patients with increased pain sensitivity before undergoing spinal cord stimulator trial were found to have the least amount of analgesic relief from SCS (30). High levels of pain sensitivity have also been associated with increased risk of pain medication misuse.

Case Study

The patient is a 47-year-old Caucasian female who was referred for psychological evaluation for consideration of spinal cord stimulation (SCS) of her chronic neck pain. She had an 8-year history of neck and upper extremity pain following a motor vehicle accident. She underwent multiple interventions for her neck pain, including interventional blocks and several medication trials, with limited efficacy. She subsequently underwent cervical fusion, which did not help her pain, and her condition progressively worsened over the years.

The patient reported seeing a psychiatrist for a short period of time after her father's death almost 4 years ago, then again after her mother passed away a few months later. She was tried on an antidepressant medication after her mother's death but stopped it after a few weeks because she did not notice much improvement. She was tearful during the interview and admitted to being "very depressed" with recurrent worried thoughts of how she can live her life with such pain. She has isolated herself from her family and friends, endorsed feelings of hopelessness and helplessness, and had no interest in any activities. She reported poor energy and sleep and relied on benzodiazepines to help her sleep. She has been maintained on alprazolam for several years, which she stated was for sleep and pain. She reported having occasional panic attacks in the past, but has not had any for several years.

The patient was prescribed opioid pain medications after her surgery 8 years ago. She reportedly had poor control over her pain pills; she described taking more pills than prescribed and ran out of them early. She described hiding them from her family so they would not know how much she had taken. She was no longer maintained on any opioids at the time of evaluation. She denied abusing illicit substances but reported a strong family history of addiction to alcohol, cocaine, and pain pills. Her medical problems included headaches, hypertension, and sleep problems. Her current psychotropic and analgesic medications included hydroxyzine (Vistaril), quetiapine (Seroquel), tizanidine (Zanaflex), topiramate (Topamax), tramadol (Ultram), diclofenac 1% gel (Voltaren Gel), and alprazolam (Xanax).

She had three children aged 27, 23, and 22. She had been married for almost 30 years. She stayed at home by herself all day because her husband worked full-time. She stated that her family was not supportive and that she no longer had any friends because of being constantly in pain. She has not worked for the past 8 years since her accident. She has previously worked as a special education teacher but has been on disability for the past 6 years. She stated that her family was in significant financial strain because of her unemployment.

The patient was seen in a face-to-face interview along with her husband. She ambulated to the interview room with a normal gait. She appeared to be in moderate distress from her pain. She was guarded initially but became more relaxed as the interview progressed. She showed significant pain behavior during the interview session. Her mood was depressed and her affect showed significant emotional lability. There was no indication of a psychotic process, and she denied any current suicidal ideations. She was asked to complete several questionnaires, including the Beck Depression Inventory-II, the Coping Strategies Questionnaire, and the Pain Catastrophizing Scale. She scored low on the Coping Strategies Questionnaire, indicating fairly low levels of adaptive pain-coping skills, but showed high scores on the Beck Depression Inventory-II and the Pain Catastrophizing Scale.

Despite her interest in SCS, the patient was informed that she presented with several risk factors that could interfere with her benefiting from the implanted device, including

her unstable depression, poor support, and unreasonable expectations. Following the evaluation, her physician was informed that she would not be a good candidate for an implanted device at this time but would instead benefit more from a multidisciplinary pain management approach that would address her depressed mood, coping skills, and current stressors. The patient actively participated in physical therapy and individual cognitive therapy to better manage her mood and recurrent negative thoughts. She gradually showed improvement in her mood, sleep, activity, and coping. She tapered herself off the benzodiazepines, and her psychotropic medications were optimized.

A repeat evaluation after 6 months showed that, despite significant pain, the patient made a number of improvements in coping with her pain. Her mood had significantly improved, she was engaged in a regular exercise program, and she had returned to work part-time. Three months later, she had a successful stimulator trial with a reported average pain rating of 2 out of 10 (down from 7). One-year follow-up showed that the patient had less pain and her periodic flare-ups were appropriately managed with the SCS. She was coping well with her condition, her function had improved, and her mood remained stable.

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Chapter 4

Patient Education for Surgical Interventions for Pain

Elizabeth Scanlan

Introduction

Patient education is key to successful outcomes of pain procedures and surgery. With appropriate patient education, a patient's behavior can be influenced and his or her attitudes and habits can be modified (1). In addition, patients have a right to receive appropriate education and to use the knowledge they gain to participate in the decision-making process and care processes (2). Florence Nightingale, who wrote her famous treatises on nursing in the 1850s, including "Notes on Nursing: What It Is and What It Is Not," had a strong belief in a nurse's role in patient education (3). This philosophy has continued to this day, and nurses continue to play a key role in helping patients make appropriate health choices.

The Importance of Health Education

Adherence to a medical or nursing plan of care is often complicated, as there are many factors that play a role between the initial education and observed patient action. These factors may include differing cultural beliefs, family dynamics, and social and economic issues. In addition, the patient and provider relationship has an impact on whether the patient is ready to adhere to the education and treatment goals.

Health education is paramount in patients with chronic pain. As one of the leading causes of primary care visits, and with the changing healthcare environment, healthcare organizations are finding that they must be accountable when managing chronic diseases such as chronic pain. However, providers find they have less time to teach and counsel patients on an individual basis (4). It is up to the provider and various health systems to find a way to bridge these conflicting realities. When a patient with chronic pain presents on multiple medications and appears drowsy, it is up to the provider during this short visit to determine if the patient's symptoms are due to medication error or some other cause. Was a medication error made because the patient did not understand the instructions? Or did the patient not have access to medications for a period of time due to tight finances, and resumed multiple sedative medications at the same time once money became available? Was the patient advised by friends or family to take more than what was prescribed? Despite the dichotomy between time pressures versus finding a way to teach a patient about the medications, the changes in the healthcare system can provide many opportunities for health education. In fact, patient-centered care may foster improved healthcare outcomes (5). Using the previous example, appropriate education can reduce medication errors, and can lead to a decrease in utilization of emergency care and hospital readmissions, which can then lead to better health outcomes (6, 7). Not only are the health outcomes improved, but patient satisfaction can also be improved—all by using appropriate, patient-centered education (8).

Health Literacy and Patient Education

Health literacy is an integral part of patient education. "Health literacy is the ability to obtain, process and understand health information and to make informed choices about health care" (9). Providers should be aware that there are certain high-risk groups, including the elderly, low-income patients, patients with limited English proficiency, homeless patients, prisoners, and patients with limited education (9). In fact, some studies indicate that 45% of high school graduates have low literacy (10). Other red flags for low literacy include multiple no-shows for appointments, incomplete registration or pre-visit forms, difficulty remembering the names of medications and the purpose of medication, difficulty giving a sequential history, and lack of follow through on tests and referrals (9).

Patients with chronic pain may be more vulnerable to the effects of low health literacy because of comorbid health conditions, taking sedative pain medication, and coexisting psychiatric disorders including anxiety, depression, or post-traumatic stress disorder. As a result of these factors, patients with chronic pain may have trouble understanding the information that medical providers give during a medical exam or procedure. Some studies indicate that patients retain only half of the information discussed by their physicians (11). This percentage could be lower in patients with chronic pain. For example, pain and depression may make the patient less mentally astute, adversely affecting memory and comprehension. In general, patients are expected to be able to remember the names and dosages of medication, to understand side effects of medication, to prepare for pain procedures, and to remember to ask appropriate questions to a busy healthcare professional. Further exacerbating the problem, patients may be ashamed of poor reading skills and may hide their difficulty in understanding the instructions. "I forgot my glasses" is a frequent excuse (12).

Patients may feel intimidated, may be less likely to ask questions, or may admit that they do not understand medical terminology. In fact, patients often leave a healthcare visit with a different idea of what they are expected to do, compared to the healthcare provider's instructions (13). For example, a provider may carefully explain the need to stop anticoagulation therapy before a spinal cord stimulator is placed, but the patient may not remember to stop the anticoagulation medication. This can lead to both patient and provider frustration.

Physicians and nurses often use patient handouts to explain procedures and treatment. These handouts might be written at a reading level above the patient's reading ability. In addition, patient handouts often have medical terminology that is complicated or not appropriately explained and therefore is difficult for some patients to understand. Many patients with low literacy skills may only read at a 6th-grade level and thus may have difficulty understanding written information, including surgical consent forms, discharge instructions, and medication instructions (14). Patients with limited health literacy may be less likely to ask their medical provider questions if they are unsure of the care plan and are less likely to participate in medical decision-making. This lack of engagement has implications for the success of pain management surgical procedures (15).

How to Conduct Patient Education

The model of patient-centered medical care encourages patients to share responsibility for their health. One of the first steps in conducting patient-centered education is to begin an educational session by assuming that the patient does not understand your instructions. It is important to set expectations, address the patient's concerns, and encourage a patient to ask three questions (16):

1. What is my problem?
2. What do I need to do?
3. And why? (i.e., what are the benefits to me?)

These questions can help prioritize what the patient needs to know and can help the patient to set goals, negotiate with the provider, and prioritize. Communication is an important part of improving the patient's understanding of pain procedures and treatment plans. The Health Literacy Universal Precautions Toolkit identifies several strategies to improve communication (17, 18).

- Explain diagnoses, procedures, or medications using non-medical language (see Table 4.1 for examples).
- Focus on and repeat key messages and actions.
- Use a "teach back" or "show me" technique to clarify and check for understanding.
- Encourage questions.
- Use patient-friendly educational materials.

The "teach back" method (19) can identify gaps in patients' understanding of the treatment plan, and there is some evidence that the use of the "teach back" method improves diabetes control. These methods may also improve patients' ability to prepare for surgical procedures used to treat pain. When using the "teach back" method, the provider explains, assesses, and clarifies the patient's understanding. Instead of asking," Do you understand?" or, "Do you have any questions?" the provider should say, "Tell me what you understand," or should ask, "I want to be sure I explained how you should take your medicine. Can you tell me how you will take this medicine?"

In addition to using plain language and using the "teach back" method, Rollnick et al. suggest 7 additional tips for clinicians to improve patient communication (19) (see Box 4.1 for further detail). Limiting information to a few key points can increase the likelihood that patients will remember the more important aspects of the clinical visit. Try to be as specific as possible when explaining topics to patients, and avoid speaking in generalities. Written materials alone will not provide adequate patient education, and patients may prefer to receive messages verbally from their clinicians in addition to written materials. Some clinicians' drawings are

Table 4.1 Key Medical Phrases Using Nonmedical Language

Medical Term	Explanation
Topical	On the skin
Adverse drug reaction	Harm that might come from taking a medication
Degenerative disc disease	Pain in spine or back
Kyphoplasty	Treats fractures or breaks in spine
Spinal nerve stimulation	Surgical implant like a pacemaker that sends electrical signals to nerves
Discography	A test used to see what part of the spine is painful. A needle puts numbing medicine and dye into spine.

BOX 4.1 SEVEN TIPS FOR CLINICIANS TO HELP IMPROVE PATIENT COMMUNICATION

Use non-medical language.
Limit information (3–5 key points).
Be specific and concrete, not general.
Demonstrate, draw pictures, or use models.
Repeat and summarize.
Have patients "teach back" and confirm understanding.
Be positive, hopeful, and empowering.

DeWalt DA, Callahan, LF, Hawk VH, Broucksou KA, Hink A, Rudd R, Brach C. *Health Literacy Universal Precautions Toolkit*. Chapel Hill, NC: The Cecil G. Sheps Center for Health Services Research; 2010. Pub. No.10-0046-EF.

useful in explaining complex procedures and can be helpful for patients with low literacy. Plastic models of the spine with disc and nerves are also useful in explaining pain procedures. The clinician should repeat and summarize the important points of the visit, then should ask the patient how he would explain the surgical procedure to a family member in order to demonstrate what the patient knows and understands about the procedure. Finally, a practitioner who is approachable and empowering can create an environment where a patient feels comfortable asking additional questions.

How to Promote Successful Outcomes

The goal of patient education is improved health outcomes. Explaining how spinal cord stimulators work, for example, is one level of patient education, and this is information sharing. However, the more important level of patient education is coaching behavior change (20). For example, smoking decreases wound healing and increases pain. Most patients know that smoking is bad for their health. Unfortunately, despite this knowledge, many patients continue to smoke. The information about the health effects of smoking needs to be internalized and personally applied to improve the chances that change will occur. A patient-centered approach, using motivational interviewing techniques, can help patients identify goals and develop behaviors to meet these goals. Motivational interviewing has four guiding principles (21):

- Resist the "righting reflex" (i.e., resist the urge to tell patients why a behavior is bad).
- Understand and explore the patient's own motivation.
- Listen with empathy.
- Empower the patient and encourage hope and optimism.

Find out what the patient wants. Ask questions, such as, "What do you hope to achieve?" "What are your concerns?" "What are you worried about?"

Help the patient understand the risks and problems with the behavior. Ask what would happen if the patient did not make any changes, and help the patient realize that current behavior will not support his or her personal goals. Help the patient make a plan and decide on the best course of action. Recognize that behavior change takes time, and improvement in health outcomes does not happen in one educational session.

In summary, the key to effective patient education is to tailor the education to the patient's cultural and personal values, reading and education level, comorbid conditions, and expectations. It is helpful to involve the patient and family and to identify the behaviors and skills that have the highest priority in pain procedures. Concentrate on teaching patients self-care skills, such as how to prepare for pain procedures and how to recognize surgical complications. Evaluate understanding using the "teach back" method, and continue to coach the patient using motivational interviewing techniques. Collaboration with all the healthcare team members will improve communication and patient outcomes.

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Part II

Surgical Procedures and Operations

Chapter 5
Implantable Drug Delivery Systems

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Introduction

Intrathecal drug delivery systems (IDDS) allow for the titration of medications directly into the intrathecal space in doses significantly smaller than oral or parenteral routes. IDDS can be used for non-malignant pain, spasticity, or malignant pain. Patient selection, indications, technique, and postoperative issues are discussed further in this chapter.

Preoperative Considerations for Non-Malignant Pain

Chronic pain is a complex and multifactorial phenomenon that persists longer than 3 to 6 months after an initial injury or beyond the usual course of acute disease. It is associated with chronic pathologic processes, which may cause continuous or intermittent pain for months or years, could continue in the presence or absence of demonstrable pathology, and may not be amenable to routine methods of pain control (1). It is estimated that 1.5 billion people worldwide suffer from chronic pain and approximately 3 to 4.5 percent of the global population suffers from neuropathic pain (2). In the United States alone, it is estimated that 100 million Americans suffer from chronic pain, costing between 560 billion and 635 billion dollars, when combining the medical costs of pain care with the economic costs related to disability, lost wages, and decreased productivity (3). Unfortunately, none of the currently available treatments eliminates pain for the majority of patients (4). Intrathecal (IT) drug delivery may offer long-term benefits to a select patient population in disease states including spinal stenosis, failed back surgery syndrome, osteoporosis with compression fractures, and peripheral neuropathies (5–7). The goal of IT therapy is to improve the safety and efficacy of treatment by delivering medication directly into the cerebral spinal fluid (CSF) by closely approximating medicine with its target receptors in the spinal cord. This delivery drastically reduces dose requirements, thereby minimizing side effects and increasing tolerability (5).

While there are many benefits in using IT therapy for the management of non-malignant pain, this modality continues to be debated. The treatment of chronic non-malignant pain is complex and is best approached through a multi-disciplinary model which includes opioid and non opioid pharmacologic management, injection therapy, ablative techniques, physical therapy, as well as complementary and alternative medicine (i.e. acupuncture) (8). Only when conservative therapeutic modalities are maximized and proven to be ineffective should IT therapy be considered (8). As a final step before initiating IT therapy, the patient should undergo psychologic screening (discussed further in Chapter 3) followed by a trial (9).

Preoperative Considerations for Spasticity

Spasticity may be defined as a velocity-dependent increase in muscle tone with joint movement (10). Patients suffering from spasticity often describe symptoms of muscle stiffness, tightening, involuntary jerking, pain, and weakness (11). The pathology has been traced to a damage of the upper motor neuron system (either at the spinal or cerebral location) with subsequent excitation of spinal reflex arcs and loss of descending inhibitory mechanisms (10, 12). This may result from any number of neurologic insults including stroke, demyelinating diseases such as multiple sclerosis, spinal cord injury, and cerebral palsy, among others. The Ashworth Scale and the Modified Ashworth Scale are most commonly utilized for assessing spasticity by measuring passive joint resistance and play an important role in assessing functional improvement with treatment. Management of spasticity is crucial in order to prevent further deterioration of physical function from painful contractures and spasms of the affected body region (12).

Baclofen, a synthetic pre- and post-synaptic gamma-amino butyric acid type B (GABA-B) receptor agonist, is a typical first-line oral medication utilized for treating patients with disabling spasticity (13). Since GABA is an inhibitory neurotransmitter, pre-synaptic binding of baclofen to the GABA-B receptor blocks calcium influx, while the post-synaptic binding increases potassium flow, causing a hyper-polarization, which inhibits the release of excitatory neurotransmitters such as glutamate. The resulting effect is a decrease in both muscle tone and spasm through inhibition of spinal reflexes. Studies also suggest that baclofen may have an additional analgesic effect through reduced release of substance P from nociceptive afferent nerves (14–16).

Another oral medication frequently used for the treatment of spasticity is tizanidine, a centrally acting α-2 agonist. Currently, the FDA has approved baclofen and tizanidine for the treatment of spasticity resulting from multiple sclerosis and spinal cord disease. Diazepam, other benzodiazepines, and dantrolene, are typically utilized as adjuncts in the treatment of spasm (13). A meta-analysis by Montané et al. in 2004 concluded that there was weak evidence to support the efficacy of oral anti-spasmodic agents in the treatment of spasticity from non-progressive neurologic disease and that adverse drug reactions from dose escalation (mainly drowsiness, sedation, and muscle weakness) were common (17).

Botulinum toxin injection is an additional option for the treatment of focal or localized spasticity. Utilizing electromyography (EMG), the Botulinum injection may be targeted to the affected muscles to improve spasticity by inhibiting acetylcholine release at the neuromuscular junction. Repeated injections, however, may promote the formation of antibodies against the toxin and decrease the efficacy of the injection (12). It is important to note that both oral medication and interventional approaches to spasticity are used in conjunction with physical therapy as part of a multimodal approach to maximize patient care and rehabilitation.

Goals

When treating individuals with non-malignant chronic pain or spasticity, the goal is to improve quality of life by reducing pain and spasm, respectively. The ideal treatment modality would increase functional range of motion and promote autonomy in activities of daily living while minimizing systemic adverse effects. Thus, the potential benefit of a titratable intrathecal IDDS becomes evident.

Advantages

Chronic oral opioid or baclofen administration often results in numerous side effects including confusion, sedation, respiratory depression, muscle weakness, and nausea

(12, 18). A difficulty with oral baclofen in particular is its hydrophilic nature which restricts penetration into the central nervous system, thereby requiring high doses to achieve a benefit. Since GABA-B receptors are found in particularly high concentrations in the dorsal horn of the spinal cord, this provides a good target for intrathecal baclofen infusion (14–16, 19). Furthermore, the plasma drug concentrations of both baclofen and opioids are reduced more than hundred-fold in intrathecal delivery as compared to oral delivery, resulting in reduced systemic side effects (11). Intrathecal baclofen is currently approved by the FDA for the treatment of spasticity and has been utilized since the mid-1980s (20). Various studies have demonstrated the efficacy of this treatment modality in the management of severe spasticity resulting from spinal and cerebral origin, including multiple sclerosis, cerebral palsy, spinal cord injury, dystonia, and hypertonia (11, 21–22). Morphine and ziconitide are currently the only two FDA-approved IT medications for the treatment of chronic pain management, although many other medications are widely used in "off-label" fashion.

Alternative Treatments and Procedures

Intrathecal baclofen IDDS is currently considered the main technique for functional neurosurgery of severe spasticity (23). Alternative surgical options remain part of a multidisciplinary approach to the patient's underlying illness following the failure of conservative management, and are aimed at improving function and alleviating pain (22, 23). Neurosurgical options to reduce spasticity include irreversible neuro-ablative techniques such as peripheral neurotomies, selective dorsal rhizotomy, dorsal root entry zone (DREZ)-lesion, as well as reversible techniques such as spinal cord stimulation and cerebellar stimulation (though these have few indications currently). Of note, the irreversible neuro-ablative techniques result in permanent hypotonia and are only indicated in select patients with localized spasticity, as they can decrease useful muscle tone (21, 23). Orthopedic surgery may also be indicated for the treatment of contractures, misalignments, and musculoskeletal deformities, particularly in children, who may require a combination of tendon-lengthening procedures, tendon transfers, selected osteotomies, and arthrodesis (22).

Alternative therapies for non-malignant chronic pain include medication management, physical therapy, serial injections/nerve blocks, radiofrequency ablation, spinal cord stimulation or peripheral nerve stimulation, psychological support and surgical intervention.

Preoperative Considerations for Malignant Pain

Patients with cancer suffer from pain due to underlying diseases as well as toxicities of cancer-directed therapies (24). In fact, up to 50 percent of cancer patients will experience moderate- to-severe pain during the course of their illness while almost 100 percent of patients with advanced metastatic disease will experience pain (24–26). Not only is pain more prevalent in later stages of disease but the severity of pain may also increase (25, 26). While readily available guidelines for pain control are present, this population of patients remains under-treated. This is perhaps due to insufficient knowledge of cancer pain by treating physicians, concerns about side effect profile and addiction, and a focus on disease management rather than pain control (25). The most utilized standard in the approach to malignant pain is the World Health Organization (WHO) treatment paradigm. This stepwise guide to cancer pain management focuses on non-opioids, titration of progressively stronger opioids, and adjuvants for cancer pain relief, but does not currently address the role of interventional therapies. Despite adherence to the WHO guidelines, many patients still have inadequate and undermanaged pain, which underscores the importance of implementing a comprehensive pain management strategy (25).

IT therapy is a valuable treatment option for cancer patients with moderate-to-severe intractable pain despite adherence to the WHO treatment paradigm and/or patients with intolerable side effects to their current treatment regimen (24, 27–33). In this patient population, IT therapy may be advantageous over traditional routes because it reduces systemic exposure to the drug and its metabolites as the medication is administered directly to the central nervous system. Since IT therapy uses a fraction of the oral dose, the side effect profile, which is most notably related to effects on cognition and the gastrointestinal tract, is much reduced (24, 27–34). In addition to these benefits, IT therapy also allows for the administration of various opioids and non-opioid agents.

Goals

It is important to discuss with the cancer pain patient and, if appropriate, his or her family, to clearly define the goals of care. Improving and optimizing quality of life for the cancer patient should be a common goal for the primary care physician, oncologist, pain physician, palliative care team, social worker, and faith-based providers alike, and necessitates clear communication between all providers. The goal of an IT pump would be to improve quality of life by minimizing the adverse effects of pharmacologic treatment, decrease pain by delivering a continuous infusion of medication, and increase mobility and range of motion.

Alternative Treatments and Procedures

Although there are many potential benefits from IT therapies, careful thought must be given to placing an IDDS in a patient. The decision to implant requires a comprehensive assessment to ensure success of this treatment modality. Patient preference, patient co-morbidities, disease progression, prognosis, life expectancy, goals of care, and economics of implantation should all factor into the decision (24, 31–32).

For example, if the patient has diabetes mellitus and obstructive sleep apnea, they are at a higher risk for wound infection or complications from the anesthesia required from IT implantation. Furthermore, if the cancer patient is bed-bound, cachectic, and living at home, it would be difficult for in-office visits for medication titrations/refills and the pump pocket would be at higher risk for wound dehiscence.

Additionally, economic factors should be considered. The upfront cost of implantable intrathecal drug therapy is significant due to the hardware itself, operating room time, and total

hospital stay. However, over time, intrathecal therapy could lead to cost savings. Several studies provide data that shows intrathecal drug therapy is cost effective (35, 36, 37, 38). Hasselbusch et al. in 1997 showed that externalized systems were more expensive than internalized pumps in the long term for treatment of pain in the terminal cancer patient, with the cross over occurring at about 3 months (35). For chronic non malignant pain, he found that implantable systems were more cost effective than conventional medical management when treatment exceeded 22 months (35). More recently in 2013, when treating cancer pain, IT therapy achieved cost equivalence at an average of 7.4 months when compared to high cost conventional therapies, (high dose opioid, non generic drugs, and parenteral drug administration) (36). For non malignant pain a study in 2002 by Kumar et al estimated the total cost of intrathecal delivery to be $29,410, as compared to $38,000 for conventional treatments, along with an improvement in disability, over a five year time period. The cross-over point appeared to be about 28 months, when the total cost of conventional therapy began to exceed that of IT therapy (37). Another more recent study by the same author concluded in 2013 that IT therapy was cost effective when compared to conventional medical therapy (38).

The economics of IT implantation should be considered in the context of the holistic picture of the patient's quality of life and the goals of care identified by the patient and his family. For example, if a patient's main goal of care is to return home to spend their remaining time surrounded by loved ones, and if an IT pump, by reducing pain and side effects of opioids, could best facilitate this successfully despite a short prognosis this is an outcome that is invaluable.

Patient Screening and Trial of Therapies

When assessing potential candidacy for IDDS therapy, the practitioner should ensure that patients have already participated in multidisciplinary care and have tried the maximum oral therapeutic regimens available. Only patients who fail optimized oral therapy or who have intolerable side effects should be considered candidates for intrathecal therapy (14). Further screening needs to include analysis of the patient's support system, psychological history, and potential issues of secondary gain that may interfere with the success of the IDDS therapy. While approximately 90 percent of patients suffering from non-malignant chronic pain and/or spasticity receives a psychological assessment as part of the pre-implant screening process (often required by health insurers), it should be noted that only 10 percent of patients suffering from cancer are similarly assessed. Patients who are candidates for an intrathecal baclofen trial will also require established care with a physical therapist to gauge effectiveness of the trial and to improve functionality post-implantation (14). Additional selection criteria for IDDS placement may include constant or nearly constant pain requiring continuous levels of opioid therapy and a clear organic pain generator. In patients with cancer, studies suggest that there should be no tumor encroachment of the thecal sac, and the individual must have a stable enough medical condition to tolerate a surgical procedure (20). Patients with chronic non-malignant pain must be amenable to attending the sometimes frequent follow-up appointments to refill their intrathecal pump, which does require skin puncture. Only after this thorough assessment is the patient scheduled for a trial of intrathecal therapy to determine whether pump implantation will be performed. Patients should also be encouraged to create and define individual, specific, and quantifiable goals before the trial begins. This practice aids in patients' expectations for their own pain management, since complete ablation of pain is rarely achievable (39).

The Polyanalgesic Consensus Conference (PACC) is an expert panel composed of clinicians with experience in the use of intrathecal analgesics for pain management. In 2012 they reviewed existing data on trialing of intrathecal therapies and developed several recommendations to

be considered when planning a trial (39). The medication infused during the trial may be delivered either through an intrathecal or epidural catheter, or via a single intrathecal bolus dose. No trialing method is currently considered superior to another (39). Prior to trialing, discontinuation of anticoagulation therapy is required as per the American Society of Regional Anesthesia and Pain Medicine (ASRA) guidelines (39, 40).

For single bolus techniques utilized in baclofen trials, the effects are usually assessed by the physician or physical therapist within a few hours of administration of medication (since the peak effect of intrathecal baclofen takes place 4 hours post-injection and weans by 8–12 hours) (14, 41). Success is typically defined by decreases in the Ashworth or Modified Ashworth scores in the lower extremities, with a 1 point decrease in mean Ashworth score being clinically significant for cerebral spasticity and a 2 point decrease significant in spinal spasticity (11, 41). The goal of the trial is to ascertain if the patient's condition will respond to intrathecal baclofen. The most common side effect from the baclofen trial is under or over dosing, which may warrant careful dose adjustment in the final pump settings should the patient decide to proceed with implantation. The importance of dose titration in trials and implantation is especially true in ambulatory patients who utilize some degree of spasticity to walk. Therefore a balance exists between eliminating excessive spasticity and retaining the ability to ambulate. If the patient gets an unacceptable degree of weakness they should be informed that titration post implant would be likely to achieve their goal, or the trial may be repeated with a lower dose. If the trial is inconclusive for reasons of inadequate dose it should be repeated with a higher dose since certain spastic conditions are not sensitive to intrathecal baclofen, and implantation is unlikely to lead to success if the trial is equivocal. Less commonly, patients may also experience sedation, bradycardia, autonomic instability, and respiratory depression during trials. Any significant side effects warrant thorough discussion between the patient and physician regarding the benefits of decreased spasticity versus the side-effect profile of intrathecal baclofen administration. Although the FDA-approved intrathecal baclofen bolus test dose is 50 mcg, incremental doses ranging from 25 to 100 mcg are typically utilized depending on patient characteristics and response (0.5–1.0 mcg/kg) (11, 42). The 2012 PACC recommended intrathecal bolus trialing doses for several analgesic medications, which may be utilized in malignant and non-malignant pain treatment algorithms, include morphine (0.2–1.0 mg), hydromorphone (0.04–0.2 mg), fentanyl (25–75 mcg), ziconotide (1–5 mcg), and clonidine (5–20 mcg) (44).

Trials utilizing an epidural or intrathecal catheter are typically performed over a 2- to 7-day period. The advantage of using a catheter versus a bolus injection is that the catheter tip may be placed at or near the dermatomal level involved in pain and thus may more accurately correlate with the actual analgesia achieved by the IDDS (8). The purpose of a trial is two-fold: a) efficacy or establishing an analgesic response and b) future dose estimation by assessing dose-response over time. Single dose trials provide only the first, while continuous trials can deliver more information. Placebo responses can complicate both types of trials.

Immediately after trial initiation (of any kind), the patient should be monitored under the care of a nurse with performance of serial neurologic checks and application of pulse oximetry (14). The 2012 PACC recommended that most individuals undergoing a trial be monitored either in an inpatient setting "or in another appropriate environment" for at least 24 hours. Overnight monitoring is recommended for bolus trialing of short-acting intrathecal opioids in order to reduce morbidity and mortality. An inpatient setting is also recommended for trials in patients with cancer pain, individuals with a tunneled catheter, and patients with non-cancer-related pain who are receiving opioids (39). Of note, in selected patients with cancer related pain it may be permissible to implant IDDS directly without a trial.

Techniques for trials differ widely, even within the paradigm of single shot vs. catheter techniques. At our institution the vast majority of trials are done as an inpatient, with catheters mostly placed in the epidural space and occasionally in the subarachnoid space. Once the trial epidural catheter is inserted an infusion of opioid and/or dilute local anesthetic is begun. The systemic opioid dose is reduced and the epidural opioid dose increased concurrently until analgesia is established, with minimal need for breakthrough pain medication. Physical therapy consultation provides a daily assessment for any improvement in functional status and/or attaining a pre-determined goal mutually decided between patient and physician.

Knight et al. suggested that in order for a trial to be considered successful, one should expect at least a 50% improvement in pain score and/or function (8). It is important for patients to continue whatever oral pain (or spasticity) medication regimen they were taking before the trial, as abrupt withdrawal prior to the trial may confound the results. The final dose of medication chosen for either intrathecal bolus or catheter infusion–based trialing is determined by the patients' individual requirements.

Preparing the Patient for Surgery after a Successful Trial

A thorough description of the procedure should be provided, and patients need to be aware of the cosmetic implications of an implanted pump, with the pocket likely located in their lower abdominal region. They should also be well versed in identifying signs of medication withdrawal and have proper contact information should this develop. As alluded to earlier, the patient and physician must discuss the realistic pain-reduction goals that the therapy can offer (39). The preoperative opioid regimen for non-malignant pain patients should also be decreased as much as tolerated prior to trial or implantation, or even in the first 3 months after surgery. This reduction in oral/transdermal opioid administration may improve the outcome of the IDDS through reduction of opioid-induced hyperalgesia (43). Patients should also be medically optimized for surgery during this time period, which may include an appropriate cardiac workup, weight loss for morbidly obese patients as risk for obstructive sleep apnea, smoking cessation, diabetic regimen optimization, and anticoagulation therapy clarification.

The updated 2012 PACC recommendations for intrathecal therapy consist of an intrathecal drug selection algorithm based on the best available evidence from published reports and panel discussion from experts in the field. Two separate algorithms were developed, one for neuropathic pain and another for nociceptive pain management. The medication regimens are arranged from first-line recommended therapy (supported by extensive clinical experience and published literature) through fifth-line treatment approaches. First-line recommended therapy for neuropathic pain includes morphine; ziconotide; and morphine + bupivacaine. First-line recommended therapy for nociceptive pain includes morphine; hydromorphone; ziconotide; and fentanyl. Dose calculation based on the preceding trial is used to decide the starting dose after implant. Recommended starting intrathecal dose ranges were also made for morphine (0.1–0.5 mg/day), hydromorphone (0.02–0.5 mg/day), fentanyl (25–75 mcg/day), ziconotide (0.5–2.4 mcg/day), bupivacaine (1–4 mg/day), sufentanil (10–20 mcg/day), and clonidine (40–100 mcg/day). The 2012 PACC concluded that "these algorithms were created to help guide clinicians in the safe and effective use of IT therapy; however, physicians should use their own best clinical judgment in making treatment decisions for their patients" (44). For patients with spasticity, the suggested daily dose of baclofen intrathecal therapy typically ranges from 50 to 1,000 mcg per day (20, 45).

Intraoperative Management for Non-Malignant Pain, Spasticity, and Cancer Pain

Antibiotic Prophylaxis

The typical antibiotic prophylaxis regimen used for implantation of intrathecal devices is administered within 30 minutes prior to skin incision and includes cefazolin 1–2 g IV, based on weight, or clindamycin 600 mg IV (for beta-lactam allergy). If there is a history of methicillin-resistant Staphylococcus aureus (MRSA) or allergy to the prior listed agents, Vancomycin 1–2 g IV based on weight may be used (8, 46). Cephalosporins and Vancomycin are used most widely, given their efficacy against staphylococcus, which is a common cause of infection (8). Antibiotic prophylaxis is further discussed in Appendix 11. The ultimate choice of antibiotic depends on local pathogens and sensitivity, and implanters should refer to their institutional antibiotic guidelines (43). A rule of thumb to consider is that the dura mater is entered and there is a foreign body placed—both factors that necessitate an extra layer of antibiotic coverage. In addition to pre-incision IV antibiotic administration, infection prevention also relies upon strict sterile technique within the operating room. As the majority of implanters are not trained surgeons, this is even more imperative, and a low threshold is to be maintained to change gloves or gown or add additional drapes if any contamination is suspected. Furthermore, bacterial colonization of the skin can also be reduced by pre-treating with an antibacterial soap such as Hibiclens prior to the operation (47).

Prior to Incision

It is useful to review relevant imaging prior to surgery, with particular reference to check the level where the spinal cord ends and also to measure the distance from the skin to the subarachnoid space (in case a longer needle may be needed), and to plan an appropriate trajectory.

Patient Positioning

Prior to arrival in the operating room, it is important to designate the location of the intrathecal pump reservoir pocket, depicted in Figure 5.1. This necessitates a formal discussion with

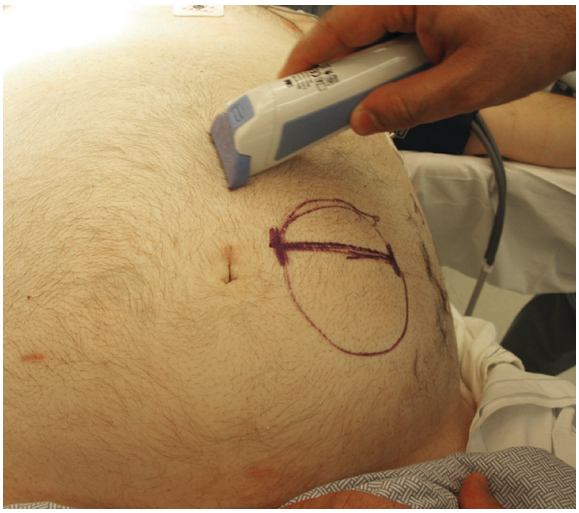

Figure 5.1 Hair removal pump pocket site.

the patient in the preoperative area and a focused examination of the proposed insertion site. The most common site for implantation is typically either the right or left lower quadrant of the abdomen. The patient should be placed in the sitting position and a surgical marking pen utilized to draw the proposed pocket location. A helpful question is asking the patient to show where his or her "belt line" typically is located, and to draw the proposed pocket above this line, taking into consideration the size of the pump. Further, if a patient prefers to sleep on one side of his or her body, the pump should be placed on the opposite side. Inadvertent pump reservoir placement contacting the ribs or other bony prominences may lead to significant discomfort and the need to relocate the pump pocket on a future OR visit. Finally, if a patient has intact gall bladder or appendix, it may be advisable to choose the left lower quadrant over the right side in order to avoid confusion in the postsurgical assessment of acute abdominal pain. The choice may be limited in patients with malignant disease due to the presence of a colostomy, previous incisions scars hernia, or abdominal wall or other metastases. Occasionally no room is available in the abdominal area, in which case an alternative site needs to be chosen: the thigh, the back, or the infraclavicular region. Most of the alternative sites may only accept the smaller 20 ml device. Thus, careful pocket positioning and planning before entering the operating room is a critical step. Failure to mark the pocket site in the preoperative area with the patient in the sitting position may lead to unintended malposition of the operative pocket, as the intended location site may be shifted in the operating room when the patient is in the lateral decubitus position. In most cases the incision is in the same horizontal line with the umbilicus, beginning about one to one and a half inches lateral to it, and extending for 7 cm, which is the diameter of the device. On insertion approximately one-third of the device will be above the incision and two-thirds below. Current manufacturer's recommendations are to place the device completely below the incision; our thinking is that this causes difficulty reaching the distal suture loops in the depth of the incision and results in potentially an insecure and mobile device. The back should be examined carefully, as previous scars and surgery may affect the location of planned incision; decubitus ulcers in the chronic spastic population or malignant ulcers may need to be covered and kept out of the operative field.

As previously mentioned, patients are typically placed in the lateral decubitus position on the operating room table with the designated pump pocket insertion site on the nondependent (up) side of the patient for ease of surgical exposure (see Figure 5.2). The patient's back is brought to the edge of the table and an axillary roll placed. Proper padding of all pressure points is a necessity. Care is to be taken to adjust the arms such that they are out of the X-ray field, especially when high thoracic or cervical catheters are planned. Depending on physician preference and/or patient comorbidities, the procedure can be performed under either general anesthesia or local anesthesia with IV sedation as needed. Alternatively, a spinal anesthetic can be added once the catheter has been threaded to T10 vertebral level, the guide wire is removed and 1 cc 0.5% bupivacaine is injected into the subarachnoid space, resulting in dense spinal anesthesia of the desired dermatomal locations where surgery is to occur.

Preparation

The most common complication of IDDS is wound infection (24, 48), making the skin preparation step of utmost importance. Multiple products are available for surgical site skin preparation, including products containing alcohol, iodine, and chlorhexadine gluconate. Of the various prep solutions available, only surgical chlorohexidine preparation is supported with conclusive evidence (24, 49). Additionally, a 2010 article published in the *New England Journal of Medicine* showed a 40% overall reduction in surgical site infection in patients treated

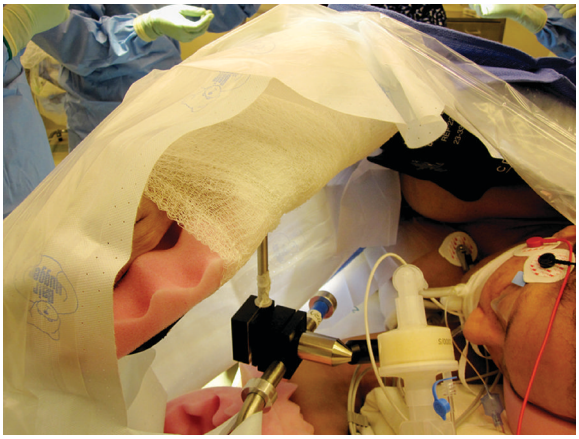

Figure 5.2 Positioning after anesthesia.

with chlorhexidine-alcohol compared to povidone-iodine. This study demonstrated that chlorhexidine-alcohol was significantly more protective against both superficial and deep incisional infections (50). Double prep is to be done for high-risk patients; for elective patients coming from home, a Hibiclens shower prior to coming to hospital is suggested. Appendix 11 further discusses skin preparation.

Draping

Sterility cannot be overemphasized with regard to surgical site infection. It is recommended that the boundaries of the surgical field are initially defined with a clear polyurethane adhesive drape such as 3M Steri-Drape, which adheres to dry skin to help prevent fluids from running under drape and patient, minimizing the risk of body fluid exposure to healthcare personnel and making cleanup easier. It is important to drape the surgical field as widely as possible as the area decreases in size with each successive layer. The widely draped area is then prepped with the selected antiseptic solution and is allowed to dry in accordance with the manufacturer's labeling. Sterile towels are then placed around the prepared region. It may be necessary to staple the towels together, as the lateral towels may not stay in place when the patient is in the lateral position, or to use plastic towel clips (versus metal ones, which will show up in the X-ray field). A half-sheet is then placed over the patient's lower extremities. Next, the surgical field is covered with a povidone-iodine-impregnated plastic adhesive incise antimicrobial surgical film, such as Ioban, 3M Healthcare. The purpose of this is to protect the skin from contaminating the implanted device. Finally, a transverse laparotomy drape is then placed over the surgical field and is cut appropriately to ensure appropriate exposure and further cover the patient to ensure complete sterility of the operative field. Other choices include a chest (or breast) drape, which has a larger operating window; or two U-shaped drapes can be used, depending on the body habitus of the patient. Additionally, the fluoroscopy machine should be draped sterilely, and a three-quarter sheet is placed to allow lateral fluoroscopic views during the procedure.

Special Equipment

It is important to ensure that all components of the intrathecal system, including the catheter, pump, anchors, and appropriate connectors, are available prior to taking the patient to the

operating room. Additionally, the selected intrathecal medication should be available prior to implantation. Fluoroscopy should be available to facilitate access of the intrathecal space at the appropriate level and to ensure appropriate catheter placement. Once the operation is underway, the appropriate pump should be opened and prepared, and filled carefully after checking the medication: this should proceed in parallel concurrently with surgery so that it is ready when needed without wastage of time. Figure 5.3 shows the implanter preparing the pump.

Surgical Technique

After the patient has been sterilely prepped and draped, it is advisable to perform a safety timeout involving all members of the OR team in order to confirm the correct patient, correct surgery, correct site, correct and timely delivery of antibiotic, presence of necessary equipment and imaging, as well as to address concerns from anesthesiology and nursing colleagues. Once ready to begin, fluoroscopy is used to identify the entry point of the spinal introducer needle and the ultimate location of the catheter tip. The side of the image is decided (we prefer left of the image is the left of the patient) and the X-ray beam is adjusted to obtain alignment of the end plates of the upper lumbar vertebrae such that the inter-laminar gap is best visualized. The gap where the subarachnoid space is to be entered is chosen, and then the skin entry point is kept at the pedicle of the vertebra one level below. The planned entry site is then marked and anesthetized with local anesthetic, typically a mixture containing 1% lidocaine and 0.25% bupivacaine in a ratio of 1:1 with 1:200,000 dilution of epinephrine to decrease bleeding. If the patient is under general anesthesia, the choice of local anesthetic is less important. The spinal introducer needle is advanced under fluoroscopic guidance in a paramedian oblique fashion to the level of L2–L3 until the subarachnoid space is entered and CSF is flowing freely. It is best to avoid entering T12 L1 because of the danger of accidentally entering the spinal cord. L1-2 may be approached with caution. In this regard conducting

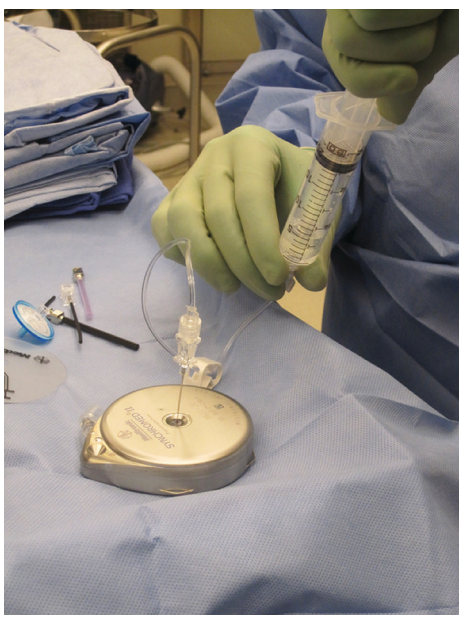

Figure 5.3 Preparing the pump.

needle-and-catheter placement phase of the operation with the patient able to respond may be ideal. Take care to replace the stylet once CSF is obtained, as loss of CSF leads to a post-dural puncture headache and the potential necessity of doing a blood patch in the immediate postoperative period, an avoidable problem.

The catheter is then threaded through the introducer needle, as shown in Figure 5.4. It is important to position the needle so that the tip enters the intrathecal space as close to midline as possible in order to minimize lateral catheter migration during threading. The catheter is advanced under "live" fluoroscopic guidance to the target level that corresponds to the chosen dermatomal level of the pain. Usually the catheter tip is placed in the middle dermatome of the pain area, which is delineated rigorously over the course of the trial. This target level is also influenced by the choice of medication or combination of medications used; hydrophilic medications like morphine tend to have greater spread compared to more lipophilic medications like fentanyl and sufentanil. When inserting an IDDS for delivering intrathecal baclofen, the catheter tip location sites include T10–12 for spastic diplegia, C5–T2 for spastic quadriplegia and C1–4 for generalized dystonia (47). Once the catheter tip is in the proper location, the spinal needle is pulled back 1–2 centimeters to ensure that it is out of the intrathecal space, but is still able to protect the catheter during the subsequent dissection and placement of sutures. An approximately 3-inch incision parallel to the axis of the spine is made using a 15-blade scalpel cephalad and caudad to the needle insertion site. Consideration may be given to making incision prior to needle placement, as experience grows. The blade must be perpendicular to the skin surface to avoid oblique incisions. Blunt or cautery assisted dissection (with a protected tip) is performed until the lumbar paraspinous fascia or supraspinous ligament is visible surrounding the needle shaft. Care should be taken to 'square off the incision' such that each deeper tissue layer is at least as long as the initial skin incision such that the eventual wound is rectangular in cross section rather than cone shaped. A clear area of the deeper tissue is established without fat or filaments of subcutaneous tissue such that the next phase may proceed facilely.

A purse-string suture using 0 Ethibond is placed around the catheter, followed by two anchoring sutures in the fascia on either side of the catheter, shown in Figures 5.5 and 5.6. The suture is roughly 1 cm radius away from the needle, and each bite approximately 1 cm long and 2 mm deep. Eventually this results in a polygonal suture loop ('the purse string') around

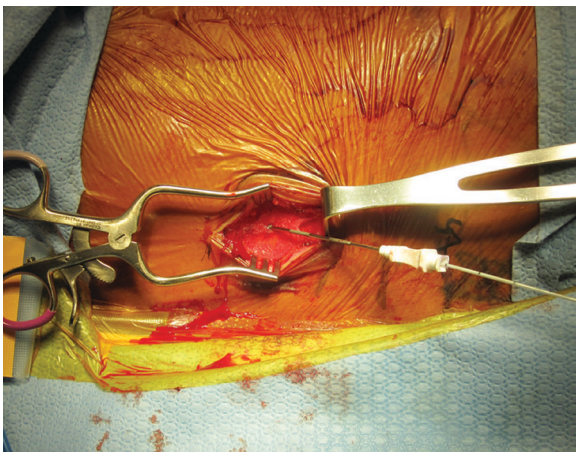

Figure 5.4 Intrathecal needle in place with catheter.

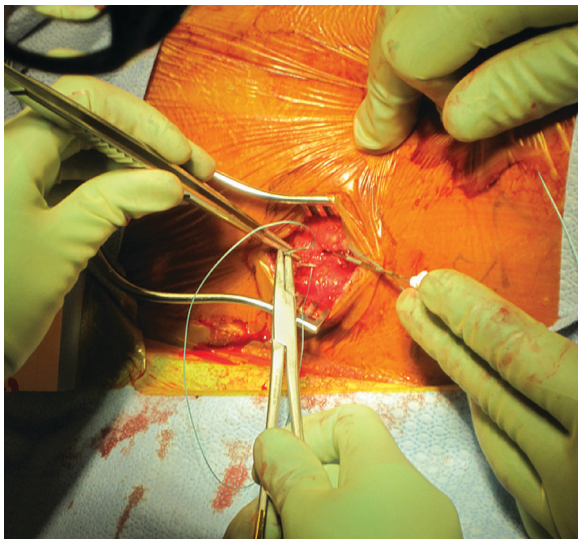

Figure 5.5 Purse-string suture.

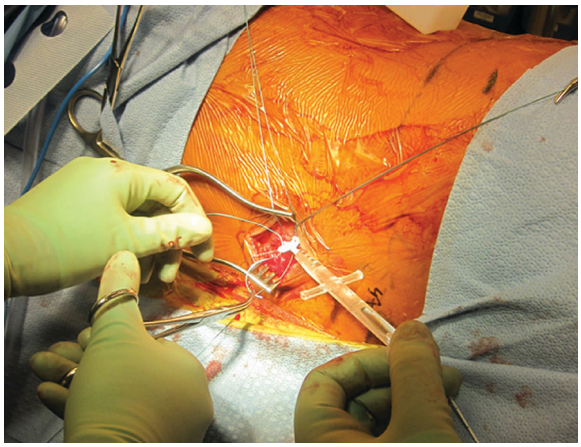

Figure 5.6 Stay sutures for anchor.

the needle. The anchoring sutures are 1 mm wide and deep and close to the needle where the eventual winged suture loops of the anchor are to fall. The spinal introducer needle and the catheter stylet are then removed and CSF is again confirmed, trying to keep the needle and catheter in as straight a line as possible, as this makes it easier to remove the needle over the catheter (see Figure 5.7). The anchoring device is then advanced with the tip buried in the fascia. The anchor is then secured in place using the two previously placed sutures. It is important to ensure that the distal aspect of the anchor remains buried in the fascia at this step, as shown in Figure 5.8. Kinking of the catheter within this section may be one reason for disappearance of CSF after initial visualization. Once complete, the purse-string suture is pulled taut incrementally to tighten the fascia around the catheter to prevent a CSF fluid

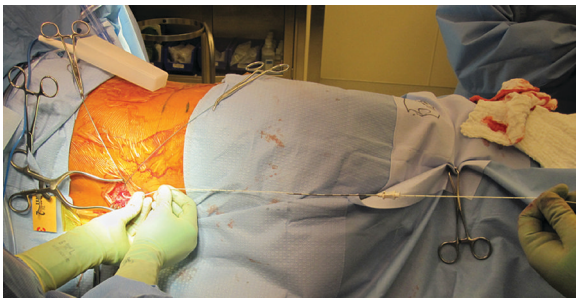

Figure 5.7 Removing introducer while catheter is held as straight as possible.

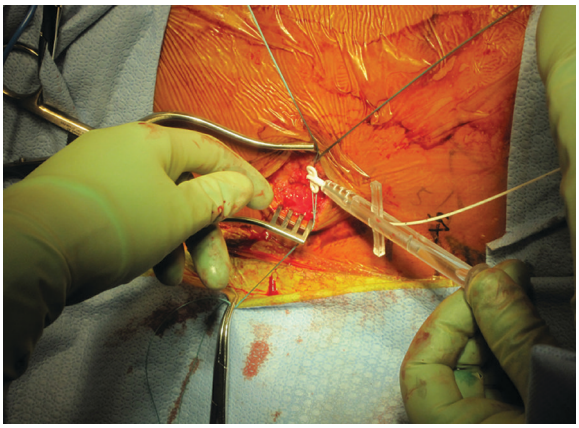

Figure 5.8 Positioning of anchor with tip within needle track.

collection or hygroma (see Figure 5.9). Free CSF flow is again confirmed for a third time after tightening of the purse string. An X-ray picture of the tip of the catheter ensures that there has not been inadvertent displacement.

Attention is then drawn to creating the pocket. After the skin has been anesthetized with a 1:1 mixture containing 1% lidocaine and 0.25% bupivacaine with 1:200,000 dilution of epinephrine, an incision is made using a 15-blade scalpel in the predetermined location, typically on the anterior-lateral aspect of the lower abdominal wall, beginning about one inch from the umbilicus and extending laterally for 7 cm, which is the diameter of the pump. The size of the incision should correspond to the size of the pump, and care should be taken to hold the blade perpendicular to the skin surface so that the incision is not at an angle to the surface. Ideally, the tissue should be dissected down to just below Scarpa's fascia, which is loosely connected to the rectus abdominis muscle by areolar tissue. This plane tends to be less vascular and should decrease the incidence of hematoma formation. Depending on the size of the patient, however, this may not be possible, as the pump should not be more than 1 inch below the skin's surface to provide appropriate cushioning and to facilitate pump refill. However, the need for a stable anchoring of the pump takes priority over distance from the surface; the tissue over the pump can be compressed, or an antenna may be used if the pump has to be placed deeper than one inch. If the subcutaneous fat layer is thick an amount approximately equal to the pump volume may be removed. A combination of blunt dissection with fingers and

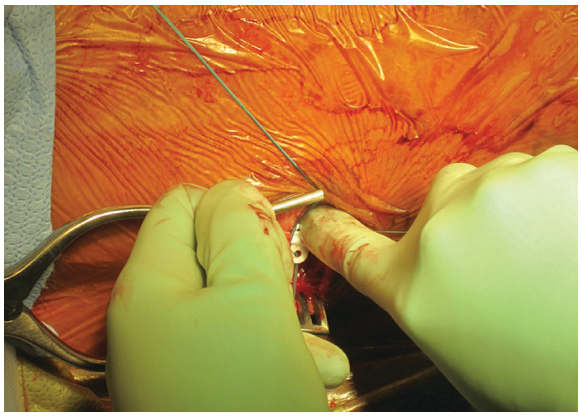

Figure 5.9 Securing the anchor.

Metzenbaum scissors, followed by electrocautery to ensure hemostasis, is recommended. The pump should fit snugly in the pocket, as excess pocket volume may increase the likelihood of a seroma, pocket hematoma, or (rarely) rotation of the pump within the pocket, making it more challenging to access percutaneously. After creation of the pump pocket, an antibiotic-soaked sponge is then placed in the wound.

The catheter is then tunneled from the back to the location of the pocket using a tunneling tool, shown in Figure 5.10. Additionally, we recommend that a standard epidural catheter be tunneled alongside the intrathecal catheter. The epidural catheter may then be pulled through the length of the tunnel while slowly injecting local anesthetic to anesthetize the track before being discarded. CSF flow is again confirmed, and excess catheter length is precisely measured and trimmed. The catheter is then attached to the intrathecal pump. To secure the pump in the pocket and to prevent rotation or flipping, suture can be used through the anchoring eyelets of the pump and secured to the fascia. Alternatively, the pump may be placed in a Dacron pouch, which is sutured to fascia overlying the muscle. When placing the pump in the pocket, gentle loops in the excess catheter should be fashioned to prevent

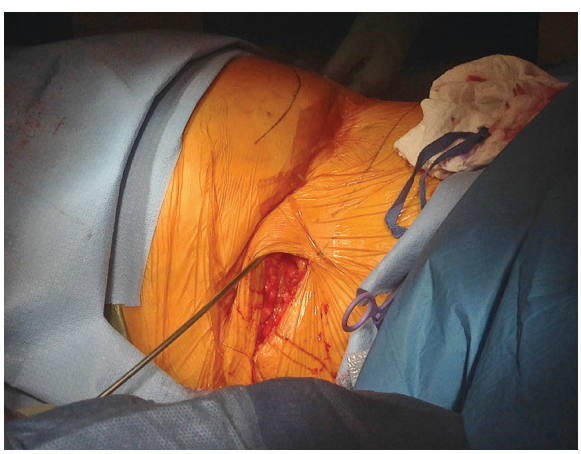

Figure 5.10 Tunneling.

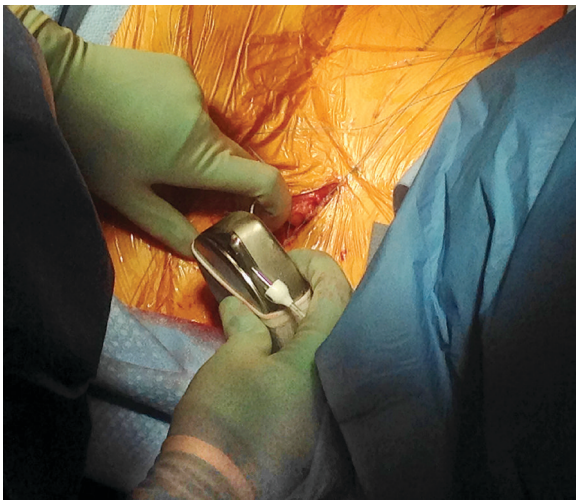

Figure 5.11 Pump being inserted into the pocket.

catheter kinking. The nipple of the pump should point towards the side of the body where the catheter will go to avoid unnecessary turns that could lead to kinks. Finally, the pump is placed in the pocket and sutured in place, taking care that the catheter is not trapped within the suture. Figure 5.11 shows the insertion of the pump into the pocket.

All wounds are then copiously irrigated with low-pressure antibiotic irrigation solution, and a multilevel closure is performed on all incisions. The subcutaneous layer is closed first, using 2-0 Vicryl simple interrupted sutures to bring together Scarpa's fascia, shown in Figure 5.12. It is important to take bites of fascia to ensure the strength of the closure. Suturing subcutaneous fat instead will ultimately increase the likelihood of wound dehiscence and will lead to empty space within the pocket, which could increase the risk of seroma or hematoma formation and possible infection. This is the first layer of defense against superficial skin infections, which can then be treated with confidence, knowing

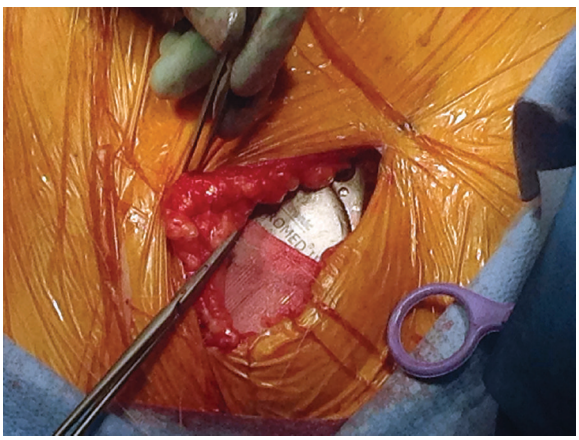

Figure 5.12 Pump in the pocket.

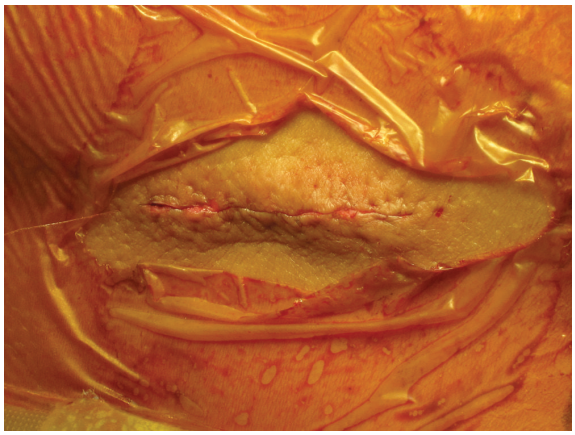

Figure 5.13 Skin closure with 4.0 monocryl.

there is less likelihood of contaminating the metal. Once this layer has been sutured, digital pressure should be exerted to check for gaps and loose areas. The metal of the device should not be palpated. After the fascia is closed, the deep dermal layer is closed, using 3-0 Monocryl with simple inverted interrupted sutures. If any irregularities of the layers or the two sides of the incision are seen, they should be corrected at this time. It is important to keep the knots in the deepest aspect of the wound to decrease the likelihood of surfacing. However, if surgical skill is rudimentary, then routine noninverted sutures are sufficient. The skin is closed with a running subcuticular stitch, using 4-0 Monocryl absorbable suture, with care taken to bring the edges carefully together. This step is shown in Figure 5.13. Finally, a skin adhesive is used, followed by longitudinally placed thin, adhesive strips such as Steri-strips, and a waterproof transparent dressing, such as Tegaderm, separated by a layer of gauze or telfa. Figure 5.14 shows the application of Steri-strips to the wound. Do not stretch the Tegaderm to accommodate the wound or dressing size, as this leads to skin blisters; use a second Tegaderm.

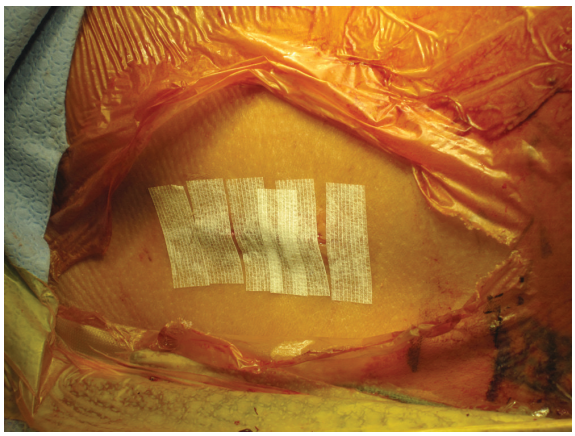

Figure 5.14 Steristrips over incision.

Patients are given strict injuction not to get the wound wet until seen in first postoperative visit one week later. For malignant pain, patients often stay hospitalized until they can be discharged; patients with spasticity are often sent to rehabilitation facilities where final titration can be accomplished along with appropriate therapy. Non-malignant pain patients are usually discharged the same day or within 24 hours. Final titration of the device is accomplished over the next 2–4 weeks on an outpatient basis.

Common Intraoperative Complications and Their Management

When suturing the intrathecal catheter to the anchor, it is possible to inadvertently occlude the catheter; therefore, one should always check for free-flowing CSF prior to final attachment of the catheter to the pump reservoir (8).

Wound hemostasis is crucial to obtain prior to closure. During the preoperative evaluation, it is important to identify patients taking anticoagulants, which may need to be held prior to the procedure. As stated previously, the ASRA guidelines for anticoagulation and spinal/epidural techniques provide consensus data for managing anticoagulants (40). Complications of significant bleeding can include epidural hematoma with spinal cord compression. Any postoperative patient with significant back pain that subsequently develops neurological deficits (such as sensory changes and motor weakness) deserves immediate evaluation for epidural hematoma, including imaging and neurosurgical consultation for possible hematoma evacuation (8).

Neurologic injury to nerve roots or the spinal cord itself is always a concern during catheter placement in the intrathecal space. Any new postoperative neurological findings, especially pain, motor and sensory changes, and bowel and bladder dysfunction should warrant prompt examination and workup, with neurologic injury as part of the differential diagnosis.

Postoperative Management

Common Postoperative Complications and Their Management

Complications such as a CSF leak, catheter malfunction, and infection have been known to occur, albeit rarely, after implantation. CSF leaks are thought to occur in up to 20% of patients, likely due to performing a dural puncture with a 15 gauge needle followed by the insertion of a much smaller catheter. The most common presenting symptoms are those of a post-dural puncture headache. Classically, this presents as a positional headache improved by lying down, worsened by sitting or standing, and often accompanied by photophobia or phonophobia. If excessive, VIth cranial nerve palsy may result. These symptoms may often be treated with bed rest, caffeine, IV/oral hydration, and an epidural blood patch. If a blood patch is undertaken, it is advisable to perform the procedure under direct fluoroscopic guidance, in order to avoid catheter damage. Additional thought should be given to the increased chance of infection while traversing a recent wound. Radiographic verification should be obtained when a suspected leak persists beyond a trial of conservative therapy. If the catheter-pump system appears on CT scan to be intact and continuous with the intrathecal space, then a leak may be suspected. A dye study may be performed in order to identify a potential leak, and consideration may be given to performing an epidural blood patch (8). A CSF leak draining transcutaneously, however, represents a surgical emergency, and is a high risk for infection (47). Spine surgeon consultation is strongly advised when limits of surgical skill are reached.

Catheter-related malfunctions represent a common class of complications after implantation. These may impact the delivery of analgesia to the patient, and therefore prompt diagnosis and early intervention are essential. Problems can include dislodgement/migration (6.1%), fracture/break (5.1%), kink/occlusion (4.0%), cut/puncture (3.0%), and disconnect from the pump (0.7%), among others (8, 51). These complications have been reported to range from 20% to 40% in some instances (20). Of note, catheters may also develop a microleak, which may be difficult to visualize on dye studies. A microleak can be associated with postural symptoms, whereby patients with intrathecal baclofen, for example, feel more relief of spasticity while maintaining certain positions. Despite normal radiographic investigation of "intermittently effective catheters," microleaks may still be found intra-operatively with manual manipulation of the catheter (47).

A much less frequent, but far more serious, catheter-related complication is intrathecal granuloma formation, which is an aseptic inflammatory mass located at the tip of the catheter. Contributing factors are thought to include high opioid drug concentration, an increasingly high daily dose of opioid, and long duration of therapy (20). This concept holds true for both opioid monotherapy and opioids administered in combination with non-opioid medications (43). The lowest effective opioid dose and concentration possible is always the goal. The opioids most commonly associated with granulomas are morphine and hydromorphone. It is believed that these medications trigger a local arachnoid mast cell migration and degranulation, with subsequent inflammatory changes likely contributing to granuloma formation (43, 52). The clinical presentation of a granuloma may include loss of analgesia/decreased therapeutic response, or new and increasing pain in spite of increasing intrathecal opioid infusion rates, with or without development of new neurologic symptoms, such as new onset radicular pain, motor and sensory changes, and bowel or bladder dysfunction. An intrathecal granuloma is best visualized by performing an MRI of the spine with contrast. A neurosurgical consultation should be sought if a granuloma is identified. If neurologic symptoms/deficits are present, then surgical decompression may be indicated, as the granuloma may be compressing the spinal cord. However, granulomas identified on MRI that do not cause neurologic deficits may be monitored conservatively by either discontinuing therapy (stopping the opioid infusion or replacing it with normal

saline), decreasing the concentration and/or dose of the drug administered (usually the opioid), switching agents, or monitoring the patient with serial MRIs until the mass spontaneously resolves over 2–5months (8, 53).

Side effects from excess intrathecal baclofen include drowsiness, weakness, cognitive impairment, urinary retention, and gastrointestinal disturbances (21, 45). Abrupt discontinuation of intrathecal baclofen administration (from pump malfunction, catheter leak, etc.) can result in baclofen withdrawal, which is a potentially life-threatening condition and requires an astute physician to make an early diagnosis. As expected, the earliest signs of baclofen withdrawal are typically an increase in or return of spasticity. Other progressive symptoms include mental status changes (typically drowsiness), seizures, hyperthermia, tachycardia, hypertension, and rhabdomyolysis leading to acute renal failure, respiratory depression, disseminated intravascular coagulopathy (DIC) multiorgan system failure, and even death. While attempting to diagnose the problem with the IDDS, the patient should be started on oral baclofen dosing (13, 45). Large doses of oral baclofen may be necessary, and even this might be insufficient to achieve high enough CSF levels to avoid withdrawal (45, 47). According to the "ITP Therapy Best Practice Forum" expert panel in 2004 (funded by Medtronic, Inc), oral baclofen may be insufficient to prevent withdrawal if the dose of intrathecal baclofen was > 900 mcg/day (47). In these instances, the panel suggested the use of a lumbar drain, which can be connected to an external microinfusion pump used to administer intrathecal baclofen until the oral levels are effective (45, 47).

Ineffective hemostasis in the operating room may lead to hematoma or seroma formation at the pump pocket. The site may appear swollen or bruised, and may be painful to touch. This may last for 2 months, is often self-limiting, and is managed conservatively through application of direct pressure from abdominal binders (8). Occasionally this may need repeat aspiration at the time of refills, especially if the etiology is edema from lower extremity vascular occlusion in malignant pain. If there is any suspicion of infection, then it is prudent to aspirate the fluid from around the pocket and send it for culture and Gram stain, without injuring the catheter. Therefore aspiration should be done with fluoroscopic guidance, or after careful examination of imaging done prior. Of note, seromas typically contain an elevated number of WBCs; therefore the presence of bacteria is required to officially confirm or rule out an infectious process (8).

Wound infections are another serious complication that needs prompt intervention in the postoperative period. Any signs of fever, increasing erythema, warmth, and tenderness at the operative site should prompt immediate workup, including CBC to check for leukocytosis and culture if possible (8). While superficial surgical site infections may be treated effectively with appropriate antibiotic coverage, infections of the pocket or catheter may require explantation of the entire IDDS, aggressive irrigation and debridement of the operative site, in addition to a course of antibiotic coverage of the involved organism. Any signs of infection reaching the epidural or intrathecal space require immediate device explantation, intravenous antibiotics, as well as neurology and infectious disease consultation with imaging as appropriate. Epidural abscesses typically present with an evolving sequence over days, with symptoms of localizing spine pain, changing first to radicular pain, then to motor and sensory deficit, and culminating in potential paralysis. In contrast, intrathecal infections present with symptoms representing inflamed meninges with characteristic fever, nuchal rigidity, photophobia, altered mental status, and positive CSF cultures (8).

Diagnosing and Managing of Loss of Analgesia

When evaluating loss of analgesia (or increase in spasticity), a stepwise approach is most useful. It is important always to start with a thorough physical examination, focusing first on patient safety and signs of medication withdrawal. Next, evaluate the intrathecal pump mechanics as well as catheter continuity and patency. This can typically be done by interrogating the

pump and obtaining plain films of the catheter to look for migration or discontinuity. If pump interrogation is normal and plain films are inconclusive, then CT imaging may be appropriate to visualize fully the entirety of the catheter course. If these fail to demonstrate a defect, then a radionuclide study is often performed for complete functional evaluation of the IDDS by injecting the radionuclide into the reservoir and monitoring the progress of the radionuclide as it travels to the subarachnoid space (54). A side port injection of contrast material (after aspiration of CSF to remove concentrated drug from the catheter) under live fluoroscopy is the next step to confirm mechanical continuity of the system. The entire course of the cathter is to be examined for extravasation of dye with special reference to 5 areas: the junction of the catheter and pump including the extra catheter behind the pump, the lateral course of catheter, the area of the anchor at the lumbo dorsal fascia, the tip of the catheter and the ensuing myelogram. If this is being performed intra operatively then a rubber shod artery forceps can be used to pinch the catheter and an injection performed under pressure to identify small leaks between the segments from pump to anchor and beyond the anchor into the spine. A rotor study is performed next to confirm proper funtioning of the device itself. If these investigations reveal a normally functioning device and patent catheter, yet patients are still not receiving adequate analgesia despite several dose increases, then the physician may choose to rotate or change the infused medications (44). The possibility of disease progression should always be on the differential diagnosis when considering causes of decreased analgesia. Finally, continued unsatisfactory results may warrant exploration of adjuvant therapy such as oral medication supplementation, physical therapy, further interventional techniques, and possibly spinal cord stimulation (44). Occasionally, in cancer related pain when the pain spreads into an area not covered by an intrathecal pump an additional epidural catheter can be placed as a desperate measure, or a cordotomy performed if facilities are available.

Nursing Considerations for Patients with Implantable Devices

The nursing staff should be prepared to treat respiratory depression after IDDS implantation, especially in patients who are receiving opioid intrathecal therapy. Patients should have their respiratory rate, oxygen saturation, and vital signs monitored closely (43). Opioid antagonists such as naloxone should be readily available for emergency use.

Rehabilitation Considerations for Patients with Implantable Devices

Surgical site dressings should be removed by the physician at postoperative day 7, yet abdominal binders should continue to be worn for 4–6 weeks after surgery. It is prudent to avoid showering or soaking in water for at least 24 hours after implantation.

Rehabilitation is important as part of a sound multidisciplinary approach to pain management of patients with intrathecal delivery systems, and is especially crucial for patients starting intrathecal baclofen in order to maximize the effects of reduced spasticity by increasing function. Patients should be counseled to refrain from heavy lifting and straining for a 6-week period to avoid catheter migration. A benchmark of lifting no greater than 10 pounds is often used. Further, the patient should be advised against extreme reaching or stretching with their arms above their head for a similar length of time.

Treatment with intrathecal opioids may have several effects on the endocrine system, including decreased levels of growth hormone, follicle-stimulating hormone, luteinizing hormone, and testosterone (43, 55–56). Should these result in concerning symptoms, consultation with an endocrinologist may be warranted. There is also an increased risk of peripheral edema in patients receiving intrathecal opioids. The edema typically develops early in therapy and is seen more commonly in patients with a history of medical problems prone to edema, such as venous stasis, heart failure, and renal disease. Lowering the intrathecal opioid dose may improve the edema, as well as conservative measures such as compression stocking and leg elevation (43).

Case Study

A 46 year old female presented for a intrathecal pump refill, placed several years prior for cervical post laminectomy syndrome. She had a history of cervical rib resection and two cervical spine operations, including a spinal fusion. She reported an abrupt loss of analgesia about 2 weeks prior to presentation. In addition she reported mild symptoms of withdrawal which were temporally related to the loss of analgesia. Interrogation of the event log of the pump was unremarkable. Aspiration of the reservoir volume of the pump was within normal limits of infusion accuracy. A provisional diagnosis of catheter leak was made. However an x-ray of the system revealed no discontinuity of the catheter. Consideration was given to contrast injection through the side port of the pump. However because aspiration of the catheter is not often possible with a suspected leak, and an injection of contrast could likely cause an overdose from drug within the dead space of the catheter, an Indium 111 scan was scheduled.

Indium 111 was injected into the pump reservoir at the Department of Nuclear Medicine. At injection the scintigraph showed the presence of the nucleotide in the pump. At 24 hours the catheter was outlined but no presence of drug noted in the intrathecal space. At 48 hours tracer was noted in the intrathecal space and was evident over the cerebrum (See Figure 5.15). The Indium 111 containing reservoir was aspirated and the pump was refilled with new drug and the radionucleotide contaminated drug was disposed as required through nuclear medicine protocols. The study however is reported as a patent catheter without any evidence of leak. This was not congruous with the patient's symptoms.

An examination of the pump printout provided the answer. The total catheter volume was noted to be 0.139 ml along with a internal pump volume of 0.2 ml resulting in a total dead space of 0.339 ml. With a dose of the primary drug being 5.295 mg of hydromorphone per day and at a concentration of 10 mg/ml, the nucleotide containing drug mixture should have reached the intrathecal space in less than 24 hours; however it was delayed by 24 hours (See Figure 5.16). Based on this calculation, the presumptive diagnosis of catheter leak was made and surgery was scheduled.

After induction of anesthesia the patient was turned to the lateral position with her pump containing side uppermost. This was a two piece catheter system, with the connection in the posterior spine area, and the most likely site of the leak was thought to be at the catheter splice. Both the pump and spine area are prepped. Dissection of the catheter splice was undertaken and it freed from scar tissue. The side port of the pump was accessed with a syringe filled with Omnipaque contrast 150 mg/ml and fluoroscopic imaging performed with injection. The catheter was clamped with a rubber shod mosquito forceps proximal to the spliced section. Injection was attempted but appropriately, resistance was noted, and no contrast was seen along the catheter track leading to the conclusion that the catheter to this point was undamaged. The same procedure was then attempted with the forceps compressing distal to the splice, and this time the leak was identified by the extravasation of dye, seen on fluoroscopy. The catheter was repaired, the connection to the pump was opened and CSF drained to clear the entire catheter of residual drug. Resected catheter length was subtracted from the original length recorded in the programming and a bridge bolus programmed. The intrathecal dose was also reduced by 30% as a precaution (and accounting for the portion of the dose that was leaking).

At one week follow-up the patient reported complete restoration of her pain relief.

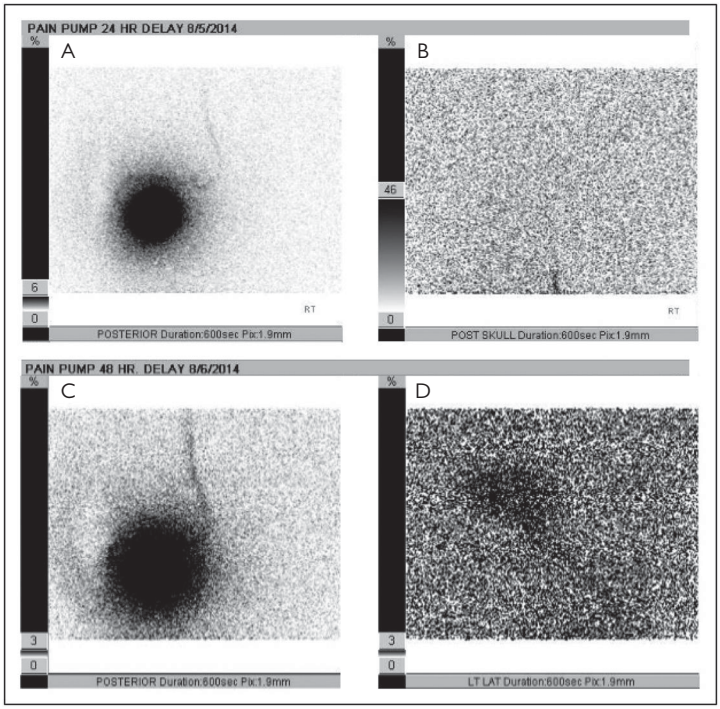

Figure 5.15 Indium-111 scan. A/B at 24 hours: Radioactive tracer present in pump, faintly in catheter, and not in CSF. C/D at 48 hours: Tracer present in pump, strongly present in catheter, and in CSF of brain and spinal cord.

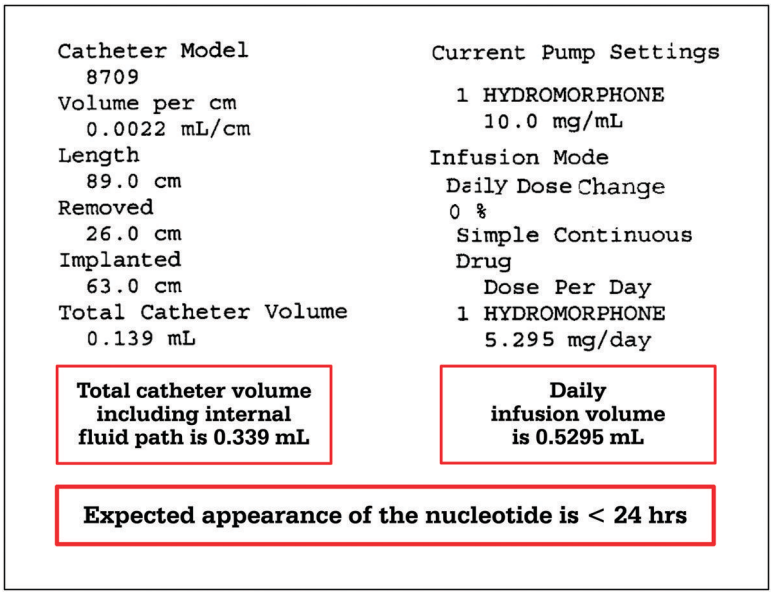

Figure 5.16 Pump telemetry. Total volume = sum of internal pump tubing (0.200 ml) and total catheter volume (0.139 ml). With a hydromorphone concentration of 10 mg/ml, at the dose of 5.295 mg per day, tracer should have reached the CSF in less than 24 hours.

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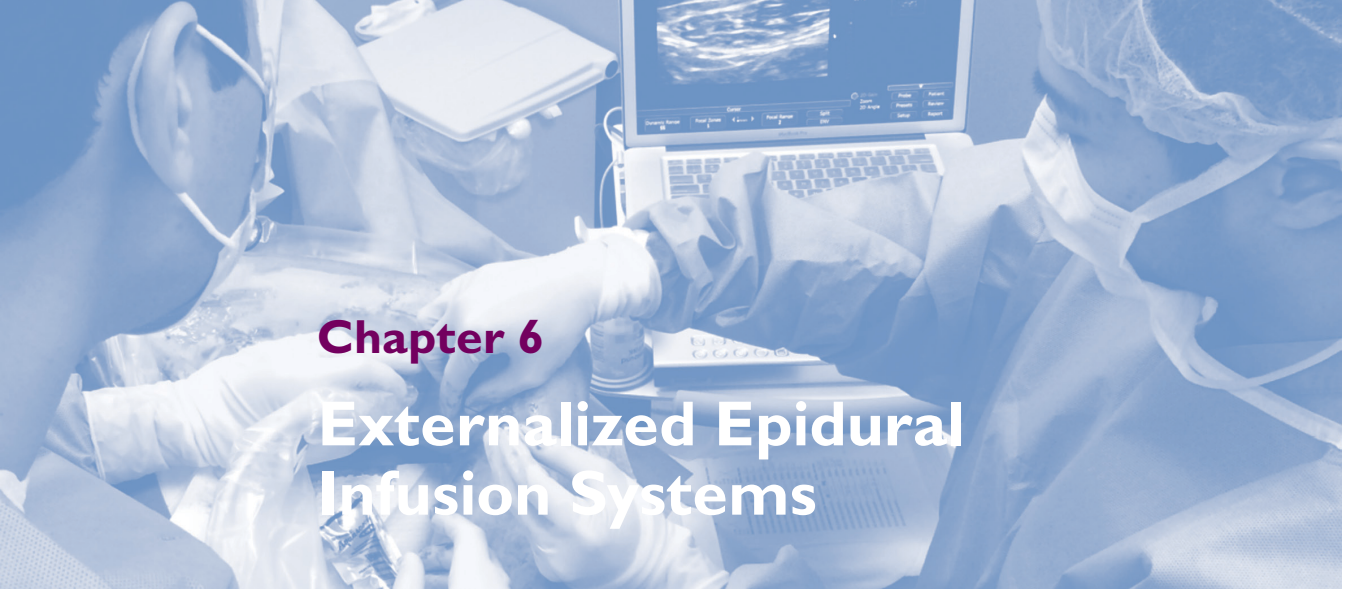

Chapter 6

Externalized Epidural Infusion Systems

Julie H. Y. Huang and Elizabeth M. Rickerson

Introduction

Continuous externalized neuraxial analgesia serves to provide relief for patients with severe pain and a limited prognosis. In this chapter, we detail the technique, care, and management of the externalized epidural system in common usage. Much of the information in this chapter could apply to externalized intrathecal systems as well. On occasion, these systems can also be implanted in the area of a peripheral nerve or plexus, such as the brachial plexus for a patient with severe upper extremity pain.

Preoperative Considerations

Non-Surgical and Medical Management

Generally speaking, opioid and non-opioid adjuvant medications are initially started as part of a comprehensive pain treatment plan. Interventional approaches may be considered:

1. If pain persists despite high doses of opioid medications, or
2. If the patient is intolerant of opioids and/or adjuvant pain medications and their
3. Pain is refractory to other modes of pain management, especially if
4. The pain is in a particular region of the body served by a single defined nerve or set of nerves.

Current analgesic doses of medications (opioids, non-opioids, and adjuncts) should be evaluated to assess the patient's baseline needs and to determine whether a continuous regional analgesia technique is an appropriate modality. It is essential to request an estimate of prognosis from the treating physician and assess the patient's psychosocial situation and home environment to decide if an external system would be appropriate. A reliable home infusion company with a USP 797 compliant pharmacy and visiting nurses who can maintain the system are mandatory.

External infusion systems allow longer-term, continuous drug delivery with an external infusion pump and a compounded drug mixture. These systems are more suitable for patients with a life expectancy of less than 3 months. This prognostic limitation is due to the relatively high risk of infection and malfunction over time when compared to internalized intrathecal pumps (1). Economic considerations also contribute to this suggestion; there are older data indicating that the overall costs of externalized epidural infusions exceed those of intrathecal pumps for cancer patients after 3 months (2). However, economics are not the only factor to consider when deciding whether to implant an externalized system or an internalized intrathecal pump, as an unstable home situation, a noncompliant or delirious patient, lack of insurance coverage for home infusions, or an unreliable pharmacy or home-care company can be important considerations for both systems as well.

The most common system currently used at our institution is the Smiths Medical Epidural Low Profile Port-a-Cath II. Historically, the Du Pen and the Arrow epidural catheters have been used, but these are either not available or not in use anymore. In addition to the information presented in this chapter, we recommend reading the instruction manual included with each device as it will include information specific to the device being implanted. If a patient's prognosis is days to weeks and the severity of illness precludes an operating room procedure, then epidural catheters from any standard epidural kit may be used and the procedure can be done at the bedside. A second epidural needle may be used to tunnel the catheter below the skin from the entry point of the first needle, thereby delaying the onset of infection and prolonging the life of the infusion.

Patient Screening and Trial of Infusion

The patient's medical history and medications should be evaluated to determine the presence of any condition that may increase the risks involved with neuraxial anesthesia, such as factors affecting coagulation status. American Society of Regional Anesthesia and Pain Medicine (ASRA) Conference on Neuraxial Anesthesia and Anticoagulation are the standard guidelines used in determining the most appropriate and safest period for placement (see Appendix 1). Individual clinician judgment may vary, and the risks and benefits of the procedure to the individual patient must be weighed.

The patient's history of sensitivity to local anesthetics, adverse drug reactions, or prior history of complications related to neuraxial placement should be reviewed. Physical examination includes an evaluation of the spine for evidence of scoliosis, focal infection or pain, scars,

limited range of motion, or central obesity, all of which can make positioning and placement more difficult. The target region of the segmental blockade should be determined. Externalized epidural infusion systems can be used at any level of the epidural space, but motor function of the upper or lower extremities can be affected, depending on the location of the catheter placement and concentration of the local anesthetic. Discussion of this possibility with the patient and family prior to placement is obligatory. In our practice we avoid the L1 to L4 vertebral levels as motor block of the lower extremities often results. Patients with tumor in the epidural space should be carefully assessed for the level and degree of involvement as this may make placement more difficult or may be a contraindication to the procedure.

Most patients should have an epidural catheter placed as a trial to determine efficacy prior to implantation of the system. Typically, a temporary catheter is placed either at the bedside or guided by fluoroscopy. The drug mixture is infused for 24-48 hours; during a successful trial, systemic opioids are often titrated down dramatically as the epidural opioid dose and local anesthetic is increased. If it is determined that the temporary catheter helps with the pain significantly, implantation is indicated. The decision to perform a trial prior to implantation has to be balanced with the wisdom and advisability of performing two procedures in a patient who is very ill, so implantation may occasionally proceed without a trial. All medications given neuraxially should be preservative-free to avoid damage to neural tissues. Epidural solutions may consist of local anesthetic alone or may be combined with opioid and/or an adjuvant such as clonidine, an alpha-2 adrenoceptor agonist (3, 4). See Box 6.1 for a list of typical continuous neuraxial infusion solutions at our institution. Custom mixes with other agents or higher or lower concentrations of any agent can be tailored to the individual patient.

Preparing the Patient for Surgery

The port should be placed at a site where it will allow maximum mobility and cause minimal discomfort to the patient. The site should be over a bony structure, such as the ribs or iliac crest, so that there is a hard surface to push against when accessing the port with the needle. At our institution, we typically place the port over the lower ribs. (see Figure 6.1). The target level for the catheter in the neuraxial space should also be determined, usually based on the trial of an epidural infusion.

BOX 6.1 NEURAXIAL INFUSION SOLUTIONS USED AT OUR INSTITUTION

Bupivacaine 0.06% + Hydromorphone 20 mcg/ml
Bupivacaine 0.06% + Hydromorphone 40 mcg/ml
Bupivacaine 0.06% + Hydromorphone 60 mcg/ml
Bupivacaine 0.06% + Hydromorphone 20 mcg/ml + Clonidine 0.5 mcg/ml
Bupivacaine 0.06% + Hydromorphone 40 mcg/ml + Clonidine 0.5 mcg/ml
Bupivacaine 0.06% + Hydromorphone 60 mcg/ml + Clonidine 0.5 mcg/ml
Bupivacaine 0.06% + Hydromorphone 80 mcg/ml + Clonidine 0.5 mcg/ml
Bupivacaine 0.125% + Hydromorphone 20 mcg/ml + Clonidine 0.5 mcg/ml
Bupivacaine 0.125% + Hydromorphone 40 mcg/ml + Clonidine 0.5 mcg/ml
Bupivacaine 0.125% + Hydromorphone 60 mcg/ml + Clonidine 0.5 mcg/ml
Bupivacaine 0.125% + Hydromorphone 80 mcg/ml + Clonidine 0.5 mcg/ml
Bupivacaine 0.06% + Fenantyl 1 mcg/ml
Bupivacaine 0.06% + Fentanyl 2 mcg/ml

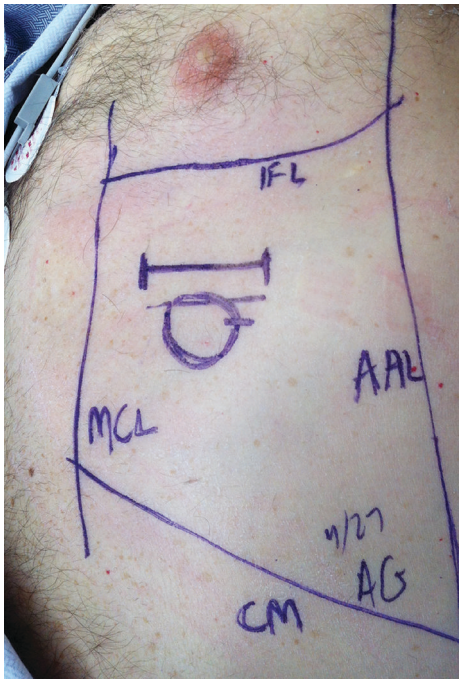

Figure 6.1 Markings for port site overlying the ribs. The line indicates the proposed incision site. The circle indicates the proposed site of the epidural port-a-cath with placement inferior to the incision line.
MCL = mid-clavicular line; AAL = anterior axillary line; CM = costal margin; IFL = inframamary line.

Intraoperative Management

Prior to Incision

A combination of local anesthesia and intravenous sedation is usually sufficient for placement of most external systems, and most are performed in the operating suite under fluoroscopic guidance. Preoperative antibiotics should be administered as per institutional guidelines (see Appendix 11 for further information on antimicrobial prophylaxis).

Pre-procedure anatomical planning is important, with identification of relevant surface anatomy, including the location of the port near the middle of the quadrilateral formed by the infra-mammary line, anterior axillary line, the costal margin, and the mid-clavicular line. (see Figure 6.1). The spine is also examined and bony landmarks are marked for intraoperative reference.

The patient is usually placed in the lateral decubitus position with the desired port access site side facing up. In this position, ensure proper head and leg flexion, avoid shoulder rotation, and keep the posterior aspect of the patient close to the edge of the bed. The arms should be raised to the level of the shoulders so that they do not obscure the X-ray field. Sterile prep and drape should be followed per institutional protocol (further discussed in Appendix 11). Fluoroscopy is needed to confirm the catheter placement location.

Special Equipment

The components of the Smith Medical Port-a-Cath system are detailed in Figure 6.2.

Surgical Technique

Epidural Catheter Placement

If a trial catheter is in place and has been effective, contrast can be injected through it to confirm the appropriate vertebral level. This is more important if the epidural was not placed under fluoroscopic guidance and the exact level of the catheter is unknown. Injection of contrast may obscure the area for intra-operative manipulations of the new catheter, so if confirmation of the level is desired, use a minimal amount of contrast and flush the catheter afterwards. Consideration can be given to dosing the trial catheter with stronger long acting

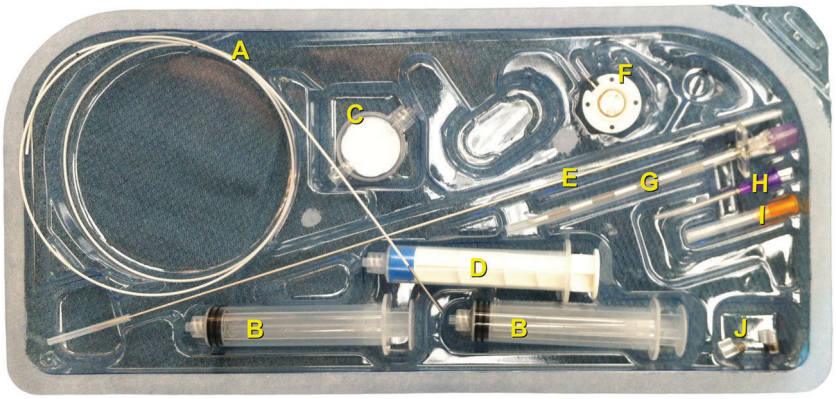

Figure 6.2 Smiths Medical Low Profile Epidural Port-a-Cath II with contents.
A = catheter with guidewire; B = 12-ml syringes; C = filter; D = loss of resistance syringe; E = tunneling tool; F = low profile Port; G = introducer needle; H = noncoring needle to access Port; I = blunt needle to access catheter; J = catheter connector.

local anesthetic solution to provide pain control during the period of the surgery. Once this is done, the trial catheter is removed. The entire posterior midline back, flank, and chest should then be prepped and draped in sterile fashion.

The desired location of skin entry should be determined by fluoroscopy. Align the end plates of the chosen vertebrae and hold the patient in a strict anteroposterior (A-P) position. To help facilitate A-P positioning, place a hand on the hip and gently maneuver it back and forth until the spinous process and the pedicles of the chosen vertebra are equidistant. Using fluoroscopy, isolate the target vertebral level where the tip of the catheter will eventually reside. Generally speaking, the catheter is stable if at least 5 cm of length is within the epidural space, so entering the epidural space two levels below the eventual target level is adequate. The entry point at the level of the skin, should be one or two vertebral levels below the intended level of entry into the interlaminar space as a shallow angle of needle placement allows easier exit of the catheter and decreases the chances of kinking. For example, if the catheter tip is intended to be at T8, then entering the epidural space at T10–T11 is adequate; however, skin entry would then be at the level of T12 or L1.On the ipsilateral side of the intended port placement, infiltrate the para-vertebral skin and deeper tissue overlying the pedicle with local anesthetic. At the skin, a 15-blade scalpel is used to make a one-centimeter cranio-caudal stab incision at the needle entry site. It is important for the incision to be of adequate depth, extending from the skin to the dorso-lumbar fascia and definitively creating access to the plane between muscle below and the full thickness of skin above. Tunneling takes place easily and smoothly in this plane, but is quite difficult if attempted in the shallower fat layer or the deeper muscle layer.

Once the incision is made, the 16-gauge introducer epidural needle from the kit is inserted and guided towards the neuraxial space with fluoroscopy. The lateral or contralateral oblique view can be used to confirm proper depth as the epidural space is reached using a “loss of resistance” technique. Contrast can be injected through the needle to confirm placement in the epidural space after negative aspiration for heme or cerebrospinal fluid (CSF). Aspiration with return of CSF indicates puncture of the dura mater, and blood may indicate intravascular placement or perforation of the vertebral venous plexus. Consider injecting saline or local anesthetic as a test dose to confirm the position of the needle, to develop an analgesic block for the tunneling procedure, and to open the space for easy catheter passage. Injecting local anesthetic in the epidural space is not without risk, as the patient’s perception of parasthesias and pain with placement of the catheter or needle within neural elements will be diminished. If the catheter enters the subarachnoid space with accidental dural puncture, the catheter can be left as an intrathecal infusion, if desired with dosages adjusted accordingly.

Once the epidural needle is confirmed in the epidural space, the radiopaque catheter and guide wire are advanced under fluoroscopic visualization through the epidural needle until the catheter tip reaches the desired level. It is essential to go slowly and gently, especially as the catheter exits the needle, because the guide wire is soft and malleable and becomes difficult to use once bent. Opening a new kit to obtain an additional catheter and guide wire adds expense. After initially advancing cautiously, 0.5 cm at a time, and ensuring that the catheter stays in midline, the catheter can then be advanced more quickly, using fluoroscopy to ensure it does not deviate laterally. Figure 6.3 shows midline insertion of the epidural catheter. Always insert the epidural catheter with the guidewire in place under live fluoroscopy to avoid penetrating the dura, epidural veins, or the spinal cord. Note that the markings on the epidural catheter are 5 cm apart, starting 5 cm from the catheter tip.

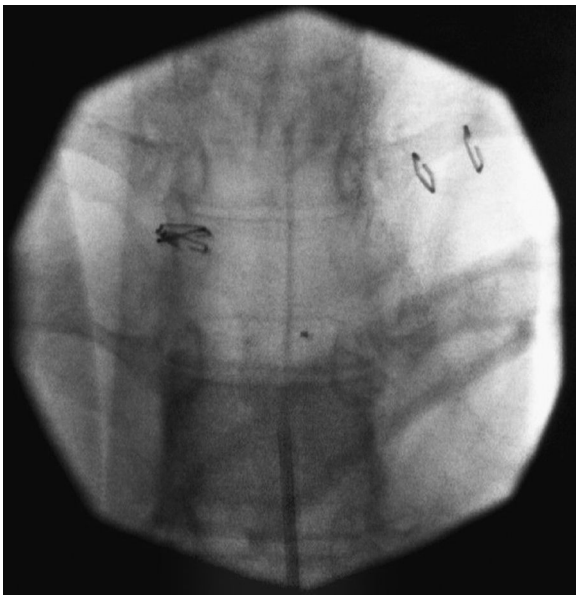

Figure 6.3 Midline insertion of the catheter in the epidural space.

Once the catheter is in the desired position, hold it securely at the needle hub and do not allow it to move. Carefully remove the needle from the insertion site—do not remove the guidewire first. Hold the catheter securely and withdraw the needle slowly and gently, without simultaneously pulling out the catheter. As soon as the needle exits the skin, hold the catheter at the skin insertion point. Fluoroscopy can be used to confirm that the catheter remains in the intended position. If major repositioning is necessary, completely withdraw the needle and catheter as a unit. Withdrawing the catheter back through the needle may damage the catheter or break it off in the epidural space. If the catheter remains in the desired position, continue to hold it at the skin, and withdraw the guidwire from the catheter completely (this sometimes requires some steady force and is easier if the catheter is kept as straight as possible). Finally, pull the needle off over the end of the catheter. At this point, a blunt 25 gauge needle attached to a syringe can be used to aspirate the catheter to confirm that there is no CSF or blood. A few milliliters of sterile saline should be injected to ensure that the catheter is patent. The guide wire construction is such that cutting it leads to unravelling; this is to be avoided.

Port Pocket Creation

Once the catheter is in position and the needle and guidewire are removed, the pocket for the port is made. The depth of the pocket should be about 1 cm below the skin surface. A port that is too deep and not over an osseous structure may be difficult to palpate or access. A port that is too superficial may erode through skin; this is often of special concern in cancer patients who may be cachectic. The entire port must fit in the pocket below the level of the incision so that repeated access with the needle does not require insertion through the surgical wound (see Figure 6.4 for port placement in the subcutaneous pocket). A 15-blade scalpel is used to make a four-centimeter lateral incision across the superior aspect of the pocket. The pocket itself is then created by blunt dissection inferiorly. Place the port in the pocket to ensure that it is large enough to accommodate the port.

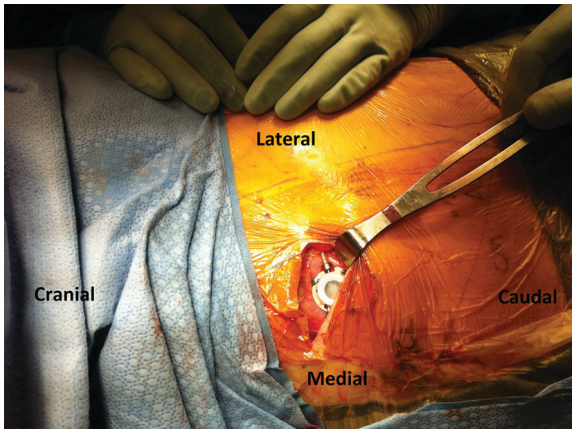

Figure 6.4 Port placement in the subcutaneous pocket. Note that the epidural catheter is tunneled from back to front and is attached to the port.

Tunneling the Catheter

The tunneling tool can be shaped slightly to the patient's body curvature by bending it towards a C-shape with both hands. Remove the shield from the rounded end of the tunneling tool, and insert it into the lateral aspect of the paravertebral incision. Again, the ideal plane for tunneling is between the muscle below and the full thickness of skin and fat above. Advance the tip of the tunneling tool from the paravertebral stab incision to the port pocket site, rotating it as needed to direct it toward the port pocket. Tunneling often requires a two or three step process. Smaller stab incisions can be made and the tunneller and catheter pulled through, reinserted, and advanced to the next stage. An initial stab incision near the posterior axillary line is usually adequate for most patients. If the patient is obese or the appropriate plane is difficult to reach, more than one stab incision may be necessary. Of note, if stab incisions are needed, make sure to attach the barbed tip of the tunneler to the catheter prior to removing the tunneller from the initial stab incision. Once the pocket is reached with the tunneller, ensure that the catheter is attached to the barbed end (the barbs should be covered completely) and pull the catheter through to the port pocket. Make sure to firmly hold the catheter at the spine incision site while pulling the rest of the catheter through the tunnel to prevent displacement. Cut a few centimeters off the catheter to remove it from the tunneller.

Connecting the Catheter to the Port

To minimize that amount of air in the system, the port is accessed with the 24-g needle provided in the kit and is flushed with saline. Throughout this process, care is taken that air is not entrained in the components of the system. At this point, the catheter can be trimmed to remove excess length; make sure to allow sufficient length for the patient's movement afterwards. The catheter connector has one end that will attach to the port; this end has a "flap." The other end has a "ring". Thread the connector onto the catheter so that the ring is on the proximal side of the catheter and the flap end is distal (towards the port). Gently slide the catheter over the port outlet, making sure to bring the catheter as close to the hub of the outlet as possible. Try not to twist or stretch the catheter during this process, and do not use an instrument to bring the catheter over the port outlet as this can cause damage. The flap end of the catheter connector is then placed over the port outlet; there is an indentation in

the connector that corresponds to the hub on the port outlet. Once the indentation is lined up over the hub, close the connector flap. The hinge of the flap is stiff and should be closed once (whereupon it loosens) prior to threading it on the catheter. The ring from the proximal side of the connector is then brought down with a Debakey forceps over the closed flap to lock it in place.

Once connected, ensure that the system remains patent by accessing the port with the 24-g needle provided in the kit and flushing it with saline. Flushing the system should not require extreme force. If resistance is encountered, check the connections and make sure that there are no visible kinks in the catheter. Excessive pressure (greater than 40 psi) can damage or fracture the catheter. (6).

Closing the Incisions and Accessing the Port

To anchor the port, place it in the pocket in the desired position, ensuring that it will lie inferior to the pocket incision. Use permanent sutures (i.e., 0-Ethibond or 0-Silk), to place 4 sutures, one through each of the holes in the port and into the underlying fascia. Irrigate with an antibiotic solution, and then close the port pocket with at least a two-layer closure technique. If stab incisions have been made, these can usually be closed with a topical skin adhesive such as Dermabond. For the back incision, a single layer closure technique may be sufficient, and the site can be dressed with gauze and a sterile transparent dressing.

We recommend accessing the port for the first time while in the operating room under sterile conditions. Based on the patient's body habitus, select the appropriate length non-coring needle (i.e., Huber, PORT-A-CATH) and extension set. Prime the extension set and needle with saline to remove all air. Insert the needle perpendicular to the skin and the port and slowly advance the needle until it reaches the bottom of the port chamber. Once the septum is punctured, advance the needle without twisting or rocking it to minimize damage to the septum and prevent future leakages. Aspirate to confirm that there is no CSF or blood prior to flushing the needle with saline. Secure the needle with a sterile transparent dressing and replace the syringe with an injection cap or extension tubing. Sterile gauze can be placed under the dressing as a cushion around the needle for patient comfort. A 0.2-micron filter should be used, and the infusion can be started in the operating room if desired. The epidural catheter should be clearly labeled as such to minimize confusion.

Postoperative Management

Surgical Site Dressing and Needle Changes

The dressing over the wound on the spine can typically be removed after 3-4 days. The dressing over the port site, the access needle, and the extension tubing should be changed at least weekly and more often if signs or symptoms of infection develop. After the old dressing is removed, the new dressing should be applied under sterile conditions. The manufacturer recommends 3 povidone-iodine swabsticks or wipes: start over the port and clean outwards in ever widening circles and let dry completely. Do not use cleaning solutions that are neurotoxic, such as alcohol. Each time the port is accessed or the needle and tubing are changed, the injection cap or extension set hubs should be sterile or cleaned with povidone-iodine solution. A 0.2-micron filter should be used, and the needle and tubing should always be flushed to minimize the amount of air introduced into the system. Prior to re-initiaing the infusion, aspirate to confirm that there is no CSF or heme.

Hospital Stay

Patients with continuous neuraxial infusions can be monitored during their hospital stay with continuous pulse oximetry and frequent blood pressure checks, and nursing should report any concerns for hypoxia, hypercarbia, apnea, or cardiovascular instability. Patients should be monitored for any signs or symptoms of complications discussed below, including local anesthetic toxicity (perioral numbness, tinnitus palpitations, seizures), epidural hematoma, epidural abscess, post-dural puncture headache, inadequate or unilateral analgesia, new onset of neurologic deficits, etc. Urinary retention may occur, especially with higher doses of local anesthetic; output should be monitored closely. Signs of infection should be evaluated, including erythema and purulent drainage at incision sites. During the first 24-48 hours post-op, the drug mixture concentration and volume can be titrated and a patient controlled epidural analgesia (PCEA) function can be introduced. At our institution, the drug mixture is started at the effective dose and rate determined at the time of trial (starting rate of 6 ml/hour with a 2 ml bolus available to the patient every 20 minutes). The basal rate can be adjusted up or down as needed (up if a larger area of coverage is needed and down if the patient is experiencing numbness or weakness) and on discharge a range of 6-14 cc per hour is advised so that the visiting nurse at home may be able to adjust the device as needed. The PCEA dose range is from 2-4 cc. Once the optimal drug concentrations and volumes are determined, the patient can be discharged from the hospital (assuming that other medical conditions are stable).

After Discharge from the Hospital

Patients may be discharged to home or to another health care facility. The staff of the home infusion company or the facility at the time of discharge should understand how to use the external pump, change the tubing, and access the port. If the access needle or infusion extension tubing becomes dislodged, the port should be re-accessed with a new needle and extension tubing under sterile conditions. Signs and symptoms of local anesthetic and opioid toxicity should be reviewed with the patient, caregivers, and staff. They should also be given a 24 hour phone or pager number to contact the pain management team with any emergencies that arise.

Postoperative Complications and Their Management

Complications specific to external epidural infusions can be drug, system, or procedure-related. In the postoperative period, bleeding and infection are the most immediate risks; watch

closely for wound hematomas, signs of infection, and new neurologic deficits. Pain at the incision sites and minor back pain are usually self-limiting, and can be treated with NSAIDs, acetaminophen, or low dose opioids. Extra caution should be taken with patients who have more than one port-a-cath system in place (i.e., intravascular or intraperitoneal); each system should be clearly labeled.

Bleeding

The major concern with post-operative bleeding is epidural hematoma formation. The risk of this is higher if the patient is coagulopathic or thrombocytopenic. Epidural hematomas can cause spinal cord compression and ischemia, and emergent surgical decompression is then required.

Infection

Patients with external epidural infusion systems are at risk of infection in the post-operative period because of their surgical wounds. After the incisions are healed, however, the risk remains high, as the port must be re-accessed at least weekly. Throughout the use of the port-a-cath system, the patient should be vigilantly monitored for signs and symptoms of infection such as erythema, warmth, or purulence at the incision sites. Meningitis and epidural abscess formation are concerns; pain on injection of medication may be an early sign of epidural abscess. Other signs of epidural abscess include back pain, radiculopathy, and lower extremity weakness. Often the pain is worse with percussion or palpation of the spine; progression to paralysis can be rapid. Definitive treatment of an epidural abscess includes antibiotics, removal of the system, and surgical decompression or percutaneous drainage.

Over time, the catheter and/or port can erode through the skin introducing an additional potential source of infection into the system. This erosion is more likely in cachectic patients and is of particular concern in the cancer population.

Drug Related Complications

Patients can have adverse drug reactions to any of the drugs in the infusion mixture. Local anesthetic toxicity and opioid overdose are the major concerns, and patients and their caregivers should be educated about the signs and symptoms of both. Local anesthetic toxicity symptoms include lightheadedness, tinnitus, perioral numbness, confusion, palpitations, seizures, and cardiovascular collapse. Treatment includes stopping the epidural infusion, IV intralipid infusion, and cardiopulmonary support as needed. Opioid overdose symptoms include respiratory depression, nausea, vomiting, pruritis, delirium, and sedation. Treatment includes stopping the epidural infusion and any systemic opioid injection, naloxone administration, and cardiopulmonary support as needed.

Each time the external pump drug mixture is changed, there is an opportunity for error: the mixture and/or concentration of the drugs can be incorrect, or the container can be labeled incorrectly. Close attention to detail is important when exchanging the new drug container for the old one, and the patient should be closely monitored during the time period just after an exchange for changes in analgesia or signs of drug under or overdose.

Catheter and Needle Malposition/Migration

The epidural catheter can be positioned incorrectly at the time of placement, or it can migrate after implantation into the subdural or subarachnoid space. Subdural injection of local anesthetic may result in a “patchy” sensory block, hypotension, and a mild motor block. Intrathecal

injection of local anesthetic may result in a high spinal with respiratory depression, hypotension and bradycardia. The treatment for a subarachnoid or high spinal is cardiovascular and respiratory support as needed.

If the dura is punctured during placement or the catheter migrates intrathecally post-placement, CSF leaks can cause postdural puncture headaches. Conservative treatment is with PO and IV fluids, caffeine, analgesics, and bedrest. An epidural blood patch can be performed at any level below the indwelling epidural catheter to ensure that the catheter is not damaged.

The most common postoperative problem is the incorrect placement of the needle into the port resulting in the infusion going into the subcutaneous plane or even outside the patient. Unlike vascular ports, confirmation of needle placement isn't possible by drawing back on the needle and getting blood return. The feel of the 'back stop' and the ease of injection usually help decide the correct location. This is a learned skill, and can be especially difficult in the patient with large body habitus. Sometimes the problem is not discovered for hours, when the patient's clothing becomes wet or swelling develops under the skin and there is precipitous loss of analgesia.

Nerve Injury

The risk of nerve damage after epidural blocks is thought to be 0.03–0.1% (5). The damage can be caused by direct trauma to the spinal nerves and cord, from injection of neurotoxic drugs, or from epidural hematomas or abscesses. The cause of the nerve damage should be determined and removed, if possible.

System Occlusions and Leaks

The externalized epidural infusion system can be occluded and/or develop leaks at multiple sites. Peripheral and plexus catheters are more prone to blockage. The catheter can become disconnected from the port, and it can break or fracture at any point along its length. With time, a fibrin sheath can form over the catheter tip and cause an occlusion, or tumor growth can compress the catheter. The port itself can become occluded; of note, the manufacturer recommends against injecting heparin into the system. If the system cannot be flushed easily, if fluid accumulates at the port site, if the pattern of analgesia changes, or if the patient loses pain control all together, the system should be examined to ensure that there are no breakages or obstructions. Fluoroscopy (with or without contrast) may be needed. If the patient's level of analgesia changes or decreases, it may be useful to inject the catheter with concentrated local anesthetic to determine the dermatomal level of the blockade. The needle used to access the port may be placed such that the tubing is kinked by patient movement, leading to periodic occlusion alarms.

Conclusion

Externalized infusion systems are a very useful method of delivering pain relief, and the surgical technique to implant them can be learned more easily than other implantable devices such as intrathecal pumps. These external infusion systems can cause less physiologic damage when implanted, and can be managed in a home setting leading to increased convenience for the patient and a profound improvement in quality of remaining life.

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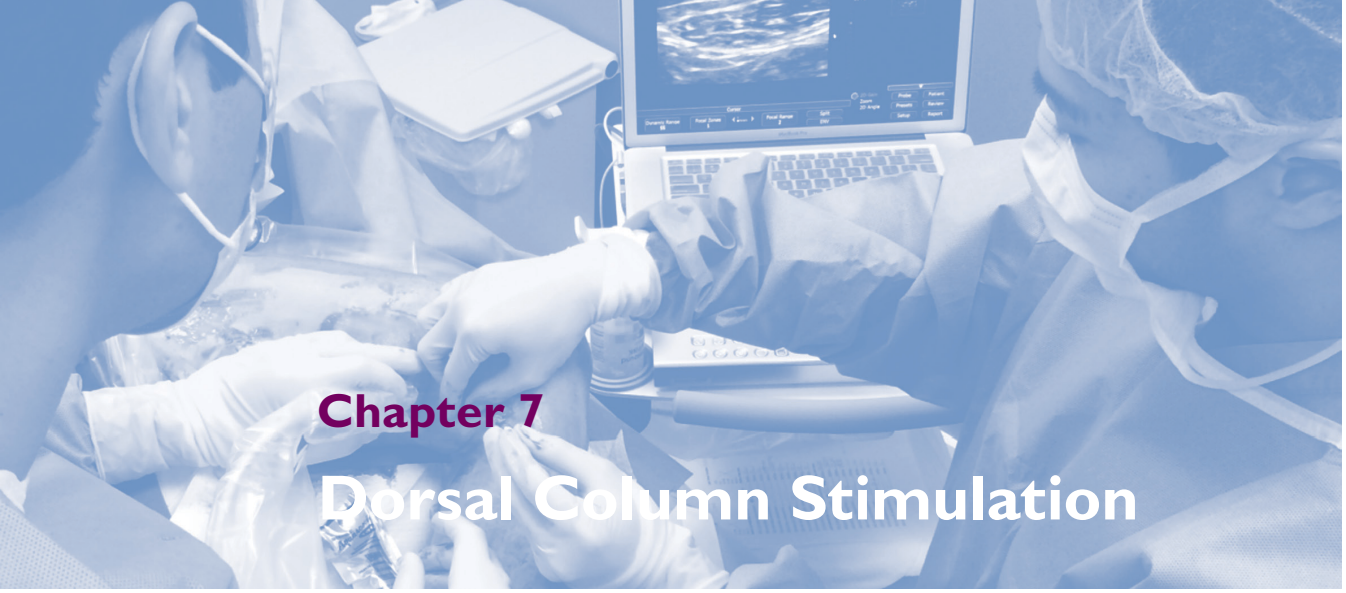

Chapter 7
Dorsal Column Stimulation

Brendan McGinn, Ziev B. Moses, and Travis S. Tierney

Introduction

Dorsal column stimulation, more commonly known as spinal cord stimulation (SCS), is a safe and effective therapy used to help treat intractable chronic neuropathic pain, stemming most commonly from failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS). However, a range of other conditions, including painful plexopathy, arachnoiditis, painful peripheral neuropathy, post-herpetic neuralgia, ischemic leg pain, and intractable angina, have been treated using SCS (1, 2). The gate control theory of Melzack and Wall, published in 1965, postulates that both large and small afferent nerve fibers vie for passage through a hypothetical "gate" where synapses occur in the dorsal horn (3, 4). Assuming that only one type of nerve fiber is allowed to pass through the gate at a time, increased activity of larger myelinated nerve fibers could theoretically prevent the passage of impulses from smaller pain fiber signaling, essentially "closing the gate." Although this theory forms the basis for the rationale of how dorsal column stimulation works by inducing paresthesias to relieve pain sensations, it is widely agreed that the mechanisms involved are much more complicated. After an appropriate patient is selected, a trial period of stimulation, if successful, is followed by permanent lead and implantable pulse generator placement. Presurgical and postsurgical care of the patient undergoing dorsal column stimulation with both percutaneous leads and surgical (paddle) leads are reviewed in this chapter, with attention given to the technical details of the procedures as well as commonly encountered complications. The chapter concludes with two case reports involving both types of implantable systems.

Mechanism of Action

In terms of the gate control theory, it is thought that stimulation of nerves along the dorsal or posterior column of the spinal cord will close the gate on the ascending nerves of the spinothalamic tract that transmits pain sensations. This is a simple enough explanation, but in reality the mechanism of action of SCS is still poorly understood. Neuropathic pain may be attenuated secondary to the activation of inhibitory pathways such as the GABAergic system, which can reduce the level of excitatory amino acids such as glutamate. The fact that intermittent stimulation can provide extended relief after the system has been switched off suggests that there is underlying neuromodulation, possibly in the hyperexcitable wide-dynamic-range neurons in the dorsal horn. Ischemic limb pain may be relieved by the inhibition of sympathetic outflow, along with the release of vasoactive substances, resulting in redistribution of blood flow and a reduction in tissue oxygen demand. This redistribution of blood flow may also apply to the coronary arteries in the case of relieving pain due to intractable angina pectoris. Regardless of the underlying mechanism, paresthesias localized to the area of perceived pain are generally necessary for SCS to provide pain relief. This can be deduced from the fact that pain from complete nerve root avulsions in brachial plexus injury and deafferentation hypersensitivity pain in the setting of spinal cord transection generally do not respond to SCS, suggesting that intact ascending and possibly descending pathways must exist for SCS to work (5, 6).

Preoperative Considerations

Non-Surgical and Medical Management

As with any medical condition, treatment should always begin with the least invasive therapy with the least number of side effects. Any treatment plan for a chronic neuropathic pain condition should include rehabilitation therapy, consisting of exercise and occupational therapy, as well as psychological support to address the depression and anxiety that often accompany chronic neuropathic pain conditions. Medications employed to treat neuropathic pain include but are not limited to nonsteroidal anti-inflammatory medications, corticosteroids, gabapentinoids and other anticonvulsants, tricyclic antidepressents, seretonin-norepinephrine reuptake inhibitors, topical local anesthetics and, investigatively in the treatment of CRPS, the N-methyl-D-aspartate (NMDA) antagonist ketamine (7). Transcutaneous electrical nerve stimulation units may also be used. More invasive therapies include epidural steroid injections as well as peripheral nerve, nerve root, and sympathetic nerve blockade, depending on the etiology of the chronic neuropathic pain.

As SCS is a reversible procedure, it is reasonable to consider a trial if there are no contraindications and if all reasonable conservative approaches are unsuccessful before pursuing more permanent procedures such as surgical sympathectomy or repeat back surgery.

Goals

Alleviation of chronic neuropathic pain is the obvious initial goal of SCS. However, the benefits that arise from this pain relief may be numerous. Aside from the generally accepted goal of a 50% reduction in the Visual Analogue Scale (VAS) score compared to the pre-SCS score, SCS can lead to decreased usage of medications, improved overall function with the ability to better perform activities of daily living (ADLs), and a return to work. If achieving these goals is an indication of SCS efficacy, a 50%–70% success rate can be based on the outcomes of more than 500 clinical trials since 1973 (5). As FBSS remains the most common indication for SCS, when it is used to treat this condition a 50% reduction in pain can be seen in up to 60% of patients (8). One systematic review of 13 individual studies looking at SCS for FBSS showed improved participation in ADLs as well as sleep quality (9), and a randomized controlled trial looking at SCS versus conventional medical management (CMM) showed SCS providing improved leg and back pain relief, quality of life, and functional capacity, as well as greater treatment satisfaction versus CMM (10).

Advantages

SCS has advantages over CMM. These include reductions in the number of physician's office visits (and ideally a reduction in polypharmacy and/or high-dose opioid prescribing), the number of nerve blocks needed for temporary pain relief, the number of radiographic studies required for evolving pain complaints, the number of emergency room visits or hospitalizations, and the number of more invasive surgical procedures performed. All of these reductions lead to a long-term cost-effectiveness that offsets the initial treatment costs of SCS (11).

Patient Screening and Trial of Therapies

Before pursuing SCS, all patients should first undergo a careful history and physical examination, appropriate imaging studies, and a psychological evaluation to determine if SCS may be beneficial to the patient or to determine if any contraindications exist. "On-label" indications for SCS include FBSS, CRPS type I and II, radiculopathy from damage to nerve roots, peripheral plexopethy, arachnoiditis, peripheral neuropathy causing pain, multiple sclerosis, and post-herpetic neuralgia. "Off-label" indications include peripheral neuropathies such as

chronic migraine headaches (discussed elsewhere in this book), ischemic leg pain, and intractable angina (most commonly used in Europe), as well as axial low back pain (5). Although axial low back pain may be musculoskeletal in nature, there are neuropathic forms that may respond to SCS (12). However, the optimal lead positioning for low back pain coverage is often difficult to attain.

Relative contraindications for percutaneous SCS include previous back surgery that may have caused extensive epidural scarring or adhesions, or anatomical abnormalities such as scoliosis or spinal stenosis, which may impair or prevent passage of a lead in the epidural space. Caution is required when recommending SCS to patients requiring serial magnetic resonance imaging (MRIs) for the monitoring of various disease progressions. At this point, only certain Medtronic SCS systems have approval for full body MRIs, although magnet strength is still limited to 1.5 Tesla or less. Patients with cardiac pacemakers also require special consideration to ensure compatibility with SCS systems. Other relative contraindications include the need for ongoing anticoagulation or antiplatelet therapy, as well as psychological comorbidities, with the most severe of these, such as suicidality, considered absolute contraindications. Other absolute contraindications include but are not limited to a surgically correctable serious neurologic deficit such as lower extremity weakness, an anatomically unstable spine, current pregnancy, cognitive impairment making appropriate use of the SCS system unlikely, and ongoing substance abuse (13). The practitioner should also take into consideration a patient's medical comorbidities such as diabetes, chronic kidney disease, or active smoking, all of which may make a patient more prone to postoperative infection. However, these are not absolute contraindications, so deciding whether or not these patients are candidates for SCS is at the discretion of the provider.

Once a patient has been deemed appropriate for SCS, a screening trial is conducted in either the clinic setting or the operating room. The patient should be taken through the entire process step by step before moving forward with the SCS trial. It should also be clearly explained that there is always the possibility that coverage of the painful area with a paresthesia may not actually cause pain relief and may even be unpleasant to the patient. Both percutaneous (temporary) and tunneled (permanent) trials exist, and both have their advantages and disadvantages. A percutaneous trial can be performed in an office setting under fluoroscopy, requiring only a needle insertion for lead placement. Figure 7.1 depicts a single lead placed for trial stimulation.

The patient may go home, resuming normal activities, and upon return to a clinic for re-evaluation can have the lead(s) easily removed. One major disadvantage is the amount of time (2–4 weeks depending on the provider) between trial and permanent implantation to allow adequate healing of the lead track. Advantages of tunneled trials include having a more stable electrode in place for the trial, the need to not replace the trial lead (and therefore replicate a paresthesia) with a new permanent lead, especially after difficult initial placement, and cost-effectiveness by not wasting a lead or leads after a successful trial, as well as the fact that a patient may proceed to surgery immediately after the trial. Disadvantages include the need for a second OR booking and the fact that an incision has been made, regardless of whether the trial works or not, and the increased risk of infection. The presence of postincisional pain during the trial period may also interfere with adequate assessment of the implanted leads' efficacy due to less mobility and the need for pain medication. This may be especially true if a patient is already on high-dose opioids, making the patient susceptible to postoperative hyperalgesia.

The level at which a lead must be threaded in the epidural space to produce a paresthesia is based on the painful area of the body that is to be covered. The dermatomal level in the spinal cord is much higher than the actual corresponding vertebral level. Generally, lower

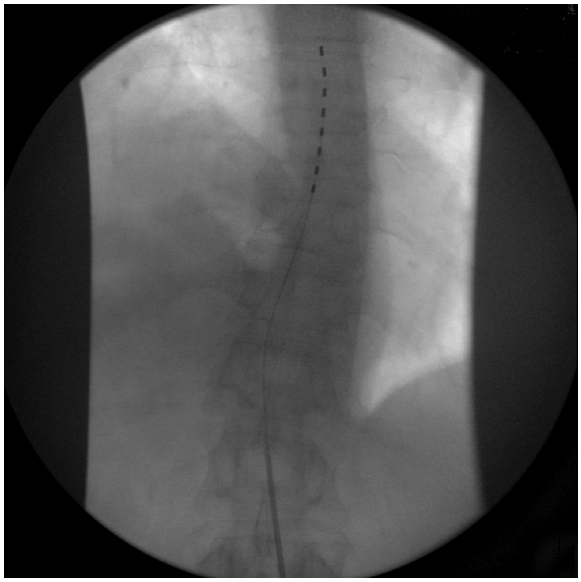

Figure 7.1 Fluroscopic image of a single electrode placed for trial stimulation.

extremity coverage requires the tip of a lead to be placed somewhere between the L1 and T5 vertebral levels. Upper extremity coverage requires the tip of a lead to be placed somewhere between the T1 and C2 vertebral levels (14). Figure 7.2 depicts target vertebral level based on anatomic target (12, 15). The skin entry point for a percutaneous lead should be 1–2 vertebral segments below the level of the epidural space/inter laminar gap to be accessed in order to enhance lead manipulation and stability. After trial leads have been threaded to an initial level, the ends that exit the skin are connected to a trial generator. Stimulation is then provided, with the patient giving feedback on the location of the paresthesia so a lead can be further manipulated to optimally cover the area of pain. Once coverage is deemed appropriate, the trial generator and leads are anchored to the skin with special adhesives, observing strict sterile technique so as to avoid trapping excessive bacteria adjacent to the skin-penetrating lead. The trial generator should be secured to the side of the back the patient usually does not sleep on. The patient should be given instructions on how to operate the temporary SCS system before going home. Over the course of a week, the patient should keep a log of how various programming combinations helped or did not help his or her pain condition. The patient should avoid showering or baths but should be encouraged to remain as active as possible to see if the SCS makes a difference in his or her overall ability to function. The technique of lead implantation is similar for the trial placement and permanent placement. The specifics of lead implantation are discussed in the section "Percutaneous Technique Following Temporary Trial."

The choice to pursue a permanent percutaneous SCS versus a surgical or paddle lead SCS is based on many factors (see Table 7.1 for a summary of the advantages and disadvantages of percutaneous vs. paddle lead placement). This can be simply based on the specialty of the provider, with anesthesiologists performing percutaneous implantations and neurosurgeons implanting paddle leads. Since a trial is always performed percutaneously, a patient may be more inclined to pursue the same technique for permanent placement, especially if they had a successful trial and are anxious about open surgery.

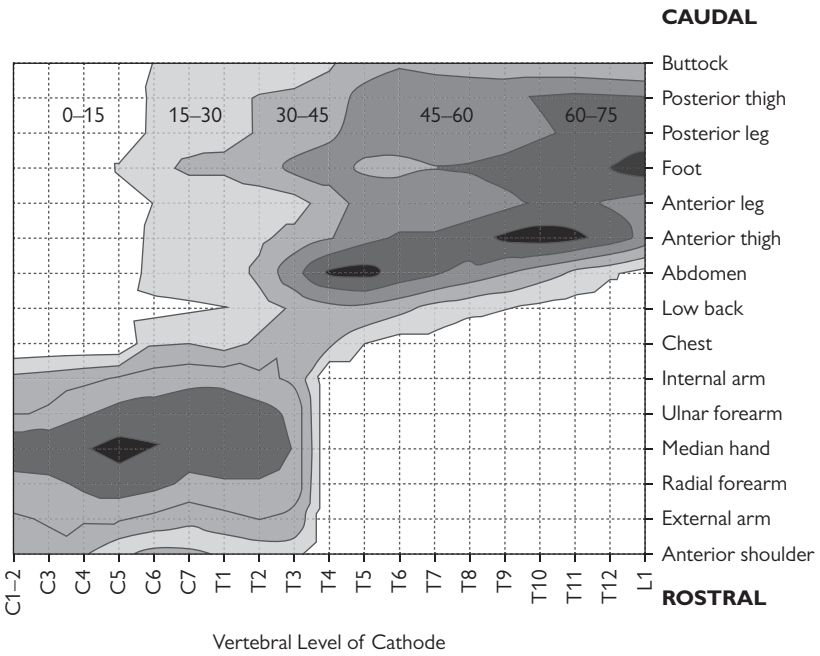

Figure 7.2 Target vertebral level of electrode placement for various anatomic locations.
Adapted from Barolat G, Oakley JC, Law JD, North RB, Ketcik B, Sharan A. Epidural spinal cord stimulation with a multiple electrode paddle lead is effective in treating intractable low back pain. *Neuromodulation*. 2001;4(2):59–66; Molnar G, Barolat G. Principles of cord activation during spinal cord stimulation. *Neuromodulation*. 2014;17:12–21.

Table 7.1 Advantages and Disadvantages of Percutaneous Versus Paddle Lead Placement

Lead Options and Advantages/Disadvantages of Spinal Cord Stimulation	Percutanous Lead	Paddle Lead
Invasiveness of procedure	Generally easier through epidural needle	Requires laminotomy
Visualization of electrode location	X-ray only, for 3D location tracking requires AP and lateral	Direct visualization
Previous surgery in area required for coverage	Difficult to not feasible	Better option
Lead fracture	Easiest to replace	Requires open replacement
Likelihood of lead movement in caudal cephalad direction	More likely but can be reduced with appropriate anchoring technique and pulse generator placement	Generally accepted as less likely
Likelihood of lead movement in side-to-side direction	More likely	Less likely
Lead trolling for ideal coverage	Easy	Difficult
Trialing for efficacy	Ideal	Not appropriate

Percutaneous leads do have a greater propensity to migrate, even with proper anchoring and epidural fibrosis, whereas a paddle lead tends to scar into the dura and resist migration. However, this fibrotic encapsulation can cause difficulty with reprogramming and can make adjustment or explantation of a paddle lead difficult. As anchoring technologies improve, percutaneous lead migration should be mitigated. Percutaneous leads can also be easily removed by simply freeing them from the paraspinal anchors and pulling them out of the epidural space. Placing a paddle lead bypasses the existence of substantial epidural scarring or fibrosis from prior back surgeries which may prevent the passage of a percutaneous lead to the desired vertebral body level. A paddle lead may be more appropriate in a younger patient who may be more active, especially if the target area of lead placement is in the neck, due to the wider range of motion in this area compared to the thoracic spine. A recent retrospective cohort study looking at over 13,000 patients over a 9-year period who either received a percutaneous or paddle lead SCS showed that while paddle leads are associated with slightly higher initial postoperative complications, they are associated with significantly lower long-term re-operation rates. However, long-term healthcare costs are similar between percutaneous and paddle leads, although revisions for paddle leads are much more difficult (16).

Preparing the Patient for Surgery

Once a successful trial has been completed and both the patient and pain management team feel it is appropriate to move forward with a permanent SCS implantation, the patient must be prepared for the permanent implant. Benefits must be elucidated, which may include only a partial but not complete resolution in pain, increased quality of life, the ability to more fully participate in ADLs, and less utilization of the healthcare system, with a reduction in medication usage. Surgical risks must also be fully explained. These include but are not limited to bleeding, infection, damage to the dura and spinal cord and adjacent nerve roots, with the worst-case scenario being complete paralysis. Inadvertent dural puncture during the percutaneous technique or sustaining a dural tear during the surgical technique can result in leakage of cerebrospinal fluid (CSF), which may lead to a low pressure headache that could require an epidural blood patch if not resolved with conservative measures (hydration, caffeine, Fioricet, etc.). The perioperative process must be reviewed and should include describing the operating room atmosphere, patient positioning, and the expected level of sedation. The postoperative course should be fully explained as well and should include the expected length of hospital stay, when the patient should return to clinic, the importance of restricting activity as the healing process progresses, and the fact that optimizing pain relief is an ongoing dynamic process between the patient and the entire healthcare team.

Alternative Treatments and Procedures

Alternative treatments include all of those listed in the earlier section “Non-Surgical and Medical Management.” There are more invasive procedures that one may consider if SCS has been deemed inappropriate or ineffective. Dorsal root entry zone lesioning for chronic neuropathic pain has been performed for over 40 years with reports of up to a 75% success rate in achieving relief of painful radiculopathy with lesioning at the level of injury (17). Sympathectomy can also be performed for CRPS I and II when patients fail to respond to SCS or intrathecal drug infusions. Retrospective studies of surgical sympathectomy for the treatment of CRPS demonstrated successful long-term outcomes in 70%–85% of cases with thoracic sympathectomy and slightly less with lumbar sympathectomy (18). Other alternatives include cordotomy, motor cortex stimulation, and deep brain stimulation.

Intraoperative Management

Special Equipment

Besides a C-arm, Jackson table, and appropriate surgical instruments, a percutaneous implantation requires equipment to properly access the epidural space. A 14G introducer needle is used to allow for easy passage of a lead once the epidural space is accessed (making the potential for significant and symptomatic dural puncture higher than when using standard smaller epidural needles). Various tools may be used to navigate the epidural space once it has been accessed and a lead does not pass easily. These include a standard wire and a stiffer steerable catheter (Racz, Epimed). Clearing a path for the lead through epidural fat or fibrosis will allow for easier passage but does not mean that small lead adjustments will be any easier.

Technique

Percutaneous Technique Following Temporary Trial

After the patient has been placed under monitored anesthesia care with adequate sedation and has been prepped and draped in a sterile fashion, the vertebral level at which the introducer needle is to enter the skin is found under C-arm fluoroscopic guidance using a metal pointer. Care should be taken to align the endplates as much as possible in order to improve the accuracy of the image. We also recommend uniformly keeping the left side of the patient as the left side of the fluoroscopic image to simplify the orientation. The areas paramedian to this level at either medial aspect of the pedicles (which corresponds to the lateral edges of the lamina) are marked and anesthetized with local anesthetic such as 0.5% Lidocaine or stronger. Under fluoroscopic guidance, the 14G introducer needle is then inserted through the skin at an angle of approximately 45 degrees and is advanced in a medial and cephalad direction to the chosen vertebral levels above the initial entry point. This allows the angle at which the introducer needle enters the epidural space to be shallow enough so as to guide a lead in a cephalad direction. The superior edge of the target level's lamina should be touched with the needle tip and advanced past, as little as possible, to engage the needle in ligament. A glass syringe and stopper can then be attached to the needle. Using a loss of resistance technique to either air or saline, the epidural space is accessed with the needle, taking care to enter it in the anatomical midline, as the space is widest in this region and manipulation is facilitated.

The level at which the needle is inserted and the level at which the epidural space is entered depends largely on the patient's body habitus. A patient with very little tissue between the skin surface and ligamentum flavum posterior to the epidural space may allow a needle to pass between lamina at a shallow enough angle only one level above the entry site. One with extensive muscle and adipose tissue may require the needle to traverse three vertebral levels before entering the epidural space at a shallow enough angle to pass a lead without kinking. Longer and special curved tip needles are available to lessen the chances of dural entry.

After the epidural space has been entered, a lead should then be passed in a cephalad direction under fluoroscopic guidance, adhering to the midline as much as possible. Figure 7.3 illustrates midline placement of the introducer while using the lead hand for radiation protection. Alternatively lead gloves may be used for protection. Small movements of the lead are recommended until the path is established, and if the lead veers off track it is advisable to return to the location where the deviation occurred and start again. Lateral adjustments to address a unilateral area of pain can be made once a lead has been properly advanced in the midline. Extreme lateral migration of a lead may lead to contact with a spinal nerve root, resulting in a painful paresthesia. If a patient is too heavily sedated, this paresthesia may not elicit a response, which could lead to significant pain or damage if stimulation testing were to

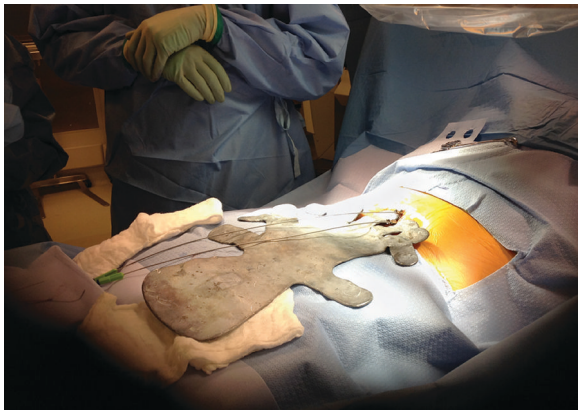

Figure 7.3 Midline placement of introducer while using lead hand for radiation protection.

occur in this location. Despite the best attempts to keep a single lead as midline as possible, only 27% of leads placed in the radiological midline produce a symmetrical paresthesia (19). A contralateral oblique view is sometimes obtained to confirm epidural placement, especially when subarachnoid lead migration is suspected in the setting of extremely low amplitudes, causing painful stimulation (see Figure 7.4). The lateral view can confirm if the leads have passed anteriorly especially in the setting of motor stimulation.

A second lead advanced adjacent to the first lead can help provide bilateral coverage should it be needed, as well as structural support. A second lead is usually introduced at a level above or below the initial lead on the same side. This is not required, but it does prevent the need for two incisions on either side of the midline. An alternative is to place two lead introducers adjacent to one another near the midline. Figure 7.5 depicts two leads placed adjacent to

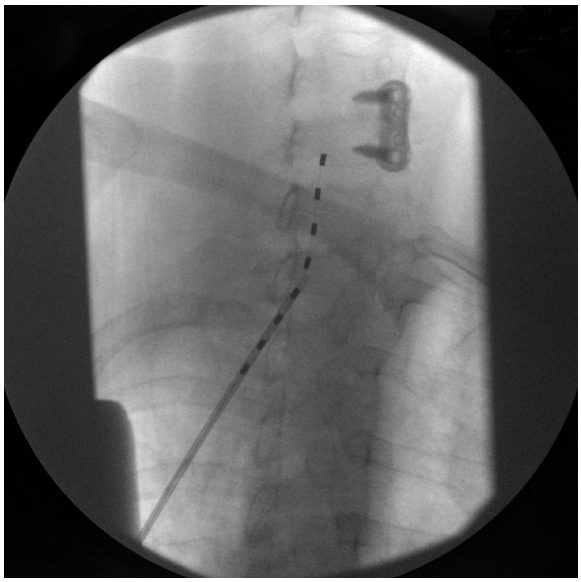

Figure 7.4 Contralateral oblique fluoroscopic image showing ventral electrode placement.

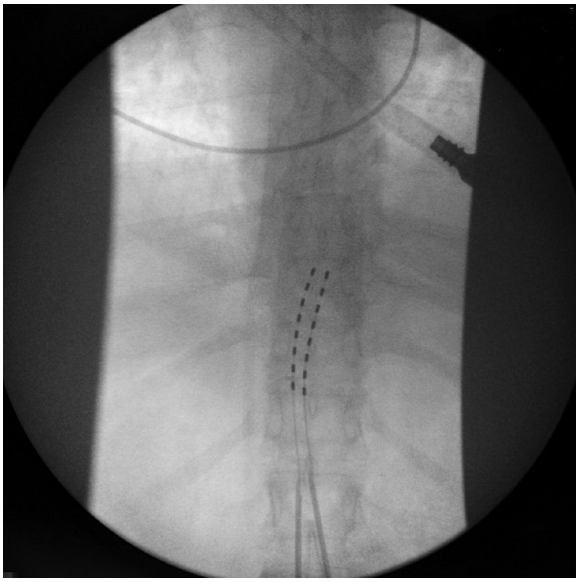

Figure 7.5 Two lead introducers placed adjacent to one another near the midline.

one another. Another technique utilizes placement of two paramedian introducer needles on either side of the spine. A midline incision is made over the spine between the two needles. The subcutaneous tissue is undermined on both sides of the incision till the leads are reached, whereupon they are gently withdrawn into the incision and anchored (John Huffman, MD, Holy Cross Hospital, Silver Spring, MD —personal communication).

It is important to remember that the radiographic midline and anatomic midline do not always overlap. Medial and lateral differences in electrode placement as little as 1–2 mm can be the difference between success and failure. Table 7.2 provides a guide to patient reported paresthesias and electrode location (20).

If there is any difficulty passing the lead, a wire can be passed cephalad to create a track that the lead can subsequently follow. A stiffer steerable catheter may also be used if the wire is not able to pass, but one must be careful, as any forced wire or catheter advancement through fibrotic tissue can cause trauma, such as a dural puncture or tear. Failure of the lead or wire to pass out of the catheter tip may mean that the epidural space has not been completely entered by the needle. There can sometimes be a small flap of ligament preventing the passage of a lead requiring slight needle advancement or rotation of the needle bevel. Further advancement of the needle should always be done with caution so as not to compromise the dura. A small or tight epidural space can also prevent passage of a lead. This space can be expanded with the gentle administration of 1–2 ml of saline through the needle, though this potentially changes the conductance and therefore should be a last resort. Finally, and most importantly, if there is difficulty with lead entry, or lead manipulation to the desired area, despite confirmation of being in the epidural space, time shouldnt be wasted with multiple attempts; the needle should be withdrawn and the epidural space re-entered at a more appropriate location, at the same or another level.

If the dura is compromised by the direct visualization of CSF dripping out of the needle hub or by the appearance of a lead being advanced too easily or obviously below the level of the epidural space with a lateral fluoroscopic view, the needle and/or lead should be removed

Table 7.2 Guide to Patient-Reported Paresthesias and Electrode Location

Electrode Location	Clinical Response	Remedy
Dorsal columns	Therapeutic parestheisas, ipsilateral and caudal with threshold above 1 volt. The patient reports analgesia and comfortable stimulation	None, this is the desired location.
Ventral placement (pyramidal tracts)	Muscle cramping even at sensory threshold amplitudes	Remove or pull back electrode. Use lateral view to track lead as it is advanced.
Intrathecal placement	Painful paresthesias with amplitude increases of the smallest increments	Pull lead out and replace epidural needle at a different level.
Lateral placement	Radicular abdominal wall stimulation at low amplitudes	Redirect lead to more midline location.
Spinothalamic tract	Contralateral feeling of warmth	Redirect lead more medially.
Dorsal root or dorsal root entry zone	Ipsilateral paresthesias at the level of electrode	Can be a target for single-level spinal nerve, or if ineffective consider more medial placement.
Ventral root	Ipsilateral muscle contraction at the level of electrode	Pull lead back, review course and determine location where lead began ventral course.
Dura or ligamentum flavum stimulation	Back pain with stimulation, unable to increase amplitude because of pain	Activate different electrodes, advance or retract electrode. If no improvement, consider paddle lead.

Adapted from Levy RM. Anatomic considerations for spinal cord stimulation. *Neuromodulation.* 2014;17(1):2–11.

and a different level should be chosen from which to reinsert the needle and find the epidural space. This is also the case if very low stimulation parameters cause intense stimulation. Some providers abandon the procedure entirely in the setting of a dural puncture or tear and return on another day.

The choice of lead type depends on the size of the painful area to be covered and the need for selectivity and confining the paresthesias. If an entire lower extremity is affected due to CRPS, a lead with electrodes spaced closer together with deeper penetration of the cord will ensure full coverage (see Table 7.2). If more selective coverage is needed, wider spaced electrodes will tend to confine the area of stimulation more. For more on stimulation strategy and theory, see Appendix 6. If bilateral extremities are to be covered or a unilateral painful area has a complex distribution, dual leads may be inserted. Two and sometimes three lead arrays exponentially increase the combinations and strategies available to the programmer. The information obtained from the trial is not only important for efficacy, but also provides insights into the needed electrode configurations and ideal lead locations. Saved images for trial lead locations are essential for reference when permanent electrode implantation occurs. Alternately, implanted epidural trials utilizing percutaneous extensions have been advocated because of the need to only place the lead or leads once. If the trial is successful, then the percutaneous extension is discarded and the permanent implantable pulse generator (IPG), which is the most expensive component of the SCS system, is connected to the permanent lead or leads and implanted during a second surgical procedure. This second procedure is essentially the same as the implantation of permanent percutaneous leads and IPG after a

successful temporary trial in the office setting, as described below. The advantages and disadvantages of the tunneled trial approach are discussed in the section "Patient Screening and Trial of Therapies."

Once the target level has been reached, the lead is again connected to a trial generator, as in the initial trial (see Figure 7.6). The generator's cable is then passed to the programmer who will provide the trial stimulation. The intra-op trial process requires the patient to have his sedation decreased by the anesthesiologist so that simple questions can be answered appropriately. The programmer then proceeds to dial in combinations of electrodes on the lead or leads, making changes and increasing the intensity based on patient response. Generator parameters such as pulse width, frequency, and power can all be manipulated. This may take time, as there are numerous lead combinations that may need to be trialed to address each patient's specific coverage area. There are times when the area intended to be stimulated is only partially stimulated or is completely covered but also includes an unwanted area of the body. If this occurs, then lead manipulations either cephalad/caudad or medial/lateral may be required. It is almost always necessary to fine-tune the programming at the first follow-up appointment 7–10 days postoperatively, when incisional pain has largely subsided, as this can be a distraction to the underlying pain pathology. Specific aspects of SCS programming and theory are found in Appendix 5.

After the lead is deemed to be at the optimal level and the electrodes have been configured to provide consistent and adequate paresthesias in the affected body part or area, the leads can be removed from the trial generator. An incision is then made in a longitudinal direction cephalad and caudad on either side of the introducer needle, with the cephalad portion longer than the caudad in keeping with the needle's track. Blunt dissection and electrocautery are used to expose the paravertebral fascia. The needle is kept in place to protect the lead during dissection. Stay sutures can be placed while the needle protects the lead. The needle is then withdrawn so that the lead is exposed as it dives through the tissue and into the epidural space. Care should be taken to avoid displacing any previously placed electrodes by checking with live fluoroscopy as the needle is removed. An anchoring device is then used to secure the lead to the paravertebral fascia. Proper technique when suturing the anchor to the fascia and tying it to the lead is extremely important, as this is the only point along the length of the lead that is preventing lead migration in the first few weeks of wound healing. Figure 7.7

Figure 7.6 Connecting the lead to a trial generator.

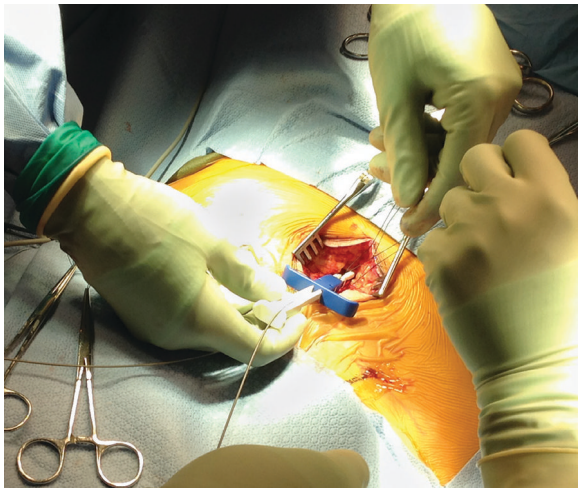

Figure 7.7 Deployment of the anchor into the paravertebral fascia.

shows deployment of the anchor into the paravertebral fascia. There must also be some lead redundancy or slack in the midline incision to ensure that axial movement in the back or neck does not cause a lead to migrate. If a patient is particularly tall or the IPG pocket is located far from the midline incision, a lead extension may be required.

An IPG pocket can be made in the posterior superior gluteal area below the belt line, lumbar paraspinal area, flank area, or abdominal area for lumbar/thoracic lead placements and in the mid-axillary line, posterior gluteal area, or lumbar paraspinal area for cervical lead placements. Considerations for placement should include aesthetic appearance, maximizing mobility, avoidance of pressure points, and the ability to easily recharge the unit. The IPG template should be placed over the pre-marked incision site to confirm width and depth requirements of the pocket. The skin overlying the incision site is then anesthetized with local anesthetic and an incision is made. Using blunt dissection, the deep fascial layer is exposed and a pocket is created at this level. The pocket opening should be no more than 1 or 2 cm below the skin when using a rechargeable IPG, as deeper pockets could impede effective charging. The pocket should be undermined toward the spine incision, and vice versa, to facilitate tunneling.

Using a tunneling device, the spine incision should be reached via a subcutaneous route from the IPG pocket, or vice versa. Care should be taken to not tunnel too deeply so as to avoid entering the peritoneum or pleural spaces. Along the subcutaneous plane is ideal, as if its too superficial then it can be felt through the skin and is a source of perennial discomfort to the patient. This can be done by keeping one hand over the tip of the tunneling device, ensuring that it is always felt just below the skin in the subcutaneous space. Once the lead has been tunneled to the IPG pocket, it can be attached to the IPG and secured with a set-screw kit. Impedance checks are performed before placing the IPG into its pocket to ensure that the lead has not been damaged during the implantation process and that the lead connection is sound. Care should be taken to ensure that all connections are clean and dry, and that no blood or other fluids are left on electrical conducting surfaces. Care should also be taken to ensure that all connections are moisture tight with the supplied insulators, which are further secured by ligatures that are sufficiently tight to ensure a good seal. The IPG can then be placed into the pocket and secured with non-absorbable sutures. There are typically two suture holes on the IPG for this purpose. After copious irrigation with antibiotic solution,

the pocket and midline incisions can be closed with 3 layers of sutures in the fascial, dermal, and epidermal layers, followed by the application of appropriate dressings. Direct visualization of the suture needle throughout at least the first two layers of closure is important to ensure that a lead has not been incorporated into a stitch or damaged with the needle tip.

Serious complications that may arise during the implantation process include both puncture of the pleura or peritoneum during the tunneling process and damage to the spinal cord and associated spinal nerves during needle advancement into the epidural space, though fortunately this is very rare. A pneumothorax or perforated viscus sustained after tunneling may not manifest symptomatically until the postoperative period and should prompt an appropriate surgical consultation, urgent imaging studies, and emergent interventions if a patient is unstable. Although SCS implantations are performed under fluoroscopic guidance and, in the case of surgical implantation, under direct visualization, anatomy can be variable, and direct injury to the spinal cord and surrounding neurologic structures is possible. This can be difficult to detect when a patient is receiving deep sedation and is not able to report any acute pain or neurologic deficit. Light sedation can also endanger patients if they become disinhibited, with sudden movements during skin incisions, needle placement, and tunneling. Hence a skilled anesthesiologist is essential to succcess.

Open Surgical Technique

The procedure is performed under either general anesthesia, or local anesthesia with deep sedation, according to surgeon preference and testing requirements. Some surgeons employ neurophysiological monitoring during the procedure. Sterile prep and draping followed by localization using C-arm fluoroscopy is performed similarly to the percutaneous technique. A midline incision is made and generally incorporates a level above and below the target entry site for the paddle electrode insertion. Access to the epidural space is obtained via a standard midline laminotomy. When in the neck, the nuchal ligament is incised in the midline to expose the spinous processes. The supraspinous ligament is left intact and a subperiosteal dissection is performed to the laminae. Muscle attachments are lateralized with blunt dissection. A Penfield-1 is used to identify the inferior edge of the lowest lamina. Using a Kerrison punch, a few millimeters of bone are removed on either side of the spinous process insertion within the confines of the facet joint. A diamond burr is used to thin the cortical bone, and a Kerrison punch can be used to complete the laminotomy, including removal of the underlying ligamentum flavum that overlies the epidural space. Next, the epidural passing elevator is slowly introduced with minimal force in the midline at a shallow angle to avoid a spinal cord contusion. Following this, the surgical lead is positioned using rubber-tipped forceps to handle the proximal lead paddle. The stimulating electrodes are positioned to face the dura mater, and the lead is advanced until the entire paddle is in the epidural space. Fluoroscopy is then used to verify lead placement. Figures 7.8 and 7.9 depict AP and lateral views of surgical paddle placement. For bilateral pain, the lead is placed closer to midline.

Intraoperative testing to confirm satisfactory paresthesia coverage occurs in a similar fashion, as described above, with the patient giving continuous feedback. However, rather than moving the lead, the electrode settings are first changed before repositioning occurs to confirm direction of lead movement. Once a satisfactory paresthesia is obtained, the surgical leads are disconnected from the trial generator and anchored. The IPG pocket creation, tunneling, impedance check, and closure are all similar to the percutaneous technique.

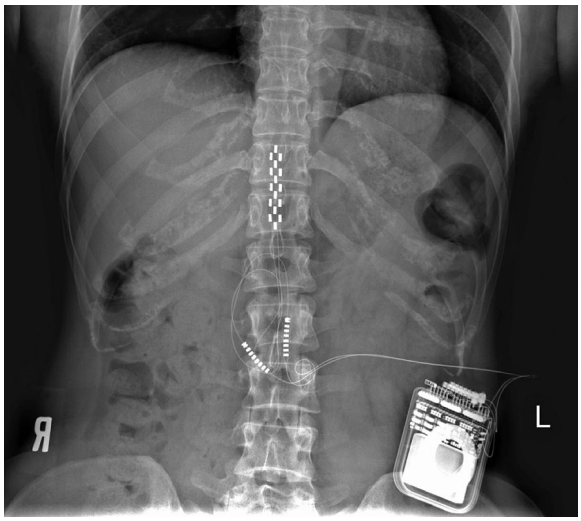

Figure 7.8 AP fluoroscopic image of paddle lead placement.

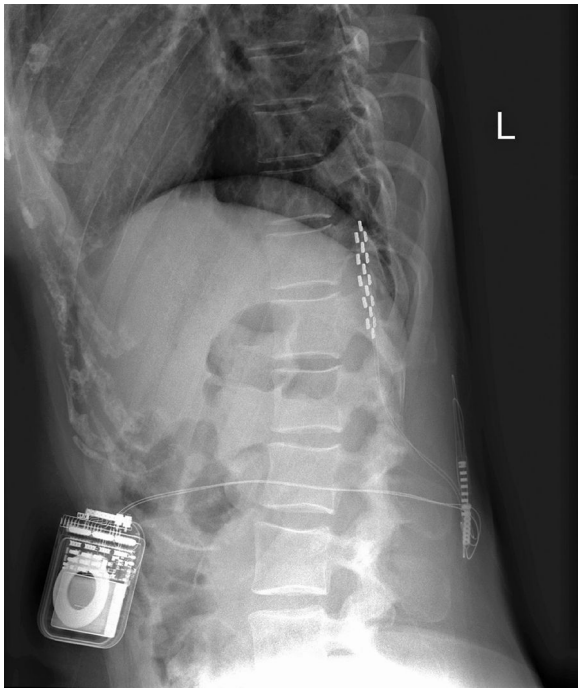

Figure 7.9 Lateral fluoroscopic image of paddle lead placement.

Postoperative Management

Common Postoperative Complications and Their Management

Infection is one of the most costly and potentially devastating postoperative complications. Surgical site infections (SSI) tend to occur in the first 3–5 days after implantation and may be treated conservatively with IV antibiotics or more aggressively with removal of the SCS system. Treatment depends on the severity of the infection, the comorbidities of the patient, and the experience of the provider. Staphylococcus aureus and Staphylococcus epidermis are the most common infectious skin organisms, with methicillin-resistant Staphylococcus aureus (MRSA) becoming ever more prevalent in the community. Pseudomonas has also been implicated in 3% of hardware infections in at least one study (21). If the hardware is exposed, removal is necessary. One risk assumed by not explanting an SCS system in the presence of an SSI includes meningitis if the infection tracks along the leads into the neuraxis. Infection tracking along leads could also lead to epidural abscess formation, which, when accompanied by neurologic deficits such as saddle anesthesia, loss of bowel and bladder function, or lower extremity weakness, is a surgical emergency requiring decompression and drainage of the abscess as well as removal of the SCS system.

Cellulitis is often the first indication of an underlying IPG pocket infection, and although this may be treated as such, there is always the concern for involvement of the underlying IPG and leads essentially connecting the subcutaneous tissue to the neuraxiom (22). The decision to treat any infection conservatively versus removal of hardware is at the discretion of the provider and must be individualized to each patient. Always consult an infectious disease specialist for formal recommendations if there is concern for possible involvement of underlying hardware.

Another complication of SCS implantation is epidural hematoma, which, when accompanied by neurologic changes similar to those found with an epidural abscess, is a surgical emergency. The risk of epidural hematoma is exceedingly low but can be assumed to increase in patients who must resume anticoagulation or antiplatelet medications post-implantation. It is important to ensure that anticoagulation or antiplatelet medications have been held appropriately before surgery (see Appendix 1 for anticoagulation guidelines).

Complications at the site of the IPG include hematoma and seroma. These tend to spontaneously resolve and do not generally require evacuation unless they become infected. Fluid collections can be avoided by ensuring proper hemostasis before closing the wound, as well as minimizing tissue trauma when creating the IPG pocket.

Wound dehiscence is a more serious complication, usually occurring about a week after implantation due to tissue weakness. This is generally avoided with proper multilevel suturing involving the fascia, dermis, and epidermis while being mindful to avoid excessive suture tension that may cause ischemia and tissue necrosis. Patients who smoke, have diabetes, are using angiogenesis inhibitors, or are chronically immunosuppressed are at greatest risk for dehiscence.

Incisional pain is to be expected after SCS placement and may be exacerbated in chronic pain patients who may be prone to hyperalgesia. Although complete wound healing can take up to 6 weeks, incisional pain usually subsides after 7–14 days. Persistent pain beyond this time frame may indicate a subacute infection, especially in the presence of fever or warmth or redness over the incisions. Postoperative pain may also be secondary to an IPG being placed just below the rib cage or above the anterior superior iliac spine, resulting in soreness with flexion as the IPG rubs against these structures. Often it is a self-limiting issue that may improve once the IPG becomes more scarred into its pocket, preventing excessive

movement, but if the pain does not improve with time it may be necessary to move the IPG to another anatomic location.

Diagnosing and Management of Loss of Analgesia

Lead migration or displacement is the most common reason for loss of analgesia in SCS. This is suspected when the area of induced paresthesia changes, which is usually associated with a decrease in or total loss of pain control. This is more often seen with cervical leads than thoracic leads, due to the larger range of motion inherent in the neck. Usually a simple X-ray of the spine can assist in confirming lead migration. If the lead is only slightly displaced, reprogramming of the electrodes may lead to the regaining of optimal coverage. Paddle leads have a lower frequency of migration than percutaneous leads due to the anchoring of the paddle lead to the dura and deep fascia, with subsequent scarring and fibrosis. Although improved lead and IPG technology has made reprogramming better able to regain coverage, surgical revision is required when reprogramming is not effective.

Electrode fracture is another postoperative cause of acute loss of pain control. An X-ray may show an obvious site of breakage, but this is often more insidious, and a diagnosis must be based on impedance checks. An impedance check greater than 4,000 Ohms is indicative of a lead fracture. The electrode must be surgically replaced if a lead fracture is diagnosed and coverage cannot be restored (see Appendix 6 on diagnosing and troubleshooting stimulator system malfunctions).

One must also consider the possibility of worsening underlying pathology pertaining to the condition being treated with SCS. This could include worsening vertebral spondylosis or osteophyte growth, resulting in a more painful radiculopathy, CRPS migrating to other limbs or parts of the body not covered by the initial SCS placement, and plexopathies complicated by enlarging neuromas.

Nursing Considerations for Patients with a Spinal Cord Stimulator

Prior to discharge following permanent lead implantation, troubleshooting tips, a patient ID card, and a manual for the device should be provided to the patient. A 7–14 day course of low-dose prn opioids should be provided to cover incisional pain. This should be in addition to whatever chronic pain medications the patient is currently taking, even if these include high-dose opioids. A follow-up appointment should be made with the surgeon for suture (if these are used for skin closure) or dressing removal. Wound care instructions should include not wetting or removing any dressings and refraining from showering or taking a bath until follow-up. If the incisions are in the thoracolumbar region, wearing an abdominal binder should be encouraged for as long as possible until the wound-healing process has completed, ideally for 4–6 weeks. The patient should also refrain from driving until his follow-up appointment and should refrain from operating heavy machinery or performing strenuous tasks in the future while the stimulator is on. Although newer SCS systems are becoming MRI compatible, depending on the manufacturer, area of the body to be imaged, and magnet type, the patient should initially avoid MRI scans as well as ultrasound devices. Although most airport scanners will not interfere with SCS systems, patients should still be given an ID card to exempt them from security systems that produce an electromagnetic field.

Rehabilitation Considerations for Patients with Implantable Devices

Patient education postoperatively includes instructing the patient to avoid sleeping on the stomach for at least 4–6 weeks postoperatively to reduce the risk of lead migration (this is more relevant in patients having undergone percutaneous placement). In addition, twisting,

bending at the waist, raising the arms above the head, or lifting heavy objects should be avoided in the first month after the procedure to prevent lead migration until adequate scarring further reinforces lead positioning.

Patients who were previously debilitated by the pain that led to the SCS placement may now be able to participate in more activities or even pursue a course of physical therapy as part of their overall rehabilitation. Although some providers may insist on reducing a patient's chronic opioid dose before implanting a stimulator, the pain relief provided by SCS should hopefully allow a patient to further wean, with the goal of aggressively reducing or completely coming off opioids.

Case Report (Percutaneous Technique)

A 41-year-old male with work-related chronic axial low back pain with left lower extremity radiculopathy underwent an SCS paddle lead placement for his left leg pain and to a lesser extent his low back pain 10 years ago. A paddle lead was likely chosen given his young age. This initially brought his overall pain from an 8/10 to a 3/10. However, his paddle lead had to be surgically revised twice due to subtle migration after he sustained falls in the setting of transient ischemic attacks (TIAs). After his second revision, adequate coverage could not be obtained without eliciting concomitant unpleasant paresthesias down his right leg. He became debilitated to the point where he could not work, required a cane to walk, and even had difficulty performing his ADLs. Without an optimized SCS system, he was managed on high-dose opioids, which did not control his pain and caused excessive sedation and severe constipation. He presented to our clinic for possible further revision of his existing SCS system. Despite his paddle lead being to the left of midline at the level of T8–9, it was thought that a new percutaneous lead inserted on the left could be introduced to pull current further to the left, essentially using the paddle lead as anode and the new lead as cathode. This would ideally allow the paresthesia to fall completely along the left side while avoiding the right. Before moving forward with a trial, the patient was seen by our clinic's pain psychologist. He was deemed appropriate for an SCS revision after a plan was put in place to begin weaning his opioids. He was on Plavix for his history of TIAs, which was stopped 7 days before his trial. During his trial, adequate coverage down the left leg was elicited with a single lead at the T11–12 level with some residual paresthesias down his right leg, as shown in Figure 7.10. The trial did not allow the combined programming of the paddle leads and percutaneous lead due to the obvious fact that the IPG where the paddle leads were attached was not exposed, so the leads could not therefore be connected to the percutaneous trial IPG.

After one week, he still reported 50%–60% relief in his left leg pain, and the decision was made to proceed to the OR. Four weeks later, after the trial lead track was able to heal completely, he had a permanent lead placed in the OR. After placing the new percutaneous lead at the T11–12 level, similar to the trial in the office setting, a midline incision was made to anchor the new lead as well as expose the old paddle lead extension connectors, so the proximal portion of the left lead connecting to the paddle could be detached and used in the same trial generator as the new percutaneous lead. After lengthy intraoperative programming with percutaneous lead manipulation and patient feedback, the patient's left leg pain and the majority of his axial low back pain was covered. There were no unwanted right-sided paresthesias now that the pre-existing left-sided paddle lead could be incorporated into programming permutations. The leads were then removed from the trial IPG. The percutaneous lead was then tunneled to the pre-existing paddle lead IPG pocket after it was reopened. The left-sided paddle lead was reattached to its extension

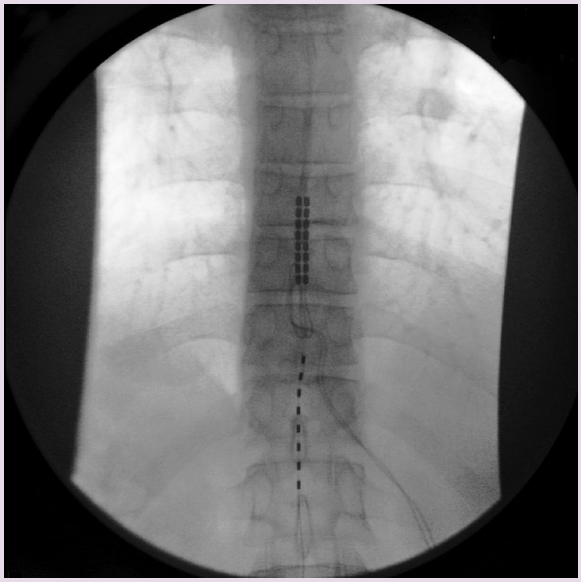

Figure 7.10 Single percutaneous lead placed at the T11–12 level. Note paddle lead at T8–9.

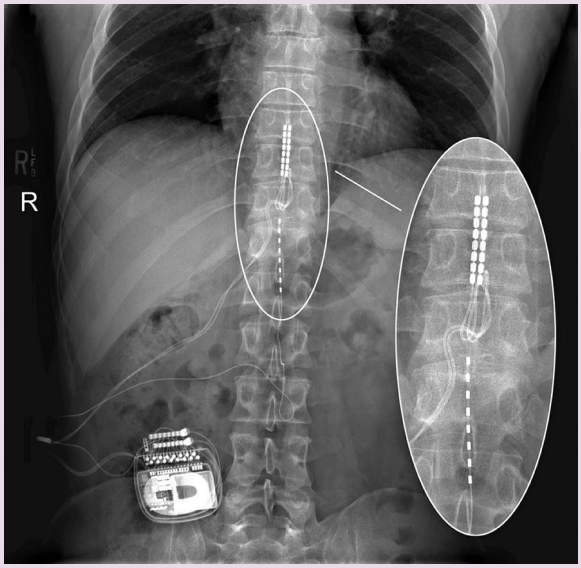

Figure 7.11 Final placement of single percutaneous lead placed at the T11–12 level. Note paddle lead at T8–9.

and was left in place in the IPG. The right-sided paddle lead extension was removed from the IPG and was pulled out of the subcutaneous tissue. The new percutaneous lead was then secured in the IPG where the right-sided paddle lead had been. The IPG pocket and midline incisions were closed, with the proximal end of the right-sided paddle lead left unconnected in place, deep in the midline incision, as it could not be removed from the

original unexposed thoracic paddle. At follow-up one week later, his programming was further revised and was deemed optimal. He did sustain another fall one month after his new lead placement that altered his coverage. However, he regained appropriate coverage with reprogramming, likely because there were two electrode arrays overlying most of the left-sided aspect of his dorsal column providing more left-sided programming permutations. Figure 7.11 shows final placement of percutaneous lead and paddle lead.

Case Report (Surgical Technique)

A 47-year-old female whose arm was struck by a train 20 years ago, resulting in a left-sided brachial plexopathy, had suffered from constant intractable neuropatic pain in her left arm since then. She received modest relief from high-dose gabapentin and lidocaine infusions until her arm pain was exacerbated by a herpes zoster outbreak along a dermatome that extended into her left arm. Since then, her pain has been refractory to all conservative therapies. She was referred to our clinic for an SCS and, after being deemed appropriate by our clinic's pain psychologist, underwent a percutaneous trial with a lead placed at the C5–6 level. Intraprocedural programming provided good coverage of the affected portions of her left arm.

Given the satisfactory result from her week-long trial, she was brought to the operating room for a permanent paddle lead implantation one month later. She was positioned prone on the Jackson table with gel rolls. After localization of the T1–2 interspace with fluoroscopy, the region of interest was prepped and draped in the fashion described above (see Figure 7.12). A laminotomy was made over T1 and an epidural passing elevator was used to create a path for the lead (see Figure 7.13). A 2 x 8 paddle lead was inserted (see Figure 7.14). Fluoroscopy confirmed the location of the lead at C3–6. Intraoperative programming resulted in excellent paresthesia coverage over the affected region of pain. A representative image from the tunneling and IPG placement is seen in Figure 7.15. The

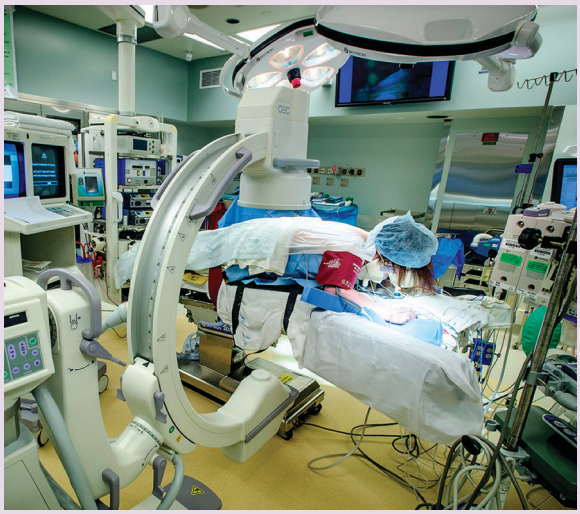

Figure 7.12 Intraoperative photo from surgical electrode implantation. The patient is positioned prone on the operative table with chest bolsters. The arms are well padded with foam cushions. The C-arm and associated image station are in place for intraoperative localization.

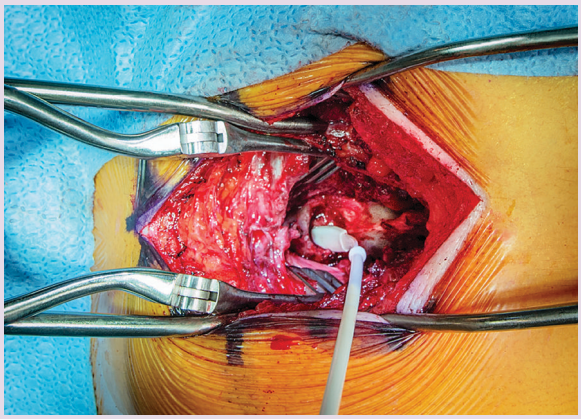

Figure 7.13 An epidural passing elevator can be seen through the laminotomy defect at a shallow angle in the midline of the underlying spinal cord to avoid a cord contusion.

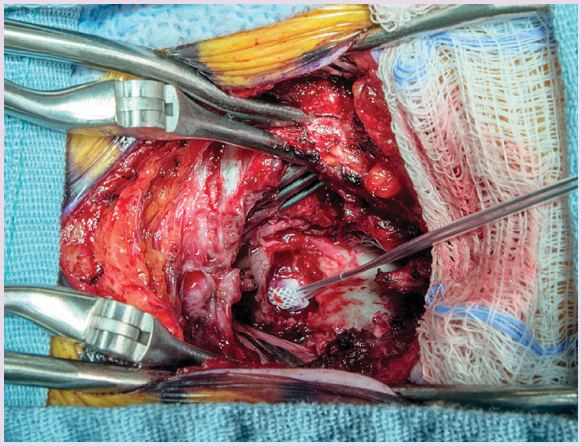

Figure 7.14 The surgical lead has been placed through the laminotomy defect. Its position is eccentric to the left, given the location of the patient's pain. The stimulating electrodes are positioned to face the dura.

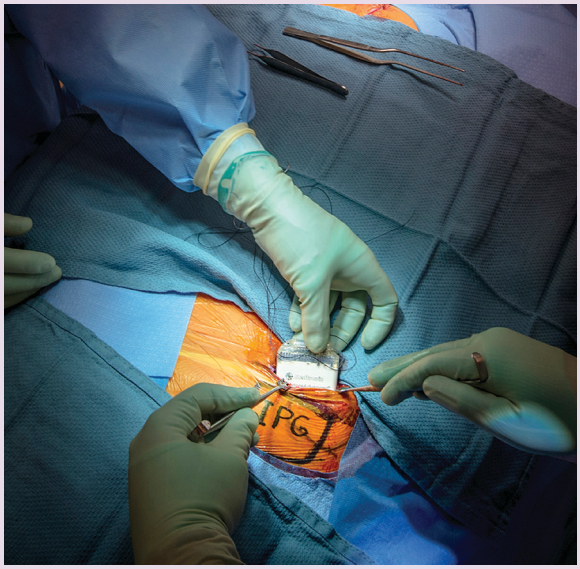

Figure 7.15 The pocket for the implantable pulse generator (IPG) has been made over the right buttock below the waistline.

lead was anchored and the wound was closed in layers. She was then turned supine, general endotracheal anesthesia was induced, and she was repositioned for the IPG placement. The patient was successfully extubated after the operation and was brought to the postoperative anesthesia care unit. She was admitted overnight for observation and was discharged the following day.

At her follow-up visit for suture removal, all incisions were well healed and she reported satisfactory reduction of her chronic pain with the appropriate SCS programming.

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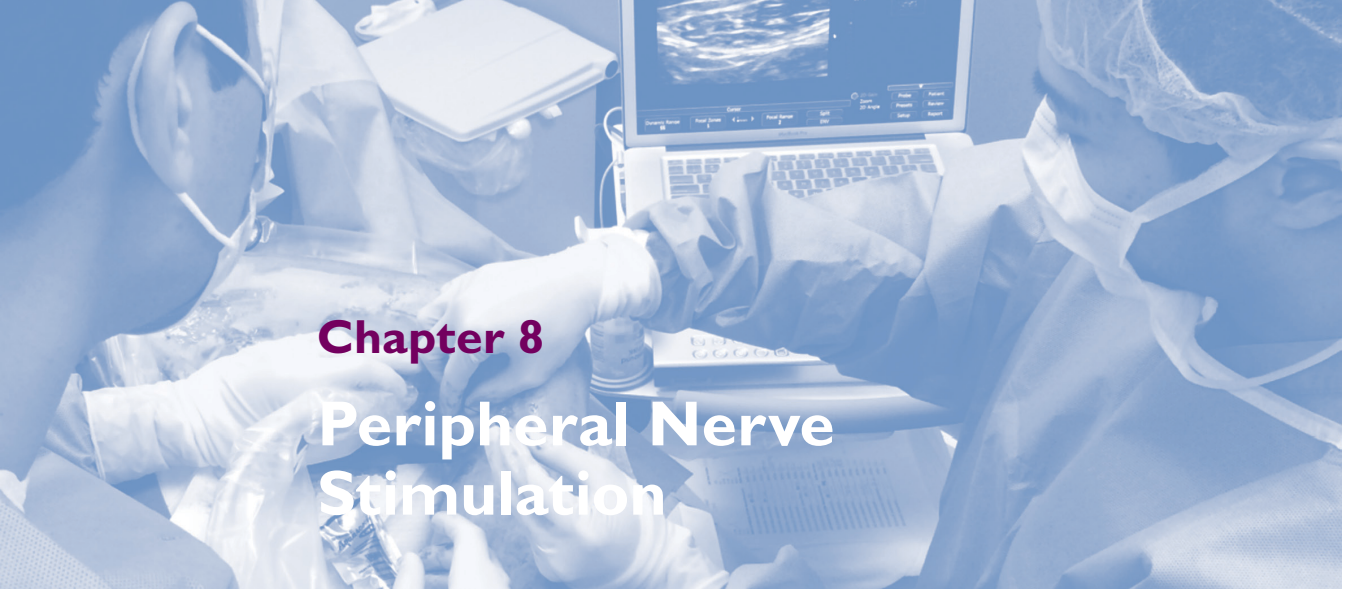

Chapter 8
Peripheral Nerve Stimulation

Christian Peccora, Jorge Mendez, and David Janfaza

Introduction

Peripheral nerve stimulation is primarily a treatment modality used to address neuropathic pain. The use of electricity to treat pain dates back to as early as 46 AD, when fish-like animals that emitted an electric charge over painful areas of the body were placed on patients (1). Advances in the twentieth century allowed for the precise placement of electrical stimulating leads near specific nerves subserving a region of neuropathic pain. Indeed, peripheral nerve stimulation (PNS) has been employed as a treatment modality for intractable mononeuropathy since the 1960s (2). Melzack and Wall's "gate theory of pain" initially provided a theorized mechanism of action for PNS (3). Indeed, one postulated mechanism for the efficacy of PNS is the activation of peripheral A-beta fibers, which results in the inhibition of A-delta and C fibers. This inhibition is theorized to occur via inhibition of post-synaptic potentials, excitation of inhibitory interneurons in the dorsal root, and activation of medial lemniscal pathways subserved by A-beta fibers, which causes stimulation of the ventral posterior medial nucleus and thus does not allow the transmission of messages from other nociceptive tracts (4). Still, the primary mechanism of action of PNS appears to be inhibition of peripheral nerves rather than central nociceptive pathways. Scientists are attempting to elucidate these and other mechanisms that may result in nociceptive inhibition associated with PNS, including suppression of dorsal horn activity or nociceptor axon firing (5–10). These mechanisms may also help reduce central sensitization (4).

PNS is primarily used as a treatment for neuropathic pain that can be localized to a specific peripheral nerve or nerves. PNS is increasingly being used to successfully treat complex regional pain syndrome (with PNS shown to be more efficacious than spinal cord stimulation for CRPS Type II [11]), peripheral neuralgias and mononeuropathies, trigeminal neuralgia, low back pain, chronic pelvic pain, phantom limb pain, chronic abdominal and inguinal pain, coccydynia, pancreatitis pain, cancer pain, cervicogenic pain, post-herniorrhaphy pain, neuropathic pain related to tarsal or carpal tunnel surgery, post-herpetic neuralgia, and headaches and cranial neuralgias (4, 12–20). PNS for headaches and cranial neuralgias are discussed further in Chapter 9. Spinal cord stimulation (SCS) is an alternative treatment for some of these entities, but PNS may be preferable when a smaller area of paresthesia is desired or anatomic considerations make PNS more desirable (i.e., scoliosis or anticipated difficulty with SCS lead placement).

A significant body of research supports the use of PNS. Mobbs et al. found that, of 38 patients who had PNS implanted for pain from peripheral nerve injury or entrapment, over 60% had greater than 50% reduction in their pain (21). Nashold showed significant pain relief in 52.6% of patients with upper extremity PNS and 31% of patients with lower extremity PNS (22). Novak and Mackinnon's results showed good or excellent pain relief in 11 of 17 patients with PNS, whether the intervention was for upper or lower extremity pain (23). Picaza reported 50%–100% pain relief in 20 of the 23 patients who had PNS implanted (24). Numerous studies have shown improved functional status, increased rates of return to work, decreased depression, and decreased use of analgesic medications (2). Eisenberg followed patients (most of whom had traumatic or surgical injury to nerves) for a median of 10.8 years and found that 78% of patients continued to have at least 50% pain relief (25). Johnson and Burchiel reported effective treatment of facial pain from trigeminal and post-herpetic neuralgias with PNS (26). There is some evidence that PNS not only decreases pain, but can also improve sensation and motor function of the affected area as well (27). Studies have also shown that PNS can improve pain associated with failed back surgery syndrome (28).

Preoperative Considerations

Non-Surgical and Medical Management

Treatment of the underlying disease process is an integral part of treating pain syndromes or mononeuropathy amenable to PNS, but pain often persists during and after addressing these underlying causes. Intractable chronic pain in a specifically identifiable nerve distribution has been treated with varying degrees of success by physical therapy, anticonvulsants (oxcarbazepine, topiramate, lamotrigine), opioids, serotonin and norepinephrine reuptake inhibitors, gabapentin, pregabalin, tricyclic antidepressants, muscle relaxants, topical anesthetics, capsaicin, surgical neurolysis, and nerve blocks. Phantom limb pain has been treated with transcutaneous electrical nerve stimulation, rhizotomy, and dorsal root entry zone lesions (29). There is not significant evidence underlying the recommendations for one treatment modality over another. The side-effect profile of some of these medications and interventions includes nerve injury and worsening of pain, anticholinergic symptoms, cognitive changes, orthostatic hypotension, peripheral edema, nausea, constipation, hyperalgesia, and neurologic deficits associated with surgical interventions on affected nerves. Some of these treatments provide temporary pain relief or require increasing doses as tolerance develops. In contrast, PNS may provide improved efficacy, long-term pain relief, and fewer side effects compared to other treatment modalities.

Goals

The goals of PNS include decreasing or eliminating the patient's pain, improving functional status, reducing the need for medications and thus avoidance of side effects, and improved mental and emotional well-being. Indeed, PNS has been shown to increase functional capacity, improve sleep, decrease the number of visits to pain clinics or emergency rooms, and lessen the amount of medications required to control pain (2). While other treatments sometimes provide temporary relief, the goal of PNS is to provide a more permanent source of pain control.

Advantages

PNS offers advantages over pharmacologic treatments, nerve blocks, and surgical interventions. It provides more permanent therapy than a nerve block for eligible patients, but, unlike surgeries such as rhizotomy or nerve decompression, a temporary trial of therapy can be performed prior to a placement of the PNS. In fact, nerve blocks, percutaneous leads, or PNS stimulator trials are temporary interventions that may be suggestive of the efficacy of permanent PNS for a patient. Another advantage to PNS is that, unlike some surgical interventions, PNS placement can often be done with local anesthesia and sedation, avoiding the risks and postoperative recovery of a general anesthetic. Furthermore, PNS offers minimal side effects compared to many pain medications, and patients can often decrease or even taper off current pain medications. Finally, patients who are frustrated by the fact that satisfactory pain relief from nerve blocks is sometimes temporary may have more long-term pain relief from a PNS (30). This method of pain treatment can be efficacious for nerve pain despite varying neural characteristics, such as variance in epineural tissue and cross-sectional area (4). PNS effectiveness will likely improve further as research into stimulation customized to the anatomic and histologic characteristics of particular nerves is taken into account (4).

Patient Screening and Trial of Therapies

Commonly applied criteria for patient selection include pain along an identifiable nerve distribution. For example, in a patient with neuropathic pain in the median nerve distribution, a

stimulator lead can be placed to stimulate the median nerve directly. Figure 8.1 depicts a fluoroscopic image of a median nerve stimulator lead. Other criteria for employing PNS include failure of conservative treatment approaches (i.e., nerve blocks, neurolysis, medications, physical therapy), preservation of some sensation in the affected region, absence of preferable surgical interventions (i.e., release of an entrapped nerve), and acceptable responses to blockade of the involved nerve with local anesthetic or pain relief from stimulation by a temporary percutaneous lead (2, 31). Worsening of pain with transcutaneous electrical nerve stimulation (TENS) suggests that PNS is less likely to work (2). Some practices also include favorable psychological evaluation as a criterion (31). As discussed in Chapter 4, neurostimulation is more likely to be successful in patients with certain characteristics, including self-confidence, ability to cope with setbacks, realistic assessment of their disease, psychological stability, strong social support, and optimistic outlook regarding treatment (32). Research suggests that PNS is most likely to be efficacious in patients with traumatic peripheral nerve injuries and less likely to provide complete relief in patients with sciatica or cancer pain (33). Anatomic factors may limit the placement of spinal cord stimulators for chronic pelvic pain, but this type of pain may be amenable to treatment via PNS (30).

Assessment of a patient for PNS includes determining what interventions have been unsuccessful and whether nerve blockade or electrical stimulation provides relief. Patients presenting for PNS therapy have often failed conservative therapy, and studies assessing the efficacy of PNS frequently include patients that have already undergone conservative treatment and occasionally even neurolysis. A thorough history and assessment of what treatment modalities have been tried and to what degree they have ameliorated pain symptoms will help in determining whether the patient is a good candidate for PNS and what nerves should be targeted. Though some studies required patients to have abnormalities on electromyography- or somatosensory-evoked potentials or a certain level of relief from nerve blockade before

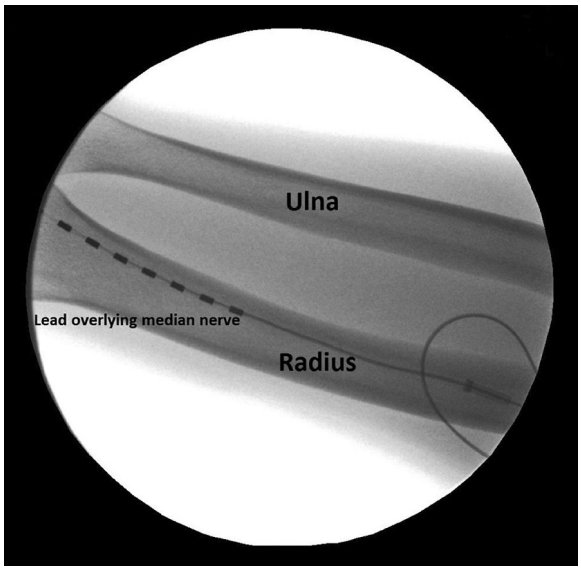

Figure 8.1 PNS is efficacious for neuropathic pain along an identifiable nerve distribution, such as the median nerve, as shown in this image.

installation of PNS (34), clearly delineated criteria have not been established for clinical practice.

There are few absolute contraindications to PNS. They include the inability to tolerate the procedure (in particular, general anesthesia in cases that require it), significant coagulopathy, and infection, in particular near the site of implantation (35). Even distant infection is a concern. If an infection is located at or near the area of PNS insertion, we recommend waiting 2–4 weeks after the infection has cleared before performing the procedure. However, there are no data to support any timeline for waiting for an infection to clear. The cause and natural history of the infection should be taken into account. Insight from an infectious disease specialist is often obtained. The urgency of PNS implantation and the type of infection will influence these suggested time courses.

Preparing the Patient for Surgery

Imaging of the affected region can sometimes reveal whether there is a reversible cause of the pain and can suggest an appropriate corrective measure. Whether X-ray, computed tomography (CT), magnetic resonance imaging (MRI), or another imaging modality is warranted depends on the differential diagnosis being considered. Newer imaging modalities that allow visualization of peripheral nerves, such as MRI neurography, may prove to be particularly useful in the future, not just in determining whether treatments other than PNS are advisable, but what kind and location of PNS would be optimal. In addition to imaging, electromyography and nerve conduction studies are part of a complete workup and may also reveal a reversible cause of pain.

Preparing the patient and his or her family for what to expect can contribute to whether this therapy proves successful. Complete pain relief may not be achieved, and setting expectations regarding what degree of relief is acceptable prior to proceeding is important. Education regarding the sensation caused by PNS, possible complications surrounding the surgery or in the coming years (such as migration of leads), and limitations to future activities (if any) will make the implantation process and postoperative course go more smoothly. To reiterate, assessment by a psychologist or psychiatrist who specializes in treating patients with chronic pain increases the efficacy of pain treatment and can help in better use of pain medications, as well as management of expectations regarding the placement, side effects, and likely reduction in pain from PNS. Treatment of concomitant depression or anxiety is also important. This is discussed further in Chapter 4. Significant efforts are dedicated to educating a patient regarding the procedure and what to expect in the postoperative period. One should also have a discussion with the patient about the location of the generator and the tingling sensation that will be associated with PNS.

Generators are implanted in various areas, depending on the targeted peripheral nerve. If the brachial plexus is targeted, for example, the implantable pulse generator (IPG) could be placed in the infraclavicular area. If the sciatic nerve is being targeted, the generator could be placed in the gluteal region. Other sites include the abdominal wall or anterior thigh, again depending on the targeted peripheral nerve. Figure 8.2 depicts placement of the IPG in the lateral thigh to facilitate stimulation of the saphenous nerve. Also, the patient should be warned if the PNS is a contraindication to future MRI. The patient should also be informed that the number of electrodes, as well as the amplitude, duration, and frequency of stimulation, could affect the battery life of the pulse generator (27).

A PNS trial should be performed prior to implantation of a PNS. This is an outpatient procedure. During the trial period, the patient is observed during his or her typical activities for one week. A shorter period is sometimes appropriate, but a slightly longer trial period allows the patient to experience more activities of daily living and get a better sense of how the stimulator will affect day-to-day life. If pain is diminished by 50% or if functional capacity is significantly improved, one can proceed to permanent PNS placement. An alternative is

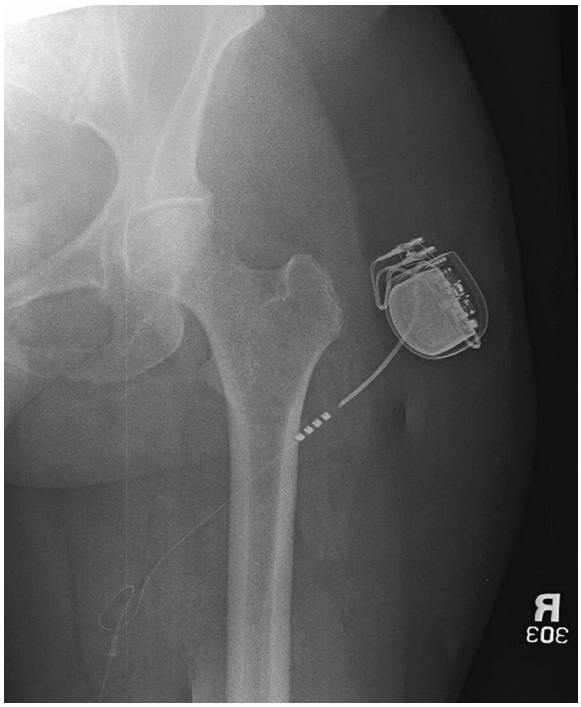

Figure 8.2 Placement of the IPG depends on anatomical considerations, minimizing the chance of tension on leads and thus migration, and patient preference. This image shows an IPG location that proved optimal for a saphenous nerve stimulator implantation in the left lower extremity.

to have clearly defined endpoints established via discussion with the patient. For example, if recuperation of a particular movement without evoking excessive pain is a satisfactory result for the patient, then achievement of that goal should define whether the trial was successful.

An explanation of what the surgery will involve is merited since there are a variety of options for implanting a PNS. Permanent PNS implantation can often be done under local anesthetic and sedation, allowing rapid recovery. This is particularly the case when percutaneous rather than open implantation is used. General anesthesia is sometimes warranted based on patient comorbidities and the location of PNS implantation. Open incision and dissection down to the affected nerve is sometimes performed, but less invasive or percutaneous approaches that employ nerve stimulators to detect proximity to the affected nerve are being increasingly used (27). Some practitioners have started using ultrasound to facilitate percutaneous placement of leads (28).

Alternative Treatments and Procedures

Conservative treatment of mononeuropathies and neuralgias include opioids, TENS, nonsteroidal anti-inflammatory drugs (NSAIDs), steroid injections, nerve blocks, radiofrequency ablation, physical therapy, and surgical interventions, including rhizotomy, neurolysis, and nerve decompression (28, 36). Some practitioners recommend PNS only after SCS has failed or is not an option due to anatomical factors (28). See the section on non-surgical and medical management above for more information.

Intraoperative Management

Antibiotic Prophylaxis

Antibiotic prophylaxis is discussed in further detail in Appendix 11.

Patient Positioning

The patient should be in a safe and comfortable position that allows adequate surgical exposure, as well as access for the anesthesia team to perform their duties. Because the location of the PNS depends on the underlying nerve, positioning must take this into account. The patient may be in a prone, supine, or lateral decubitus position to allow for lead placement over the peripheral nerve as well as placement of the IPG. For example, if the peripheral nerve of interest lies posteriorly, such as the sciatic nerve, the patient should be positioned prone. If the peripheral nerve of interest lies anteriorly, such as the femoral nerve, the patient should be positioned supine on the OR table. The placement of the IPG should be discussed with the patient prior to the procedure, as well as alternative placements should the original placement not be feasible. Another important consideration is the mode of visualization needed for the procedure. As we often use ultrasound machines and fluoroscopy for our PNS placements, it is important for the patient position to accommodate these modalities, and it is important to place the patient on a proper table (such as the Jackson table for fluoroscopic imaging).

Coordination with nursing and the anesthesia team is crucial to preventing injury to nerves and joints during these procedures. The use of pillows, blankets, and foam or gel pads is often used for proper support and padding of all pressure points and to minimize any neuropathies. Any pillows or padding used should be secured prior to draping and should be monitored throughout the procedure. While it is preferred that the patient remain in the desired position throughout the procedure, shifts in the patient's position may occur. It is important to be aware of this, and to have plans of action and the ability to adapt appropriately to successfully perform the procedure safely and efficiently.

Skin Preparation and Draping of the Patient

Skin preparation and draping are discussed further in Appendix 11. Specific to peripheral nerve stimulation, the area of skin that is prepared for surgery is tailored to the area of interest. Any hair located in the area should be removed. We recommend prepping as widely as possible to allow adequate visualization of the anatomical structures and to allow for difficult insertion or multiple insertion points. Do not forget to also define and prepare the area where the IPG will be placed.

Special Equipment

Much of the equipment required for performing implantation of PNS, including leads, lead extensions, pulse generator, and a programmer, is provided by the vendor. For open PNS implantation, only the Quad Plus and On-Point electrodes (manufactured by Medtronic) are approved by the FDA, though a variety of other electrodes manufactured by St. Jude's and Boston Scientific are used for open implantation on an off-label basis (4).

Standard surgical tools, including clamps, forceps, scalpels, sterile drapes, syringes, sutures, and needles for instillation of local anesthetic are required. Naturally, the availability of ultrasound and fluoroscopy services in the operating theater is necessary. The provision of preference cards to OR nursing staff facilitates efficient preparation of all tools that a particular surgeon commonly requires for PNS implantation. See Appendix 10 for examples of our institution's surgeon preference cards for peripheral nerve stimulation.

Surgical Technique

The surgical technique begins in the preoperative area, where the peripheral nerve should be identified with ultrasound and marked on the skin, and the IPG site should be discussed with the patient and marked on the skin. It is also wise to discuss a second IPG option with the patient. As stated previously, the sites for IPG placement depend on the targeted peripheral nerve and may include the gluteal region, the subclavicular pectoral region, lower abdominal region, and below the axilla in the mid-axillary line. It is important to take into consideration the relationship between the pocket placement and the location of the patient's garments. For example, the pocket should be placed above or below the belt line and the bra straps, as this can be a source of irritation and discomfort. For this reason the patient should be fully clothed when determining the pocket location. Although it is not technically difficult to adjust a pocket site, it is relatively expensive, it disrupts therapy, and it predisposes the patient and the surgeon to possible complications associated with surgical procedures.

Lead Placement and Testing

Precise placement of the electrode will likely require the use of an ultrasound, a peripheral nerve stimulator (twitch monitor), and fluoroscopy. Once visualization of the targeted nerve is made with ultrasound, an insulated regional block needle is advanced until stimulation of the nerve is achieved using 1mV at 2Hz. At this point, the depth and trajectory of the needle are measured, as these will serve as the parameters for advancing the 14-g Tuohy needle for lead placement. A small incision is made at the anticipated lead entry site after anesthetizing the skin with local anesthetic (a mixture of 1% lidocaine and 0.25% bupivacaine with epinephrine 1:200,000). The 14-g Tuohy needle is advanced for lead placement. The lead is carefully advanced under direct visualization parallel to the targeted nerve. The lead should be handled with care, as lead fracture is one of the leading causes of hardware failure in SCS, and this may also be true for PNS (37). The patient should be awake or only slightly sedated to allow meaningful interaction to prevent nerve injury with the needle or the lead. Once the lead has been advanced adequately, it should resemble the PNS trial placement (if a trial was performed). At this point, lead testing is done to ensure that the lead is working properly, and that an appropriate parasthesia can be induced within acceptable parameters for the chosen make and model of IPG to be implanted. This is important, as battery life will be directly related to the output needed to create the desired paresthesia.

Lead Anchoring

Proper lead anchoring is important to avoid lead migration and thus therapy failure. Anchoring can be particularly challenging when leads are placed in areas of the body that are near large musculature or adipose tissue and are prone to significant movement of underlying anatomy. For example, Figure 8.3 depicts a saphenous nerve stimulator that must be secured well given the need for significant flexion, extension, and rotation of the lower extremity.

IPG Pocket

The area for the IPG pocket is marked in the preoperative area. Using this mark, the incision site is anesthetized using local anesthetic (a mixture of 1% lidocaine plus 0.25% bupivacaine with epinephrine 1:200,000). Using a #10 or #15 blade, a 4–5-inch incision is made. The pocket is then made by using blunt dissection to a depth of 2–3 cm. If the pocket is too deep, charging of the IPG can be difficult. The pocket should be sized to snugly fit the IPG, as this will reduce the risk of seroma formation. Once the pocket is made, it is prudent to ensure proper hemostasis to prevent hematoma formation, which can lead to increased surgical site pain and infection or postsurgical re-exploration. An antibiotic-soaked 4 x 4 gauze can be inserted into the pocket while proceeding with the next steps, prior to inserting and securing the IPG.

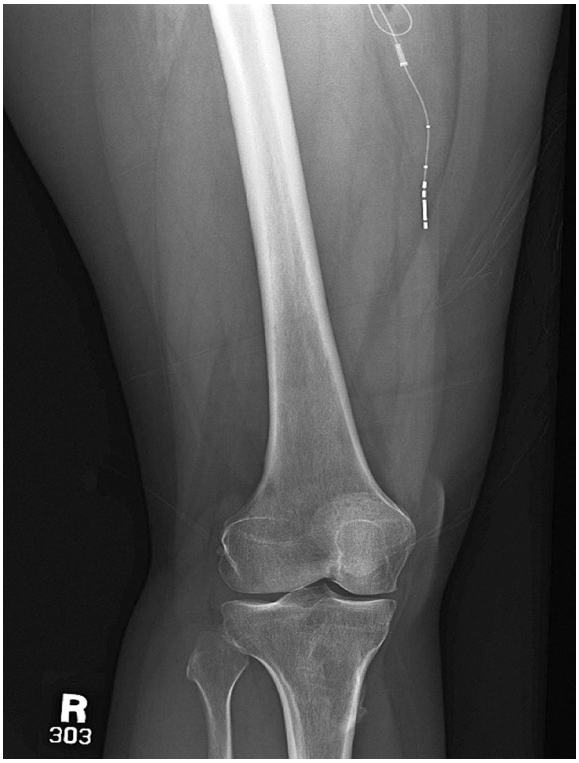

Figure 8.3 Placement of PNS in an extremity that will undergo significant movement requires securely anchoring the lead. This figure depicts a saphenous nerve stimulator and its associated anchor. The lead is a Medtronic asymmetric tined electrode.

Lead Tunneling

The implanted lead is subcutaneously brought (tunneled) to the IPG pocket site using a tunneling tool, which consists of a plastic cannula over a malleable metal shaft with a semi-sharp tip. Using caution, the shaft of the tunneling tool is bent slightly to allow the tip to travel superficially in the subcutaneous tissue. The shape and body habitus of the patient, as well as the trajectory needed to reach the pocket site, will determine the amount and location of the bend. It is prudent to ensure that the patient is adequately sedated, as this portion of the procedure can be uncomfortable. The trajectory of the tunneling tool should be injected with local anesthetic to reduce pain and the need for excessive sedation. At this point, steady force is applied with the dominant hand along the projected path, while guiding the tip with the non-dominant hand along the subcutaneous tissue. It is crucial to maintain a subcutaneous path, as vital structures can be easily punctured if the tip is too deep. It may be necessary to make an incision along the projected path to stage the tunneling if it is difficult or unsafe to tunnel in one step. In the event of a tunneling injury, a prompt consult with general surgeons may be warranted. Appropriate postoperative observation may be required, including hospitalization for close monitoring of vital sings, laboratory values (CBC/WBC), and any other indicated diagnostic testing.

IPG Implantation

Once the leads are tunneled to the pocket site, it is time to connect the leads to the IPG and test for proper function. The tools for lead connection are unique to the device company and should be reviewed with the device company representative prior to placement. Once the lead is attached to the IPG, hemostasis is confirmed, and the wound is irrigated copiously with antibiotic solution. The IPG can then be carefully inserted into the pocket. After the IPG is placed in the pocket, the device should be interrogated to ensure adequate impedances. It may be prudent to choose an IPG with longer battery life as the output needed for peripheral nerve stimulation is often more than a centrally placed lead.

Wound Closure

We prefer a 3-layer closure to adequately close the pocket for the IPG. A subdermal 2-0 braided (Vicryl) suture can be used to approximate the wound edges and create a strength layer for the closure. A second layer using 3-0 braided (Vicryl) suture is then used to approximate the edges of the wound. The final subcuticular layer, can be approximated using a running 4-0 monofilament (Monocryl) suture. Small wounds (less than 2 cm) can be closed in a single layer interrupted suture with a monofilament suture, or with a surgical bio-adhesive like Dermabond.

Bandaging

Over the Dermabond we often use steri-strips, followed by a cosmetic bandage consisting of Telfa dressing or folded gauze, with a bio-occlusive dressing like Tegaderm on top. Finally, an elastic abdominal or chest wall binder should be used for about 4 weeks, as tolerated, to ensure lead stabilization, proper pocket formation and to decrease seroma or hematoma formation. The Tegaderm and Telfa can be removed at the postoperative visit in one week. Clear instructions for postoperative wound care should be given both verbally and in writing.

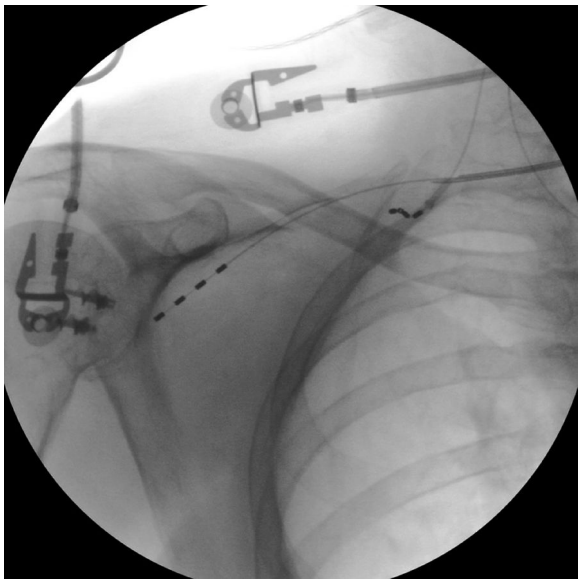

Figure 8.4 Placement of introducer needle for lead implantation in the brachial plexus is done carefully to avoid injury of nearby vascular, respiratory, and neural structures.

Common Intraoperative Complications and Their Management

Though there are many studies investigating complications with SCS, there are minimal studies investigating the incidence of intraoperative complications with PNS. Events such as nerve damage, inadvertent damage to vascular structures surrounding the nerve or along the tunneling course, and infection are all certainly possible. Meticulous dissection, appropriate use of ultrasound or fluoroscopy, and appropriately selected and timed antibiotics may decrease the probability of a complication. This is particularly important when employing large introducer needles and tunnelers to implant leads in the thorax and upper extremity, given the numerous and major vascular, respiratory, and neural structures near the neck, upper chest, and brachial plexus (Figure 8.4 depicts placement of stimulator leads within the brachial plexus). With improved PNS implantation techniques, intraoperative neural injury has become very rare, and rather pre- or postoperative nerve damage from compression, contusion, or other trauma to a stimulated nerve is more likely (4).

Postoperative Management

Common Postoperative Complications and Their Management

Many of the complications seen with PNS implantation during the early years of its use are no longer seen, as a result of improvements of design at the lead-neural interface (4). One of the most common complications associated with PNS implantation is lead migration, which makes providing slack during the lead placement and properly securing leads of utmost importance. Fractured leads, erosion of lead through skin, local infection, bleeding, nerve damage, and equipment malfunction are also possible complications (4, 20). All of the above complications are rare, but should be taken into consideration in the postoperative period.

Diagnosing and Management of Loss of Analgesia

Occasionally a patient will report pain in an area that had previously been well controlled with PNS. This may be due to lead migration, which would require interrogation using the manufacturer's programmer to assess impedance changes and attempt to ameliorate the new symptoms via changing electrode settings. If this is unsuccessful, surgical exploration may be necessary. Lead fracture, low battery, or equipment malfunction may also result in changes or loss of stimulator efficacy. Changes in the patient's position may result in a change in electrode positioning that can affect nerve stimulation. Finally, central sensitization and thus increased central pain pathway activation may decrease the efficacy of PNS (4).

Nursing Considerations for Patients with Implantable Devices

It is generally our practice to leave the stimulator turned off after implantation to allow for the nociceptive stimulus associated with wound healing to subside. Nurses in the recovery area should thus be aware that there is no pain relief being provided by the PNS. Some patients requiring PNS have tolerance to opioids and other pain medications from long-term use, and thus will require appropriately elevated doses of pain medicines and a multimodal pain treatment regimen to optimally control postoperative pain. Nursing staff must participate in meticulous care of wound sites, including appropriate dressing changes and monitoring for signs of bleeding or seroma formation. Excessive flexions, extension, or other movement involving the surgical site in the first few days after surgery can be associated with lead migration. Nursing staff can help limit mobility of the area involved in the surgery to avoid this. For example, we commonly provide cervical collars or arm slings to avoid movement of leads placed in or tunneled through the neck or extremity. Finally, nursing staff must carefully administer the ordered postoperative antibiotic course so as to decrease the possibility of infection.

Rehabilitation Considerations for Patients with Implantable Devices

The aforementioned concerns that nursing staff must address in the postoperative period also apply to rehabilitation staff. It is particularly important that the needs for physical and occupational therapy be balanced by the increased probability of lead migration until scarring at incision sites seats leads more securely. One of the major goals of PNS is to significantly improve use of the affected extremity, but abstaining from exercise therapy or other vigorous physical rehabilitation for about 6 weeks postoperatively is recommended (4).

Case Study

The patient is a 55-year-old female with a past medical history significant for gastroesophageal reflux disease (GERD), hypertension, and depression. She presented to her doctor with an 11-cm mass on her right medial thigh. Workup revealed a high-grade myxofibrosarcoma that was treated with radical dissection and postoperative radiation. The disease recurred, and subsequent problems with wound healing required right above knee amputation. The patient developed phantom limb pain of the right lower extremity.

What Initial Treatments Would you Provide for this Patient?

Pharmacologic treatment of phantom limb pain includes carbamezapine, gabapentin, pregabalin, amitryptiline, and opioids. Depression is common in amputees and may be worsening her chronic pain syndrome. Referring her to a psychiatrist who specializes in chronic pain patients is advisable. A workup is merited to ensure that an underlying process (e.g., ischemic stump, neuroma, pressure point ulcers, etc.) is not causing the pain. Nerve blocks may benefit occasionally. Phantom limb pain tends to subside over time in most patients, though other sensations continue.

Despite these interventions, the patient's pain was poorly controlled. After 2 years of suffering and poor mobility worsened by pain, a spinal cord stimulator trial was performed. Unfortunately, it provided minimal relief, and besides the patient found the programming to be confusing. Shortly thereafter, an intrathecal pump trial was instituted which benefited the patient immediately. An IT pump providing a continuous infusion of hydromorphone, clonidine, and bupivacaine was placed, and she initially received some amelioration of the pain. After a few months, however, pain control was again poor, despite modified drug combinations and higher doses of intrathecal drug delivery, and the use of PCIA (Patient Controlled Intrathecal Analgesia). Furthermore, she developed concomitant left lower extremity numbness at the higher doses which limited mobility even further. In addition, her pain exacerbated her poorly controlled hypertension, and pain medication resulted in sedation. Workup for alternative causes of the pain was negative. Despite excellent social support at home, she was becoming increasingly depressed and stopped reading, despite always having loved books. She agreed to see a psychiatrist who specialized in patients with chronic pain. A meeting was held with her psychiatrist, physical therapist, and pain specialist to decide on a course of action.

Is this Patient a Candidate for PNS? What Would You Tell the Patient to Expect?

As described previously, the literature suggests that PNS is often efficacious when there is pain along an identifiable nerve distribution, conservative measures have failed, there was some response to blockade, and appropriate psychological evaluation has occurred. PNS has been shown to be effective for phantom limb pain. The patient understood that there is a trial period with temporary nerve stimulation to assess whether this intervention is efficacious before proceeding to permanent PNS implantation. She was told to expect that these procedures were usually done under local anesthesia and sedation as an outpatient procedure and that mild tingling associated with electrical stimulation may occur. She was encouraged to know that, if PNS were effective, she could taper down or off some of her medications and thus decrease side effects associated with them. An MRI neurography was used to elucidate the anatomy relevant to her pain syndrome and potential PNS implantation.

The decision was made to place a PNS. The patient presented to the day surgery unit. After being counseled regarding the risks of the procedure, the peripheral nerve stimulator

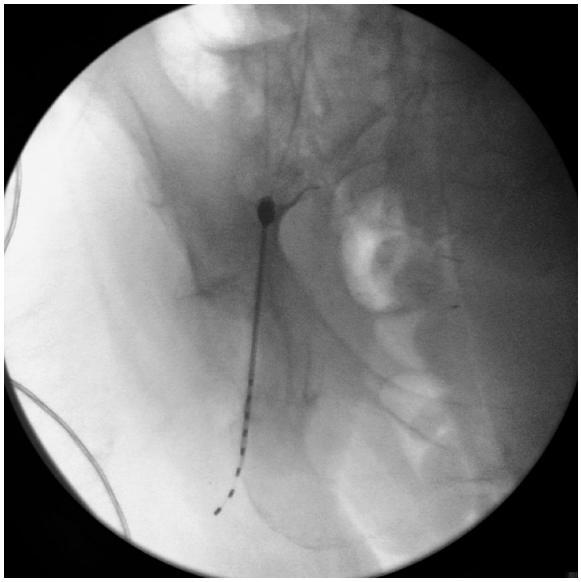

Figure 8.5 Insertion of sciatic nerve stimulator leads through introducer needle.

trial was performed under local anesthetic and sedation without complications, and she went home that evening. During the week-long trial, pain control was significantly improved, the dose of intrathecal drug delivery was able to be decreased so as to minimize left leg numbness and increase mobility, and symptoms of depression and anxiety also improved slightly. At the end of the week, the patient presented for implantation of a right sciatic nerve stimulator. The procedure was performed transcutaneously using ultrasound, peripheral nerve stimulation,

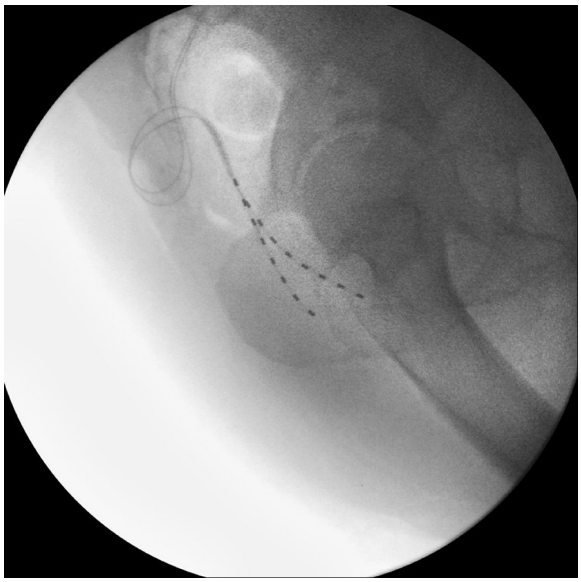

Figure 8.6 Final placement of sciatic nerve stimulator leads.

and fluoroscopy, and required deep sedation. First, the ultrasound was used to identify the sciatic nerve. Once this was identified, a stimulating needle was used to verify the correct position of the needle trajectory. A 14-g introducer needle was placed in the same trajectory as the stimulator needle. An incision was made at the insertion point, and the leads were threaded through the introducer needle, as depicted in Figure 8.5.

Once the leads were in place, and test stimulation covered the area of pain appropriately, the leads were anchored and a strain relief coil was made. The pocket was created at the right flank area, as was determined preoperatively after discussion with the patient. The leads were easily tunneled to the pocket site and connected to the IPG. Figure 8.6 depicts the final lead placement. After assuring adequate hemostatis and antibiotic irrigation, the IPG was placed in the pocket and the system was checked for impedances. These were deemed to be appropriate. The sites were closed using a 3-layer closure, dressed with dermabond and Telfa dressings, and an abdominal binder was placed. The patient was then taken to the recovery unit and stayed in 23-hour observation. Prior to discharge, extensive discussions regarding battery life, maintenance, and follow-up appointments were provided. In the ensuing weeks following implantation, pain relief was greater than 90%, and she was able to taper her intrathecal medications to a minimal dose. She states that the paresthesias are not bothersome and sometimes even feel pleasant. Her mood is significantly improved, her social engagement is significantly better, according to her psychiatrist, and she has started volunteering at the local Veterans Affairs Hospital and counseling soldiers with phantom limb pain. The patient's pain specialist plans to continue tapering and eventually discontinue intrathecal drug delivery.

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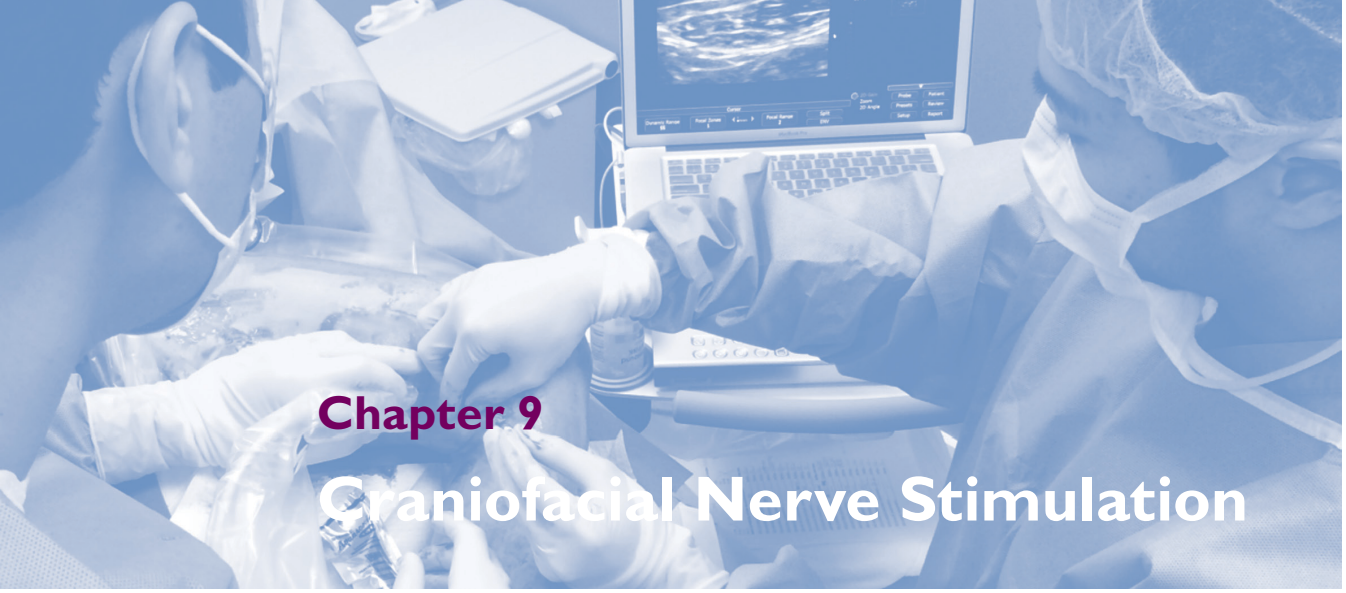

Chapter 9
Craniofacial Nerve Stimulation

Jeremy C. Jones and Edgar L. Ross

Introduction

The origin of modern neuromodulation for headache disorders can be traced back to the late 1990s, when Weiner and Reed (1) first described a percutaneous approach for occipital nerve stimulation (ONS) in presumed occipital neuralgia. A later positron emission tomography study of Weiner and Reed's patients demonstrated that 8 of the 13 patients had patterns more consistent with a diagnosis of chronic migraines (2), suggesting that the technique may be useful in other headache disorders. The success of peripheral nerve stimulation (PNS) applied to occipital nerves in headache disorders has led to the application of PNS to other cranial nerves.

The observation that stimulation of the occipital nerve can modulate pain not only in the territories that it innervates, but also in the trigeminal nerve distribution, can be explained by the functional and anatomical connections from the cervical and frontal regions. Goadsby and colleagues (3) demonstrated a connection between the cervical and trigeminal system in an area within the brainstem and upper cervical spinal cord, the trigeminocervical complex. It is here that the sensory nerve fibers in the descending tract of the trigeminal nerve (trigeminal nucleus caudalis), supplying sensation to the anterior head and face, converge and interact with sensory nerve fibers from the upper cervical roots, supplying sensation to the posterior head. This anatomic and functional connection also explains very common headache referral patterns from the posterior to frontal region. The main targets for craniofacial nerve stimulation and their indications are summarized in the following sections.

Occipital Nerve Stimulation

Occipital nerve stimulation (ONS) is the most studied and most common neuromodulation procedures for the treatment of intractable headaches. In addition to occipital neuralgia, ONS has been used for the treatment of primary headache disorders, including chronic migraine (4) and cluster headache (5). Initial encouraging results for the use of ONS in chronic migraine (6, 7) led to three multicenter randomized trials by each of the major device manufacturers (8–10). Medtronic's Occipital Nerve Stimulation for the Treatment of Intractable Migraine (ONSTIM) study demonstrated that 39% of the 29 chronic migraine patients had a 50% or greater decrease in headache days per month or a 3-point or more decrease in pain intensity from baseline at 3 months of follow-up. Success rates from studies of ONS in chronic cluster headaches showed slightly more promising rates, although none of these was a randomized controlled trial (11–15). Published studies are plagued by difficulty in blinding, due to the patient's awareness of the parasthesia during stimulation. The ICON study is a prospective, double-blind, parallel group randomized control trial of patients with intractable chronic cluster headaches that addresses the blinding issue by comparing high-amplitude stimulation with low-amplitude stimulation (16). Figure 9.1 shows an AP fluoroscopic image of an occipital stimulator lead.

Supraorbital Nerve Stimulation

In recent years, the use of supraorbital nerve stimulation (SONS) both alone and in combination with ONS have emerged as a viable treatment for various head and facial pain syndromes. The first successful application of supraorbital stimulation for cluster headache was published in 2009 (17).

A more recent retrospective study of five cluster headache patients further reinforced the effectiveness of SONS (18). There have also been several favorable reports of combining SONS and ONS (19, 20). In a single-center study of 14 chronic migraine patients treated with simultaneous SONS and ONS, a decrease of 50% or greater in pain severity was achieved in 71% of patients (21). Figures 9.2 and 9.3 show AP and lateral views of the implanted SONS leads used in conjunction with ONS.

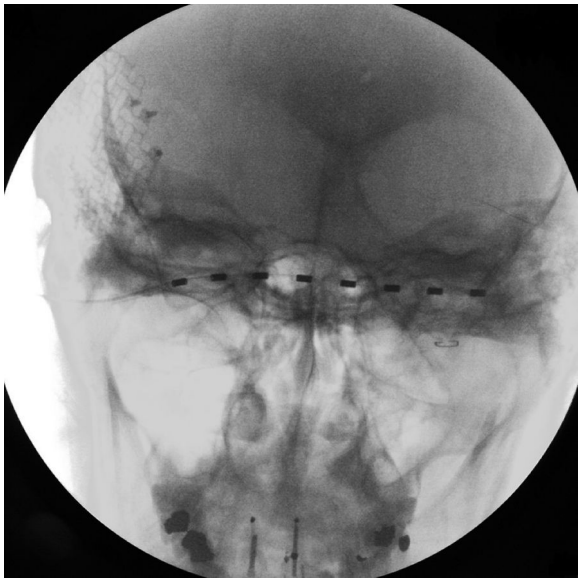

Figure 9.1 AP fluoroscopic image of an occipital stimulator lead.

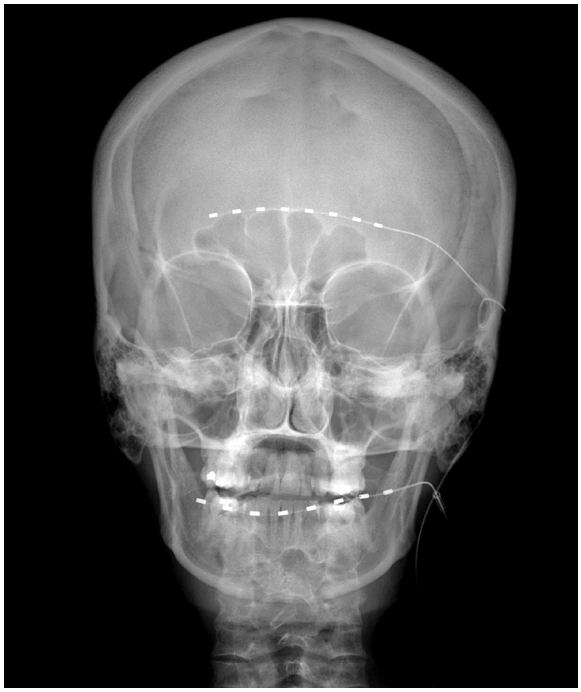

Figure 9.2 AP view of the implanted supraorbital nerve stimulator leads used in conjunction with occipital nerve stimulation.

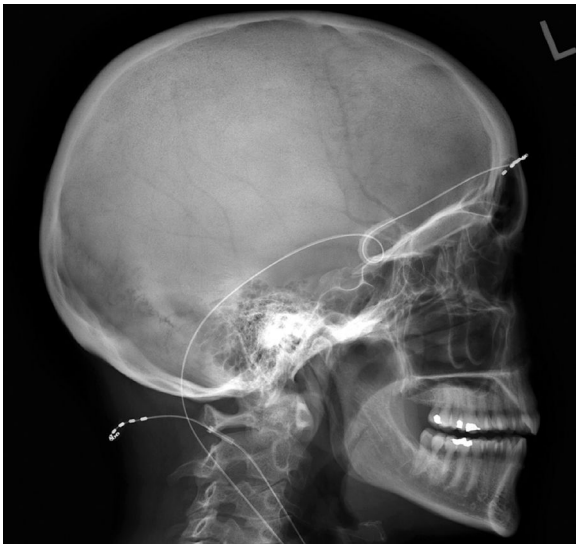

Figure 9.3 Lateral view of the implanted supraorbital nerve stimulator leads used in conjunction with occipital nerve stimulation.

Sphenopalatine Ganglion Stimulation

Less commonly, the sphenopalatine ganglion (SPG), an extracranial autonomic ganglion, is targeted for neuromodulation. It is one of the key structures involved in the expression of cranial autonomic symptoms due to connections with the trigeminovascular system, superior salivary nucleus, and hypothalamus (22). As a target for neuromodulation, it is thought to lead to an inhibition of outflow from the SPG. Several studies have reported SPG blockade for chronic cluster headaches (CCH) to provide patients with temporary relief (23–25). The SPG has also been targeted by ablative techniques for more permanent relief (26).

Studies investigating SPG neuromodulatory approaches to treating refractory CCH patients are promising. A small pilot study of 6 patients showed that SPG stimulation provided complete resolution of 11 of 18 reports of acute cluster attacks and partial resolution in 3 attacks (27). Interestingly, another showed that low-frequency SPG stimulation can trigger CH attacks within 30 minutes in 50% of patients and that high-frequency SPG stimulation terminated attacks (28).

A multicenter randomized double blind and sham-controlled trial was carried out in order to determine the efficacy of acute SPG stimulation on refractory CCH using a novel miniaturized implantable stimulator developed by Autonomic Technologies, the ATI SPG Neurostimulator. The device is implanted into the pterygopalatine fossa under general anesthesia. Once healed, patients are able to transcutaneously activate the device to electrically stimulate the SPG to relieve a cluster attack within a few minutes. The results were encouraging: 19 of 28 patients (68%) experienced clinically significant improvement in cluster attack pain, attack frequency, or both. Unexpectedly, 10 of the 28 patients had a reduction in attack frequency during the treatment period, raising questions about the use of the device for preventative treatment of CCH (29). The most common side effect (81%) was loss of sensation in the maxillary region, which seemed to improve over time.

Spinal Cord Stimulation

Although spinal cord stimulation (SCS) falls outside the scope of this chapter, it is worth mentioning here that high cervical SCS may be used for the treatment of some intractable headaches. It has been shown in studies to reduce the frequency of attacks as well as the severity of pain in CCH, although lead migration and breakage remain an issue (30, 31).

Preoperative Considerations

Non-Surgical and Medical Management

Conservative treatment includes lifestyle modification, medication management with various agents depending on the classification of the headache, and peripheral nerve blocks such as occipital, supraorbital, and auriculotemporal nerve blocks.

Goals

The goal of craniofacial stimulation is to restore function and quality of life in patients with debilitating chronic craniofacial pain or chronic intractable headaches by reducing the severity of the pain and in some cases reducing the frequency of attacks. As with other peripheral nerve stimulation techniques, craniofacial nerve stimulation works in part by disrupting the nociceptive pathway, causing a generally better tolerated paresthesia in place of the patient's usual pain sensation.

Advantages

Over the past two decades, neuromodulation for intractable headaches has become an established therapeutic option for patients with severe, debilitating intractable headaches who have failed first- and second-line therapies. In contrast to neurosurgical destructive and ablative techniques such as surgical decompression, neurolysis, and rhizotomies, neuromodulation is reversible by definition and, although not devoid of major complications, represents a valid approach for restoring quality of life for patients with intractable primary and secondary headaches.

Patient Screening and Trial of Therapies

Potential candidates for neuromodulation should have had chronic headaches that have interfered significantly with their quality of life for at least 6 months, and should have failed to significantly respond to first- and second-line pharmacotherapy, as well as peripheral nerve and sympathetic blocks (32). Patients should be evaluated by an experienced headache specialist and diagnosed with a clinical syndrome that is thought to be responsive to neuromodulation. A thorough medical examination should attempt to identify and treat any underlying pathology or structural cause for the patient's pain. Medication overuse is an easily reversible common cause of chronic headaches and must be considered. Overuse of analgesics and triptans has been associated with an unfavorable outcome in migraine patients receiving ONS (33).

Potential candidates must undergo psychological examination by a psychologist with experience in the evaluation of chronic pain patients (34). This is described further in Chapter 4. The goal of the evaluation is to identify psychosocial factors that may be contributing to the patient's pain syndrome, to address psychiatric symptoms such as depression or anxiety, to assess for personality disorders or somataform disorder, and to ensure the absence of addiction. All should be accomplished prior to a trial of neuromodulation, and the findings of the psychologist may prevent proceeding with the trial. In addition, during the psychological evaluation the patient's expectations and wishes for the procedure should be explored.

Alternative Treatments and Procedures

In many patients with intractable craniofacial pain, nerve-blocking techniques with local anesthetics or steroids provide pain relief of varying duration. In patients who receive inadequate relief from nerve blocks, more invasive techniques may be considered. Some of the irreversible neurosurgical and ablative techniques, such as surgical decompression, neurolysis, and

rhizotomies, have been widely used for intractable headaches in the past (35). Complications of such procedures include development of delayed deafferentation pain in the distribution of the affected nerve.

Another invasive procedure for intractable headaches is deep brain stimulation (DBS). Several studies have shown DBS of the posterior hypothalamic area to be effective in the treatment of cluster headache (36–39). DBS remains an off-label indication for those patients with intractable headache and is reserved for those who have failed less invasive peripheral neuromodulation techniques. DBS has been associated with severe adverse events, including hemorrhage (40), transient ischemic attack (41), and even death (42).

Preparing the Patient for Surgery

It is important for patients to have appropriate expectations. They should be aware that no neuromodulation procedure will be able to completely resolve their pain. Due to the multifactorial nature of pain, the results among patients with the same diagnosis will vary. Appropriate expectations will help modulate patients' postoperative satisfaction.

A PNS trial can be difficult to execute for primary headache syndromes because, unlike neuropathic pain, the response may not be obtained for weeks. When a trial is carried out, an external stimulator is used with a patient-controlled remote that is used to activate and adjust as needed. Trials lengths vary generally from 5 to 10 days. A minimum of 50% sustained pain relief in the desired area is required for a successful trial.

Intraoperative Management

Antibiotic Prophylaxis

Antibiotic prophylaxis is discussed in further detail in Appendix 11.

Patient Positioning

Patient positioning is dependent on the desired locations of the leads. For supraorbital stimulation devices, the patient is placed in a supine position. For unilateral occipital nerve stimulation, we often place the patient in a lateral decubitus position with the side of placement facing up. If bilateral occipital nerve placement is desired, the patient can sometimes be maintained in a lateral decubitus position with the head slightly angled forward to allow access to the contralateral side. The lead can then be tunneled to the contralateral side from this position.

Skin Preparation and Draping of the Patient

Skin preparation and draping are discussed further in Appendix 11. Specific to craniofacial nerve stimulation, the hair should be shaved with clippers prior to skin preparation. This should be discussed with the patient prior to the procedure. Care should be used with Chloraprep solution, as it should not be applied to the hair or eyes. We recommend eye ointment with Tegaderm dressings to be placed over the eyes for protection. Another alternative is to use iodine-based solutions.

Figure 9.4 is an example of patient positioning and preparation for occipital nerve stimulator. This patient is supine with neck rotated to allow placement of the occipital stimulator lead. Note that the hair overlying the operative area has been shaved; clear polyurethane drapes are applied prior to the application of skin prep. Figure 9.5 shows the placement of Ioban™; Figure 9.6 shows laparotomy drape; and Figure 9.7 shows full drape over laparotomy drape.

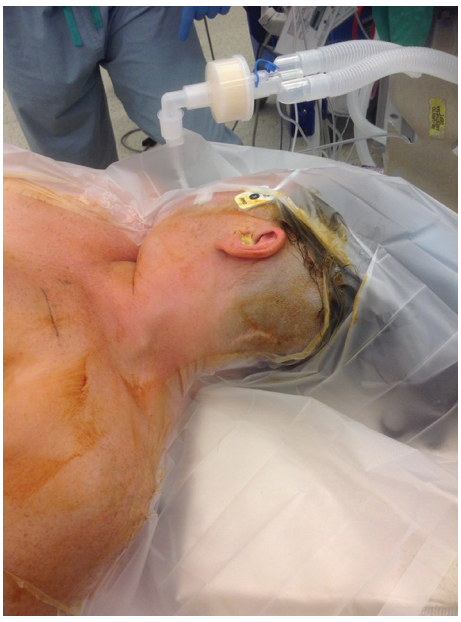

Figure 9.4 Example of patient positioning and preparation for occipital nerve stimulator.
Note the xeroform gauze placed in the prepared ear to protect the ear canal.

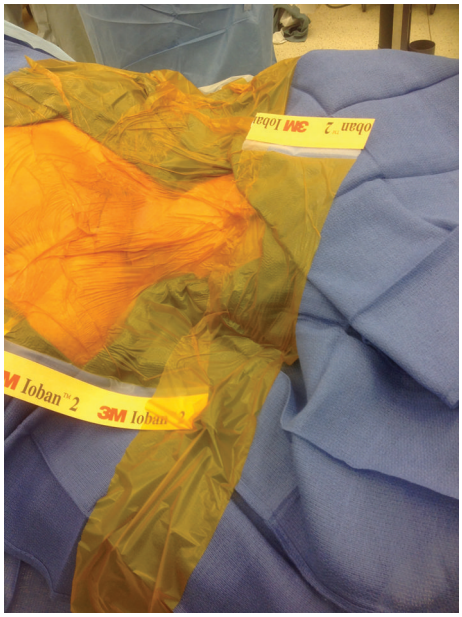

Figure 9.5 Example of Ioban placed over prepared area for occipital nerve stimulator.

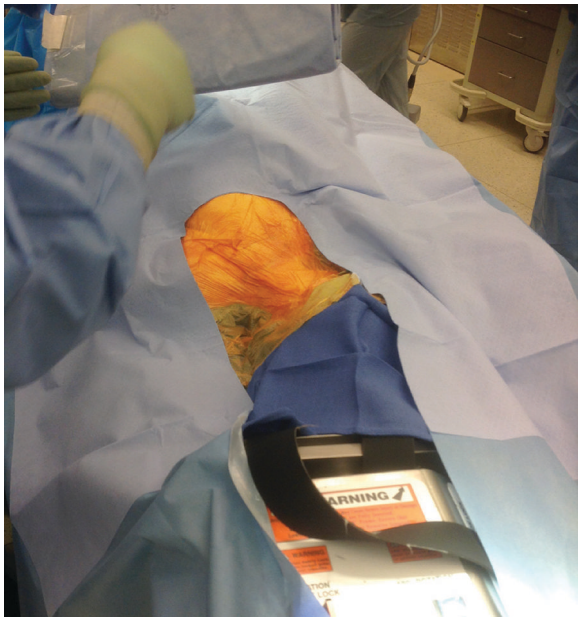

Figure 9.6 Laparotomy drape placed over Ioban and prepared patient.

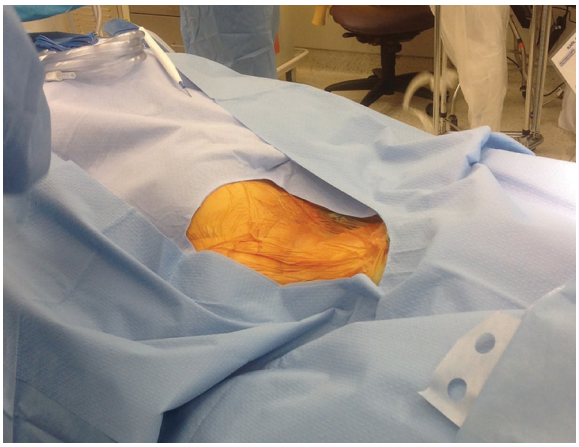

Figure 9.7 Example of final draping for occipital nerve stimulator.

Special Equipment

Much of the equipment used for craniofacial nerve stimulation is provided by the device representative. Basic equipment includes leads, introducer, lead extensions, and pulse generator (these are provided by the device representative). Surgical tools such as clamps, forceps, syringes, and scalpels are also used. See Appendix 13 for a complete list of items needed for ONS.

Surgical Technique

Craniofacial nerve stimulation utilizes the same basic elements as spinal cord stimulation: the electrodes and leads, the anchor (which serves the purpose of fastening leads to connective tissue), and the implantable pulse generator (IPG). Leads are ideally placed percutaneously via an introducer after applying local anesthetic. Figure 9.8 shows placement of the introducer,

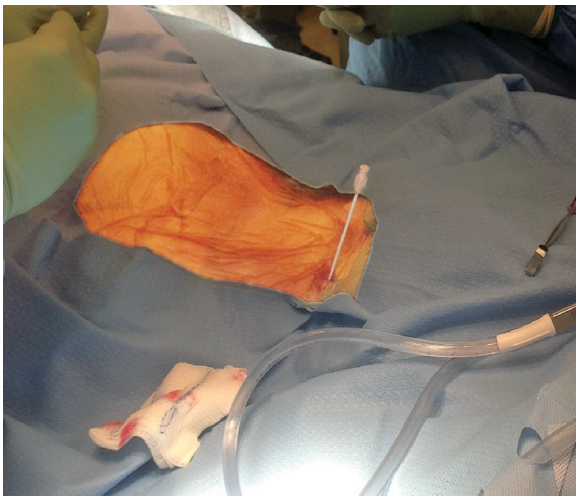

Figure 9.8 Placement of the introducer.

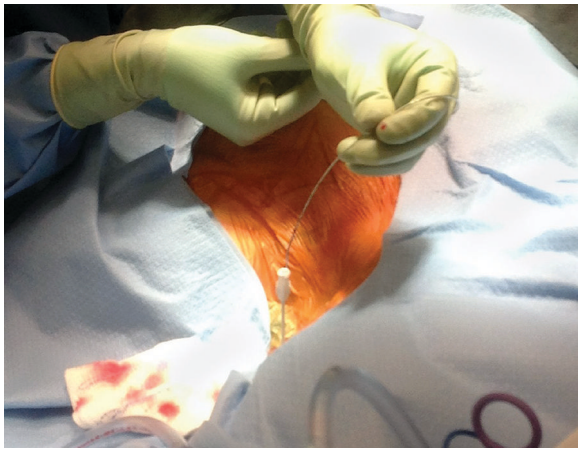

Figure 9.9 Insertion of the lead through the introducer.

and Figure 9.9 shows insertion of the lead through the introducer. The introducer is removed, leaving the lead in place (see Figure 9.10). The lead placement is done under sedation, allowing the patient to describe whether the stimulation covers the area of interest. The lead should be tunneled to the anatomic site of the nerve that is providing the innervation for the patient's pain complaint.

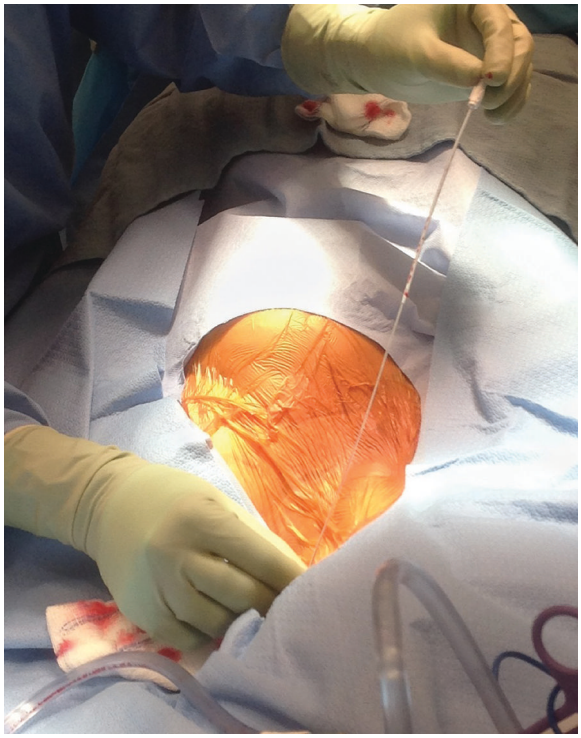

Figure 9.10 Removal of the introducer.

Once the optimal position of the electrodes is obtained, general anesthesia may be induced to allow implantation of the remainder of the system. An incision is made at the entrance of the electrode with the introducer needle in place. Dissection should proceed to the fascia layer. It is important to dissect to fascia prior to removing the needle to protect the lead from inadvertent damage. After completion of dissection and removal of the needle, the anchor, which serves to immobilize the lead, is slipped onto the lead and sutured to fascia. Figure 9.11 shows the anchor being deployed. Anchors have differences depending on the type of device, and the implanter should be familiar with each type and its optimal use. Failure to properly anchor the lead could result in a lead migration, leading to loss of coverage and requiring revision.

A pocket is created to house the implantable pulse generator (IPG.) Care must be taken not to make the pocket too deep, which would impede efficient recharging and reprogramming. The location of the pocket depends on the location of the electrode and biomechanical considerations to reduce electrode pulling, cosmetic considerations, and patient preference. Significant experience with this approach has suggested that the optimal site is the infraclavicular location for the pulse generator. Leads running parallel to an axis of high flexion or extension are more likely to migrate. Strain relief loops are often used as a technique to mitigate the risk of migration, kinking, or breakage of the leads (43). The technique simply allows the excess lead slack form a gentle loop, which can be loosely sutured to the fascia or even just placed in the incision site, provided that there is sufficient undermining of the fascial layer to accommodate the loop. Figures 9.12, 9.13, and 9.14 show the marking of the pocket site, the placement of the IPG in the completed pocket, and the IPG fully inside the pocket. The surgical technique for this procedure is very important.

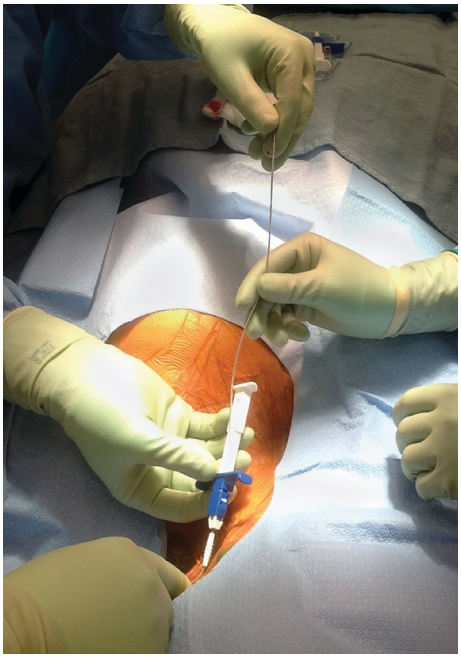

Figure 9.11 Deploying the anchor.

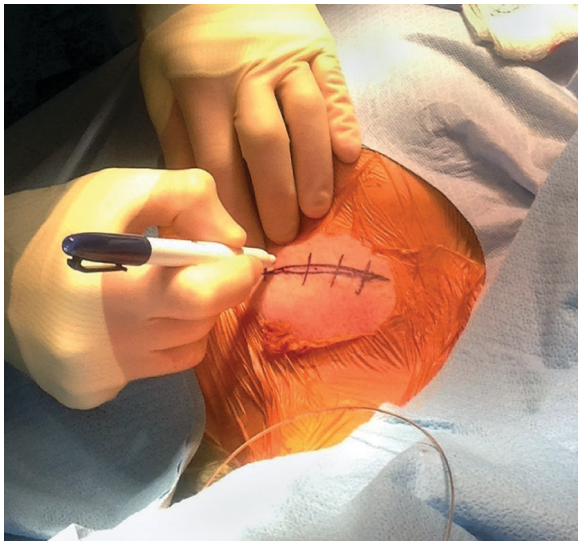

Figure 9.12 Marking of the pocket site.

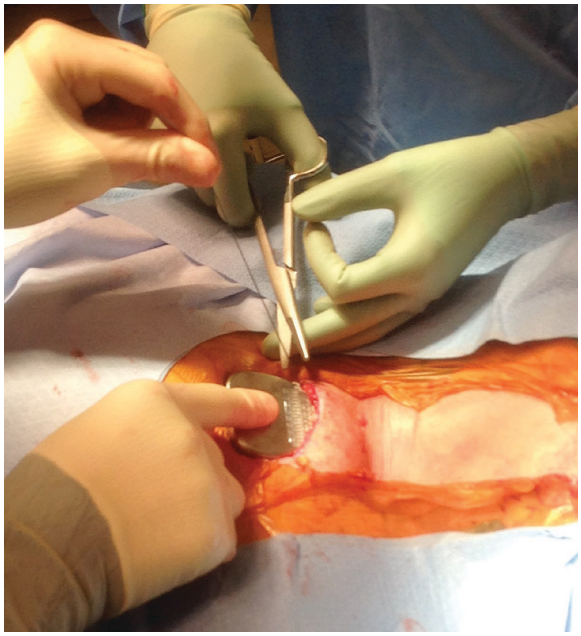

Figure 9.13 Placing the IPG in the pocket.

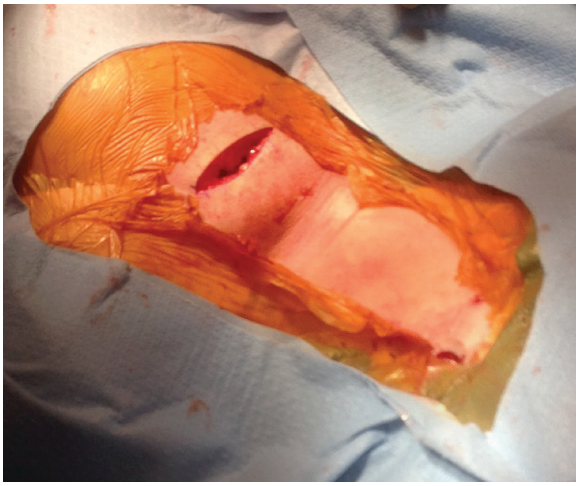

Figure 9.14 The IPG is placed fully in the pocket.

Once the pocket is created and the lead is anchored, but before placing the IPG in the pocket, a tunneling device is used to create a conduit in the subcutaneous tissues between the lead anchor site and the pocket. The lead is passed through and the tunneling device is removed, with some surgeons injecting local anesthetic through a catheter while the tunneling device is removed to help with postoperative pain. Figures 9.15 and 9.16 illustrate this process. Incisions are then closed as previously described in Chapter 7.

Miniaturized, self-contained neurostimulator devices are being developed that obviate the need to anchor or tunnel extensions. These devices are current controlled and have integrated electrodes, programmer, and battery. The bion was one such device that has been used successfully for occipital nerve stimulation (44). The safety and efficacy of these devices need to be studied on a larger scale before their role in treatment of headache syndromes is defined.

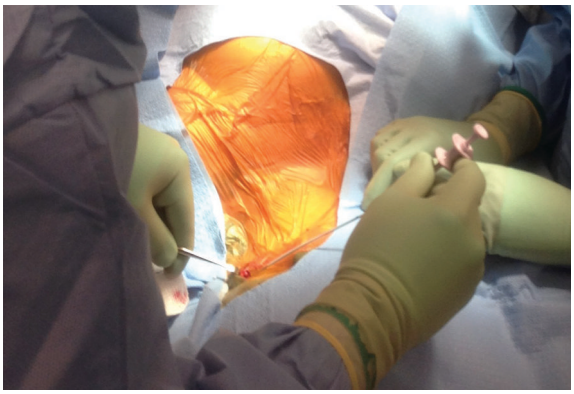

Figure 9.15 Tunneling device.

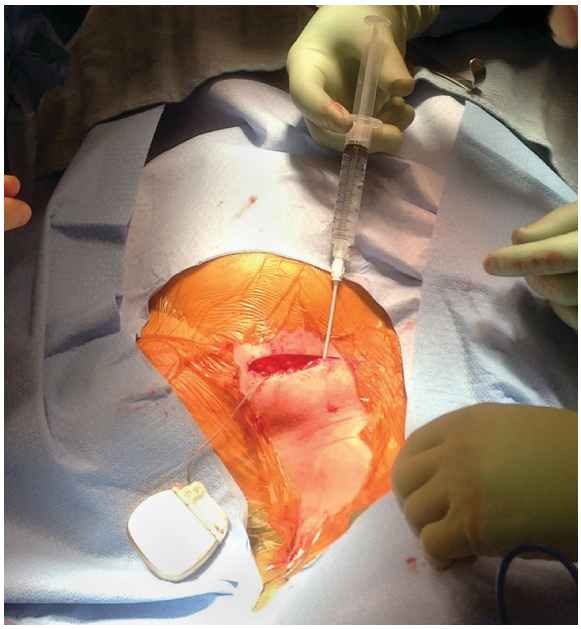

Figure 9.16 Use of local anesthetic through the tunneling device to help with postoperative pain from tunneling. Note that the local anesthetic (in the 10-cc syringe) is connected to the tunneling device and is injected as the tunneling device is removed from the subcutaneous tissues.

Common Intraoperative Complications and Their Management

Common intraoperative problems include bleeding related to tunneling. Care should be taken to note the location of major vessels and to avoid them while tunneling. If injury to a major vessel is suspected, hold pressure and consult with a vascular surgeon. With IPG placement in the chest, care should also be taken to not dissect too deeply, as the intrapleural cavity should be avoided.

Postoperative Management

Common Postoperative Complications and Their Management

Lead migration is the most commonly reported complication of the ONS studies. One of the largest randomized control trials of 105 patients reported a rate of 14% in the active stimulation group (45). Lead migration occurred in 24% of 51 cases in the ONSTIM study. Lead migration and breakage is especially of concern for leads traversing the highly mobile cervical region. In the case of lead migration, if the patient no longer receives stimulation to the target area, then the device should be reprogrammed to restore adequate coverage. If this fails, then the patient will likely require a revision in the OR. If the patient receives unpleasant or undesirable stimulation, the device can be turned off.

The rate of implant site infection in the ONSTIM study was 12%, with infection of the lead/extension tract occurring 8 times in 7 patients out of 51 patients, and infection of the implant site occurring 3 times in 2 patients. Of the 51 cases, 3 adverse events required hospitalization: implant site infection, lead migration, and postoperative nausea (46). Complications rates may vary according to surgeon experience; however, the aforementioned studies were multicenter trials. Further clinical experience and advances in device anchors should help reduce the rate of lead migration.

Diagnosing and Management of Loss of Analgesia

Loss of analgesia may be either a lead problem or an implantable pulse generator (IPG) problem. Using a programmer to interrogate the device will be the first step. If the electrodes can be reconfigured to provide acceptable relief, then likely lead migration has occurred and possibly reprogramming is all that is required. X-rays may be useful in determining if the lead has migrated. Lead breakage may not be apparent on X-ray, but may result in loss of analgesia and may require lead replacement. High impedances likely are caused by the lead becoming dislodged from the IPG. In this case a revision will be required; however, the lead may simply need to be reseated into the IPG.

Nursing Considerations for Patients with Implantable Devices

Patients in most cases will require a soft C-collar to prevent flexion and extension at the neck. Patients will be in pain postoperatively and may require patient-controlled analgesia (PCA) the first night. Many institutions do not activate the device until one week postop.

Rehabilitation Considerations for Patients with Implantable Devices

Currently the vast majority of nerve stimulator devices on the market are not magnetic resonance imaging (MRI) compatible. If these patients require emergent imaging, a computed tomography (CT) scan must be obtained. If MRI imaging is required and the situation is not emergent, then the device should be explanted. Patients with nerve stimulator devices should not receive an MRI unless the device can be proven to be MRI compatible.

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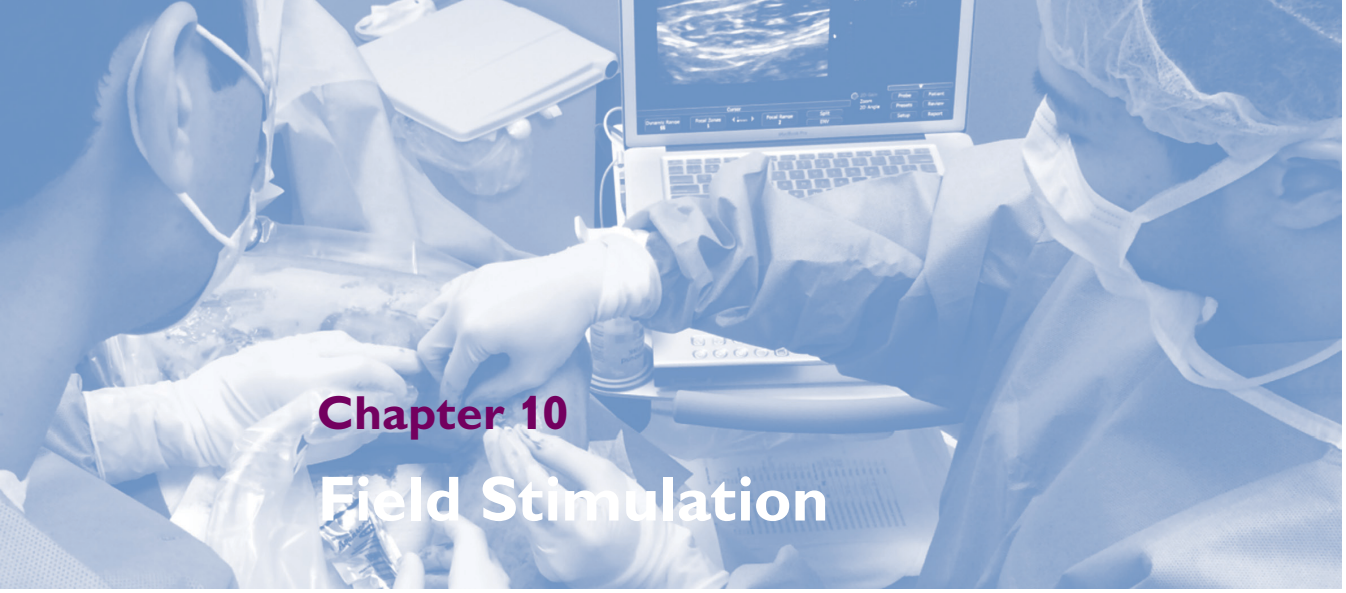

Chapter 10
Field Stimulation

Ehren R. Nelson, Andrew Vaclavik, and Milan P. Stojanovic

Introduction

Spinal cord stimulation (SCS) was first used in the 1970s as an application of the gate theory of pain which has been used to explain the mechanism of its analgesia. Spinal cord stimulation achieved through the epidural route is very versatile and can relieve many different forms of neuropathic pain. However, coverage is not always possible everywhere, or the areas that are covered are too broad and result in significant areas of unwanted stimulation. Examples of areas where coverage is much more difficult or not selective enough include pain restricted to the abdomen, thorax, or lower back, head and neck stimulation, and pelvic disorders. By convention, peripheral nerve stimulation (PNS) usually refers to stimulation of named nerves, and field stimulation (FS) refers to stimulation of unnamed nerves. In combination, these new approaches are becoming promising interventions for targets that were not amenable to stimulation before.

In addition to more precise targeting of difficult-to-treat neuropathic pain, field stimulation can be used in combination with epidural stimulation in a hybrid manner. These hybrid implants can further increase the flexibility of stimulation by allowing greater ranges in amplitude of each individual entity independently. This avoids eventual compromise between increasing amplitude to obtain improved efficacy and the resulting muscle overstimulation that occurs at higher levels while trying to intensify the analgesic paresthesia. Finally, when one generator is used for both a peripheral and epidural lead, the resulting crosstalk has further potential to shape electrical fields toward the intended targets and away from unintended ones.

The list of successful applications using field stimulation (FS) is increasing, as documented by the growing body of case series and reports as well as controlled trials. Although no consensus exists in the literature regarding selection criteria or best practices for electrode positioning over the neuropathic pain site, the benefits for patients appear to be significant and long lasting. Successful use of FS in patients has been published for pain conditions including axial back pain, chronic pelvic pain, abdominal pain, inguinal pain, and post-thoracotomy pain (1–4, 7–9).

In a prospective observational study, Paul Verrillis et al. described 100 cases of the use of peripheral nerve field stimulation (PNFS) for chronic pain involving craniofacial, thorax, lumbosacral, abdominal, pelvic and groin pain. This study reported that FS can be a safe and effective treatment for patients with intractable chronic pain syndromes (5). Dahl Morch et al. described a mathematical model for optimal lead depth in the placement of peripheral nerve leads further placing field stimulation on a scientific footing (6). Hybrid stimulation, using a combination of epidural and FS, has been used effectively in situations where a portion of a patient's pain is not completely covered by epidural stimulation alone (7, 8).

A randomized controlled crossover study by McRoberts et al. using FS in 23 patients with chronic low back pain showed improvement in pain scores at the one-year follow-up mark (10). Another prospective, observational study by Kloimstein et al. using FS in over 100 patients with chronic low back pain showed improvements in pain scores, Oswestry Disability Questionnaire scores, and Beck Depression Inventory scores (11). In addition, this study also showed a significant reduction in opioid use, with minimal complication rates following implantation, suggesting that PNFS can be effective and safe for the treatment of chronic intractable low back pain. While these initial reports are encouraging, prospective outcome studies with improved design are needed to better assess this treatment modality.

Preoperative Considerations

Non-Surgical and Medical Management

Patients being considered for surgical pain interventions for their chronic pain are likely to have tried and failed more conservative therapies. A thorough medical history should be obtained, including a detailed list of treatments the patient has received for his or her pain symptoms, along with the results. All patients should have had trials of conservative management that includes treatment outlined by the World Health Organization analgesic ladder. Many patients would have received multiple surgical and non-surgical interventions for their pain without achieving adequate analgesia.

Goals

Most patients, depending on the source and etiology of their pain, would likely have tried oral analgesics, nerve blocks, physical and psychological therapies, and some will have had surgical interventions. Some patients may have previously been implanted with a spinal cord stimulator placed that has failed to cover any or all of their pain. It is the goal of FS to provide analgesic coverage in defined areas of the body that have proven resistant to other therapies and interventions.

Advantages

The advantage of field stimulation includes its ability to target specific areas of the body that define a known region of pain for any given patient. Since it does not require access to the epidural space, patients with altered anatomy, whether from surgery or congenital anomalies, are still candidates for field stimulation lead placement. Additionally, infection risk, although rare, has a much smaller potential for catastrophic consequences that can occur with implantable devices that have a direct connection to the epidural space and can potentially become infected.

Patient Screening and Trial of Therapies

Predicting patient response for FS is difficult given the lack of guidelines and level I evidence for its use in any given neuropathic pain syndrome. Selection criteria for FS should follow the same criteria established for spinal cord stimulation. Selection criteria for FS can be differentiated into the following:

- The pain source should be a localized area of the body, as opposed to generalized body pain, vague regional pain, or visceral pain. Typically circumscribed areas of the torso, chest wall, low back, and sacroiliac region are considered reasonable targets for field stimulation.
- The area to be considered for FS must be able to accommodate a stimulator lead and an implantable pulse generator.
- Placement of the lead and generator should not extend over a joint if possible. If no alternative is available, consideration must be given to the potential tension of the lead and the likelihood of lead displacement.
- A successful trial, with the same principles used for spinal cord stimulation, should be conducted.

Additional considerations for FS are anatomical contraindications for spinal cord stimulation, such as inability to access the epidural space, either from prior extensive back surgery or any underlying neurological malformation, and failed stimulation trial using epidural leads, or surgically placed paddle leads.

Field Stimulation Overview

Because of the nearly unlimited variations in clinical presentation, no single method or technique will apply to all patients. FS implant technique could vary significantly from patient to patient, depending on the specific pain complaints and anatomical area of interest. Key points, however, should be considered for all patients.

Alternative Therapies

Prior to implantation of the FS system, patients should be aware of alternative therapies available to them. In the case of defining alternative therapies for FS, most patients will have tried most other, less invasive forms of treatment. It is the responsibility of the pain provider to discuss with the patient any prior treatments and any other potentially beneficial therapies or interventions that can and should be tried before proceeding for operative management of his or her pain.

Trial

All patients who are candidates for FS should undergo a trial to assess efficacy prior to permanent implantation. The trial can easily be done as an outpatient. The stimulator settings during the trial period should be adjusted to maximize pain relief. The trial should be sufficiently long to prove efficacy and to provide time for the patient to understand the use of the device. It is helpful for the patient to document pain scores, function, and any problems with the stimulator. As with spinal cord stimulation, an FS trial should demonstrate significant pain relief, typically greater than 50% for the patient to be considered to be an implant candidate.

Preparing the Patient for Surgery

After a successful trial with FS, a discussion should be had with the patient in preparation for surgery. This discussion should include every phase of the implantation process, including what to expect on the day of surgery, during the procedure, immediately postop, and during the short- and long-term follow-up. The patient should understand NPO (nothing by mouth) instructions to prevent delay and/or cancellation of the procedure. They should also be aware of what will happen in the operating room: whether the patient will have sedation or general anesthesia, if intraoperative stimulation testing will be required, if patient cooperation is needed, and so on. Expectations for postoperative care should be made clear and realistic. The short- and long-term follow-up plans should be clarified, and the patient should understand the importance of following wound care instructions and follow-up visits.

Intraoperative Management

Antibiotic Prophylaxis

Antibiotic prophylaxis is discussed in further detail in Appendix 11.

Patient Positioning

No specific positioning guidelines can be made for FS, given the array of possibilities of implant sites for patients undergoing implantation of FS leads. The needs for positioning differ, depending on whether the procedure will be conducted on a patient under general anesthesia or sedation. For a patient under general anesthesia, the pain provider should work with the anesthesiologist to position the patient in a manner that reduces the risk of nerve injury (either by compression or by traction), and all pressure points should be padded. With the sedated patient, the patient should be positioned in a way that provides optimal patient comfort while still allowing adequate surgical exposure.

Skin Preparation and Draping of the Patient

Skin preparation and draping are discussed in detail in Appendix 11. When prepping a patient on the operating room table in preparation for implantation of FS leads, the area of interest (lead implantation site including the IPG pocket site) should be clearly exposed. Body hair located in the target area should be shaved. A wide prep area that provides good visualization of the anatomy is always advantageous.

Special Equipment

Aside from standard surgical equipment, the specific equipment required for implantation of an FS system is provided by the manufacturer of the system. This includes the stimulator leads, introducer needle, lead extensions, anchors, the pulse generator, and a programmer. Depending on the desired implantation location of the FS leads, ultrasound and/or fluoroscopy services in the operating room may be necessary and, if so, must be available at the time of implant.

Surgical Technique

The surgical preparation and technique of the stimulator for FS are very similar to those for spinal cord stimulation (SCS), although with some important differences. Prior to administering any sedating medications, the surgical site should be identified and marked, and the region of the patient's pain should be clearly outlined on the patient's skin. Care should be taken to have the stimulating portion of the electrode to bracket the painful area(s). Both sedation and general anesthesia have been used for this procedure. If there is a concern about the potential of incomplete coverage, sedation is the preferred approach. The perioperative care should be identical to SCS implantation in all aspects. This includes antibiotic protocols, prepping, draping, and postoperative care. Appendix 11 further discusses prepping and draping.

Technical Considerations for Field Stimulation

Placing the Electrodes

Care should be taken to place the electrodes into the subcutaneous tissue overlying the painful area. Electrodes placed into muscle tissue are not analgesic and often cause pain. Widely spaced electrodes with standard configurations and electrode widths have shown the most success. A small stab incision through the skin, using care to anesthetize only the region of skin incision, is sufficient in most patients. Anesthetizing the entire track

will interfere with lead programming. Multiple tunneling methods have been described. The implanter can use the provided introducer needle, or softer and more flexible catheters sufficient in size to accommodate the stimulator leads. Fluoroscopic imaging is useful to document the final lead positions, especially if fluoroscopic images from the trial are available for comparison. Single or multiple leads may be placed in parallel or in tandem, depending on the area to be covered. Ultrasound has also been used to control the depth of the lead and to avoid too deep or too superficial a placement. Anchoring the leads requires a different strategy than for SCS. When available leads are to be secured to underlying fascia, however since the leads are often placed in subcutaneous adipose where there is no fascia, alternatives for anchoring the leads should be considered. Deploying the anchor over the lead and embedding this into the subcutaneous tissue allow the bulk to hold the lead, preventing lead migration. To further reduce the chance of lead displacement, the implanter should use strain relief loops in the lead course, avoid the crossing of joints, and place the generator as close as possible to the electrodes.

Pulse Generator Selection

The amplitudes needed for FS are generally significantly higher than for SCS. High-capacity rechargeable generators should be used where it is feasible. Considerations of pocket size, depth, and surgical formation of the pocket for the generator are identical to SCS. The depth of the pocket should be within the limits of manufacturing specifications of the pulse generator to allow for IPG charging.

Tunneling

Once the leads have been anchored and the IPG pocket has been created, the electrodes have to be tunneled from the lead insertion site to the pocket. This technique is again nearly identical to the tunneling required for SCS. Acute bends along the path of the stimulator leads must be avoided for prevention of premature lead fracture. Excess lead length should be coiled and placed underneath the IPG in the pocket. Impedances should be checked after connection to the IPG to rule out malpositioning of leads or connections. In general, FS stimulator leads have impedances higher than neuraxial leads, with readings of 3000–5000 ohms.

Common Intraoperative Complications and Their Management

Complications that occur with implantation of FS leads vary based on the location of the lead positions and IPG pocket location. Leads placed over the thorax carry the theoretical risk of pleural puncture and subsequent pneumothorax. Any concern for pneumothorax should be communicated to the anesthesiologist early, and the patient should be monitored accordingly. Bleeding is another complication that can occur during implantation. Minor vascular bleeding is common, and electrocautery can be used for hemostasis. Injury to larger vessels can be severe and can cause significant bleeding that may be beyond the expertise of the implanter to appropriately control. In this scenario, vascular surgery, if available, should be called to the OR for immediate consult and assistance in identifying and controlling the bleed. Depending on the extent of the bleeding and the degree of hemostasis achieved, the patient may require admission for observation. As FS can take place in many different areas of the body, the complications are not limited to only those mentioned here. Careful surgical technique and knowing the limitations of one's surgical abilities will help prevent complications in the operating room. Consulting an experienced surgical colleague may be of benefit when implanting leads in an unfamiliar area.

Postoperative Management

Common Postoperative Complications and Their Management

Some of the postoperative complications associated with FS implantation include lead migration, lead erosion and fracture, system malfunction, and infection. These complications are known for all implantable stimulation systems. Specific to FS, just as in PNS, lead migration remains one of the most common complications and reasons for loss of analgesic efficacy. The anatomical variation of the sites used in FS makes a uniform guideline for lead anchoring difficult to create. It is important to allow adequate lead length to prevent tension on the lead at the insertion site. While every attempt is to be made to secure the lead to a firm fascial structure, often in FS implantation there is no fascial plane to which an anchor can be securely attached, leaving the lead vulnerable to migration. In the surgical technique portion of this chapter, we outline our use of the anchor to decrease the probability of lead migration. Refer to Chapter 8 for more details on postoperative complications in PNS, which are shared with the use of field stimulation.

Diagnosing and Management of Loss of Analgesia

Loss of analgesia can occur in patients with a previously successful implantable FS system and may be due to a variety of reasons. Most likely, a loss of analgesia is due to lead migration. When presented with this scenario, the patient must be investigated for not only lead migration, but also for other causes that may lead to reduced analgesia, such as infection of the leads or IPG, or disease progression in patients with a history of cancer or other chronic disease. To evaluate for lead migration, two things can be done. First, imaging of the leads, if available, should be compared to the intraoperative images of final lead positioning. The entire length of the lead, including the IPG, should be included in the imaging to evaluate for any lead fracture or disconnection of the leads from the generator. Clear evidence of lead migration, fracture, and/or disconnection requires surgery to fix the problem. Second, the generator should be interrogated. Impedance changes can occur with both lead migration and scar tissue around the electrode. During interrogation, the electrode settings can be adjusted to attempt to provide better analgesic coverage. If analgesia can be provided with altered electrode settings, the patient can continue with the new settings and avoid further investigation. If unsuccessful, surgical exploration may be required to identify and fix the issue.

Nursing Considerations for Patients With Implantable Devices

Nurses taking care of patients with implantable FS systems in the immediate postoperative period should be aware of certain aspects of caring for these patients, in addition to the standard postoperative patient. First, many of these patients have had chronic pain for many years and may also be on chronic opioid therapy, making them tolerant to opioid medications. Additionally, the nurses should be told if the device is active. It is our practice to keep the generator off immediately postop, and the nurses should be aware that the device is providing no analgesic benefit in the immediate postoperative period. Nursing staff should also be aware of the dressings applied to the leads and IPG pocket site and should be trained in wound care. They should also be able to monitor the wound for signs of hematoma formation or excess drainage. Depending on the site of implantation, instructions for limiting the patient's mobility should be given to both the patient and the nursing staff. Excess movement in the immediate postoperative period may increase the risk of lead migration.

Rehabilitation Considerations in Patients with Implantable Devices

As with peripheral nerve stimulation, postoperative physical therapy and occupational therapy during recovery must take into consideration the increased probability of lead migration with increased activity. Holding off on exercise or other forms of physical rehabilitation for approximately 6 weeks postoperatively is recommended. This is to allow some level of scarring to occur to hold the leads more securely and to prevent migration.

Conclusion

FS is a new way of utilizing neuromodulation to reduce chronic pain. Although its mechanism of action has not been completely established, it has shown promise in alleviating painful conditions that have been difficult to treat with spinal cord stimulation alone.

Case Reports

We present four brief examples of the use of field stimulation for chronic pain.

Hybrid stimulator: Mr. B is a 45-year-old male with a history of spinal cord stimulator implant for CRPS of the lower extremity. He developed right-sided thoracic back pain, so he underwent a successful trial for field stimulation of the right thoracic back region. He then underwent placement of the field stimulator electrode 6 weeks later. See Figure 10.1 for fluoroscopic image of the field stimulator electrode as well as the epidural electrode.

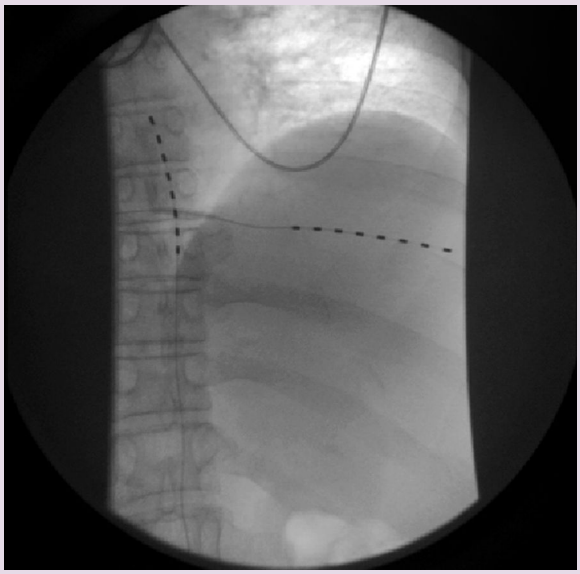

Figure 10.1 Example of hybrid stimulation with epidural lead and right lateral thoracic field stimulation.

SI joint pain: Ms. P is a 38-year-old female with chronic sacro-iliac (SI) joint pain that started in her twenties after a surfing accident. This pain was initially amenable to SI joint injections. When she started to have decreasing effect over time, water-cooled radio frequency lesioning (RFL) of the SI joints was attempted, with initially good relief; however, she started to have decreasing effect with this as well. Other causes of her pain were ruled out, and she underwent a successful trial of bilateral SI joint electrode placement. She proceeded to the OR for permanent implant and tolerated the procedure well. Pain relief has continued for 12 months post-implant. See Figures 10.2 and 10.3 for AP and lateral fluoroscopic views of the SI joint leads.

Low back pain: Ms. W is a 51-year-old female with failed back syndrome after fusion of L3–L5. This pain improved somewhat with caudal epidural steroid injections, but the relief was not significant and not sustained. She was maintained on chronic opioid therapy and eventually had an intrathecal pump placed. After achieving a ceiling effect at approximately

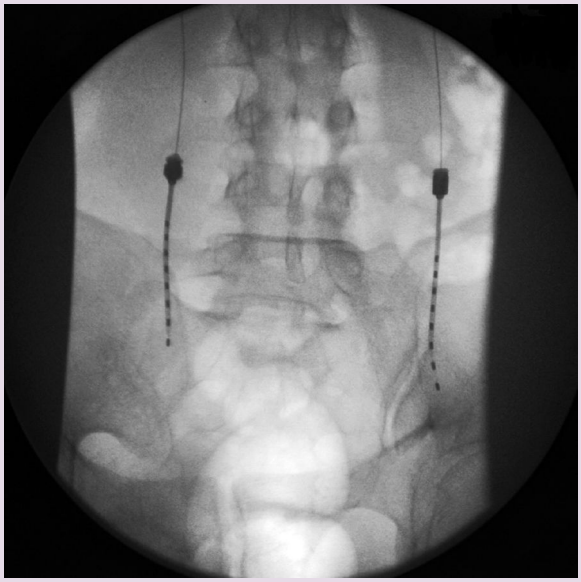

Figure 10.2 AP fluoroscopic image of bilateral electrodes being placed through introducers over the SI joints.

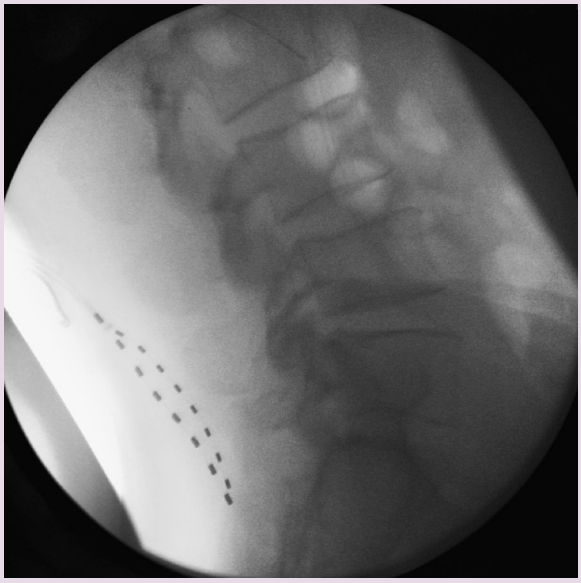

Figure 10.3 Lateral fluoroscopic image of bilateral electrodes over the SI joints area.

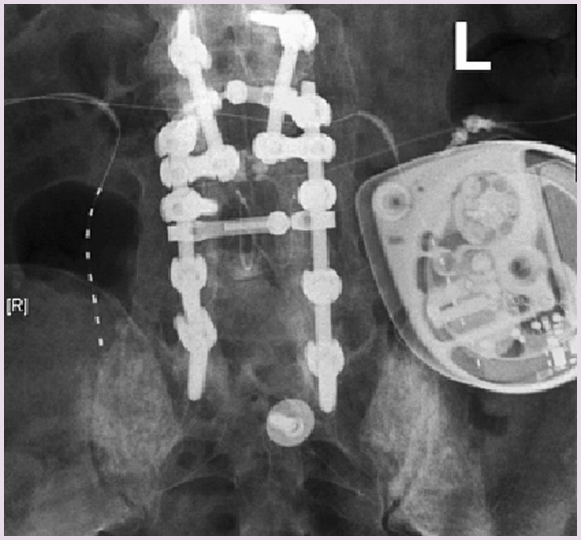

Figure 10.4 AP fluoroscopic image of bilateral lumbar paraspinal electrode. Note that the right-sided lead is obscured by the intrathecal pump placed anteriorly on the right side.

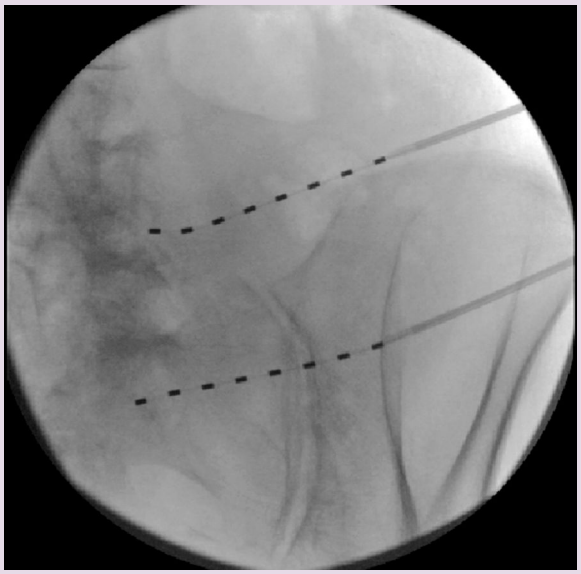

Figure 10.5 AP fluoroscopic image of left-sided abdominal field stimulation. Note the two electrodes being inserted through the introducer.

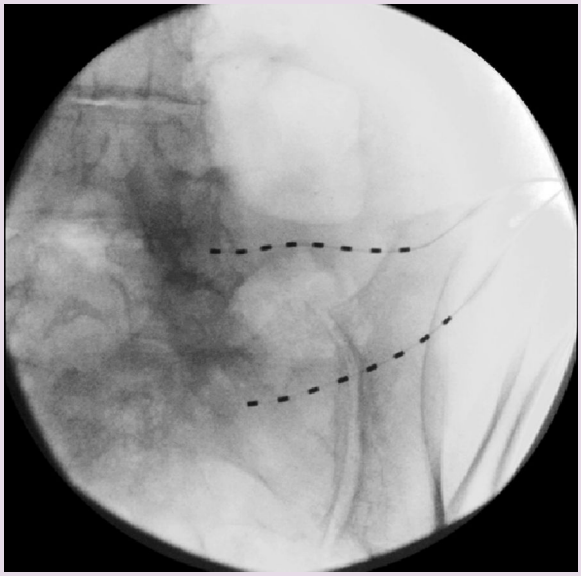

Figure 10.6 AP fluoroscopic image of left-sided abdominal field stimulation. In this image, the introducers have been removed and the leads are anchored deep into the subcutaneous tissue.

10 mg/day intrathecal hydromorphone, her pain physician suggested field stimulation of the low back. She decided to proceed. After appropriate evaluation by psychiatry, she underwent a trial that provided significant relief of her pain and allowed her to decrease her opioid dose by 10% during the trial. OR image of the bilateral low back field stimulation lead is depicted in Figure 10.4.

Abdominal pain: Ms. A is a 42-year-old female with chronic abdominal pain. Initially this was thought to be related to endometriosis, so she underwent multiple laparoscopic surgeries to remove endometriosis and adhesions. The surgeries provided temporary relief and she was maintained on chronic opioid therapy. She had some temporary success with transverse abdominal plane blocks, but this was also temporary. She underwent a successful trial of abdominal field stimulation, followed by permanent placement in the OR. Figures 10.5 and 10.6 show the placement of electrodes along the left lower quadrant of abdomen.

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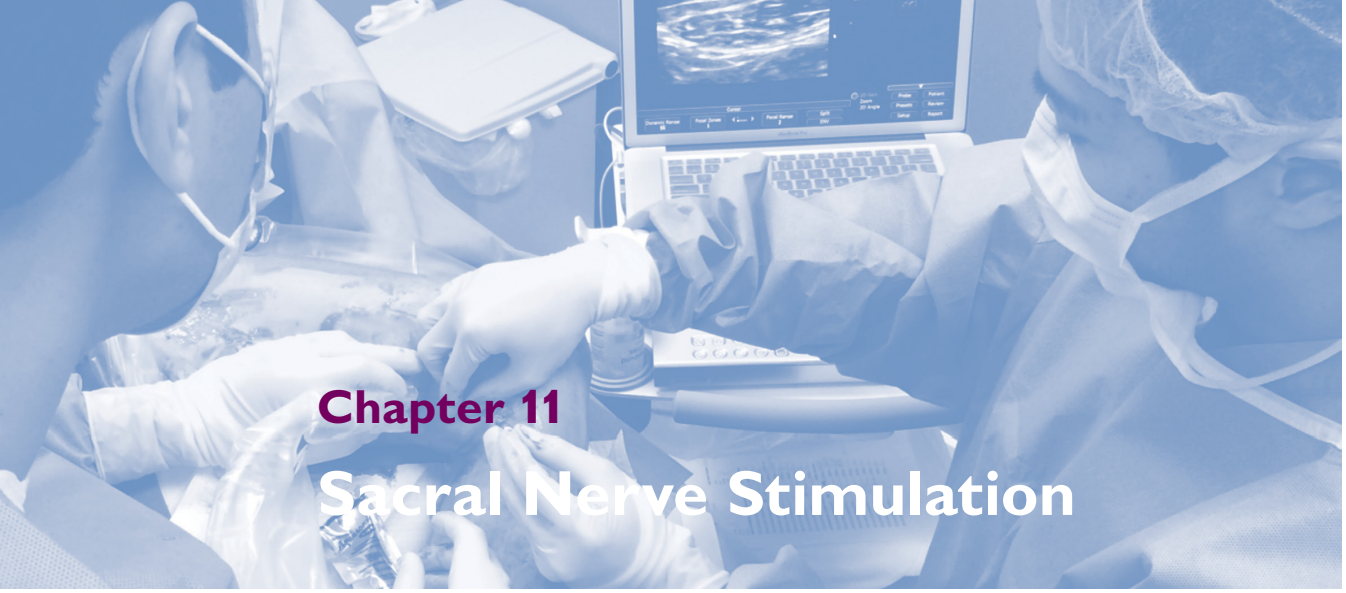

Chapter 11
Sacral Nerve Stimulation

Chris R. Abrecht, Alison Weisheipl, and Assia Valovska

Introduction

Pudendal neuralgia is a clinical diagnosis consisting essentially of pain in the distribution of the pudendal nerve (1). The anatomic region corresponding to these sensory fibers includes from the anus to the clitoris in females and from the anus to the penis in males. The pain from pudendal neuralgia can, however, also be referred to areas outside this region (2). Given the complex and functional nature of pudendal neuralgia, objective studies would be very useful in making this diagnosis. However, there are no definitive radiologic findings associated with pudendal neuralgia. Electromyography (EMG) may show neuropathy in the pudendal nerve, however this study evaluates the motor function of the pudendal nerve, and not necessarily its sensory component (1). Given this difficulty, the Nantes Criteria were established in 2007 to provide a validated set of findings to aid in the diagnosis of pudendal neuralgia, outlined further in Table 11.1 (2). Nonetheless, many patients with pudendal neuralgia today undergo extensive workups, including multiple diagnostic studies, but are left without a definitive diagnosis. For patients with pudendal neuralgia, therapy is often focused on symptomatic management through the use of medications, physical therapy, injections, and implantable devices. One such implantable technique is sacral nerve stimulation (SNS).

The first described SNS dates back to 1976, when Brindley et al. successfully used SNS implantations to treat urinary incontinence in 50 paraplegic patients (3). SNS therapy was then described in 1995 for use with fecal incontinence; it is now used for a number of disorders, including painful bladder syndrome, pudendal neuralgia, constipation, and even chronic

Table 11.1 Nantes Criteria for Diagnosing Pudendal Neuralgia

Essential Criteria	Complementary Criteria	Exclusion Criteria	Associated Signs Not Excluding the Diagnosis
Pain in the territory of the pudendal nerve	Neuropathic pain	Coccygeal, gluteal, pubic, or hypogastric pain	Buttock pain while sitting
Pain primarily occurs while sitting	Allodynia or hyperpathia	Pruritus	Referred sciatic pain
Pain does not occur while sleeping	Foreign body sensation in the rectum or vagina	Paroxysmal pain	Pain referred to medial thigh
Pain does not occur with sensory deficits	Pain worsens throughout the day	Imaging findings that can account for pain	Suprabupic pain
Pudendal nerve block provides releif	Unilateral pain		Urinary frequency
	Defecation triggers pain		Pain after ejaculation
	Ischial spine palpation during digital rectal or vaginal exam produces tenderness		Dyspareunia
	Neurophysiology studies (men or nulliparous women)		Erectile dysfunction
			Normal neurophysiology

Labat JJ, Riant T, Robert R, et al. Diagnostic criteria for pudendal neuralgia by pudendal nerve entrapment (Nantes Criteria). *Neurourol and Urodyn.* 2008;27:306–310.

pelvic pain (4). The focus of this chapter is to discuss sacral nerve stimulation for the treatment of refractory pudendal neuralgia.

No large, multicenter, randomized controlled trials evaluating neuromodulation for the treatment of pudendal neuralgia are available. In fact, a recent meta-analysis of nerve stimulation in chronic pelvic pain and painful bladder syndrome found only 3 articles describing posterior tibial nerve stimulation and no articles using SNS (5). Current FDA-approved indications for SNS include urinary urge incontinence, urgency-frequency, nonobstructive urinary retention, and fecal incontinence; SNS treatment for pudendal neuralgia is off label (6). As additional studies are underway, SNS is increasingly used as an intervention to effectively treat women with pudendal neuralgia.

Preoperative Considerations

Non-Surgical and Medical Management

Similar to the treatment of pain syndromes that may benefit from spinal nerve stimulation or peripheral nerve stimulation, the initial treatment of pudendal neuralgia consists of lifestyle modification and rehabilitation therapy, including pelvic physical therapy. Medication management (nonsteroidal anti-inflammatory medications, neuropathic medications, antidepressants, anticonvuslants, etc.) is also an important initial treatment. If the aforementioned modalities do not provide sustained benefit or provide only minimal benefit, it is reasonable to perform a pudendal nerve block using steroid and local anesthetic. Patients with good response to pudendal nerve blocks are deemed good candidates for an SNS trial and implantation.

Goals

The goal of SNS placement is to introduce a distracting paresthesia to override the patient's pain sensation. Functional improvement is desired, along with a decrease in the amount of pain medication a patient is taking. Ideally, the overall pain level will improve and the frequency of pain episodes will decrease, but the goal of increasing functionality should be stressed to the patient.

Advantages

In general, percutaneous placement of SNS is relatively safe and can help relieve pain in patients where "everything has been tried." Given the lack of randomized controlled studies investigating the effect of neuromodulation on pudendal neuralgia, it is difficult to predict the extent of increased functionality, decreased opioid medication, and overall patient satisfaction. Patients receiving SNS therapy should, however, be able to decrease their dose of opioids and enjoy improved functionality as a result of the SNS. The trial period is an excellent time to determine these endpoints.

Patient Screening and Trial of Therapies

The use of SNS in patients with pudendal neuralgia is an off-label therapy. It could be considered in patients who have failed physical therapy, medical management, and more invasive interventions. If these modalities fail, it is useful to revisit the Nantes diagnostic criteria to ensure that a proper diagnosis of pudendal neuralgia is made before proceeding with a trial of SNS. In addition, patients should have documented relief of pain after receiving a diagnostic pudendal nerve block.

Once a patient is identified as a candidate for SNS, he or she should undergo psychological evaluation. The pain psychologist's evaluation can help determine symptoms such as depression or anxiety that may contribute to the patient's pain syndrome, assess for any signs of addiction, and determine if there are any cognitive conditions that may limit the use of neruomodulation therapy (see Chapter 4 on patient education for further discussion of the psychological evaluation in neuromodulation therapies). With this specific patient population, it is also important to screen for history of sexual abuse, which is a negative predictor of successful stimulation in these patients (7).

Contraindications to sacral nerve stimulation include patients who fail to exhibit a response to trial stimulation, patients with sepsis or infection at the surgical site, patients who cannot cognitively process the simulation system, or patients who may need regular magnetic resonance imaging (MRIs) in the future. With new advances in neuromodulation technology, however, this issue is currently being addressed. Coagulation status of the patient should also be

considered prior to placing an SNS; we follow the American Society of Regional Anesthesia (ASRA) anticoagulation guidelines (see Appendix 1 for ASRA guidelines).

Once a patient has been selected for SNS placement, an SNS trial is then conducted. Our SNS trials are done in an office-based setting using no or minimal sedation. It is essential to carefully document and save any fluoroscopic images used during the trial placement. The external stimulator is turned on and left in place for one week. In this week, the patients keep a pain diary recording Visual Analogue Scale (VAS) scores, functional improvement, and analgesic medication use, as well as any other symptoms they experience. A trial is considered positive if the patient achieves greater than 50% relief of his or her pain. If the trial is a success, the temporary lead is removed and the patient is scheduled for permanent lead placement in the operating room at a later date.

The nerves targeted for SNS are primarily the S3 and S4 nerve roots on the affected side(s). The S2 nerve root can also be targeted, though stimulation of the S2 nerve could lead to posterior femoral cutaneous nerve involvement. We describe two techniques for placement of the SNS: the sacral neural foramen approach and the retrograde epidural approach. For a SNS trial, either method could be used and will be described further in the surgical technique section of this chapter. The main difference between placement of the trial leads and permanent leads is that the leads used with the trial placement are not deployable and can be removed. Another difference between the trial and permanent placement is that the generator used for the trial period is not implanted; rather, it is attached to the sacral nerve electrodes externally.

Alternative Treatments

SNS is often one of the last treatments considered in patients with pudendal neuralgia after failure of medication management, pelvic floor physical therapy, and steroid injections. Other treatments (that may or may not have already been attempted prior to consideration of SNS) are pudendal nerve decompression surgery via transperineal, transgluteal, trans-ischiorectal, or laporascopic approaches, or cyroneuroablation (1).

Preparing the Patient for Surgery

Once a trial is deemed successful, the patient and surgeon may begin the process of proceeding toward a permanent implant. Potential benefits, risks, and alternatives should be deliberated, and these aspects should be discussed from the very beginning of considering SNS as a therapeutic modality. Surgical risks such as surgical site infections, bleeding, and nerve damage should also be discussed. Our patients are evaluated by an anesthesiologist within 30 days prior to proceeding with surgery. This allows enough time to obtain further investigations, studies, or consults before surgery. See Chapter 2 for further discussion of anesthetic considerations of implant therapy.

It is also important to discuss the postoperative course with the patient. We wait to turn on the stimulator until the patient's one-week postoperative visit. This is to allow full recovery from the surgical site pain so that this does not distract from adequate programming. The patient should also have reasonable expectations. Rather than focusing on the presence or absence of pain, we recommend having the patient focus on increasing daily activity and overall functionality. We prefer to wean our patients from opioid medication prior to permanent placement to reduce the risk of opioid hyperalgesia, but the opioid wean can also begin in the postoperative period. Finally, it is important for patients to realize that there are no "magic" treatments, and that they must take an active role in their pain treatment program.

Intraoperative Management

Antibiotic Prophylaxis

Appendix 11 further discusses antibiotic prophylaxis. Antibiotic prophylaxis should be targeted to skin flora such as *Staphylococcus aureus* and *Staphylococcus epidermis*. Similar to dorsal column stimulation, a preoperative dose of cefazolin (or clindamycin with b-lactam allergy) is used as antibiotic prophylaxis for SNS. In patients with a history of multi-drug resistant colonization, an infectious disease specialist should be consulted to help guide antibiotic prophylaxis.

Patient Positioning, Prepping, and Draping

The patient is placed in the prone position on a Jackson table. Support such as pillows or blankets can be placed under the abdomen to reduce lumbar lordosis. Care should be taken to place the patent's arms to reduce pressure on the brachial plexus.

Once the patient is positioned, the skin in the area of interest is outlined with adhesive drapes. We prefer to isolate a wide area, including the area over the sacral nerve roots and the flank area where the implantable pulse generator (IPG) will be placed. A surgical preparation such as ChloraPrep is then applied. Sterile towels are placed at the edges of the prep over the adhesive drapes to outline the surgical field. A half sheet is placed over the patient's legs, followed by a 3M Ioban Antimicrobial Film Incise Drape over the prepped skin. A transverse laparotomy drape is then placed to expose the operative area. Take note that the C-arm should also be draped to reduce the risk of contamination of the surgical field. Patient prepping and draping are also described in Appendix 11.

Special Equipment

Standard equipment for SNS placement includes C-arm and surgical instruments such as scalpels, sutures, clamps, and forceps, to name a few. Appendix 13 discusses various surgical instruments and Appendix 10 shows the surgeon's preference cards for peripheral stimulation. A 14G Tuohy needle, electrodes, and IPG are provided by the device company. Note that tined electrodes are used for permanent placement.

Surgical Technique

The preferred surgical approach in our practice is to use the sacral transforaminal technique, where the stimulator leads are placed directly into the sacral foramen (usually S3 and S4). As stated previously, the S2 nerve root can also be targeted, but stimulation of the S2 nerve root can also stimulate the posterior femoral cutaneous nerve and cause an unpleasant sensation in the posterior thigh. The retrograde epidural technique is also an option for the placement of SNS. It involves placement of the epidural needle from a cranial to caudad direction and driving the leads to the S2, S3, or S4 level.

Sacral Transforaminal Technique

The patient is placed under monitored anesthesia care with enough sedation to make the patient comfortable, but care is taken to avoid over-sedation, as the patient should be able to interact and communicate for lead placement. The fluoroscopy is aligned to optimize the view of the S3 and S4 nerve roots. First the sacral endplate should be squared off. The sacral foramen could be visualized in an anterioposterior view, but sometimes a slight ipsilateral oblique position is used to better visualize the foramen.

Local anesthetic such as 0.5% lidocaine is injected at the skin overlying the desired nerve root. Local anesthetic placement should be superficial and should not be deep enough to anesthetize the sacral nerve roots. A 22-guage spinal needle is used to identify the S3 foramen.

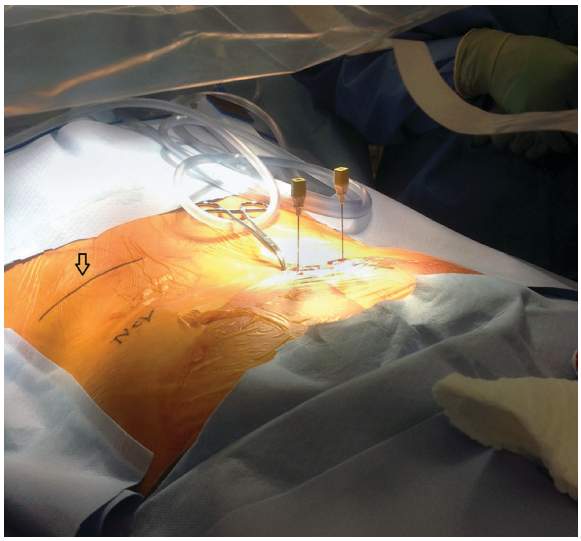

Figure 11.1 Insertion of spinal needles to identify bilateral S3 foramina.

See Figures 11.1 and 11.2 for demonstration of placement of the spinal needle through the S3 foramen. After this is identified, the introducer needle provided by the device company is introduced at the S3 foramen. Advance into the foramen if possible. Repeat for S4, S2, or bilateral placement if indicated. Omnipaque contrast should be used to identify the nerve roots. After introducer insertion, a 4-electrode lead is then passed through the introducer. The leads used for permanent SNS are tined in such a way that they do not need to be

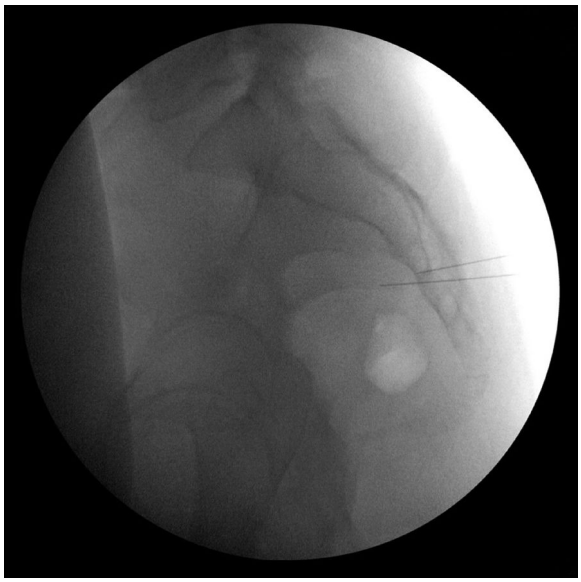

Figure 11.2 Fluoroscopic images of spinal needles inserted into bilateral S3 foarmina, lateral view.

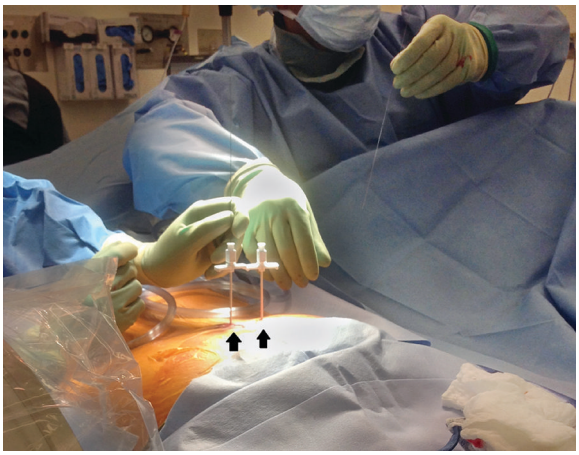

Figure 11.3 Placement of introducer into bilateral S3 foramina.

anchored. Figures 11.3, 11.4, and 11.5 illustrate lead placement through the introducer. Figure 11.6 illustrates final lead deployment.

At this point, attention can be turned to the IPG placement. A marking pen is used to identify a 5-cm incision along the buttock above the iliac crest. Local anesthetic is infiltrated, using approximately 10 ml of 0.25% bupivacaine with epinephrine 1:200,000. A 10-blade scalpel is used to make the incision. Using a combination of blunt and instrumented dissection, a small pocket is created to house the IPG in the subcutaneous fat of the lumbar area above the iliac crest. Attention is paid to the depth of IPG placement. A deep placement can interfere with recharging or programming. The lettered side of the IPG should face the skin to ensure recharging.

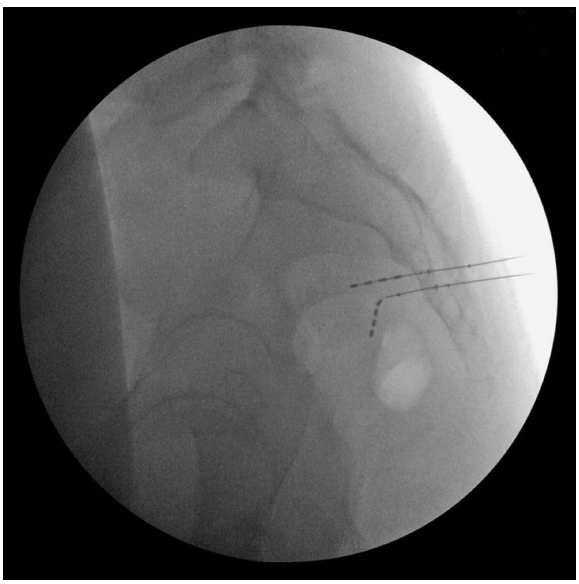

Figure 11.4 Fluoroscopic image of leads inserted through introducers, lateral view.

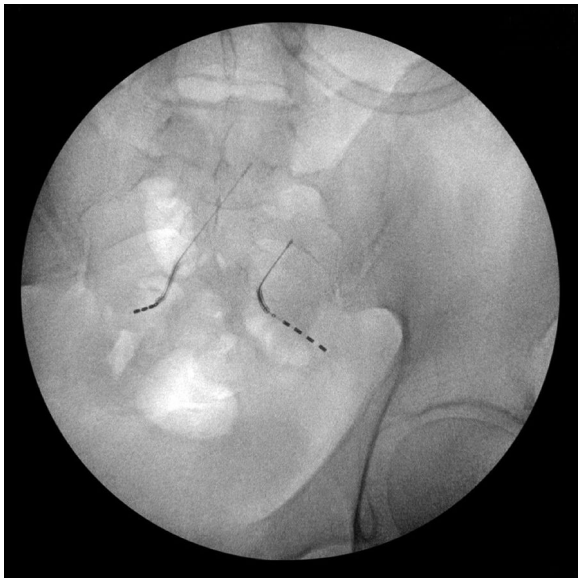

Figure 11.5 Fluoroscopic image of leads inserted through introducers, AP view.

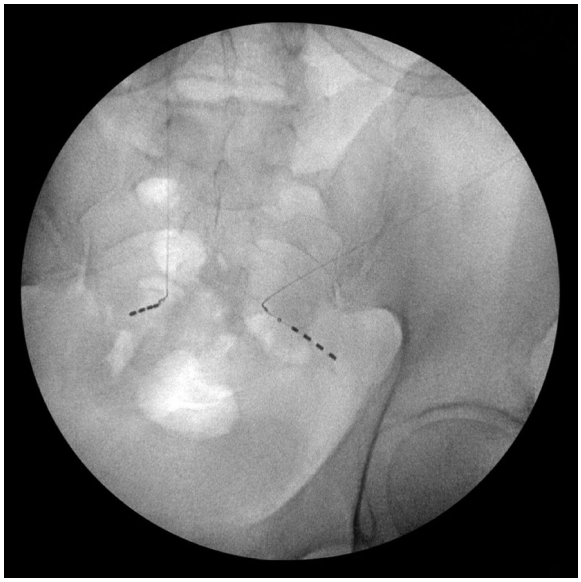

Figure 11.6 Fluoroscopic imaging showing final deployment of leads, AP view.

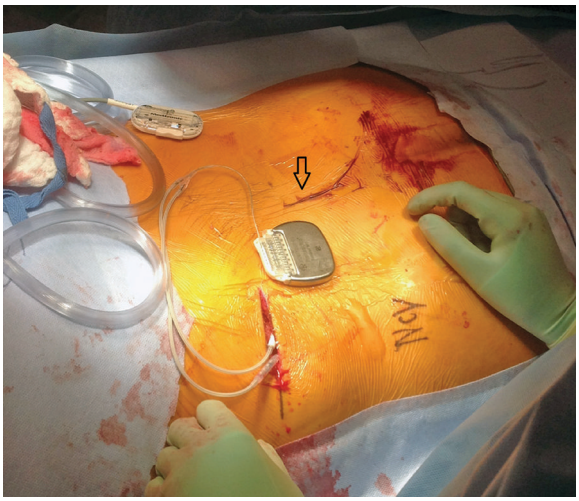

Figure 11.7 Midline incision for sacral lead tunneling (arrow). The pocket site has been created and the leads have been tunneled subcutaneously to the pocket site. The leads have been connected to the IPG, and the IPG is ready to be inserted into the pocket for closure.

Once the IPG pocket is created, a subcutaneous path for the stimulator leads is created from the sacral area to the IPG site. A tunneling device (provided by the device company) is used to create this path. Once the leads are passed through the tunneled path, they can be connected to the IPG and secured with the provided screw set. Figure 11.7 demonstrates the midline incision for the sacral nerve stimulator with the leads connected to the IPG. At this point the programmer should check for impedance to ensure that the device is functioning properly. Once impedances have been checked, the pocket site should be examined to ensure adequate hemostasis. After copious irrigation with antibiotic solution in both the pocket and the sacral nerve root area, the IPG is placed back in the pocket. Once adequate hemostasis has been achieved, it is then safe to proceed with closure of the incision. We use a 3-layer closure in the fascial, dermal, and epidermal layers, followed by application of dressings.

Retrograde Epidural Approach

Similar to the sacral transforaminal approach, the retrograde epidural approach requires that the patient receive monitored anesthesia care to achieve an appropriate level of sedation. The lumbar area is identified with fluoroscopy. The epidural space is entered at approximately L4 in a rostro-caudal direction. The leads are then advanced to target the S3 and S4 (and sometimes S2) neural foramina. The anchoring of the device, tunneling, and creation of an IPG pocket are similar to the procedures described in Chapter 7 on dorsal column stimulation.

Potential Intraoperative Complications

The patient should be alert for the placement of the leads in order to notify the practitioner to any paresthesia or pain during lead placement. The patient should also be alert to guide lead placement in the correct area. Other complications that could occur are bleeding, paresthesias, or inability to correctly stimulate the painful area.

Postoperative Management

Potential Postoperative Complications and Their Management

Infection is always a potential complication for any percutaneous placement of electrodes. Infections can range from superficial skin infection to deep infection near the spine to meningitis if the infection tracks to the meninges. Treatment depends on the severity and location of the infection, with infectious disease input and removal of the implant recommended if there is any concern for tracking along the tunnel route from the IPG to the spine.

Hematomas may also occur after SNS placement. These are more likely in a patient taking anticoagulation. If a patient experiences a hematoma near the lumbar spine, this could present as bilateral lower extremity (LE) paralysis or low back pain. Emergent surgical decompression is necessary for this serious but rare complication.

Some patients can experience pain around the electrode or IPG site. Infection, hematoma, or seroma should be ruled out. If pain is present immediately postoperatively, this is likely from incisional pain, and reassurance is given to the patient. If pain is excessive or does not improve, further investigation, such as imaging or lab studies, is warranted.

Another concerning postoperative complication is electrode displacement or electrode fracture, which manifests as loss of analgesia. This is further discussed in the next session.

Diagnosing and Management of Loss of Analgesia

As with other neuromodulatory devices, loss of analgesia can be related to lead migration. Lead migration should be suspected when a patient who was previously getting pain relief from paresthesias no longer has that sensation or has a paresthesia in a different location. To determine if lead migration is the problem, an AP and lateral sacral X-ray should be obtained to inspect for any electrode migration. A lumbar X-ray should also be obtained to examine the connections to the IPG. Sometimes, reprogramming the electrodes can again provide optimal coverage. If reprogramming does not improve the coverage, surgical revision may be required, especially if significant lead migration has occurred.

Lead fracture can also occur, although this may not be apparent on imaging studies. Again, if reprogramming does not improve the coverage, surgical exploration is warranted. Finally, worsening of the patient's underlying pathology should also be considered, especially if the paresthesia is noted in the same location, but the pain control from the device has decreased.

Nursing Considerations for Patients with SNS Devices

Most patients are not admitted to the hospital and can be discharged after an extended recovery stay, which is available at our institution. If that is not available, then overnight admission may be required. If a patient is admitted overnight, he or she may require a patient-controlled analgesic (PCA). On discharge, the patient should have a one-week follow-up appointment with the surgeon, where activation of the SNS occurs. The patient should not remove the dressings, and should avoid getting the dressings wet for one week. The Telfa and Tegaderm dressings remain for one week and are removed at the postoperative visit, if the wound healing is acceptable. If wound healing is acceptable, the patient can then bathe and allow the Steri-Strips to fall off.

The patient should give adequate time for the wounds to heal and for the leads to adhere to surrounding soft tissues. Thus, we recommend a 4–6 week period where the patient should avoid any heavy lifting > 10 pounds, avoid bending or twisting, and avoid operating heavy machinery while the stimulation is on.

In general, patients with SNS should avoid having MRI scans. However, recent technology with some of the device manufacturers is allowing SNS systems that are MRI compatible. We

recommend following individual manufacturer's recommendations. Each patient should have an ID card with the model and a customer service number if there are any concerns about the MRI compatibility of the neuromodulation system.

Rehabilitation Considerations for Patients with Implantable Devices

There are no specific rehabilitation concerns in patients with SNS. However, patients should be able to tolerate more activity and physical therapy, allowing them to become more mobile and active. Some patients who are significantly debilitated by their pain or from other conditions may require a short stay in a rehabilitation facility to gain strength and coordination. This should be evaluated on a patient-by-patient basis.

Case Study

A 37-year-old man presented with a several year history of bilateral groin and scrotal pain without any associated trauma or clear causal trigger. His initial workup included colonoscopy, testicular ultrasound, CT abdomen, lower extremity EMG, and unsuccessful ilioinguinal nerve blocks. After 2 years his care was transferred to a pudendal neuralgia specialist, who obtained groin and genital EMG revealing borderline pudendal nerve slowing. Subsequent interventions included pudendal nerve injections, performed thrice but providing minimal relief, followed by bilateral pudendal nerve surgical decompression, providing only relief on his right side. A further 2 years later, when pelvic physical therapy did not relieve his residual left-sided pain, he underwent repeat pudendal nerve decompression, via a transgluteal technique instead of the earlier sacrospinous ligament approach. Unfortunately, this second surgery did not provide much relief of his pain.

By this time the patient was disabled as his pain prevented him from sitting, and was once again bilateral, radiating from the scrotum up to his inguinal area and worse with sitting, lifting, and bending. He could lie down only on 4 inches of memory foam, had had severe pain with bowel movements as well as initiation and cessation of urination. His medications included amitriptyline, lidocaine 5% transdermal patch PRN, and oxycodone which were minimally helpful.

At our clinic, he underwent screening and was scheduled for a trial of a percutaneous sacral nerve stimulator. The bilateral S3 sacral foramina were targeted and InterStim™ leads were advanced into the sacral foramina. Intraprocedure testing identified appropriate coverage of his usual pain distribution. During his follow-up visit, he noted excellent improvement—over 50% relief - and regained the ability to sit without pain. The trial leads were then removed, and one month later he had permanent implant of the sacral nerve stimulator in the same location. Two Medtronic 3889 leads were used and connected to a RestoreUltra IPG implanted in the left lower back area.

At his postoperative visit, the device was then activated by the device representative, and the patient had excellent coverage of his previously painful areas. Eventually he was able to return to a part time job and resume many of his pre-illness activities.

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Chapter 12

Treatment of Discogenic Pain

Minimally Invasive Procedures

Alison Weisheipl and Srdjan S. Nedeljkovic

Introduction

Discogenic pain is thought to be a common cause of low back pain, accounting for up to 40% of patients with low back pain (1). Although it was initially described in the 1930s in a landmark article by Mixter and Barr in the *New England Journal of Medicine* (2), the description, diagnosis, and treatment of discogenic pain have engendered significant controversy and debate. Over time, as the anatomy and nerve supply to the disc were demonstrated and various studies showed effective diagnostic tests and treatments for discogenic pain, the concept of discogenic pain has gained more widespread acceptance. However, a lack of agreement on the etiology and causation of discogenic pain and its various treatment modalities has persisted in the literature.

Diagnosis

Intervertebral discs are innervated by a network of sensory nerves from the adjacent ventral rami with contributions from the rami communicantes, which are typically located in the outer third of the annulus. Over time or perhaps due to repetitive microtrauma, a disc may develop changes in its interior architecture or may become desiccated, with fissures and tears forming in the annulus and causing a syndrome of internal disc disruption (IDD) (3). These fissures are defined by a grading scale as grade I, II, III, or IV. Grade I fissures reach the inner anulus, grade II fissures reach the middle third of the anulus, and grade III fissures reach the outer third of the anulus. Grade IV fissures spread circumferentially. In IDD, there are internal pathologic changes with grade I, II, III, or IV fissures, but the key finding is that the anulus remains intact. Although grade III and IV fissures are more likely associated with discogenic pain, some patients with discogenic pain may have lesser findings on imaging (1).

Patients with symptoms of discogenic pain due to IDD often complain of low back pain with lumbar movements, have minimal lower extremity pain (back pain is greater than leg pain), experience decreased sitting tolerance, and have an absence of lower extremity neurologic exam findings (4). Various imaging modalities can help to establish a diagnosis of discogenic pain, including magnetic resonance imaging (MRI), computed tomography (CT), X-rays, myelography, and CT-myelography, but the specificity of these tests is low, as many radiographic abnormalities are also seen in asymptomatic individuals (5).

Malik et al. (6) found that the diagnosis of discogenic pain was inconsistent and that when imaging modalities were used to establish the diagnosis of discogenic pain, no specific patient selection criteria were used. Most commonly, MRI scanning is used to establish a finding of degenerative disc disease, whereas myelography and CT-myelography can be used as adjuvant imaging modalities to establish disc herniation and spinal or neural foraminal stenosis. Common imaging findings include degenerative disc disease, decrease in disc height, spinal instability, annular scaring, and findings of high-intensity zones (HIZs) and Modic changes (6) (see Figure 12.1). Of those findings, HIZs and Modic changes correlate more strongly with complaints of discogenic pain (1).

Once discogenic pain is suspected, it is typical to implement treatment with a regimen of physical therapy and non-opioid analgesic medications. If the diagnosis of disc pain is still uncertain, and in cases in which greater than 50% disc height is maintained on imaging, provocative discography may be performed. Provocative discography has been well described as a diagnostic tool for evaluating patients with suspected discogenic pain, yet the utility of this technique remains controversial. Provocative discography involves injecting radiographic contrast dye into a disc suspected to be causing pain symptoms, and then assessing both the pattern of spread as well as the patient's response to the injection. In order to assess patient response, the injection is also performed at an adjacent, normal-appearing disc, which serves as a control. The procedure is considered positive if the patient exhibits a typical pain pattern when the affected disc is injected and does not display this pain pattern when the unaffected disc is injected. It is thought that injection of even a small amount of substance at a low injection pressure is likely to reproduce pain in an abnormal disc. In order to reduce the subjective nature of the test, pressure monitoring was added to provocation discography. However, there is no evidence that the use of pressure manometry increases the accuracy of the discography procedure. Ideally, injection into a disc is performed with less than 50 psi above opening pressure to avoid disruption of normal disc annular fibers and also to avoid a potentially false positive result (6). Bogduk et al. (1) have reported that in normal discs, injection of a small amount of contrast under minimal pressures should not be painful.

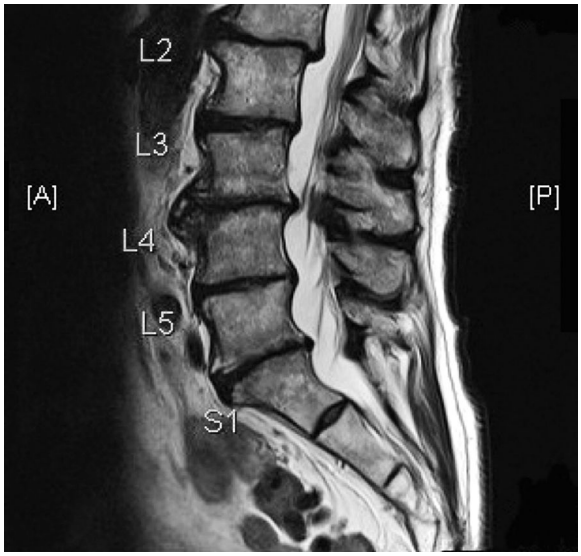

Figure 12.1 Modic endplate changes between L3 and L4, T2-weighted image.

Treatment Options

Treatments for discogenic pain have ranged from conservative management, such as implementing an exercise program with the brief use of non-opioid analgesics, to highly invasive surgical treatment options that include fusion or disc replacement. When conservative management fails, and prior to consideration of surgical interventions, a variety of minimally invasive techniques have been used to treat discogenic pain. Injection therapies (epidural steroid injections and similar therapies) have been commonly performed for discogenic pain for decades. More recently, there has been interest in thermal disc procedures, disc nucleoplasty, intradiscal injections, and disc decompression as being possible options to bridge the therapeutic gap between conservative therapy and invasive surgical procedures. In light of the natural history of discogenic pain as a condition that improves with time, but with some patients experiencing relapsing and remitting symptoms, it has been difficult to perform adequate trials to assess the relative value of these therapies. This chapter seeks to explain the indications, techniques, advantages, and disadvantages of several of the minimally invasive disc therapies. However, it is important to understand that there is a lack of high-quality evidence to prove the effectiveness of these techniques. As a result, there is little consensus on which treatment approach is best.

Intradiscal Electrothermal Therapy

Intradiscal electrothermal therapy (IDET) was first performed in 1996 as a method to treat discogenic back pain (7). Using a heated coil inserted under fluoroscopic guidance to the posterolateral aspect of the involved annulus, the heat generated is thought to denervate the annulus and reconfigure the collagen in the disc. Annular temperatures range from 65°C to 90°C over 12.5 minutes when the procedure is performed using the standard heating protocol (8). However, the mechanism of IDET is not entirely clear, and two randomized controlled trials (RCTs) on the IDET procedure found benefit in only a small number of patients, with questionable benefit over the control groups (9, 10). In their review on the effectiveness of

thermal annular therapies in discogenic low back pain, Helm et al. (11) found fair evidence with the use of IDET for short-term discogenic pain relief.

IDET is not indicated for patients with such severe degenerative disc disease that there is less than 50% disc height remaining on MRI or CT. Other relative contraindications to IDET include extruded nucleus material at the affected disc level, severe spinal stenosis, and spondylolisthesis causing instability. IDET is not recommended for patients who are pregnant, for treatment of cervical degenerated discs, or for patients who have had previous lumbar surgery at the affected disc level (4). The effectiveness of IDET may be reduced for patients who have lumbar radicular symptoms more than low back pain symptoms.

Advocates for performing the IDET procedure point out that it has an excellent safety record with minimal morbidity and mortality reported. A potential concern of the procedure involves increased temperature in the tissues surrounding the annulus, including the spinal canal and associated nerve roots. However, in one study on cadaveric human lumbar spines, temperature in the spinal canal reached only 42°C for 2 minutes, and this did not appear to have implications for nerve or tissue injury (8). Rather, Helm et al. (11) found that nerve root injuries related to the IDET procedure were primarily caused by improper placement of the introducer needle. Other complications reported after IDET include transient increases in leg pain, disc herniation, catheter breakage, and superficial skin burn (12).

Intradiscal Biacuplasty

Intradiscal biacuplasty (IDB) using the TransDiscal system (Kimberly-Clark Corporation, Irving, TX) is another minimally invasive technique used to treat discogenic pain. This procedure uses two water-cooled radiofrequency probes placed via introducers into the posterolateral aspects of the annulus fibrosis to create a bipolar arrangement. Once the probe placement is confirmed in the anterior-posterior, lateral, and oblique fluoroscopic views, the annulus is heated to 55°C over 15 minutes (13).

Unlike the IDET procedure, there is no need for a thin, long coil to be placed in the posterolateral aspect of the annulus. Advocates of performing IDB over IDET point out that the thin coil used in IDET can be difficult to maneuver and may not provide uniform lesions of the annulus (13). In addition, IDET temperatures may not reach a threshold that would be significant enough to produce lesions, whereas IDB temperatures uniformly reach 55°C.

Kapural et al. (14) evaluated IDB as a treatment modality for discogenic pain. In this report, a clinically significant improvement was found in physical function (SF-36 scores) and pain (NRS scores) in patients receiving biacuplasty, with benefit continuing for at least one year. Overall, the clinical success rate at 12 months for patients who had improved SF-36 scores and NRS ratings was 36% (8 of 22 patients). No complications were reported (14). While these results are promising, the generalizability of the study was somewhat limited by its small sample size. As the procedure becomes more utilized, additional RCTs are needed for evaluating the IDB procedure to determine its overall efficacy in the treatment of discogenic pain.

Disc Nucleoplasty

Nucleoplasty is a minimally invasive method of disc decompression that was initially approved by the FDA in July 2000 for the treatment of contained disc herniation (15). This procedure uses a bipolar radiofrequency instrument to remove nucleus material. The energy supplied by the device breaks down disc nucleus material using temperatures between 40°C and 70°C, allowing for a decrease in nuclear pressure while preserving the surrounding healthy disc tissue (15). In a review on the evidence evaluating nucleoplasty in the treatment of lumbar disc decompression, observational studies have suggested that this procedure is a potentially

effective treatment for patients with discogenic pain (15). Manchikanti et al. (16) noted that there had thus far been one randomized trial (17) comparing nucleoplasty to transforaminal epidural steroid injections. In this trial, the population receiving nucleoplasty had statistically significant improvement in pain, function, and quality of life and required fewer repeated injections over the course of 2 years (17). Subsequently, another RCT from Thailand showed improvement in patients who underwent nucleoplasty compared to conservative management, finding that patients had improved pain scores over a period of one year post-procedure and a decrease in disc bulging on MRI after treatment (18). When nucleoplasty was evaluated compared to surgical microdiscectomy, satisfactory results were reported in 78% of nucleoplasty patients compared to 94% of microdiscectomy patients (19). As of now, the nucleoplasty procedure has not been deemed medically necessary by the Centers for Medicare and Medicaid Services (CMS) and remains a non-covered procedure by some health insurance companies.

Potential advantages of the nucleoplasty procedure over open surgical techniques include simplicity of procedure, minimal tissue destruction, and relative safety (16). The disadvantages and complications related to nucleoplasty include larger needle placement compared to injection therapies with potential interaction with surrounding neural structures, the onset of new lower extremity numbness and tingling, new back pain, and potential heating of the introducer needle if the active tip is pulled into the introducer (20). In addition, accelerated degeneration of disc material has been reported after failed nucleoplasty, occurring in 15% of lumbar discs in patients who reported ongoing pain one year after nuceoplasty (21). However, there was no control group of subjects in this study who did not receive nucleoplasty.

Disc Dekompressor

The Dekompessor is a minimally invasive technique used to treat contained disc herniations. It is a single-use probe that removes nuclear material using a screw to displace the disc material. Placement of the probe under fluoroscopic guidance is accomplished using the standard technique for performing discography. In a review on the evidence on patient outcomes after disc decompression using the Dekompressor device, Manchikanti et al. (22) identified 3 observational studies of disc decompression using this technique. These 3 small studies showed both short-term and long-term improvement in pain and function, but none of the studies was an RCT. One of the studies that was evaluated was sponsored by the device company.

Advantages of the Dekompressor technique include percutaneous technique, small cannula/relatively simple placement, minimal disc destruction, ability to get quantifiable disc material for review by pathologist, and less perineural scarring than with surgery. Disadvantages to using the Dekompressor in percutaneous disc decompression include expense due to the single-use probe, less efficacy in multilevel treatment, and lack of randomized trials to assess its efficacy over natural history or alternate techniques. As a result, this procedure is also considered as investigational and frequently does not receive approval for payment from insurance carriers.

Novel Techniques

Intradiscal Methylene Blue Injection

Injection of methylene blue into a pathologic and painful disc has recently been proposed as a minimally invasive alternative to surgery in the treatment of discogenic pain (23, 24). Using the premise that discogenic pain is caused by the formation of a vascularized granulation tissue that is highly innervated with nociceptive fibers, it has been suggested that the treatment of discogenic pain could be accomplished by using methods that interrupt

nociceptive nerve conduction in the annulus (25). Methylene blue, a medication with ubiquitous use in the field of medicine, has been studied in the treatment of painful conditions such as idiopathic pruritus ani and pain due to bone fracture. Peng et al. (23, 24) have hypothesized that the intradiscal injection of methylene blue could also be used as a means to treat discogenic pain.

One well-designed RCT investigating the intradiscal injection of methylene blue showed a significant improvement in pain scores, quality of life, and satisfaction scores (24). These results exceeded the improvement that was seen in studies with IDET and radiofrequency methods, and were similar to or exceeded that of surgical fusion and disc replacement (24). While these results are certainly promising, there is only one RCT investigating intradiscal injection of methylene blue in the treatment of discogenic pain. Another smaller study (26) was not been able to replicate the findings of Peng et al. In another study, Kim et al. (27) found limited long-term effectiveness of intradiscal methylene blue injection after one-year follow-up. Further investigation should be performed to evaluate the utility of this technique.

Biological Treatments to Restore Disc Morphology

Injury to a normal disc leads to a series of metabolic and inflammatory intradiscal changes, resulting in internal disc disruption. Biologic treatments such as intradiscal injection of protein factors, genes, mesenchymal stem cells capable of regenerating disc substance, and the use of tissue engineering aim to improve the resultant catabolic state of the injured disc (28).

These methods are in various stages of the FDA process regarding clinical trials. The goals of biologic treatment are to repair the intracellular matrix of the disc, replenish the disc with viable cells, and overall decrease nociception in the disc (28). Though the efficacy of biological treatments clinically remains to be proven, a pilot study in 10 patients showed favorable outcomes when patients were compared to those who underwent surgical fusion or disc replacement (29).

Preoperative Considerations

Non-Surgical and Medical Management

There is a broad consensus that discogenic pain should first be treated with conservative management, including a short course of non-opioid analgesics, regular exercise, and physical therapy. If conservative measures do not improve pain, it may be appropriate to offer patients a trial of epidural steroid injections (interlaminar, transforaminal, or caudal approaches). Patients who have significant anxiety and depression may also benefit from cognitive-behavioral approaches to pain management.

Should those measures fail, and the pain is felt to be discogenic in nature, the next step may be to consider provocative discography to elucidate whether the disc is the major source of the patient's pain. Patients who have positive results during provocative discography may be considered for advanced disc procedures.

Goals

Minimally invasive disc procedures are indicated for patients with discogenic pain in whom conservative measures have failed. Percutaneous disc procedures may be a reasonable alternative for patients who wish to avoid surgery or for whom surgery has not been recommended. As discogenic pain is thought to be the source of pathology in up to 40% of patients with low back pain, the burden of disease is significant, and some of these patients fall into the category of having failed initial conservative management but yet are not considered surgical candidates (11).

Patients who are considering whether to undergo minimally invasive disc procedures should be aware of the potential risks and benefits of these approaches and also should have reasonable treatment expectations. The goal of minimally invasive approaches to managing discogenic pain is to reduce pain and improve function by altering the painful disc in the various ways described.

Minimally invasive disc procedures are a potential option for treatment of patients who have not improved with conservative management (i.e., non-opioid medications, physical therapy, injection treatments). Though minimally invasive disc procedures have not replaced microdiscectomy surgical procedures, they remain a reasonable, minimally invasive alternative for patients who wish to avoid surgery or who are not candidates for major surgical interventions such as spinal fusion procedures.

Alternative Treatments and Procedures

Patients should be aware of the potential alternatives to treatment when considering whether to proceed with minimally invasive disc procedures. Options include the continuation of conservative management with physical therapy and medications, epidural steroid injections and other injections, and lifestyle modification. Only after patients have considered these options should they decide about proceeding with discography.

Surgical referral is an option, whether or not a patient decides to proceed with a minimally invasive disc procedure. Various surgical approaches, ranging from discectomy (most common), to disc implants such as spacers, to spinal fusion, may be considered at the discretion of the surgeon. Patients may be advised that although the option for surgery remains open following an unsuccessful minimally invasive disc procedure, it would be less likely that a minimally invasive disc procedure would be beneficial once surgery has already taken place.

Patient Screening and Trial of Therapies

Patient should be considered as candidates for minimally invasive disc procedures if they have not improved following conservative management of their back pain and if they have undergone a trial of injection therapies without significant improvement. For patients who continue to have pain, the next step would be to undergo a provocative discography. If there is concordant pain reproduced by the discography procedure in a patient with at least 50% preserved disc height, and the disc is still well contained on MRI, minimally invasive disc procedures may be considered. Although some practitioners have advocated expanding the criteria for performing minimally invasive disc procedures to include patients with no concordant pain on discography and without annulus disruption on MRI, this is not currently the practice (30).

Preparing the Patient for the Procedure

Patients should have reasonable expectations prior to the procedure. As with any invasive technique, patients should be informed so that they have reasonable expectations regarding the level of pain relief they may experience after the procedure. They should be aware that in some patients, the improvement in pain and function may be minimal.

Prior to the procedure, depending on the institutional protocol, patients may be required to be NPO (nothing by mouth) if they are to receive sedation. Patients should be instructed not to drive immediately after the procedure and should have someone accompany them to the procedure.

Intraoperative Management

Antibiotic Prophylaxis

Discitis is a feared complication from intradiscal procedures. Both intravenous and intradiscal antibiotics have been evaluated, but no conclusive evidence exists that shows a decrease in the rate of discitis when compared to sterile precautions alone (1, 31). Though studies have reported an infection rate of zero when prophylactic intradiscal antibiotics are used, studies that evaluate the occurrence of post-procedure discitis have been quite underpowered (1). If infection is reported following a percutaneous disc procedure, the most common organisms are *Staphylococcus aureus* and *Staphylococcus epidermidis* (32).

Given the absence of definitive studies indicating whether antibiotics are necessary for minimally invasive disc procedures, and given the low prevalence of discitis after advanced disc procedures, the decision to use antibiotics ultimately remains up to the physician performing the procedure. Rathmell et al. support the use of intravenous or intradiscal antibiotics before intradiscal procedures (32) (See Table 12.1). In our practice, we typically use Cefazolin 2 g IV (or an equivalent antibiotic) administered 30 minutes prior to a planned intradiscal procedure. Sterile preparation of the skin as well as adhering to sterile technique should always be employed.

Patient Positioning

After consent is obtained, a peripheral intravenous line is placed in the patient. The procedure is performed with the patient in the prone position to allow the practitioner access to the posterolateral aspect of the disc. A pillow is placed under the head and hips for patient comfort and to decrease the lordosis of the lumbar spine. Light sedation may be given per physician preference and patient comfort. It is recommended that the patient remain conversant during the procedure, in order to reduce the incidence of unrecognized nerve injury due to needle placement.

Sterile Prep and Drape

The procedure is performed under sterile conditions. It is recommended that the practitioner should wear a surgical cap and mask as well as a sterile gown and gloves. All other personnel present in the room during the procedure should wear surgical caps and masks.

The patient's back is cleansed widely, using either a solution of povidone-iodine or chlorhexidine and alcohol. It is recommended to perform a wide prep, extending as far laterally as

Table 12.1 Antibiotic Use Before Intradiscal Procedures

Drug	Dose
Cefazolin	1–2 g IV 30 min prior to procedure
	or
	1–10 mg/ml with contrast intradiscal
Clindamycin	600 mg IV 30 min prior to procedure in penicillin-allergic patients
	or
	7.5 mg/ml with intradiscal contrast
Vancomycin	1g IV over 60 min in patients with MRSA, or for those who are penicillin allergic

Rathmell JP, Lake T, Ramundo MB. Infectious risks of chronic pain treatments: injection therapy, surgical implants, and intradiscal techniques. *Reg Anesth Pain Med*. 2006;4:346–352.

possible to account for various angles of approach by the needle. Draping is accomplished with sterile half sheets and three-quarter sheets. Further detail on skin preparation and draping is discussed in Appendix 11.

Special Equipment

All procedures

- Peripheral IV (IV, tubing, fluid)
- Access to live fluoroscopic imaging in multiple planes, with image intensification
- Nonionic iodinated contrast medium: Omnipaque dye 180 mg/ml
- Local anesthetic solution for skin infiltration: Lidocaine 0.5%
- Local anesthetic solution for injection into the disc post-procedure: bupivacaine 0.25% (per physician discretion)
- 40 mg methylprednisolone for injection into the disc post-procedure (per physician discretion)
- Sterile gauze
- Adhesive bandages and adhesive strips

IDET (Neurotherm Company)

- 17-gauge 6-inch introducer needle (also provided in 9-inch length)
- 18-gauge electrothermal heat-conducting intradiscal catheter (30 cm long with a 5 cm active tip)
- Electrothermal 20S generator; consists of heating apparatus and temperature monitoring system, extension cable, power cord, and foot pedal.

Nucleoplasty (ArthoCare Spine Company)

- 17-gauge 6-inch introducer needle with trocar type stylette (Crawford needle) (also comes in 8-inch length)
- ArthoCare System 2000 Controller, with foot control and patient cable
- Nucleoplasty probe (“channeling wand”)
- Nucleoplasty machine.

Percutaneous Discectomy (Stryker Company)

- 17-gauge minimally invasive disc decompression 6-inch straight or curved cannulae
- Stryker Dekompressor single-use kit (33): includes one percutaneous discectomy probe, one introduced cannula, one probe cleaner. Probes are 6-inch and either 13-, 15-, 17-, or 19-gauge.

Intervertebral Disc Biacuplasty (Kimberly Clark HealthCare)

- 17-gauge 15-cm insulated introducer needle (2 are needed for bilateral placement)
- Transdiscal Probe, 20-gauge, 15-cm length with 6-mm active tip
- Radiofrequency Equipment Test box for Transdiscal System Cooled RF
- Radiofrequency machine.

Procedural Techniques

Provocative Discography

The performance of minimally invasive disc procedures is based on the technique used for the discography procedure. In addition, it is recommended that patients undergo discography as part of the evaluation process to determine eligibility for minimally invasive disc procedures such as IDET, nucleoplasty, and disc decompression.

A discography procedure requires the availability of a fluoroscopy machine with the ability to perform images in the anteroposterior, lateral, and oblique views. Typically, an intravenous line is started and the patient is given prophylactic antibiotics 30 minutes prior to the procedure. It is important to confirm the patient's symptoms prior to performing the procedure, as the patient will need to verbalize whether these symptoms are being reproduced during injection into the disc. It is also important to review the patient's radiographic imaging prior to beginning the procedure, both to ensure that the intended discs are addressed and to evaluate possible angles of needle placement, the projected depth of placement, and other anatomical variables.

The patient is brought to the procedure room and is placed prone on a fluoroscopy table. Sterile prep and draping are done, with care being taken to maintain sterile technique at all times. The fluoroscopy machine will also require a sterile plastic cover, as it will be rotated in various planes during the procedure. The patient's blood pressure, respirations, pulse, and oximetry should be monitored during the procedure. If intravenous sedation is to be used, care should be taken so as to maintain a state of wakefulness in the patient, as the patient will need to respond to the provocative nature of the test.

The fluoroscope is then positioned to evaluate the disc intended for injection. Depending on the amount of lumbar lordosis and curvature of the spine, the fluoroscope will require either a cranial or a caudal tilt so that there is optimal visualization of the disc space. The image should reflect the maximal amount of width of the disc on anteroposterior imaging, such that the vertebral body endplates appear as a single line on the image without angulation or distortion. To access the disc, it is necessary to provide an oblique tilt to the C-arm such that the superior articular process (SAP) at the intended level lies in the midportion of the disc space. The SAP therefore forms the medial border of the approach to the disc, with the endplates forming the superior and inferior borders and the lateral edge of the disc forming the lateral border.

Once the broadest image of the disc has been visualized, local anesthetic is given to the skin overlying the intended point of needle insertion. Typically, an introducer needle (18-gauge, 1.5-inch length) is inserted to stabilize the next needle that is inserted, which is a 22-gauge 5-inch or 7-inch needle. The length of the needle depends on the size of the patient. The needle is advanced toward the lateral border of the SAP such that it will pass just off the SAP on its way into the disc. Once contact is made with the SAP, the fluoroscope is positioned in a lateral projection, so that the needle can be seen passing by the intervertebral foramen and then into the posterolateral wall of the annulus. It is common to perceive a slight resistance upon entering the annulus, and the patient may experience a mild discomfort. If the needle passes too closely to the nerve root, a sudden radicular paresthesia may occur, necessitating repositioning of the needle.

One the needle has penetrated the disc, the fluoroscope is positioned in the anteroposterior direction to ensure that the needle is advanced at least one-third of the way into the disc. At this point, the needle should also be fairly close to the midpoint of the disc on the lateral view. If the needle is positioned superficially, it may rest in the annulus, which will result in poor or no spread of contrast into the disc and may be perceived as a false positive result.

At this point, some practitioners will attach a pressure syringe and evaluate the opening pressure of the disc. Upon injection of contrast material, the pressure of the manometer will be noted at the onset of pain and also a maximal pressure will be documented. An intact disc should be able to hold a pressure of at least 50 psi without eliciting pain. A painful or damaged disc may not be able to hold much of a pressure at all before the onset of pain. Pain is assessed to confirm whether it is similar in nature to the patient's ongoing pain problems. A concordant discography is a positive one—the pain with injection will mimic the patient's

typical pain symptoms. Patients should be asked about the intensity, location, and quality of the pain.

Upon injection of contrast material, the morphology of the disc will be evaluated and documented. The presence of a tear or herniation can be noted by extravasation of contrast dye outside the borders of the annulus. In a dessicated disc, the contrast injection will appear as a linear spread. In a normal disc, the contrast material will appear like a balloon or a cotton ball. See Figure 12.2 for AP view of a discogram identifying the L4–L5 and L5–S1 discs.

Each suspected level should be injected similarly, and the patient's response and flow of dye with each injection should be documented. Once all of the suspected discs are injected, at least one normal disc should be injected as a control. For the discography procedure to be most useful, injection of the control level disc should not elicit painful symptoms. When a normal disc is injected, patients will often report very little sensation, or at most will report a feeling of mild pressure in their back. Upon conclusion of the procedure, images should be saved and the patient is taken to the recovery area for observation and to discuss the next appropriate steps after the procedure.

Intradiscal Electrothermal Therapy

Access to the disc for an IDET procedure is similar to that of a standard discography approach. Determine the proper vertebral level under fluoroscopic guidance and square off the superior endplate at this level. Then align the C-arm approximately 25–35 degrees obliquely until the SAP is in view approximately at the midpoint of the intervertebral disc. After skin infiltration with 0.5% local anesthetic, a 17-gauge introducer needle is inserted in a coaxial plane with respect to the X-ray beam, aiming toward the anterolateral aspect of the nucleus. Continue to check introducer position with fluoroscopy after at least 1 cm is advanced, to ensure that the introducer remains coaxial. Care should be taken to avoid the exiting nerve root, which lies inferior to the pedicle. Once the introducer needle approaches the disc, fluoroscopic views should be taken in both the anteroposterior and lateral position, and the

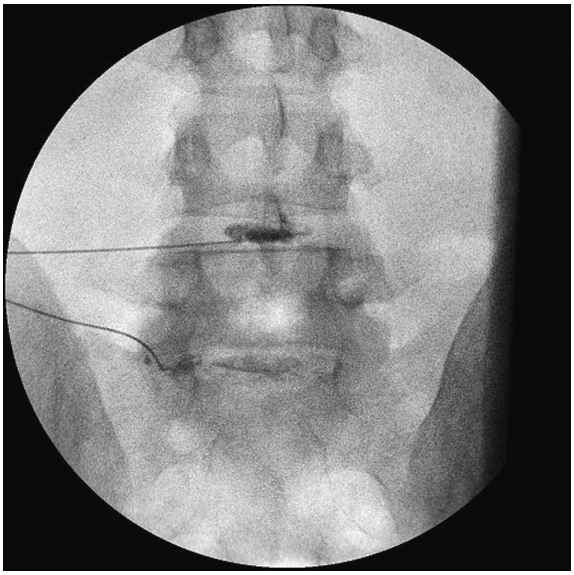

Figure 12.2 L4–L5 and L5–S1 Discogram, AP view.

needle advanced until the introducer lies in the anterolateral portion of the disc to allow for optimal positioning of the catheter.

Once the introducer is in place, an 18-gauge, 30-cm long heat-conducting catheter is introduced into the disc under lateral fluoroscopic guidance. While advancing the catheter, the proximal end can be rotated to direct the catheter in the desired direction. The final position of the catheter should lie in the posterior border of the interior part of the annulus past midline. Once this is achieved—which can be difficult without coiling or kinking the catheter—final position is confirmed with anteroposterior and lateral fluoroscopic view. The catheter is heated to 90°C (achieving a tissue temperature of 75°C), starting at 65°C and increasing to 90°C over 13 minutes, increasing 2 degrees per minute. It is then kept at a temperature of 90°C for 16 minutes (34). If the patient experiences pain suggestive of radicular origin, the catheter must be repositioned to reduce the risk of neural injury.

Nucleoplasty

The approach to the disc is similarly based on the discography procedure. A 6-inch 17-gauge introducer needle is inserted into the desired disc. The tip of the needle is targeted to the center of the nucleus in both the anteroposterior and lateral planes under fluoroscopy. Next, a green marker is slid down the needle to the level of the skin, indicating the depth of the needle when it is in the center of the disc.

Upon confirmation of needle placement into the disc, the stylette is withdrawn and the SpineWand device is inserted through the needle into the disc. The SpineWand will extend to about 5 mm beyond the tip of the needle. The patient cable from the Nucleoplasty controller module will then be attached via Luer-lock to the needle and probe until the connector dots are aligned. Upon reconfirming proper placement of the device into the disc, the controller is set at power level 2 and the COAG function is activated for a brief moment. If there is patient movement, the SpineWand needs to be repositioned. If there is no movement, then the ABLATION pedal is compressed for 5–10 seconds while the flange of the cable is rotated 180 degrees, creating a coblation zone.

If additional ablation is desired, the needle tip is positioned slightly further into or removed from the disc (about 2 mm in either direction from the center), and new coblation fields are created by pressing the ABLATION pedal for 5–10 seconds while rotating the cable 180 degrees, as with the first lesioning. The SpineWand should be completely inactivated before it is withdrawn from the patient. It is not recommended to adjust or remove the SpineWand while ablation is occurring. If the patient complains of sudden radicular pain during the procedure, the needle should be removed and the procedure ended.

Disc Decompression

Insertion of the Stryker Dekompressor device into a disc is accomplished using the standard discography technique. See Figure 12.3 for an example of the Dekompressor probe being inserted in an oblique fluoroscopic view. The cannula and stylette are inserted into the center of the intended disc for decompression. Once position of the needle is confirmed, the stylette is removed and the Dekompressor probe is inserted. Figure 12.4 illustrates the Dekompressor probe in the AP fluoroscopic view. The probe will be positioned about 2 mm beyond the tip of the needle. The probe is activated using a switch on the handheld device, causing it to remove nucleus material from the disc. The probe can be advanced and withdrawn slightly, typically about 5 mm in either direction, increasing the amount of disc material that can be removed. Patients should remain alert and awake during the procedure in order to reduce the risk of nerve injury.

The disc material will be visible in the collection chamber located on the probe. It can be removed and sent for pathologic analysis. A plastic probe cleaner is provided with the device,

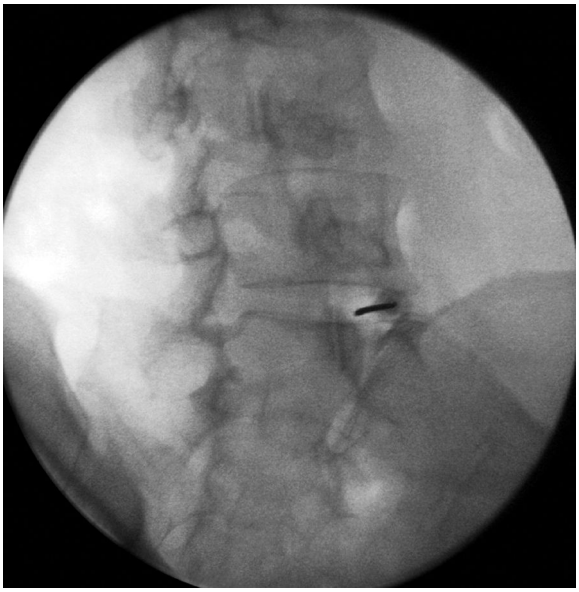

Figure 12.3 Contralateral advancement of Stryker Dekompressor device. Note that for L5–S1 disc, the S1 superior endplate is aligned first, then the S1 superior articular process is aligned to bisect the S1 superior endplate. Often the iliac crest will obscure the trajectory of needle placement, in which case a more cephalad tilt or curved needle will be necessary to facilitate device placement.

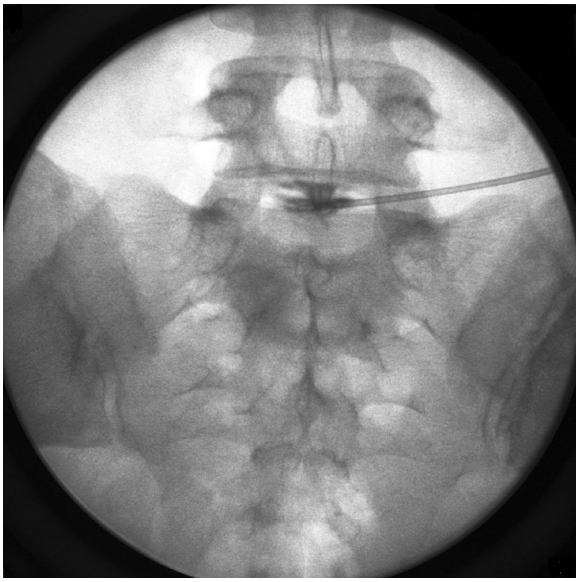

Figure 12.4 AP view of Stryker Dekompressor placement with contrast identifying the L5–S1 disc.

as disc material is usually sticky. Typically, the device will be activated for 2–3 minutes, or until the collection chamber is filled. A maximum time of aspiration of 10 minutes in divided activations of 2–3 minutes each is recommended. A green marker on the introducer cannula can be used to ensure that there is the correct amount of needle advancement and withdrawal occurring during aspiration of the disc. The probe should be monitored under live fluoroscopy while it is activated in order to confirm that the tip of the device remains within the nucleus of the disc at all times. Once the decompression is complete, the device is discarded, as it is a single-use device.

Intradiscal Biacuplasty

Similar to the other intradiscal procedures, it is recommended that prophylactic intravenous antibiotics be administered prior to the procedure. Patients are positioned prone and after sterile prep and drape, two TransDiscal 17-gauge electrically insulated introducers (Kimberly Clark Health Care) are positioned into the posterolateral disc bilaterally, using the co-axial approach typically used for discography. The introducer, which is 15 cm in length, is positioned to lie approximately one-third of the distance into the disc on the lateral fluoroscopic view. The introducer lies just lateral to the mid-pedicular line.

Next, TransDiscal radiofrequency probes (15-cm length with a 6-mm active tip) are positioned bilaterally via the introducers. Positioning is confirmed using anteroposterior, lateral, and oblique fluoroscopic imagery. After placement, the probes should like just lateral to the mid-pedicular line on anteroposterior imaging. As this is a water-cooled procedure, pump priming of saline takes 45 seconds and occurs automatically prior to delivery of RF. The radiofrequency probes are set at a temperature for 45°C and then are heated 2°C per minute to a gradual temperature increase to 55°C over a period of 11 minutes. The temperature is then maintained for an additional 4 minutes. Patients must remain awake and responsive during the procedure to report any potential paresthesias. After the procedure is completed and the probes are removed, a back brace is placed on the patient. Patients are advised to minimize hip flexion and avoid prolonged sitting for 2 weeks after the procedure.

Postoperative Management

Discharge Instructions

Each of these minimally invasive disc procedures is intended as an outpatient procedure. Procedural times will vary, but in most cases the procedure can be accomplished in 30–60 minutes.

- Activity: the patient should limit activities for 24 hours and avoid driving. Gradual return to normal activities is encouraged.
- With the IDET procedure, recovery may take the longest and occasionally there is a temporary increase in pain after the procedure. Physical therapy is recommended after 6–8 weeks, but aggressive exercise should be limited for at least 12 weeks. Pain reduction may not occur until 3–4 months after the procedure.
- After nucleoplasty, patients are advised to limit activities for 1–3 days and may resume full physical activities after about one week.
- Recovery after the Dekompressor procedure typically takes no more than 3–5 days before patients can resume normal activities.
- Wound care: keep area dry for 24 hours. Do not immerse in water (bath, swimming, etc.) for 5 days.
- Post-procedure pain: take NSAIDs or acetaminophen and use ice to the paraspinal muscles.
- Follow-up: the patient should follow up in within 2 weeks to assess the results of the procedure.

Potential Procedural and Postoperative Complications and Their Management

The risks and complications from minimally invasive disc procedures are similar to the risks that patients experience related to discography. Overall, the complication rate of lumbar discography is low and ranges from 0 to 2.5% (35).

Post-Procedure Back Pain

Post-injection back pain has been described with intradiscal procedures such as IDET and percutaneous disc decompression (34). A careful history and physical examination should be performed to evaluate for nerve root injury. Typically with post-injection back pain, patients will present with only an increase in the their typical axial back pain. Following the IDET procedure, back pain may be noticeable in the first 1–2 weeks after the procedure and should improve approximately 6–12 weeks post-procedure (15). The increase in back pain is transient and can be controlled with oral analgesics.

Injury to Spinal Nerve Root

The spinal nerve root lies just inferior to the pedicle and anterior to the transverse process of the vertebral body. Damage to the nerve root can occur, and care should be taken to not overly sedate a patient so that he or she can report any acute symptoms during the procedure. Slow needle advancement is recommended while advancing past the transverse process, and redirection of the needle should be considered if any paresthesia is illicited.

Acute Disc Herniation and Acceleration of Degeneration of the Spine

There have been reports that minimally invasive disc procedures may be associated with an increased risk of post-procedural lumbar disc herniation and accelerated degenerative changes. However, these studies are inconclusive, as the natural progression of degenerative disc disease may also lead to these findings. One study reported that patients are twice as likely to sustain a disc herniation after having a discography, but Bogduk et al.

called into question the nature of the control group in this study (1, 36). Regarding acceleration of degenerative changes, another study showed an increase in Modic changes and higher grades of disc degeneration after having discography (36), but this study was underpowered.

Although the risk of disc herniation seems to be more of a concern than the risk of accelerated degenerative changes after discography, the evidence supporting these findings after discography is weak (1). If a patient should develop pain that is new or different from his or her discogenic pain after discography, or begins to experience pain that has a radicular component, it is prudent to obtain an MRI to determine whether any new structural disc changes have occurred.

Discitis

A serious complication of intradiscal therapies is discitis, which involves an infection of the disc. The incidence of discitis after discography ranges from 0.16% to 4.9% or 0–1.3% per disc investigated (31, 32, 35). Discitis occurs when a contaminated procedure needle penetrates the disc, allowing skin flora such as *Staphylococcus aureus* and *Staphylococcus epidermidis* to enter the disc. Discitis may also occur from systemic spread of infection to the intradiscal space. Symptoms of discitis include worsening back pain, leukocytosis, and elevated C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) (32, 35, 37). These symptoms can develop days to weeks after the procedure, with an average onset of 28 days (37).

If discitis is suspected, MRI with contrast is the imaging modality of choice. Findings of discitis include diminished disc height, reduced signal intensity on T1-weighted imaging, and increased signal intensity on T2-weighted imaging (37). However, these findings could also be present acutely after the procedure, so clinical correlation is necessary, along with confirmation of an infectious process by laboratory testing.

There are varying recommendations as to the treatment of discitis, but combination therapy is preferable to using a singular agent (37). It is important to treat based on specific microbial data (if available), in addition to selecting an antibiotic that can penetrate the disc. Aminoglycosides and vancomycin have showed superior penetration of the intervertebral discs, but specific antimicrobial selection should be selected based on bacterial sensitivity analysis and in association with consultation by an infectious disease specialist (37).

Epidural Abscess and Hematoma

Case reports of epidural abscess, prevertebral abscess, and spinal subdural empyema after discography have been demonstrated in both the cervical and lumbar discs (35) after provocative discography. Treatment may require emergent surgical laminectomy. Overall, the incidence of severe complications following discography is low. A report of 10,663 patients who underwent 37,135 discography injection procedures reported only 2 cases of discitis and no cases of epidural abscess or hematoma (38).

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Chapter 13
Vertebral Augmentation

Yi Cai Isaac Tong and Ram V.S.R. Chavali

Introduction

Vertebral compression fractures (VCF) of the thoracolumbar spine are common in the elderly, and have been estimated to have an incidence of approximately 1.5 million VCFs annually in the general US population (1). Approximately 25% of all postmenopausal women in the United States have a compression fracture during their lifetimes (2). The prevalence of this condition increases with age. The annual incidence is greater in women, with an incidence of 10.7 per 1000 women and 5.7 per 1000 men (3). Vertebral compression fractures are common in Asian and Caucasian women, and less common in African American women.

Vertebral compression fractures can cause severe physical limitation. The most common symptom is chronic back pain, which can lead to functional limitations and significant disability. Multiple adjacent VCFs can lead to progressive kyphosis of the thoracic spine, which can lead to pulmonary complications and decreased appetite. The direct annual economic impact has been estimated at $746 million dollars (4).

Etiology

The most common cause of VCFs is osteoporosis, while other etiologies can include trauma, infection, and neoplasia, metastatic as well as primary (benign and malignant). Postmenopausal women have the greatest risk because of hormonal changes that can lead to osteoporotic bone. It is estimated that approximately 44 million Americans have osteoporosis and that an additional 34 million Americans have low bone mass (5). A significant risk factor of VCFs is a prior VCF. Lindsay et al. report that having one or more VCFs lead to a 5-fold increase in the patient's risk of developing another vertebral facture. Having 2 or more compression fractures increases the risk of having another fracture by 12-fold (6).

Compression fractures of the thoracolumbar spine typically have a flexion compression mechanism of injury. This is the compressive failure of the anterior column while the middle and posterior columns fail in tension. The insult usually involves the anterior longitudinal ligament and anterior half of the vertebral body resulting in a typical "wedge-shaped" fracture. The most common presentation is pain. Such fractures usually do not involve retropulsion of bone to narrow the vertebral canal so neurologic deficits are quite infrequent.

In severe osteoporosis, even the slightest excess force, such as lifting a light object (a bag of groceries), a vigorous cough or sneeze, or turning in bed, can result in a fracture. The hypothesized mechanism is an increased load on the spine caused by contraction of paraspinal muscles (7). Some literature reports that up to 30% of compression fractures in patients with severe osteoporosis occur while the patient is in bed (8). The history is one in which he or she just awoke with severe back pain.

In patients without osteoporosis, the most common cause of a spinal compression fracture is severe trauma, such as an automobile accident or a fall from a height. In patients under 55 years of age, malignancy should be considered as a possible cause of fracture. Table 13.1 shows the symptoms and complications of vertebral compression factures.

Table 13.1 Common Symptoms and Complications of Vertebral Compression Fractures

Signs and Symptoms	Complications
• Back pain (knife-like, aching) • Increased back pain during standing or walking • Decreased pain with laying on back • Increased back pain while rising from supine to sitting or upright position. • Pain on palpation over affected spinous process	• Chronic low grade back pain • Thoracic kyphosis or lumbar lordosis • Impaired pulmonary function • Early satiety and weight loss • Constipation/bowel obstruction • DVT from inactivity • Accelerated osteoporosis

Risk Factors for Vertebral Compression Fractures

The most important risk factor for VCF is osteoporosis. The lists of modifiable and non-modifiable risk factors are listed in Table 13.2. Counterintuitively, obesity is protective against fractures. Obesity decreases the risk of bone loss, as high stress on bone induces a stronger bone-remodeling response. Aromatase, contained in adipocytes, is responsible for extragonadal production of estrogen, which is especially protective in the postmenopausal female. The osteoblast-stimulating/osteoclast-inhibiting effects of estrogen are a putative mechanism of the protective action of fat on bone.

Falls are also an extremely common risk factor associated with fractures. Between 3% and 12% of falls in the elderly result in fractures; as such, this should be viewed seriously as a modifiable risk factor. Smoking, steroids, and antiepileptic medications also are risk factors for increased osteoporosis. It should be kept in mind that immobility and bracing, while improving pain, accelerate osteoporosis.

Table 13.2 Risk Factors for Vertebral Fractures

Modifiable	Non-modifiable
Alcohol consumption	Advanced age
Tobacco use	Female sex
Osteoporosis	Caucasian race
Antiepileptic medications	Dementia
Low body weight	Susceptibility to falling
Premenopausal amonorhea for >1 year	History of fractures in adulthood Family history of fractures in first-degree relative

Lambrinoudaki I, Flokatoula M, Armeni E, Pliatsika P, Augoulea A, Antoniou A, Alexandrou A, Creatsa M, Panoulis C, Dendrinos S, Papacharalambous X. Vertebral fracture prevalence among Greek healthy middle-aged postmenopausal women: association with demographics, anthropometric parameters and bone mineral density. *Spine J*. 2014 Aug 5.

Classification of Vertebral Compression Fractures

A vertebral fracture may be defined as reduction in vertebral height by 15% or greater. VCFs can be classified in three categories: wedge, biconcave, and crush (burst). The most common locations for VCFs are the lower thoracic and lumbar regions; specifically T8, T12, L1, and L4 levels are involved (9). The physiologic thoracic kyphosis places the greatest axial load at T8. The most common wedge fracture morphology accounts for the majority (more than 50%) of all VCFs (10). This class of fractures occurs in the midthoracic region and is characterized by compression of the anterior segment of the vertebral body. Biconcave compression fractures are the second most common, accounting for approximately 17% of all VCFs. Crush or burst-type compression fractures are the least common, accounting for only 13% of all VCFs. Complex fractures account for the remaining 20% (11). Burst fractures are relative contraindications for spinal augmentation.

Patient Presentations and Physical Examination

A detailed history should be obtained. The patient interview should focus on the patient's back pain, mobility, steroids, bisphosphonates, calcitonin, and hormonal replacement therapy. Patients with atypical pain and symptoms should be evaluated for concomitant diseases, such a discitis or epidural abscess.

A focused physical and neurological examination to evaluate for possible radicular symptoms or neurological deficits should be done. Vertebral levels should be examined for sites of point tenderness to percussion and to palpation. Examination under fluoroscopy is ideal. A lack of preoperative spinous process tenderness does not preclude clinical success of vertebroplasty. Any concomitant process, such as facet or disc disease, should be worked up as well. A patient's ability to lie prone without excess pain and pulmonary compromise should be assessed to confirm that the patient can tolerate the planned interventional procedure under conscious sedation.

Diagnosis

Imaging is crucial in the evaluation and diagnosis of patients with VCFs. While ideal, magnetic resonance imaging (MRI) or computed tomography (CT) is not always necessary to make the diagnosis. Plain radiographs are usually the initial diagnostic modality; however, without serial imaging, plain film imaging cannot always discern new compression fractures and cannot differentiate healed ones. A complete spine series is preferred since multiple VCFs are found in 5%–20% of patients presenting with compression fractures. Radiographic features suggesting vertebral disruption include loss of vertebral height, facet dislocation, and an increase in interpedicular and interspinous distance (> 7 mm) (12). The main limitations of radiographs include the complete inability to assess microfractures (a source of pain, which may progress to further loss of height), difficulty with evaluation of retropulsed fragments, and of course any concomitant acute disc herniation, which are relative contraindications in the acute setting (see Figure 13.1). Still, osteoporotic postmenopausal females with documented uncomplicated

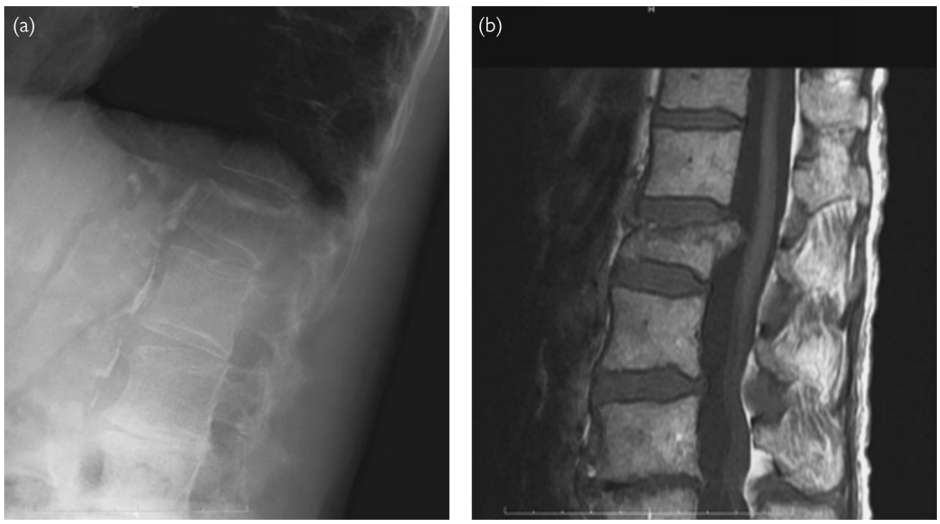

Figure 13.1 92-year-old female s/p fall on ice. X-ray (a) shows moderate compression, MRI (b) reveals retropulsed fragment abutting cord (relative contraindication), easily missed on radiography.

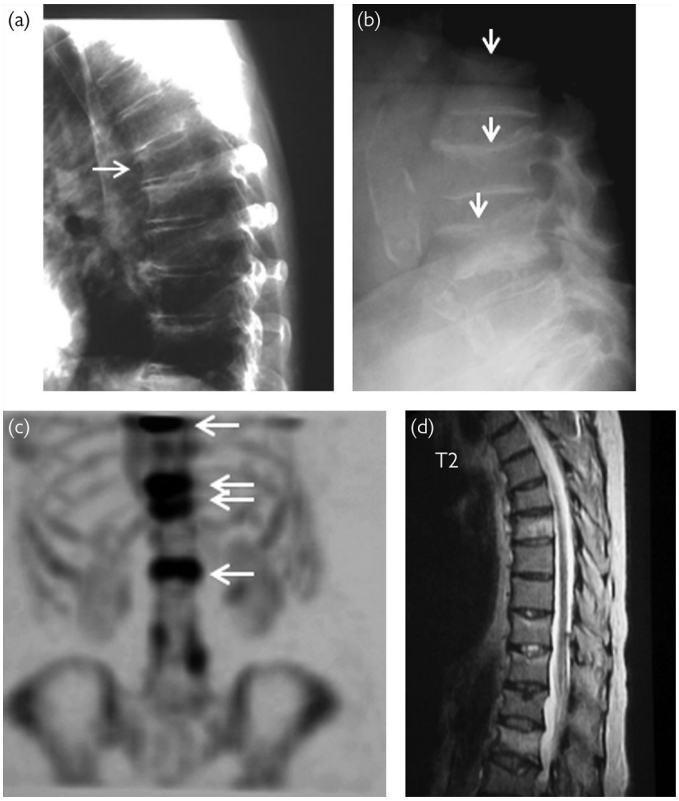

Figure 13.2 Elderly female s/p fall c/o mid-thoracic and lower back pain. Plain films (a, b) demonstrate slight loss of height of a mid-thoracic vertebra and multiple lumbar compressions. Bone scan (c) reveals abnormal uptake in at least 4 vertebral bodies with more facet-like uptake near the lumbosacral junction. MRI (d–f) reveals edema within T7 and L1, which were treated with complete resolution of pain (g, h).

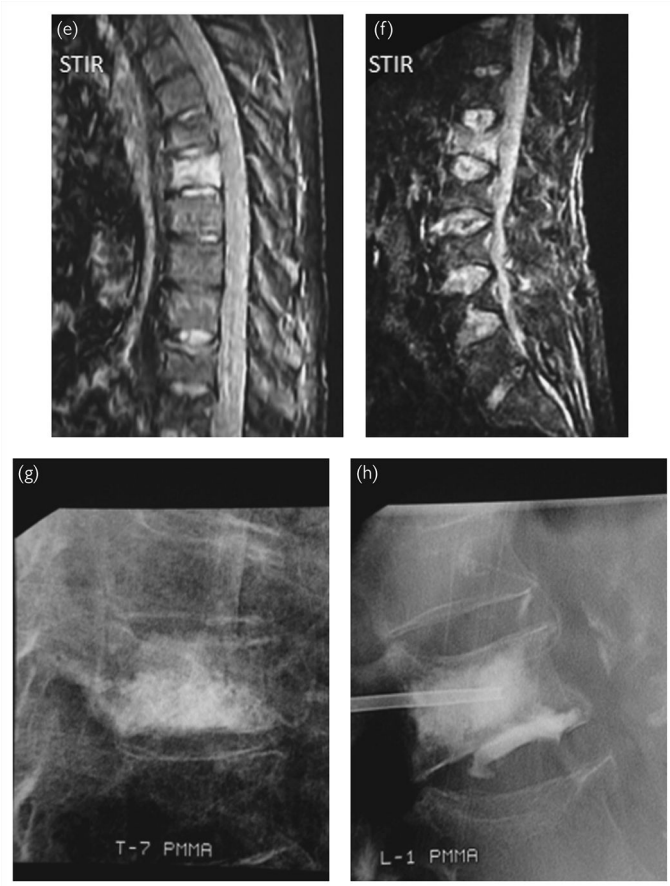

Figure 13.2 Continued

new or subacute fracture on plain radiographs who meet the clinical criteria may proceed to vertebroplasty without other imaging (13).

Patients may already have an MRI as part of their diagnostic evaluation prior to their referral to a pain specialist. An MRI or bone scan imaging is very useful for identifying active fractures. An MRI study may demonstrate recent fractures, evidence of bone marrow edema, and inflammatory changes. An MRI will demonstrate decreased signal on T1-weighted sequences and increased or inhomogeneous signal on T2-weighted sequences (14). Edema may involved the entire vertebral body or may be limited to the area adjacent to an endplate. A limited MRI study consisting of T1 and short-tau inversion recovery (STIR) sagittal images may provide enough evidence to spot vertebral body edema (see Figure 13.2). Patients whose fractures show extensive edema are more likely to exhibit a positive clinical response to vertebroplasty (15). An MRI also permits evaluation of other conditions that may contribute to the patient's symptoms, such as myeloma, lymphoma, fibrous dysplasia, hemangiomas, and unsuspected metastatic lesions.

For patients who cannot undergo an MRI (pacemaker, claustrophobia, etc.), a limited CT scan through the area of the fractures can be done with multiplanar reformatting for 3D viewing/

evaluation (see Figure 13.3). CT can be used to evaluate the integrity of the posterior wall of the vertebral body, to locate fracture lines involving the vertebral body and pedicles, and to evaluate the size of the pedicles in addition to evaluating for disc herniations, neoplasia, and infection.

Bone scintigraphy or bone scan has been shown to be more accurate than MRI in the detection of older fractures (16). In patients suspected of having active VCFs with no obvious acute fracture on MRI, one may consider performing a bone scan as a final determination. One must be careful not to confuse degenerative facet disease with a partially collapsed vertebral body on a routine scan (see Figure 13.2c).

Laboratory Evaluation

Prior to the procedure, the patient's coagulation status (PTT, PT, and INR) should be verified if there is any suspicion that a coagulopathy exists. Serum creatinine is not necessary because the amount of contrast utilized in vertebral venography is unlikely to cause any significant renal toxicity. If anesthesia is required, further workup may be necessary.

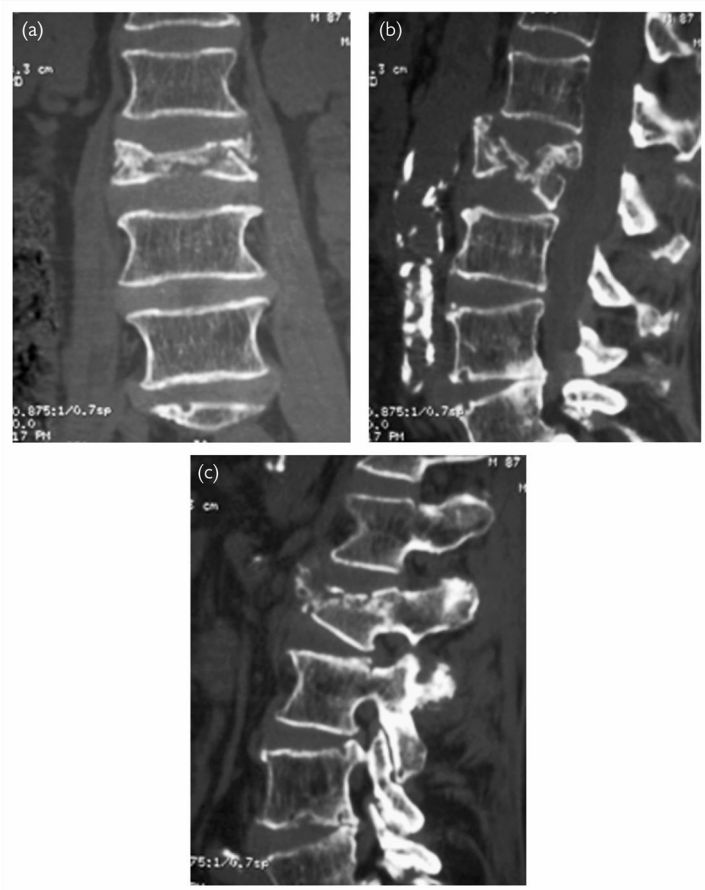

Figure 13.3 87-year-old fell while playing tennis. CT with 3D reformatting reveals severe burst type compression fracture (a) with posterior wall break (b) and fracture line through the pedicle (c). Patient was treated in a delayed fashion after conservative measures failed.

Preoperative Considerations

Non-Surgical and Medical Management

Because pain associated with VCFs is often self-limited, lasting from 2 weeks to 3 months, treatment of acute fractures has largely been conservative. Conservative management of vertebral compression fractures includes bed rest followed by gradual mobilization with or without external spinal orthoses. Localized heating pads, ice packs, massage therapy, or trigger point injections may be useful.

Braces may be beneficial for the first few months. A hyperextension brace is used since VCFs are flexion injuries. Younger patients tolerate bracing better than older patients, as elderly patients tend to experience more pain with bracing (17). As a result, elderly patients may have reduced activity, predisposing them to venous stasis and pulmonary embolisms. External spinal orthoses have also been found to lead to inactivity, pressure ulcers, urinary tract infections, and progressive deconditioning. Lebanc et al. reported that bone mineral density decreased 0.25%–1% per week in patients who are on bed rest (18).

Radiotherapy is often indicated for pain relief in patients with pathologic compression fractures from cancer. Radiotherapy has been cited to reduce pain in approximately 50% of patients with VCFs due to myeloma, prostate, and breast cancer (19). It should be noted that chemotherapy and radiation therapy are not affected by vertebroplasty, and in addition to the benefit of rapid pain reduction, there is structural reinforcement of weakened bone.

Alternative Treatments and Procedures

Intervention is indicated for those patients with intractable back pain who are refractory to conservative therapy or where there is evidence of impending or existing neurologic deformity. Operative management of VCFs has been shown to provide rapid significant and sustained improvement in back pain, function, and quality of life. There are several surgical options for the management of painful osteoporotic fractures. Minimally invasive techniques such as kyphoplasty and percutaneous vertebroplasty are among the most commonly used and are discussed in this chapter.

Goals, Advantages, and Patient Selection Criteria

The primary criterion for patient selection is the ability of the intervention to decrease pain and improve mobility. Prevention of further vertebral body collapse is a secondary goal. Surgical intervention should be directed toward affected patients who have failed a reasonable course of medical therapy. The guidelines for spinal augmentation set forth by the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), the American Society of Spine Radiology (ASSR), the Society of Interventional Radiology (SIR), and the Society of NeuroInterventional Surgery (SNIS) are listed in Box 13.1.

Patient Screening and Evaluation

Careful review of all pertinent aspects of the patient's presentation and workup is necessary to identify patients who will benefit from an intervention. Potential patients who may undergo an intervention should fulfill relevant documented clinical and radiological criteria. A protocolized screening method should be employed.

Preparing the Patient for Surgery

Vertebroplasty and kyphoplasty are usually performed on an outpatient basis. It is helpful to evaluate the patient's ability to lie prone on a hard table. The institutional guidelines for

BOX 13.1 GUIDELINES FOR SPINAL AUGMENTATION

Indications: ACR, ASNR, ASSR, SIR, and SNIS Guidelines for Intervention

Painful osteoporotic vertebral fracture(s) refractory to medical therapy.

Vertebral bodies weakened by neoplasm.

Symptomatic vertebral body microfracture (as documented by magnetic resonance imaging [MRI] or nuclear imaging, and/or lytic lesion seen on computed tomography [CT]) without obvious loss of vertebral body height.

Absolute Contraindications: ACR, ASNR, ASSR, SIR, and SNIS Guidelines

1. Septicemia
2. Active osteomyelitis of the target vertebra
3. Uncorrectable coagulopathy
4. Allergy to bone cement or opacification agent.

Relative Contraindications: ACR, ASNR, ASSR, SIR, and SNIS Guidelines

1. Radiculopathy in excess of local vertebral pain, caused by a compressive syndrome unrelated to vertebral collapse. Occasionally preoperative vertebroplasty can be performed before a spinal decompressive procedure.
2. Retropulsion of a fracture fragment causing severe spinal canal compromise.
3. Epidural tumor extension with significant encroachment on the spinal canal.
4. Ongoing systemic infection.
5. Patient improving on medical therapy.
6. Prophylaxis in osteoporotic patients
7. Myelopathy originating at the fracture level.

same-day surgery should be followed. As the patient usually requires sedation or general anesthesia, the patient should be fasting for the appropriate time prior to the procedure. A responsible adult must be available to transport the patient home after discharge from the recovery unit. Informed consent is obtained for all cases. Risks cited should include infection, bleeding, fracture, extravasation of acrylic into the surrounding epidural or paravertebral veins resulting in worsening pain or paralysis, pulmonary compromise, and death. The consent should inform the patient that the potential for immediate surgical intervention may be needed.

Intraoperative Management

Antibiotic Prophylaxis

The role of antibiotic prophylaxis in vertebroplasty and kyphoplasty is specific to each institution. If the patient is immunocompromised for any reason, we may consider giving preoperative antibiotics. The senior author uses a sterile specimen cup to evenly mix vancomycin powder with the PMMA powder (polymer) prior to adding the liquid monomer. The use of vancomycin powder to decrease surgical site infections is discussed further in Appendix 11.

Patient Positioning

The procedure is performed with the patient in the prone position. This allows the practitioner access to the pedicles, which is the preferred access route in the thoracic and lumbar spine. For patient comfort, we place a soft cushion on the table with pillows under the shoulders and head for support. This may permit more efficient respiration and can decrease venous bleeding that can occur with increased abdominal pressure in the prone position. Great care should be used with elderly patients. Patients with VCFs are often extremely osteoporotic, and fractures of the rib and occasionally other bones can occur during mobilization.

Once the patient is properly positioned on the procedure table, sedation is initiated by appropriate personnel. The hemodynamic and respiratory status is also monitored throughout the case by an anesthesia provider. Supplemental oxygen is given as needed. Equipment and medications for emergency resuscitation should be available.

Prepping

The procedure is performed under strict sterile conditions. All personnel in the room should have surgical caps and masks. The operators should wear sterile gowns and gloves. The level to be treated should be identified under fluoroscopy and marked. The patient's back should be prepared in a sterile fashion with povidone-iodine and alcohol or chlorhexindine and draped. A wide area should be prepped because angles of approach can vary. The point of entry and angle of approach are affected by factors such as the degree of scoliosis and kyphosis, the degree and number of compression fractures, and the patient's overall body habitus.

Procedures for Vertebral Augmentation: Vertebroplasty

Equipment

- Styleted needle (11- or 13-gauge) or kyphoplasty kit
- Syringes for storing and injection (1 cc Luer locked) or a cement delivery system
- Polymethylmethacrylate powder (PMMA)
- Sterile barium sulfate powder (often comes premixed with PMMA)
- Liquid methacrylate monomer
- Sterile barium sulfate powder for radio-opacity
- Vancomycin powder (500 mg vial, approximately 250 mg per PMMA pouch)
- Syringe (10 ml) and tubing (optional for venography)
- Nonionic iodinated contrast medium (optional for venography)
- Sterile scalpel and hemostat
- Sterile gauze
- Adhesive bandages and adhesive strips
- Local anesthetic for skin infiltration
- Spinal needle (22-gauge)
- Lateral and anterioposterior fluoroscopy.

Technique of Needle Placement

The classic approach is to align the vertebral body in the straight anteroposterior and lateral projections. The superior endplate is aligned to a single line on the AP view, with both pedicles visible and the spinous process centered in the midline of the spine. The position should provide adequate view of both sides of the vertebral body for needle placement.

Another approach is to utilize an oblique angle centering on and optimally visualizing the pedicle. This "down the barrel" view allows optimal visualization of the medial cortex of the pedicle, ensuring safe transpedicular advancement without breaching the epidural space and further increases the likelihood of the needle tip reaching close to midline by the time it advances into the anterior one-third of the vertebral body on lateral view (see Figure 13.4). This affords the best opportunity for bilateral cement deposition from a unipedicular approach (20). Parapedicular or extrapedicular approaches may also be considered.

Once the operator is satisfied with the view, the skin should be infiltrated with local anesthesia. The tract of the needle should be infiltrated to the pedicle and the periosteum utilizing a 22G spinal needle, which may be left in place. A small skin incision is then made with a scalpel to guide the passage of the large caliber needle through the soft tissue using the spinal needle as a guide to the upper outer pedicle. The needle is then placed in the mid- to upper outer third of the pedicle and advanced into the vertebral body.

Fine needle trajectory manipulation within the pedicle is critical, as such adjustments are less effective the further into bone one is, and may result in pedicle fracture if excessive torqueing is done. Also, trauma to the spinal cord or tearing of the epidural veins may occur if the needle is advanced past the medial cortex. The needle should remain lateral to the medial cortical edge of the pedicle until it has passed anteriorly into the vertebral body. An error in anterior needle placement has the potential for perforating the aorta and inferior vena cava. Biplane imaging is helpful for simultaneous and easy access to the intended target area.

Vertebral Venography

Venography previously was a routine aspect of the procedure but now is only rarely utilized. It helps determine whether the needle is in the proximity of a rapidly draining vein and may also be used in the case of hypervascular tumors (hemangiomas, renal cell metastasis) in order to guide subsequent cement deposition. When needle placement is complete, venography may be performed through the needle; 3–5ml of contrast should be injected to determine the degree of vascularity. If the needle is in or directly adjacent to a vein, the initial methacrylate injection could cause dire consequences; as such, the needle can be repositioned before beginning careful cement injection and the initial thickness of the cement and injection rate adjusted accordingly. If performed, it is good practice to flush out any remaining contrast within the needle or vertebral body with saline in order to not confuse cement and contrast agent.

Cement Preparation

Practitioners have various methods of preparing the cement. Our practice is to combine PMMA powder, vancomycin powder, and barium sulfate in a capped specimen cup and then add the liquid monomer and mix to a very liquid consistency. This is drawn up into 10-cc BD syringes (capped and immediately placed in a ice water bath), from which 1-cc syringes are backloaded into 1-cc thick stemmed syringes, which are then used to inject into the patient through the indwelling trochars. These ingredients are mixed in liquid methacrylate to provide an injectable solution. When using kits, it is wise to follow manufacturer guidelines.

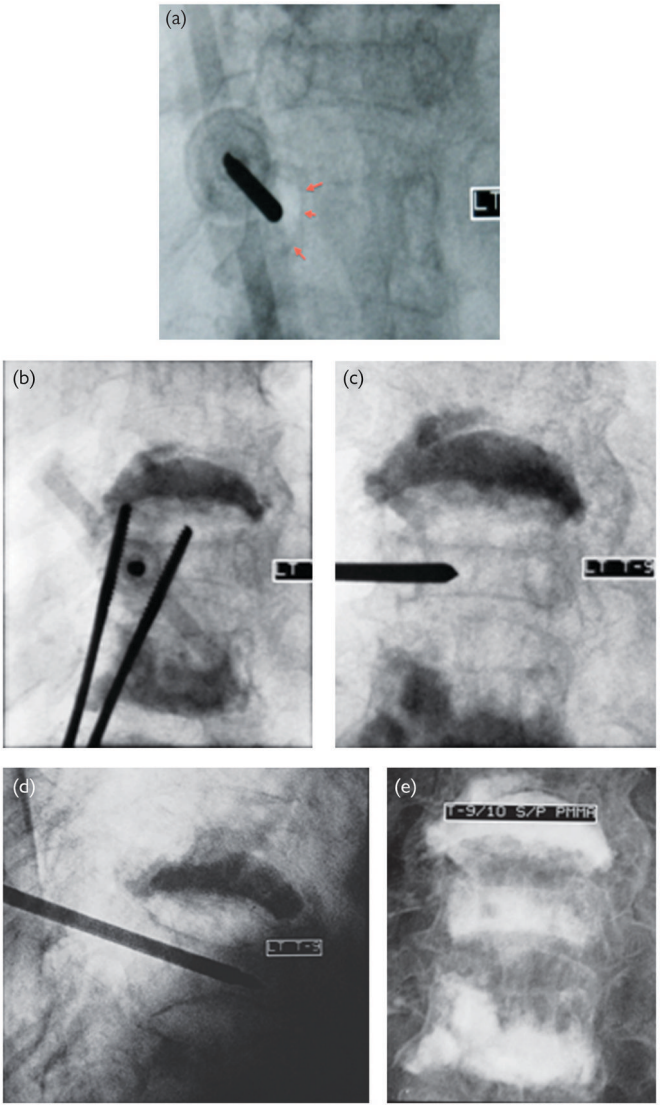

Figure 13.4 Slight RAO oblique view with red arrows delineating T10 pedicle medial border (a). Note T9 pedicle above. (b) Using same approach for T9, AP view (c) reveals needle tip near midline and in anterior one-third (d), allowing excellent PMMA deposition bilaterally with unilateral approach (e).

Cement Injection

Delivery of the methacrylate mixtures should be done under live or intermittent fluoroscopy with very small aliquots of cement being delivered. The process is best visualized in the lateral projection. The distribution of the cement depends on many factors, including the presence of fissures or fractures in the vertebral body, positional changes of the needle during injection, and the polymerization of the injectate with bone.

Injecting slowly and purposefully is the best way to control extravasation. There are many techniques to limit extravasation. Pausing during the injection to allow some of the cement to polymerize with bone and repositioning the needle can sometimes stop extraosseous cement deposition. A small amount of extension into the adjacent disc space attests to reaching the fracture plane and may at times be unavoidable. However, a small amount within the disc space usually has no clinical effect. While not proven, the presence of PMMA in the disc space may increase the chances of fracture of the adjacent vertebral body.

Once the needles have been removed from the patient, AP and lateral radiographs should be taken. The skin is thoroughly cleansed once more and adhesive strips and sterile dressings applied, and the patient is ready for the recovery room.

Procedures for Vertebral Augmentation: Kyphoplasty

Kyphoplasty was introduced in 2001 as a new technique for percutaneous augmentation of osteoporotic VCFs. In kyphoplasty, the vertebral body is accessed in a similar technique as vertebroplasty, but a balloon catheter is used to create a space within the hemivertebra prior to cement injection. The theoretical advantages of kyphoplasty over vertebroplasty include the potential for vertebral body height restoration, reduction of kyphotic angulation of the spine, and lower rate of cement extravasation (20). It has been argued that kyphoplasty reduces the risk of PMMA extravasation due to the creation of a cavity; thus cement of more putty-like consistency can be injected into the cavity under lower pressure.

Controversies

The greatest controversy between kyphoplasty and vertebroplasty relate to vertebral height restoration and reduced kyphosis. There is no definitive evidence that height restoration improves clinical outcome. Many studies show that both are effective in rapidly reducing pain, and for all compression fractures the pain reduction has been shown to be 60%–70% with vertebroplasty and 55%–60% with kyphoplasty (22). Further, it has been shown that kyphoplasty in more than one level does not further reduce the curvature (23). As such, if multiple levels are to be treated, kyphoplasty may be combined with vertebroplasty.

Interestingly, not only is there no proof that height restoration is correlated with pain relief, given enough time there is greater loss of height with patients treated with kyphoplasty than with vertebroplasty, presumably due to the smaller overall volumes and the relatively inhomogeneous, concentrated distribution of cement with the former; with vertebroplasty, there is greater uniformity of distribution through the interstices of the bone (32, 33).

Kyphoplasty materials can be double the cost of those for vertebroplasty, and most physicians perform kyphoplasty under general anesthesia in the operating room, adding additional expense. Further, the typical C-arm fluoroscopy imaging quality used in the standard case is inferior to typical angiographic equipment. Vertebroplasty most commonly employs local and conscious sedation, leading to more rapid discharge, routinely within 1–2 hours of the procedure. General anesthesia is typically used for kyphoplasty, followed by admission to the hospital for observation. The added cost of an admission for kyphoplasty adds significantly to the greater cost of kyphoplasty.

In over 5,000 levels, the senior author has not experienced a single case of symptomatic extraosseous cement placement with percutaneous vertebroplasty. Excellent biplane imaging and patience with injection of cement are mandatory. Though the typical working time of PMMA is less than 15 minutes, we routinely use PMMA through 13G needles one hour beyond mixing time by using an ice bath cooling technique to keep the cement liquid (24).

Technique

Kyphoplasty and vertebroplasty share very similar techniques. They both have the same transpedicular and extrapedicular approaches. Vertebroplasty needles are 13 or 11G in size, and in 70% of the cases a unilateral approach can be used to achieve bilateral cement filling. Kyphoplasty usually requires a bipedicular approach. After initial 10G trochars are placed through the pedicle, a drill is used to curette the tract to minimize the chance that any bone shards could rupture the balloons. The balloons are next inserted coaxially into the tract and are inflated under fluoroscopy to create a pocket for subsequent placement of thick cement under lower pressure (see Figure 13.5).

Intraoperative Complications of Vertebroplasty and Kyphoplasty

In the transpedicular approach, the most severe complication is advancing the needle past the spinal canal. Injury to the thecal sac, the spinal cord, and the cauda equina can occur. Direct injury to the spinal cord has been described. Tearing of the epidural or intradural venous plexus may result in a hematoma. Urgent surgical intervention is required if the patient develops sudden spinal cord compression. Fracture of the pedicle is another potential complication. A pedicle fracture may heal, but the patient could experience pain for many weeks.

A complication associated with injection of PMMA is extravasation of cement into the epidural space. Cement in the epidural space will result in nerve root or spinal cord compression. The patient may experience radicular syndromes and even paralysis. The most important technique to minimize this complication is to inject PMMA under live fluoroscopy in the lateral view. The proceduralist can readily see the cement injected in the lateral view. PMMA can also extravasate into the epidural venous plexus, which can lead to spinal cord infarctions or compression. A pulmonary embolus has been reported when PMMA was inadvertently injected into the venous system (21).

Infection is a rare but serious complication. These procedures should be performed under sterile conditions. When an infection occurs, long-term antibiotic therapy is warranted. Surgical debridement and corpectomy may be required.

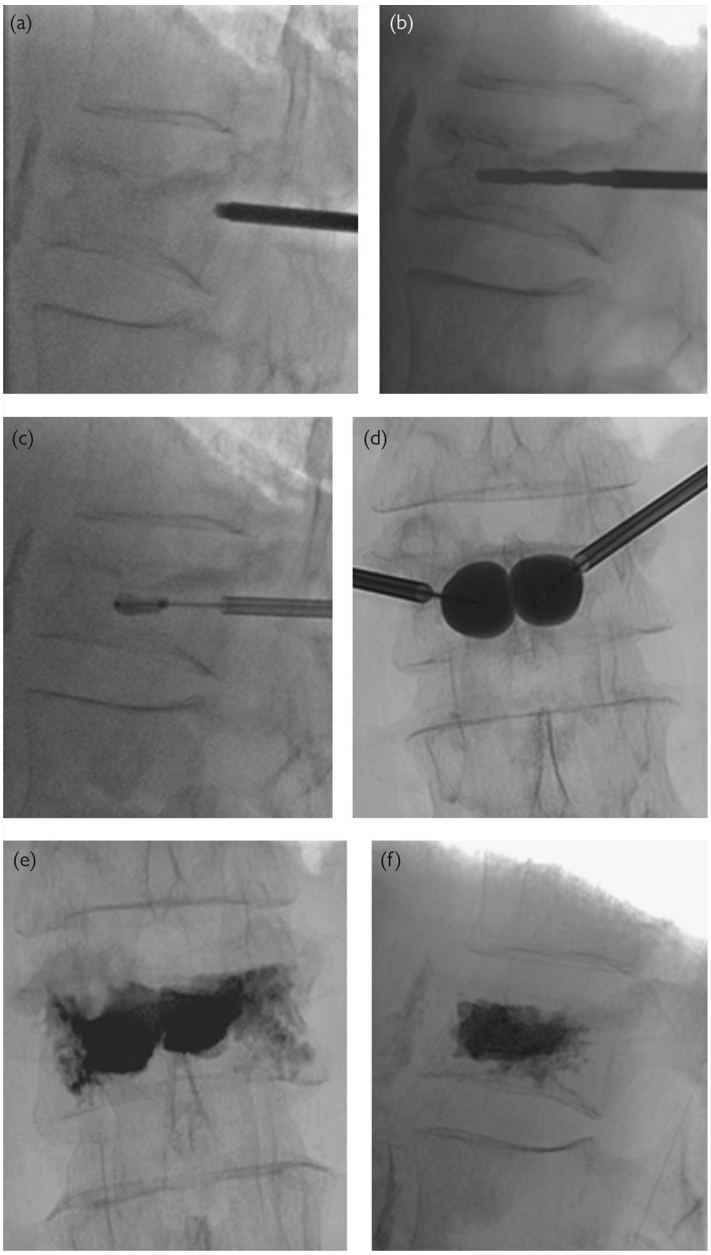

Figure 13.5 Kyphoplasty: (a) 10G trochar advanced transpedicularly to the junction of the pedicle and vertebral body. (b) Drill bit used to curette the tract for subsequent coaxial balloon placement and inflation. (c, d) PMMA cement then deposited to give final AP (e) and lateral (f) results.

Postoperative Management

When the procedure has been completed, the patient should be turned from the prone position to the supine position and transported to the recovery unit. The patient should remain supine for one hour and then allowed to raise the head 30 degrees. We use reverse Trendelenburg positioning whenever possible. Neurologic examinations should be preformed every 30 minutes for 2 hours. Discharge should be considered when the patient is hemodynamically stable, ambulating, shows no signs of neurologic deficit and pain is controlled.

Discharge Instructions

Wound care and additional instructions should be given to the patient.

1. Limit activities for 24 hours and avoid driving or conducting significant business.
2. Wound care
   a. Keep dressing dry for 2 days.
   b. If adhesive strips come off, a bandage should be placed after showering.
   c. Patient should not take a bath or swim until the wound heals (usually < 5 days).
3. Incisional pain
   a. Take NSAIDs or acetaminophen; consider Toradol.
   b. Heat or ice to the paraspinal muscles.
4. Encourage walking and return to more strenuous activities as tolerated.
5. Follow-up appointment in 1 week.

Outcomes

Both vertebroplasty and kyphoplasty are efficacious in pain relief, but questions regarding who should be treated and when remain multifactorial and elusive. All the randomized control studies have design flaws, and two recent trials published in the *New England Journal of Medicine* comparing VP with a sham procedure and another comparing VP with conservative medical management only have created contention (25, 27). There are always limitations in such studies. The flaws cited include variation of fracture acuity and MRI inclusion criteria, amount of cement variance, lack of pain generator delineation, and the fact that many patients refused to participate in the studies and were thus excluded (27–29).

While we await further studies, patients will be treated, and some take-home points should be kept in mind. These randomized controlled trials (RCTs) were specifically targeted to osteoporotic compression fractures. Pain relief is only one factor; stabilization against further collapse is a consideration. Thoracic and lumbar fractures with greater than 28.5% collapse are at greater risk of failure with conservative treatment (30). Cement volume correlates with pain relief, so one should attempt to inject as much as safely possible (31), (which demands excellent imaging). Burst fractures tend to have worse outcome with respect to pain relief compared to wedge-shaped fractures (31).

Fractures treated very early will undoubtedly lead to excess treatments, and late treatment will lead to less success; in general, those treated within 7 weeks seem to have the most consistent positive results; careful selection with imaging and clinical evaluation are of paramount importance. Patients who are relatively young (under 65), who have less than 20% loss of height, and who are able to tolerate physiotherapy may do better conservatively. Strong consideration should be given to those who are older, as pain relief promotes early mobilization and reduction in analgesic intake.

For those with metastatic pain, some 20%–30% do not achieve pain relief with radiotherapy, and osteoporosis from inflammation and subsequent recommended immobility are also

further risk factors for collapse. Maximum pain relief with external beam radiation occurs approximately one month out, and given the limited life expectancy in these patients, in our practice we promote early vertebral augmentation (31, 32).

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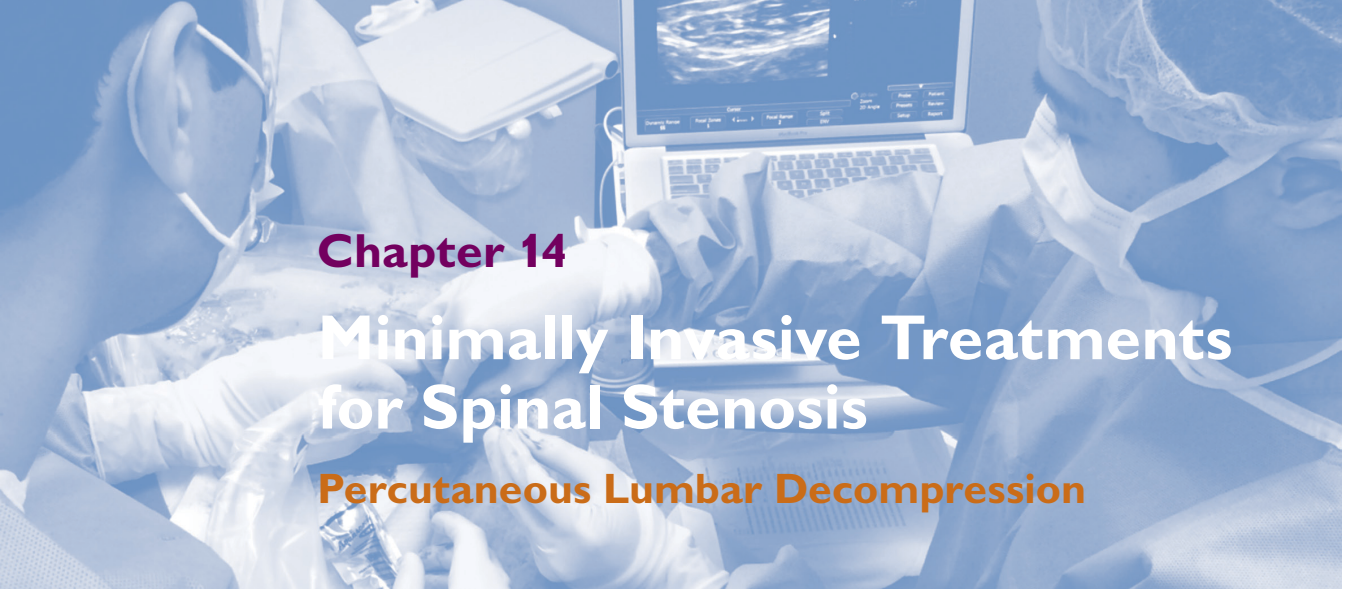

Chapter 14

Minimally Invasive Treatments for Spinal Stenosis

Percutaneous Lumbar Decompression

Jeremy C. Jones, R. Jason Yong, and Srdjan S. Nedeljkovic

Introduction

Spinal stenosis is a condition that occurs with increasing prevalence with advancing age and is most often the result of the normal aging process. A relatively small proportion of patients may have congenital spinal stenosis, which is associated with reduced pedicle length and fewer degenerative changes. This condition is more common in shorter people and in achondroplastic dwarfs. Patients with age-related spinal stenosis typically develop symptoms after age 65, whereas patients with congenital spinal stenosis first notice symptoms between age 30 and 50. Arthritic and degenerative changes begin to affect the spine in adulthood, leading to degeneration and bulging of intervertebral discs, hypertrophy and calcification of the facet joints, and hypertrophy of ligaments, including the ligamentum flavum. Patients with spinal stenosis may have central canal narrowing, lateral recess stenosis, or foraminal stenosis.

Many patients will have radiographic evidence of spinal stenosis but remain asymptomatic. Therefore, to have a diagnosis of spinal stenosis a patient generally must have symptoms of pain in the back, legs, and buttocks that is worse with walking or standing and that improves when sitting or lying down. When symptoms are compared with radiologic evidence, some patients with relatively mild narrowing radiographically may exhibit more profound symptoms than others who have more severe radiologic findings. There is no definite association between the severity of findings on imaging when compared to the extent of symptoms (1). In addition, many patients will have multiple causes of back and leg pain, including degenerative disc disease and spondylolisthesis, neuropathy, or even sacroiliac pain and dysfunction, making the diagnosis of spinal stenosis a difficult one to make at times.

Percutaneous lumbar decompression is an investigational outpatient treatment that may improve pain scores and mobility in patients with lumbar spinal stenosis (LSS). The procedure has been developed and marketed as the “mild” procedure and has been given the moniker “minimally invasive lumber decompression.” For patients to be considered eligible for this procedure, ligamentum flavum hypertrophy, as demonstrated on imaging, must be a significant contributor to the spinal stenosis. It is hypothesized that percutaneous lumbar decompression may improve pain and function by the removal of small amounts of lamina and debulking of the dorsal hypertrophied ligamentum flavum in patients with lumbar spinal stenosis. The procedure is typically done on both sides to achieve the desired amount of decompression. Care must be taken to avoid the neural structures. For most patients, the procedure does not require general anesthesia and may be performed under monitored anesthesia care with sedation and local anesthesia. An epidurogram comparing contrast dye spread patterns before and after the procedure is necessary to confirm the adequacy of decompression. The procedure potentially provides a treatment alternative between the therapeutic options of non-invasive therapy (exercise and medications), injection-type treatments (epidural steroid injections), and other more extensive surgical decompressive techniques such as laminectomy and foraminotomy.

Preoperative Considerations

As noted, lumbar spinal stenosis is a painful progressive degenerative condition common in the elderly population, with a prevalence in the United States reported to be as high as 8% (2). It is believed that structural narrowing of the vertebral canal results in neurogenic claudication, which manifests as severe pain in the lower back, buttocks, and legs and progressively worsens with standing and walking. Patients suffering from lumbar spinal stenosis will typically lean forward or bend over when standing or walking, as this may temporarily alleviate the pain. The primary spinal levels affected are L3–L4 and L4–L5; however, any lumbar levels may be affected.

Medical Management and Alternative Treatments and Procedures

Initial treatment may include physical therapy, acupuncture, NSAIDs, and opioids, although there is little evidence on the effectiveness of these treatments. Although epidural steroid injections have been used for lumbar spinal stenosis, not all patients have benefit, and some patients who have relief initially may not continue to experience benefit as their condition worsens (3). Patients who are unable to obtain acceptable levels of pain relief with these measures often consider the option of surgery, such that spinal stenosis is the most common reason for back surgery in the older population (4). Traditionally, surgery has consisted of decompressive laminectomies with or without fusion. A less invasive form of surgery involves performing hemilaminotomy and foraminotomy, which includes removing parts of the ligamentum flavum, lamina, and facet joints, but does not require fusion.

Goals

Minimally invasive percutaneous decompression has been developed as a potential treatment option for patients who have symptoms of spinal stenosis. Ligamentum flavum (LF) hypertrophy is considered a contributing cause of symptomatic LSS and may be associated with compression, traction, or ischemia of neural elements leading to low back pain (5). LF hypertrophy may contribute up to 85% of the narrowing of the spinal canal, according to Hansson et al. (6). The goal of percutaneous lumber decompression is to improve function by alleviating LSS through the removal of small amounts of lamina and debulking of the dorsal hypertrophied ligamentum flavum. For some patients, minimally invasive decompression may be a reasonable option, especially for those considered poor surgical candidates secondary to significant comorbidities.

Key Features

Percutaneous lumbar decompression is a procedure that offers the potential advantage of being a minimally invasive therapeutic option for patients with lumbar spinal stenosis who have a predominant component of ligamentum flavum hypertrophy. Typically, the procedure may be performed on an outpatient basis, and patients do not require general anesthesia. The portal insertion site is 5.1 mm, resulting in a small incision/wound. Only patients with central canal stenosis are eligible for this procedure, as it is not indicated to relieve neural foraminal stenosis or nerve compression secondary to herniated discs.

Efficacy

A number of reports have been published showing an improvement in pain scores and mobility following percutaneous lumbar decompression (7–16). Most of the literature consists of retrospective reviews of cases or observational studies. In a single site prospective observational study of 40 patients one year post-procedure, patients who underwent decompression

experienced increased standing time from 8 to 56 minutes, an increase in walking distance from 246 feet to 3956 feet, and an improvement in Visual Analogue Scale (VAS) pain scores by 3.5 points compared to pre-procedure reports. There were no device or procedure-related serious complications reported (17).

In another study on 42 consecutive patients who had percutaneous decompression, VAS pain scores improved from 9.6 +/- 0.42 pre-procedure to 5.8 +/- 2.5 30 days post-procedure, and patients reported increased ability to stand and walk (16). A review of over 250 patients who underwent percutaneous decompression reported improvements in pain scores from 7.4 to 3.9 at 3-month follow-up and improved results on the Oswestry Disability questionnaire from 48.0 to 30.9 (13).

A double-blind, randomized prospective study compared results of epidural steroid injections to percutaneous lumbar decompression in 38 patients (7). Patients who had percutaneous lumbar decompression had an improvement in VAS pain scores (from 6.3 to 3.8) 6 weeks after the procedure, compared to no improvement in VAS scores in patients who had epidural steroid injections. The percutaneous lumbar decompression group had an improvement in Oswestry scores from 38.3 to 27.4 during this time period, compared to a decrease from 40.5 to 34.8 in the epidural steroid group.

Safety

The incidence of complications such as dural tears, nerve root damage, or blood loss requiring transfusion has not been adequately evaluated in clinical trials. In several observational published studies, there were no major adverse events reported. A multicenter systematic safety review and meta-analysis of 373 patients showed no reported major device- or procedure-related adverse events (incidental durotomy, epidural hematoma, infection, or bleeding requiring transfusion) (18).

Patient Screening and Trial of Therapies

Patients who complain of pain in the low back, buttocks, and legs that is worsened with activity and improved by forward flexion should be evaluated for lumbar spinal stenosis. Walking and standing tolerances should be documented in this initial evaluation for later comparison. Standardized measurement tools may be used, such as the Roland Morris Disability Questionnaire, the Oswestry Low Back Pain Scale, and the Swiss Spinal Stenosis Questionnaire.

Imaging should be obtained confirming the presence of lumbar stenosis, typically a computed tomography (CT) or magnetic resonance imaging (MRI) scan, ideally within one year of the planned procedure. For patients to be considered for minimally invasive lumbar decompression, LF hypertrophy must be found to be a contributor of the stenosis. It has been recommended that patients who have LF thickening of greater than 2 mm may be considered as candidates for the procedure. In T2-weighted sagittal sequences, images 1 or 2 cuts from midline should demonstrate knuckling of the dura secondary to the LF hypertrophy (see Figure 14.1). In T2-weighted axial sequences, images at the level of stenosis should demonstrate a classic trefoil appearance of the dura where the LF hypertrophy indents the posterolateral aspect (see Figure 14.2). Measurements of LF hypertrophy can be taken in this view from the lamina to the dura.

Preparing the Patient for Minimally Invasive Decompression

As part of obtaining informed consent from the patient, it should be explained that the goal of therapy is to improve functional status. Patients should be given reasonable expectations on improvement in outcome. For example, if a patient currently can only walk 50 meters before

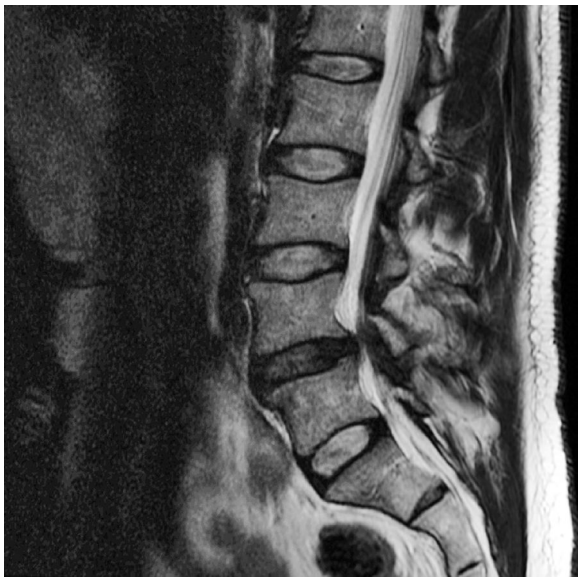

Figure 14.1 T2-weighted sagittal MRI: knuckling of the dural sac posteriorly indicates ligamentum hypertrophy.

the onset of pain, the procedure would be considered successful if he is able to improve the distance he can walk before pain becomes intolerable. Although the procedure is less invasive than full operative surgical approaches, patients should be advised that there are risks of bleeding, nerve damage, paralysis, and failure of the procedure to provide benefit.

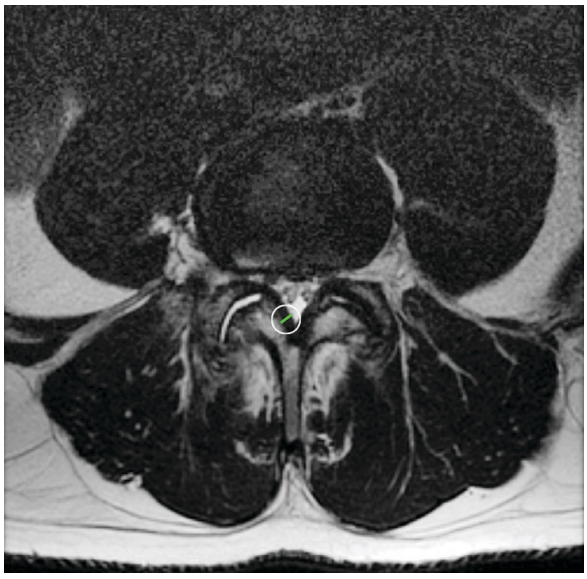

Figure 14.2 T2-weighted axial MRI: trefoil appearance of the dura indicates ligamentum flavum hypertrophy. Ligamentum flavum hypertrophy can be measured from the lamina to the dura.

Intraoperative Management

Antibiotic Prophylaxis

There are no data on whether antibiotic prophylaxis is necessary. If antibiotics are given, two grams of Cefazolin may be administered 30–60 minutes prior to the start of the procedure.

Patient Positioning, Prepping, and Draping

It is recommended that the patient be positioned prone on a radiolucent bed. The appropriate spinal area should be prepped and draped. Monitored anesthesia care with light sedation is generally used in combination with adequate local anesthetic.

Special Equipment

Figure 14.3 shows an instrument kit that is used for minimally invasive decompression. Figure 14.4 shows a typical OR setup for the procedure. In addition to the instruments shown, local anesthetic, contrast, and preservative-free normal saline should be on the surgical field. Fluoroscopy should be readily available.

Figure 14.3 Percutaneous lumbar decompression kit (mild® device kit, Vertos Medical Inc.).

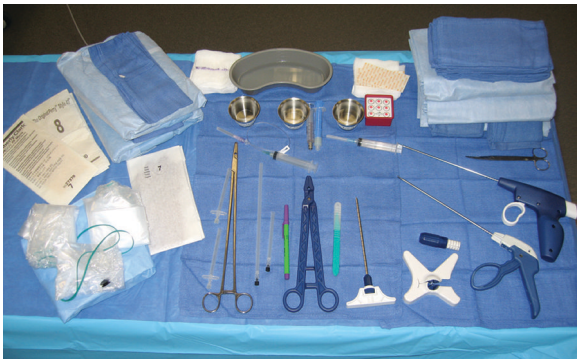

Figure 14.4 Percutaneous lumbar decompression: operating room setup.

Surgical Technique

A standard surgical "time-out" should be performed in addition to identifying the proper level and side (if unilateral) to be treated. Fluoroscopy in a true AP view is then used to mark a vertical line connecting the lumbar spinous processes. Additional vertical lines are drawn connecting the medial aspects of each pedicle.

The first step of the procedure is to perform an epidurogram. A blunt Tuohy-type epidural needle is inserted with loss of resistance technique to the superior aspect of the targeted level. A contralateral oblique view is obtained to verify an appropriate epidurogram. Figure 14.5 illustrates the contralateral oblique view. Obtaining an epidurogram at the start of the procedure is necessary in order to outline the anterior border of the procedure area. The proceduralist should avoid inserting any instruments deeper than the line of the epidurogram (also called anterior laminar line or posterior epidural line), as complications such as dural tears or epidural hematoma due to laceration of vessels may otherwise occur. After the initial epidurogram is obtained, the instrumentation for the remainder of the procedure instruments can be opened. Figure 14.6 shows the epidurogram in the contralateral oblique view.

In the AP view under fluoroscopic guidance, a spinal needle is inserted 2 pedicles below the target level, midway between the spinous process and pedicular lines drawn earlier. The spinal needle is used to identify the appropriate trajectory for portal placement. Upon contact of the lamina, adequate local anesthesia is provided to the inferior and superior lamina and the spinal needle is withdrawn. Using the same insertion point, an incision is then made with an 11-blade scalpel and the portal instrument is inserted along the same trajectory established by the spinal needle. Next the portal is docked on the posterior third of the superior surface of the inferior lamina within the treatment zone. To secure the portal in place, a stabilizer-device is placed on the portal. The trocar is removed and a depth guide is placed. Initially the depth guide is set at 0–15 mm and reduced as needed. A surgical clamp may be used as an alternative to the portal stabilizer for larger patients.

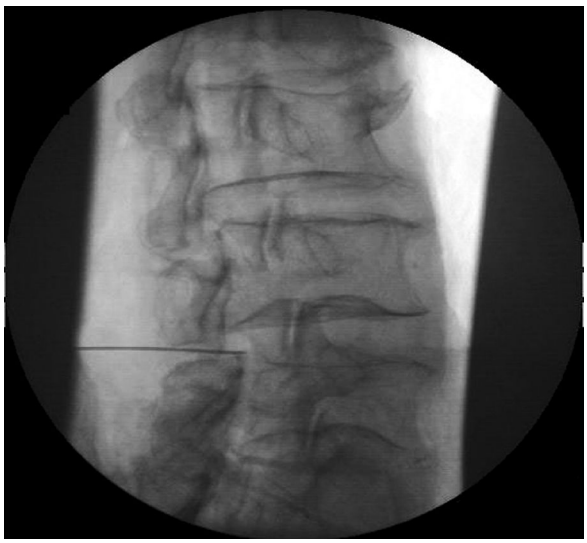

Figure 14.5 Contralateral oblique view on fluoroscopy. An epidurogram is typically performed at the superior border of the space that is to be accessed.

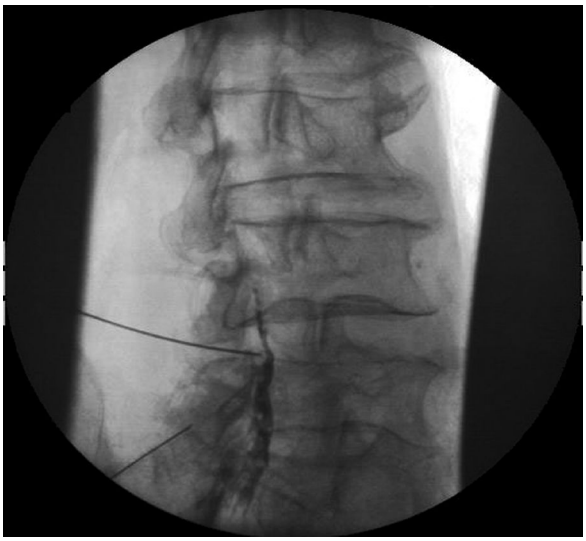

Figure 14.6 Pre-decompression epidurogram: this shows a thin epidural space caused by ligamentum flavum hypertrophy. A spinal needle can be seen approaching the inferior lamina.

A device called the "bone sculptor rongeur" is then inserted through the portal and is used to remove small pieces of lamina, starting at the inferior surface of the superior lamina. It is recommended that the bone sculptor rongeur be removed and cleaned after each piece of bone is removed. After enough bone is removed from the inferior and superior lamina, a device called the "tissue sculptor" is advanced through the portal to cut and remove sections of the hypertrophic ligamentum flavum. The sculptor device should be positioned on bottom (down) and should not be positioned superior. The sculptor will be visible in same plane as X-ray beam. After every 3 resections of ligamentum flavum by the sculptor, it should be removed from the portal and cleaned. The sculptor should always be inserted in the closed position while entering and removing from the portal. It is recommended to rotate the device slightly when entering tissue (10 degrees each way). After adequate removal of tissue and bone, an epidurogram should be repeated. Improved contrast flow patterns on epidurogram confirm that there has been decompression (see Figure 14.7). All instruments are removed from the patient together as a unit. For wound care, apply pressure, adhesive strips, and standard dressings.

Intraoperative Complications and Their Management

As with any interventional spine procedure, there are risks to this procedure. Patients may develop bleeding, infectious complications, and nerve damage. There is a risk of serious neurologic complications from rare complications such as meningitis or the development of an epidural abscess. Bleeding due to injury to epidural veins can lead to the development of an epidural hematoma. Any of these complications may lead to hospitalization and result in the need for emergency surgery on the spine. Irreversible paralysis may result. A tear in the dura may result in a spinal headache. There is no data on whether such a complication may be treated with an epidural blood patch or whether surgical repair would be necessary.

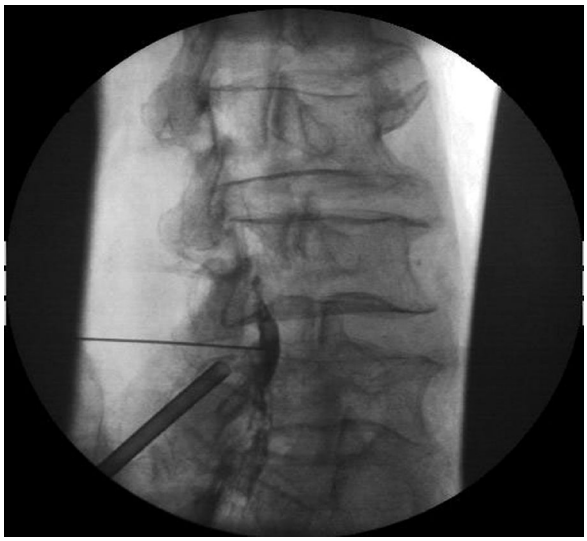

Figure 14.7 Post-decompression epidurogram: a wider epidural space can be seen representing decompression of the ligamentum flavum hypertrophy.

Postoperative Management

Common Postoperative Complications and Their Management

As with other interventional spine procedures, there is a risk of postoperative infection, including wound infection, epidural abscess, and meningitis. Bleeding and hematoma may occur after the procedure, including epidurally. There is a risk that the procedure may not lead to the desired results, leading to continued or worsened pain symptoms. An inadvertent dural tear could result in a postoperative spinal headache. Each of the complications may be managed with standard measures: antibiotics for infection, possible surgical drainage of abscess or hematoma, treatments for low cerebrospinal fluid (CSF) pressure headaches, and further pain management modalities and analgesics for continued pain.

Diagnosing and Management of Loss of Analgesia

Patients who undergo percutaneous lumbar decompression should be evaluated for functional outcomes post-procedure. Tests and questionnaires administered pre-procedure (RMDQ, Oswestry, and SSSQ) may be re-administered 1, 3, and 6 months following the procedure to evaluate for treatment efficacy. Patients who do not benefit adequately following minimally invasive decompression may remain candidates for other minimally invasive spine treatments or may be referred for further surgical evaluation.

Conclusions

Percutaneous lumbar decompression has been developed as a treatment alternative for patients with symptomatic spinal stenosis. However, in a 2014 Medicare analysis (19) regarding whether to authorize payment for the procedure, there was an adverse determination. Medicare ruled that the procedure is experimental and that payment will only be provided for patients enrolled in clinical trials. The Medicare analysis noted that there is a lack of consensus on diagnostic criteria for patients with spinal stenosis and therefore a lack of agreement on the mechanism of action by which percutaneous lumbar decompression may be beneficial. In addition, the Medicare analysis did not find the quality of the published literature to be adequate to support use of the procedure.

At this time, the future of percutaneous lumbar decompression is uncertain. Medicare reimbursement decisions are pending the development of studies that need to evaluate whether this procedure provides clinically meaningful improvement in pain, quality of life, and function compared to other treatments for spinal stenosis.

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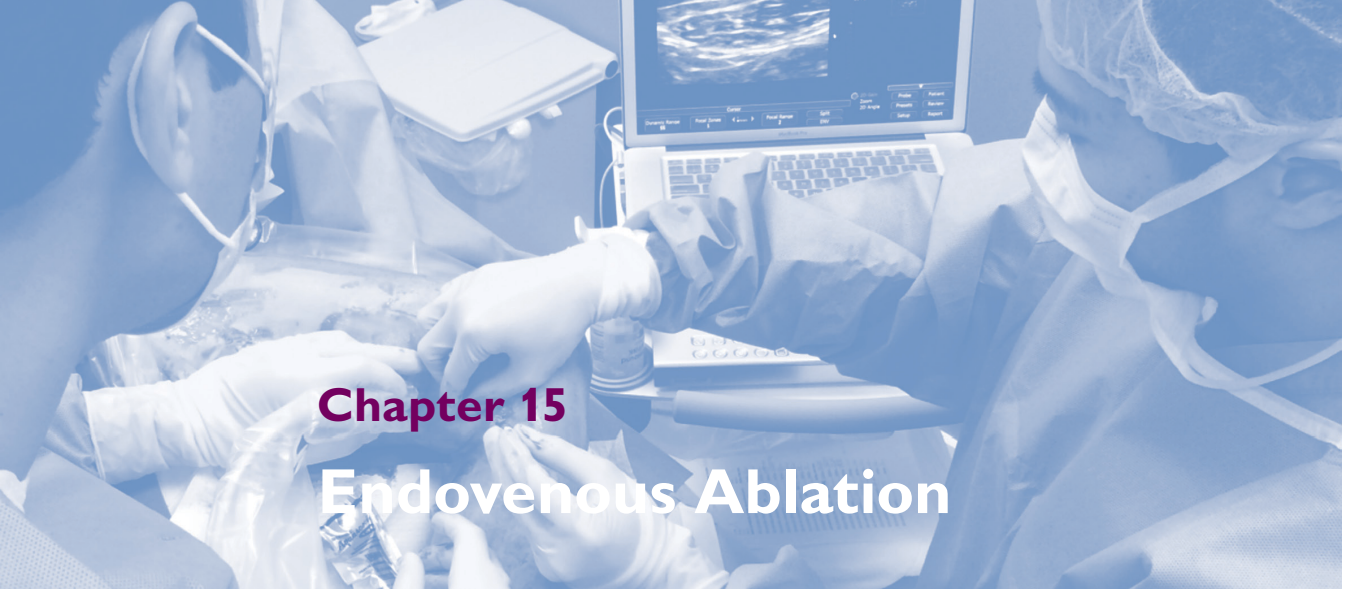

Chapter 15
Endovenous Ablation

Cyrus Ahmadi Yazdi, Michael Nguyen, and R. Jason Yong

Introduction

Epidemiology

Chronic venous disease (CVD) of the lower extremity is one of the most common diseases worldwide. Of the 25 million Americans who suffer from chronic venous insufficiency, 7 million of them have severe symptoms that manifest as varicose veins, edema, pain, skin changes, and venous ulcers (1). They are more frequent in women, and the prevalence increases with age. In addition to age and sex, occupation, lifestyle, positive family history, number of pregnancies, and geographic influences are also main risk factors. Annually, one million Americans with CVD seek medical advice. Of these, 80% of patients are managed conservatively with observation, leg elevation, and pressure stockings, while the rest are treated surgically, either with vein stripping or endovenous ablation (1, 2).

Signs and Symptoms

The clinical presentation of venous insufficiency can manifest in many different ways. The classic history of varicose veins associated with lower extremity is typically seen. However, patients may also complain of the following associated symptoms:

- lower extremity swelling
- night cramps
- leg pain—described as heaviness or dull ache after prolonged ambulation
- restless leg
- itching
- burning.

Physical exam findings include the following:

- Stasis dermatitis—chronic skin changes that are characterized by edema, hyperpigmentation, eczema, lipodermatosclerosis, and stasis ulceration
- Varicose veins (VV)
- Telangiectasias
- Spider veins
- Skin ulcers.

Clinical Classification

Chronic venous disease can be classified according to descriptive clinical, etiological, anatomical, and pathophysiological (CEAP) classification, providing a stable base for lower limb venous system status assessment (3). Table 15.1 lists the various classifications based on CEAP criteria.

Pathophysiology

The veins of the lower extremity are divided into the superficial and deep venous system. In normal veins, blood flows to the right side of the heart, driven by muscular pumps and unidirectional venous valves. In the deep venous system, muscle contractions during ambulation compress the deep veins, thus pumping the blood upward toward the right half of the heart. A thick fascial layer protects deep veins against elevated hydrostatic pressure (2).

In contrast, the superficial venous system lacks this muscular pump and is surrounded by fat and loose elastic skin. Consequently, this system is more susceptible to venous insufficiency, which typically arises from the great saphenous vein (GSV) and small saphenous vein (SSV). These chronic changes in the hemodynamics of the lower extremity veins are transmitted

Table 15.1 Clinical, Etiological, Anatomical, and Pathophysiological (CEAP) Classification

Clinical	Etiologic	Anatomic	Pathophysiologic
C0: No visible or palpable signs of venous disease	Ep: Primary	As: Superficial veins	Pr: Reflux
C1: Telangeictasias or reticular veins	Es: Secondary	Ad: Deep veins	Po: Obstruction
C2: Varicose veins	Ec: Congenital	Ap: Perforators	Pr,o: Both
C3: Edema			Pn: No venous pathophysiology
C4a: Pigmentation or eczema			
C4b: Lipodermatosclerosis			
C5: Healed venous ulcer			
C6: Active venous ulcer			
S: Symptomatic A: Asymptomatic			

Beebe HG, Bergan JJ, Bergqvist D, Eklöf, B, Eriksson, I, Goldman MP, et al. Classification and grading of chronic venous disease in the lowerlimbs: a consensus statement. *Eur J Vasc Endovasc Surg.* 1996 Nov;12(4):487–491.

into the microcirculation and ultimately result in the development of venous microangiopathy, which can produce dilation, tortuosity, and valve failure, ultimately leading to varicose veins (4).

Histologically, VVs are characterized by severe disruption of the regular architectural pattern observed in normal veins. These changes include fibrosis formation between the intima and adventitia, irregular thickening of the intima, disruption of elastic fibers, thickening of collagen fibers, and disorganization of the muscular layers (2).

Preoperative Considerations

Non-Surgical and Medical Management

Conservative management is currently restricted to compression stockings, medication, and lifestyle modification. Generally, patients are asked to wear compression stockings ranging from 20–30mm Hg with the goal of decreasing superficial varicosities. Typical conservative therapy requires 3 months of compression stockings. However, this treatment modality is met with significant noncompliance due to the discomfort and difficulty with placement.

Medication therapy is currently aimed at symptom reduction with analgesics. A trial of NSAIDs or a weak opioid can also constitute conservative therapy. Lifestyle modification includes leg elevation, regular exercise, smoking cessation, and weight loss.

Goals

The goals of therapy are to reduce symptoms related to chronic venous insufficiency. Pain is a primary endpoint that is most commonly tracked. However, if patients have venous stasis ulcers, the progression of healing can also be a marker for the success of therapy. The ultimate goal of interventional therapy is to eliminate flow through the superficial venous system and shunt venous flow into the deeper veins.

Advantages

Minimally invasive interventional therapies offer many advantages over conservative therapy and more aggressive surgical therapies. Endovenous laser ablation (EVLA), radiofrequency ablation (RFA), and ultrasonography (USS)-guided foam sclerotherapy are the most common minimally invasive procedures to treat varicose veins (5). These procedures are safe and effective ways of eliminating reflux with very low morbidity, faster recovery, and improved cosmesis.

Patient Screening and Trials of Therapy

Planning for treatment is based on the identification of the source, as well as the highest and lowest point of reflux. Reflux is the major indication for treatment. The ultrasound examination of the superficial venous system is performed in the supine and standing positions, either by an ultrasonographer or a physician trained in obtaining this exam (Registered Vascular Technologist certification). As a general rule, reflux in the GSV will result in varicose veins in medial thigh, and reflux in the SSV will cause varicosity in the posterior thigh (5). Three major different maneuvers can be performed to assess the reflux.

1. Augmentation: The calf is squeezed below the transducer; if there is retrograde flow for more than one second, the examination is positive.
2. Valsalva maneuver: Increased intra-abdominal pressure can cause backflow through incompetent valves. This technique is only sensitive in the upper thigh.
3. Retrograde compression: Direct compression of the vein above the transducer is applied. Visualized retrograde flow is consistent with an incompetent valve. Furthermore, if the GSV diameter is greater than 6 mm, reflux is very likely (5).

Patients who are pregnant, coagulopathic, have deep vein thrombosis or active infections, or are unable to ambulate postoperatively are not good candidates for endovenous ablation. The ability to ambulate is a necessity to avoid deep venous thrombosis and to also facilitate venous circulation via the calf muscle pump (6).

Alternative Treatments and Procedures

Alternatives to endovenous ablation involve continued conservative therapy or open surgical procedures. The aforementioned conservative therapy includes compression stockings, medication, and lifestyle modification. Open surgical techniques are also known as vein stripping. In vein stripping, incisions are made over opposite (proximal and distal) ends of the target vein and a special wire is then advanced through the proximal end of the vein until it is retrieved on the distal end. The wire is then secured to the proximal end of the vein. The vein is then pulled out of the body via the distal end, the incisions sutured, and pressure dressings applied. Compared with vein stripping, endovenous ablation offers lower morbidity, faster recovery, and improved cosmesis (7).

Preparing the Patient for Surgery

Surgical risks such as surgical site infection, bleeding, deep venous thrombosis development, skin discoloration, and nerve damage should be discussed with patients before the procedure. Patients are asked not to shave their legs prior to the procedure to reduce the risk of skin irritation from the skin prep. Also, compression stockings should be purchased and tried before surgery to ensure comfort. Most of these procedures are performed under local anesthesia without sedation. Procedural consent and marking are performed prior to surgery.

Radiofrequency Ablation Versus Laser Ablation

The efficacy of endovenous ablation is typically evaluated in terms of percentage of venous occlusion. The data comparing different methods of vein ablation are very limited. Randomized trial evidence suggests that in the postoperative period, RFAwill produce less tenderness and morbidity than EVLA with uncovered laser fibers (7, 8). A study by Almeida et al. showed lower rates of post-procedure pain ($p < .0001$ at 2 weeks), tenderness ($p < .0005$ at 2 weeks), and bruising ($p = .005$ at 1 month) in the RFA group than the laser group. Quality of life scores were also higher in the RFA group at 1 ($p = .006$) and 2-week ($p = .0034$) follow-up. There was no difference in quality of life scores between two treatment groups at one month; also rates of return to usual activity and work were similar. Complete ablation (to within 5 cm of SFJ) was obtained in 88% (51/58) of the RFA procedures and 84% (26/31) of the ELT procedures at 6 weeks (9).

Intraoperative Management

Antibiotic Prophylaxis

Antibiotic prophylaxis is not required for this procedure.

Patient Positioning, Prepping, and Draping

See Figure 15.1 for a sample room setup. Once the patient is brought to the procedural suite, the patient is positioned supine on the operating room table and placed in reverse Trendelenburg position to optimize venous dilation. After positioning, the entire lower extremity is prepped with chlorhexidine or povidone-iodine. Figure 15.2 illustrates proper patient positioning and draping. The distal foot is wrapped into a sterile dressing, and then a transverse laparotomy drape is placed to expose the operative area.

Figure 15.1 Sample room setup. Ample space is necessary for easy access to the patient from both sides of the table. Further space must be available for the endovenous ablation generator, tumescent pump, vital signs monitor, and ultrasound machine.

Figure 15.2 Proper positioning of the patient. The patient is in the supine position with the hip externally rotated and the knee flexed at a 90-degree angle. The ultrasound machine is placed in a position to allow the interventionalist easy visualization.

Special Equipment

Ablation generator: Either laser or RF ablation generators can be used. The RECOVERY trial suggests that RF ablation produces less pain and bruising (10). The RF system in Figure 15.1 operates at a range of 15–40 watts and a target temperature of 120°C.

Ultrasound probe: A linear probe is used to access the vein and should be adequate to provide visualization of target veins in most cases. In situations where the anatomy is difficult and visualization is poor, a hockey stick linear probe can be used.

Wires: We use a 0.018-inch guide wire supplied by Covidien for the procedure. However, certain circumstances require steerable wires. In these situations, we also carry an angled 150-cm hydrophilic guide wire, 0.89-mm, and an angled 150-cm hydrophilic guide wire, 0.64 mm.

- 21-gauge needle with guide wire
- A micro-introducer sheath of varying sizes (6F, 7F, 8F) with tapered 2F tip
- Tumescent anesthetic solution containing lidocaine 1%, epinephrine 1:1000, and sodium bicarbonate 8.4% (10)

Surgical Technique

Endovenous ablation involves ultrasound guidance to ensure proper placement of an ablation catheter. First, a guide wire is placed in the targeted vein under ultrasound guidance via a 21-gauge needle. A micro-introducer sheath of varying sizes, usually 6F, 7F, and 8F with a tapered 2F tip, is then placed over the guide wire. The initial sheath guide wire is then removed, and confirmation of venous placement of the sheath is confirmed with longitudinal and transverse ultrasound views as well as successful aspiration of venous blood from the sheath.

Once the position is confirmed, a 0.018-inch guide wire is then inserted through the sheath. The wire is followed throughout the course of the targeted vein until the endpoint is reached. For ablation of the great saphenous vein, the endpoint is 2–3 cm from the site of the sapheno-femoral junction. Careful positioning is required at this point, making sure to be at least 2 cm distal to the sapheno-femoral junction and caudal to the superficial inferior epigastric vein. For ablation of the small saphenous vein, care must be taken to be distal to both the junction of the small saphenous and popliteal vein and the junction of the small saphenous and gastrocnemius vein. See Figures 15.3, 15.4, and 15.5 regarding ultrasound images for GSV ablation.

After confirmation of the guide-wire position, an endovenous ablation catheter is then threaded over the guide wire under ultrasound guidance. Once position is confirmed, the

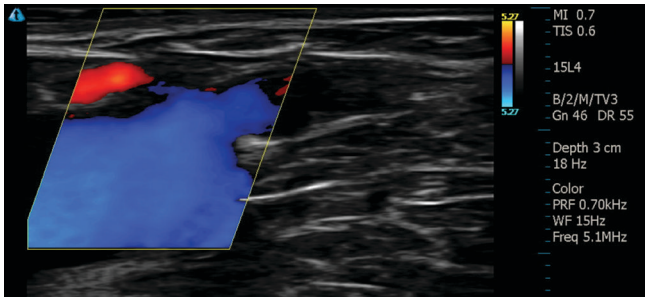

Figure 15.3 Saphenofemoral junction with patent GSV.

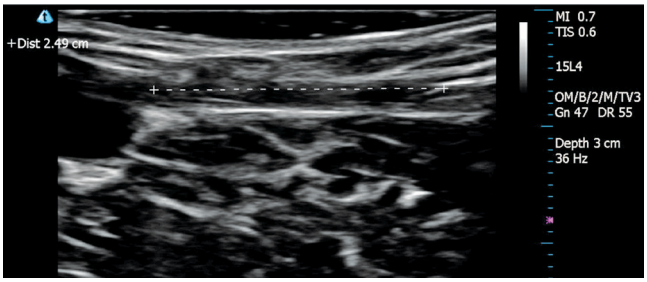

Figure 15.4 Saphenofemoral junction of patient with RF ablation catheter tip 2.49 cm from the junction.

endovenous ablation catheter length at the entry point is marked and the 0.018-inch guide wire is removed.

The patient is then placed in Trendelenburg position to minimize venous dilation. Tumescent anesthetic solution (10) (containing lidocaine 1%, epinephrine 1:100,000, and sodium bicarbonate 8.4%) is then injected around the tissue surrounding the targeted vein and along its entire length. The purpose of the tumescence is to anesthetize the vein, dissipate probe heat, and to compress the vein, thereby increasing contact of the vessel wall with the probe. Some centers use neuraxial or general anesthesia for the procedure, while others uses conscious sedation without the supervision of an anesthesiologist. At our institution, we prefer to do this completely under local, as this offers the advantage of knowing when there is inadequate tumescent anesthesia—thereby decreasing the chance of tissue damage.

Once tumescent anesthesia is applied, the RF or laser generator is then activated and the catheter is slowly withdrawn along the length of the target vein. When using the RF ablation generator by Covidien, the ablation is done segmentally. When using a laser generator, the wire is slowly withdrawn at a steady interval. At the end of the procedure, hemostasis is achieved by applying pressure over the access sites. To reduce the risk of venous thromboembolism and postoperative bruising and pain after the procedure, compression stockings and bandages are applied. After the procedure, patients are asked to walk immediately. A follow-up ultrasound study is usually performed within one week to evaluate results and to rule out thromboses. Follow-up protocols may vary but most patients are seen at one month and 3 months post-ablation for their follow-up visit (1).

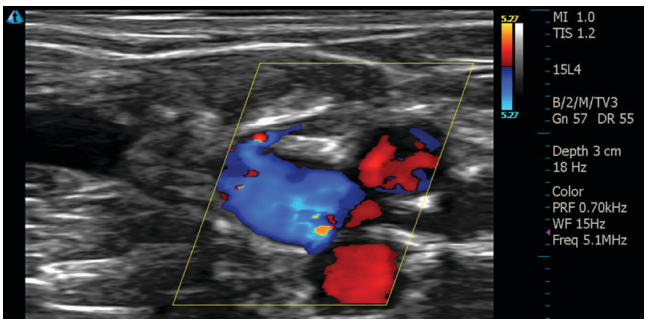

Figure 15.5 Saphenofemoral junction s/p RF ablation, revealing no flow of GSV with continued patency of femoral vein.

Common Intraoperative Complications and Their Management

A. Difficulty accessing targeted vein: Most cases of difficult access are secondary to venospasm or the smaller size of targeted veins. The following is a list of causes and how this difficulty can be prevented.
   1. Dehydration: It is recommended that patients adequately hydrate themselves prior to the procedure.
   2. Anxiety: Anxious patients may have increased risk for venospasm. Giving Valium preoperatively and playing light, relaxing music in the background will help minimize this.
   3. Temperature: To further prevent venospasm, the room temperature should not be overly cold. Some clinics have had success using heating pads.
   4. Medication: It is recommended to exclude epinephrine from the local anesthetic used to make the skin wheal at the site of venous access.

B. Pain: Severe patient discomfort during the case is an ominous sign that there is inadequate tumescent around the target vein. The procedure should be paused immediately. Before administering more tumescence, confirmation of catheter position with direct ultrasonographic visualization is important. Once proper catheter position is confirmed, further tumescent anesthesia should then be applied to the inadequate area to disperse the heat, thereby preventing tissue damage.

C. Nerve damage: Knowledge of lower extremity anatomy is paramount. When ablating veins, care must be taken to avoid concurrent thermal damage to the surrounding nerves. For example, when ablating the great saphenous vein, avoid ablating below the knee where the saphenous nerve runs close to the great saphenous vein.

D. Difficult anatomy: In patients with prior vein stripping or venous ablation, the target vein may be malformed, making the advancement of guide wire sometimes impossible. For these cases, it is recommended to create multiple access points each with their own sheath for multiple separate ablations.

Case Study

A 51-year-old female with a past medical history of hypertension presents with 3 years of left lower extremity leg pain. The patient describes her pain as an achy, crampy pain that is worse at night. Her pain is alleviated by leg elevation and exercise. The patient had a recent normal MRI and also failed Gabapentin 300 mg PO TID. Physical exam is only significant for spider and reticular veins of her left lateral leg (see Figure 15.6). There are no varicose veins present. Lab studies reveal that her electrolytes and metabolic profile are within normal limits.

A unilateral venous duplex ultrasound reveals significant left GSV reflux of 4900 ms and a sapheno-femoral junction size of 6.8 cm. The patient then undergoes left GSV RF ablation with successful closure of her left GSV. The patient returns on postop day 3, reporting that her left-sided leg pain is completely resolved.

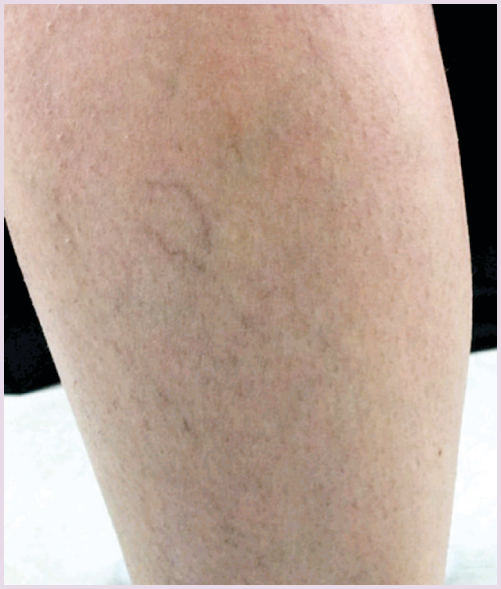

Figure 15.6 Spider and reticular veins.

Clinical Pearl

The classic physical exam findings of patients with chronic insufficiency consist of varicose veins and skin changes such as lipodermatosclerosis or ulcers. However, this is not the case for all patients. For patients presenting with unexplained lower extremity pain with minimal physical exam findings, an ultrasound duplex study can be useful in identifying venous stasis as a source of pain.

Conclusion

Chronic venous disease (CVD) of the lower extremity is a common clinical entity, and if left untreated, may result in pain and chronic leg ulcer. The primary pathophysiology of venous insufficiency is increased intravenous pressure and reflux of the blood back to the lower extremity. There are defined ultrasound features for diagnosis of venous insufficiency. Interventional treatments are considered when conservative management has failed. Endovenous laser ablation (EVLA), radiofrequency ablation (RFA), and ultrasonography (USS)-guided foam sclerotherapy are among the most common interventional procedures. These treatments are safe, effective, and offer the significant advantage of rapid recovery.

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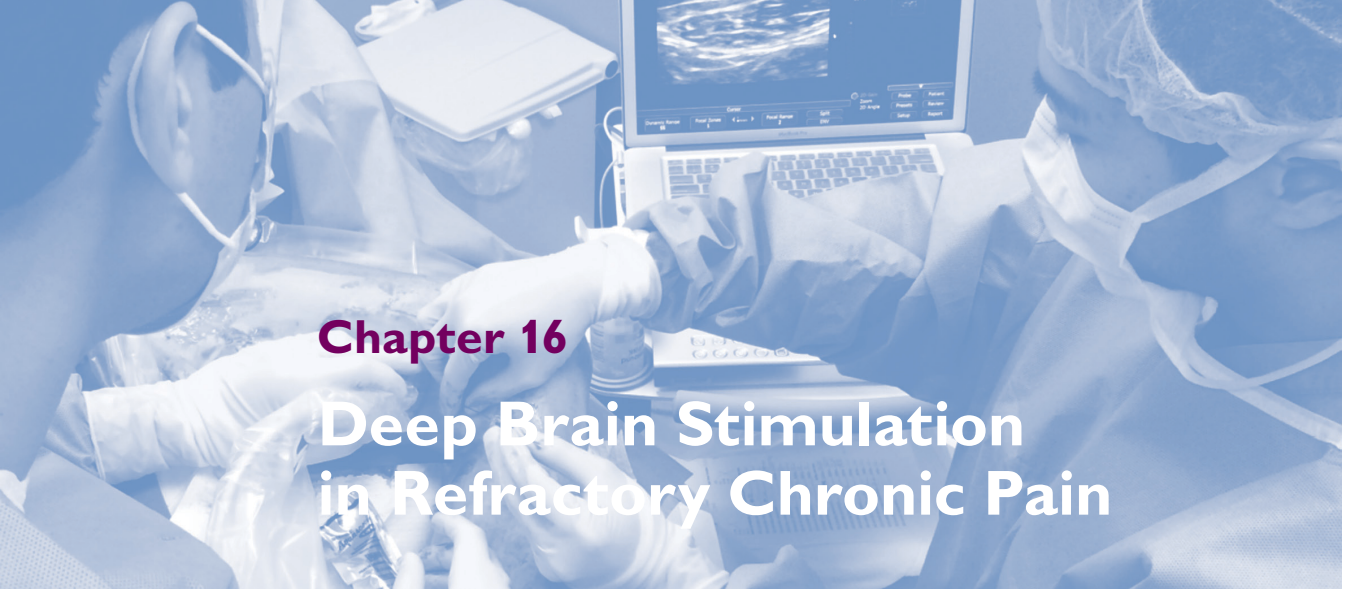

Chapter 16

Deep Brain Stimulation in Refractory Chronic Pain

Mohammed Jeraq, Ahmed Bayoumi, Ekkehard M. Kasper, and Travis S. Tierney

Introduction

Although deep brain stimulation (DBS) has been FDA approved for a number of indications, including essential tremor, parkinsonism, primary dystonia, and obsessive compulsive disorder (1–6), DBS is still considered an "off-label" option when used to treat refractory pain (7). Over the last 30 years, many promising case series have accumulated documenting the effectiveness of DBS for various forms of chronic pain, but there is still a need for definitive randomized clinical trials to provide clear evidence-based proof of the safety and efficacy of DBS in these difficult-to-treat conditions. Its inclusion in this book is more informational in nature, as only neurosurgically trained pain management practitioners would perform these procedures, and interested readers are referred to more exhaustive texts on functional neurosurgery for technical details.

Historically, several neuromodulatory pain targets have been investigated, beginning in the 1950s with the seminal observations of Heath and Mickle that septal stimulation ameliorated intractable pain (8). Two modern articles on septal stimulation were published by Schvarcz (9,10), with a success rate approaching 60%, but long-term follow-up did not support its efficacy (11). The periaqueductal/periventricular gray regions (PAG/PVG) in the midbrain (12,13) and ventrocaudal nucleus (Vc) of the sensory thalamus (14,15) have emerged as the two most common contemporary targets aimed at alleviating pain of nociceptive and neuropathic origin, respectively. Other less-studied DBS targets for chronic pain include the centromedian/parafascicular region (CM-Pf) of the thalamus (16), the internal capsule (17), and the posterior hypothalamus for cluster headache (18). Recently, Boccard and colleagues have stimulated the anterior cingulate cortex (ACC) in patients with chronic neuropathic pain in the hope of modulating the affective component of pain (19). Similar promising work is now also being pursued at the ventral capsule/ventral striatum (20).

Patient Selection and Indications

Patient selection by an experienced multidisciplinary team of clinicians, including a psychiatrist, neurosurgeon, neuropsychologist, and pain specialist, will enhance outcomes and reduce complications (21). In addition, patients should be thoroughly counseled about pain reduction, possible complications, and alternatives in order to set optimal preoperative expectations. For example, subjective pain reduction of 50% may be considered a successful outcome for some patients but may be unsatisfactory for others.

Failure of optimal medical therapy, including long-term high-dose tricyclic antidepressants, physical therapy, and biofeedback—together with a thorough psychological evaluation to exclude most major Axis I disorders and secondary gain—are absolute requirements for surgery. Major depression and generalized anxiety disorders are comorbid psychiatric conditions that almost always accompany chronic pain and should not be considered surgical contraindications. The severity of pain is more important than chronicity, but most centers will wait at least 6 months from the onset of pain before considering surgery. Conventional contraindications for DBS, including uncorrectable coagulation disorders, dementia, pregnancy, and inability to undergo an MRI, also apply to surgery for chronic pain. In addition, neurotic and uncooperative patients are poor candidates for techniques that require a patient's subjective judgment for perioperative assessment and intraoperative compliance. Finally, all patients must be willing to undergo prolonged long-term follow-up for pulse generator programming and postoperative medical management.

Assessment

Pain is an extremely challenging complaint to assess, as it is subjectively evaluated by patient self-report. Visual analogue scores (VAS) for reporting pain may not fully reflect clinical improvement in function and quality of life, suggesting limitations of the VAS as an assessment tool. The emergence of a late tolerance phenomenon or the unmasking of other types or regions of pain, concomitant with increased patient activities of daily living, may interfere significantly with global functional outcomes and study findings. Therefore, pain must be evaluated from both quantitative and qualitative perspectives by expert staff, using not only pain-scoring grades but quality-of-life instruments, such as the short-form 36-question quality-of-life survey (SF-36), McGill pain questionnaire, and EuroQol-5D questionnaires, which reflect the impact of pain modification upon daily activities (21,22).

Pain Pathways

There are two main pathways thought to be responsible for pain transmission, the lateral pain system and the medial pain system, both of which can be modulated by DBS. The lateral pain system is represented by the lateral spinothalamic tract, which connects to the ventral posterior lateral (VPL), ventral posterior medial (VPM), and ventral posterior inferior nuclei of the thalamus, which then project to the primary and secondary somatosensory areas. Damage to this system can cause chronic neuropathic pain with or without allodynia and hyperalgesia. The medial pain system connects the spinothalamic tract to the medial thalamic nuclei, limbic cortices, anterior cingulate cortex, and reticular formation. It is responsible for affective perception, as well as the emotional component of pain.

Target Selection

We will focus here on the two targets that have been frequently used over the last decade: the periaqueductal/periventricular gray (PAG/PVG) and the ventrocaudal nucleus (Vc) of the thalamus for nociceptive pain and neuropathic pain, respectively. In practice, many centers target both PVG and Vc in the same patient and later determine optimal responses during the trial phase (23). As with other standard stereotaxic procedures, we use a contrasted T1-weighted MRI, volumetrically fused with an in-frame high-resolution CT to identify the commissural plan and specific targets using indirect anatomical methods (see Figure 16.1). The target is then confirmed and adjusted intraoperatively by electrophysiological testing using microelectrode recording and/or macrostimulation. We seek to confirm that the regional area of pain is completely covered by an altered sensation, described by patients as warmth or tingling, which is more tolerable than pain.

Ventrocaudal Nucleus of Thalamus

The ventrocaudal nucleus (Vc) is also called the sensory nucleus of the thalamus and is organized somatotopically into two parts: the ventroposterolateral nucleus (VPL), which receives pain sensation from the contralateral half of the body; and the ventroposteromedial nucleus (VPM), which receives pain sensation from the contralateral half of the face. It is bounded laterally by the internal capsule, medially by the centromedian and parafascicular nuclei,

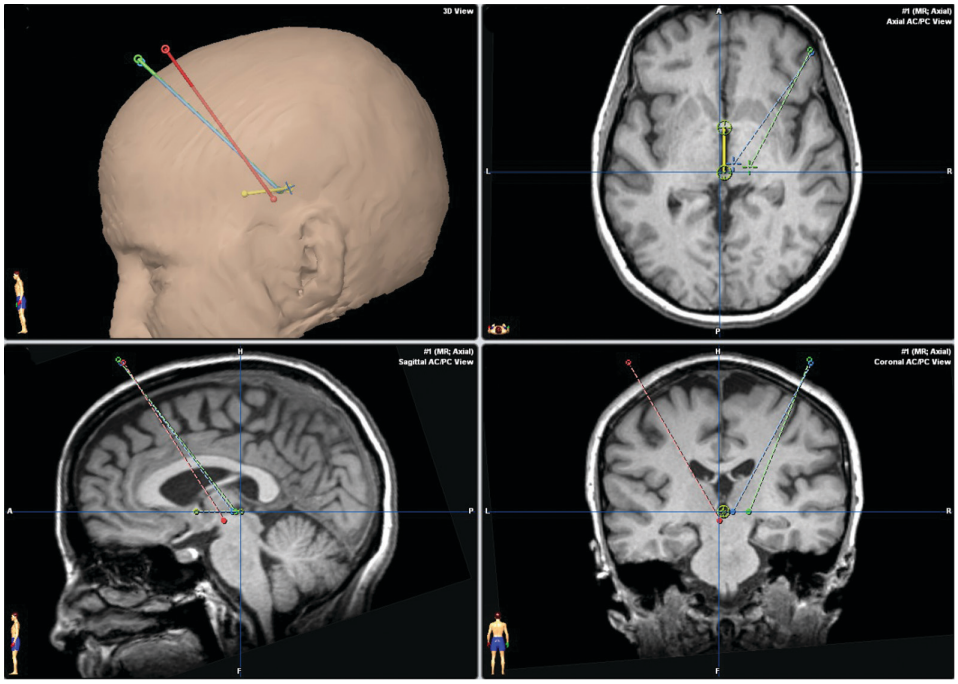

Figure 16.1 Selected deep brain stimulation targets for intractable pain with trajectories from pre-coronal burr holes. The intercommissural line is shown in yellow. An approach to the left posterior hypothalamus is shown in red. On the right side, ventralis caudalis and periventricular gray targets are shown in green and blue, respectively. Note that a number of targets for chronic pain are near the midline and often require trajectories with ventricular transgressions.

anteriorly by the motor thalamus, posteriorly by the pulvinar, and inferiorly by the thalamic fasciculus and zona incerta. On standard 1.5 Tesla images or CT, the borders of the sensory thalamus are indistinct from surrounding nuclei, and a method of indirect targeting is generally employed. Vc targets are found 3–5 mm anterior to the posterior commissure, and from 3 mm below to 2 mm above the intercommissural plane (see Table 16.1). In the mediolateral plane, VPM is located midway between the lateral wall of the third ventricle and the internal capsule about 12–14 mm from midline. The "arm area" is further lateral, about 14–16 mm from midline, and the "leg area" is located still further laterally by another 2–3 mm. A combination of intraoperative microelectrode recordings and microstimulation is then used to map receptive fields and precisely lateralize the optimal stimulation area intraoperatively (24).

Trial stimulation with lower frequencies (≤ 50 Hz) usually has better analgesic effects compared with higher frequencies (≥ 70 Hz), which may often produce hyperanalgesia. Stimulation of 5–50 Hz is performed initially, with pulse width 200–450 μs, and amplitude 0.5–5 V (23). In a large retrospective evaluation of 76 patients implanted with chronic stimulators in the thalamic somatosensory area for deafferentation pain, 44 patients reported substantial pain relief for longer than 2 years (25). In another series of 84 patients with deafferentation pain, Levy and his colleagues reported that 61% had initial success, but only 30% had long-term success after at least 2 years (26).

Periventricular/Periaqueductal Gray Area

Periventricular/periaqueductal gray area (PVG/PAG) has been shown to be effective for nociceptive pain as well as other types of pain. The target is located 2–3 mm lateral to the third ventricle at the level of the posterior commissure, 10 mm posterior to the midcommissural point. It is bounded laterally by the medial lemniscus, superior colliculus inferoposteriorly, and the red nucleus inferoanteriorly. Hosobuchi and colleagues reported that PAG stimulation was effective in 6 patients (3 carcinoma pain patients, 1 diabetic neuropathy, 1 sacral chordoma, and 1 facial anesthesia dolorosa) (13). Side effects reported in literature include nystagmus, vertigo, nausea, and ocular manifestations (e.g., oscillopsia, ocular fluttering, and/or eye bobbing) (11). More recent work by Boccard and colleagues reported a success rate ranging from 50% after brachial plexus injury to 89% after amputation (23).

Table 16.1 Suggested Nominal Indirect Stereotactic Coordinates for Four DBS Targets Used to Treat Intractable Pain Based on Distances in mm From Points Located Along the Intercommissural Line

	X—Lateral to MCP	Y—A/P	Z—D/V
Vc	12–18	3–5 anterior to PC	−3 to +2 from ICP
PVG/PAG	3	0–3 anterior to PC	−2 to +3 from ICP
CM	8–10	−1 to +6 from PC	At ICP
PH	3–4	−3 from MCP	−5 below ICP

AC: anterior commissure
A/P: anterior/posterior
CM: centromedium/parafasicular nuclei of the thalamus
D/V: dorsal/ventral
MCP: midcommissural point
PH: posterior hypothalamus
PVG/PAG: periventricular/periaqueductal gray
ICP: intercommissural plain
Vc: ventralis caudalis

Other Targets

The centromedium parafasicular (CM-Pf) complex is a unique structure of the caudal intralaminar nuclei of the thalamus with characteristic morphology and is implicated in the processes of arousal, cognition, sensation, and pain control. This complex is densely connected with the sensorimotor striatum and limbic system (27). It is suspected to play a major role in the modulation of pain, specifically through the medial pathway of pain. Medial thalamotomies were used as an early treatment for chronic pain, and more recently it has been shown that DBS at this complex initially yields excellent pain control, although long-term follow-up has yet to be reported (28,29). Stimulation of the posterior hypothalamus (PH) has been shown to be effective for patients with intractable cluster headache. Fontaine and colleagues reported on 11 patients in a prospective crossover, double-blind, multicenter study assessing unilateral hypothalamic DBS, reporting a success rate of 60% over the open phase of the trial (30). In a smaller study, Seijo and colleagues targeted the PH for 5 patients, with 2 patients becoming totally pain free, 2 patients experiencing a 90% reduction in pain, and 1 patient having a 50% reduction in the frequency of the original attacks (31). Long-term results were also reported by Piacentino and his colleagues on 4 patients who experienced a reduction in pain intensity in excess of 50% for more than 5 years (32). Side effects reported by Fontaine included transient visual disturbances, hemiparesis, micturition, and syncope (30).

Complications

In general, complications of DBS include stroke (< 1%), seizures (< 1%), hemorrhage (0.3%), death (0.1%), and infection (5%) (33). IPG revision surgery is required every 3–5 years due to limited battery life. Lead revisions have also been reported due to breakage following falls or tolerance. Specific side effects for different targets of DBS have been frequently reported in case series. These have prompted investigators to optimize both patient selection criteria and surgical technique to avoid neuromodulation of nearby structures. Table 16.2 provides a listing of reported side effects, pooled from a review of the literature on various DBS targets (11).

Table 16.2 Reported Side Effects of DBS for Chronic Pain by Target

DBS Targets	Side Effects
PVG/PAG	Oscillopsia, ocular fluttering, nausea, dysconjugate vertical eye movements, blurring vision, eye bobbing, pleasant feeling of warmth
Vc	Paraesthesia and rapid stimulation tolerance
PH	Transient visual disturbances, hemiparesis, micturition, vertigo, syncope, myosis, euphoria, diplopia, hemorrhage of the 3rd ventricle
CM-Pf	Feeling of warmth and visual effects

Overall Outcomes

DBS for the treatment of refractory chronic pain has been performed since the 1970s. Despite this history, and some promising case series, it has not been established as a standard treatment for intractable pain. Trial designs assessing the efficacy of DBS for pain have been limited by the lack of adequate placebo controls and long-term follow-up. A meta-analysis by Bittar et al. (34) suggested that DBS may be more effective for the treatment of nociceptive pain, rather than deafferentation pain (63% vs. 47% long-term success rate), and when deafferentation pain was divided into central and peripheral etiologies, it was found that DBS was successful in 51% of patients with peripheral etiologies, as opposed to only 31% of those who have a central etiology.

Summary

DBS is not currently FDA approved for the management of refractory pain, although a number of promising targets have emerged. These include stimulation of the sensory thalamus for chronic neuropathic pain, periventricular gray areas for intractable nociceptive pain, and the posterior hypothalamus for severe cluster headaches. Further work on the basic mechanisms of pain relief by DBS and well-designed clinical trials incorporating long-term placebo controls are much needed.

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Appendix 1

ASRA Anticoagulation Guidelines

Jules H. Y. Huang

These are guidelines only. This is a summary derived from the American Society of Regional Anesthesia and Pain Medicine Evidence-Based Guidelines (3rd edition). ASRA is not responsible for errors, use in any particular patient, or complications. New guidelines are expected around the time of publication and will supersede the guidelines below.

Table A1.1 ASRA Anticoagulation Guidelines 2010

SQ Unfractionated Heparin (UFH)—DVT Prophylaxis	
Mechanism of Action: Heparin binds to antithrombin III (AT). Heparin-bound AT accelerates its ability to inactivate thrombin (factor IIa), factor Xa, and factor IXa, reducing formation of fibrin clot.	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	No contraindication with SQ UFH of 5000 U twice-daily dosing
Time to wait after catheter is placed before RESTARTING MEDICATION	No current recommendation for twice-daily dosing. Felt to be safe at any interval.
Time to wait after last dose before REMOVING CATHETER	No current recommendation for twice-daily dosing. Felt to be safe at any interval.
Time to wait after catheter is removed before RESTARTING MEDICATION	No current recommendation for twice-daily dosing. Felt to be safe at any interval.
Heparin dose > 10,000 U or thrice-daily UFH	Unclear association with increased risk of spinal hematoma. Risk and benefits of TID UFH be assessed on an individual basis. Apply techniques to facilitate new/progressive neurological deficits. Minimize sensory and motor block.
Comments	Due to risk of heparin-induced thrombocytopenia, check platelet count before neuraxial block and catheter removal.
IV UFH—Systemic Heparinization	
Mechanism of Action: Heparin binds to antithrombin III (AT). Heparin-bound AT accelerates its ability to inactivate thrombin (factor IIa), factor Xa, and factor IXa, reducing formation of fibrin clot.	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	No recommendation offered
Time to wait after catheter is placed before RESTARTING MEDICATION	Delay administration for 1 hr after needle placement.
Time to wait after last dose before REMOVING CATHETER	Remove indwelling catheters 2–4 hrs after last dose of heparin and assess patient's coagulation status
Time to wait after catheter is removed before RESTARTING MEDICATION	Restart heparin 1 hr after catheter removal
Bloody or difficult neuraxial placement	No data to support mandatory cancellation. Direct communication with the surgeon and a specific risk-benefit decision should be undertaken preceding the case.
Cardiac surgery	Insufficient evidence available to determine increased risk of neuraxial hematoma when combining neuraxial anesthesia with full anticoagulation of cardiac surgery

Table A1.1 Continued

Low Molecular Weight Heparin (LMWH)—OVERVIEW	
Mechanism of Action: LMWH binds to ATIII, but has higher anti-Xa than anti-IIa activity when compared to UFH. Xa is important for conversion of prothrombin to thrombin.	
Intervention	**ASRA Guidelines/Recommendations**
Preoperative dose (general surgery dose)	Avoid neuraxial techniques in patients who were administered a dose of LMWH 2 hours preoperatively
Anti-Xa Levels	Avoid the routine use of monitoring anti-Xa levels
Concomitant use of drugs affecting hemostasis	Avoid these medications (e.g., antiplatelet drugs, standard heparin, or dextran) regardless of the LMWH dosing regimen
Bloody or difficult neuraxial placement	Does not necessitate postponement of surgery. Initiation of LMWH therapy in this setting should be delayed 24 hrs postop and this be discussed with surgeon.
LMWH—DVT Prophylaxis: Lovenox 30-40mg SQ Once Daily	
Mechanism of Action: LMWH binds to ATIII, but has higher anti-Xa than anti-IIa activity when compared to UFH. Xa is important for conversion of prothrombin to thrombin.	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	Initiate needle placement **at least 10 to 12 hours** after last LMWH dose
Time to wait after catheter is placed before RESTARTING MEDICATION	**First LMWH Dose:** 6 to 8 hours postoperatively **Second LMWH Dose:** should occur no sooner than 24 hrs after the first dose **Indwelling neuraxial catheters *may be safely maintained***
Time to wait after last dose before REMOVING CATHETER	**Minimum of 10 to 12 hours** after the last dose of LMWH
Time to wait after catheter is removed before RESTARTING MEDICATION	Restart LMWH a **minimum of 2 hours** after catheter removal
LMWH—Therapeutic and Twice-Daily Dosing Regimen	
Enoxaparin (1 mg/kg every 12 hrs or 1.5 mg/kg daily) **Dalteparin** (120 U/kg every 12 hrs or 200 U/kg daily) **Tinzaparin** (175 U/kg daily) Mechanism of Action: LMWH binds to ATIII, but has higher anti-Xa than anti-IIa activity when compared to UFH. Xa is important for conversion of prothrombin to thrombin.	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	Delay needle insertion ***at least 24 hours***
Time to wait after catheter is placed before RESTARTING MEDICATION	Administer ***no earlier than 24 hours postoperatively*** regardless of anesthetic technique and only in the presence of adequate surgical hemostasis. **Indwelling catheters *should be removed before initiation* of LMWH treatment**.

(*continued*)

Table A1.1 Continued

Time to wait after last dose before REMOVING CATHETER	If continuous technique, epidural catheter may be left indwelling overnight, but ***must be removed before the first dose of LMWH***
Time to wait after catheter is removed before RESTARTING MEDICATION	Restart LMWH **a minimum of 2 hours** after catheter removal
Twice-daily dosing	**Associated with increased risk of spinal hematoma**
Warfarin	
Mechanism of Action: Inhibits Vitamin-K dependent synthesis of calcium-dependent clotting factors: Factors II, VII, IX, X, protein C, protein S	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	**Discontinue the anticoagulant therapy 4–5 days** before planned procedure **AND** Check INR is **less than 1.5**
Time to wait after catheter is placed before RESTARTING MEDICATION	**Low-dose warfarin therapy during epidural analgesia**: monitor INR on a daily basis perform neurologic testing routinely tailor anesthetic to minimize the degree of sensory and motor blockade
Time to wait after last dose before REMOVING CATHETER	**INR less than 1.5** Remove the neuraxial catheter and continue neurologic assessment for at least 24 hrs. **INR between 1.5 and 3** Review concurrent meds with altered hemostasis capabilities, remove indwelling catheters with caution. Assess the neurologic status before catheter removal and continue until INR has stabilized. **INR greater than 3** Hold or reduce the warfarin dose in patients with indwelling neuraxial catheters. **Therapeutic INR level** No specific recommendation regarding management to facilitate removal of neuraxial catheters
Time to wait after catheter is removed before RESTARTING MEDICATION	No recommendation offered
1st dose given > 24hrs prior to surgery	Check INR before neuraxial block
Concomitant use of drugs affecting hemostasis	Avoid concurrent use of medications that may increase the risk of bleeding without influencing the INR (ASA, NSAIDS, ticlopidine and clopidogrel, UFH, and LMWH)
Side note for INR	INR of 1.5 correlates with clotting factor activity levels greater than 40%, which is associated with normal hemostasis. First 1 to 3 days after discontinuation of warfarin therapy, the coagulation status (reflected primarily by factor II and X levels) may not be adequate for hemostasis despite a decrease in INR. Therefore, **therapy must be stopped for 4–5 days and INR checked**.

Table A1.1 Continued

NSAIDS (including aspirin)	
Mechanism of Action: Irreversible platelet cyclooxygenase (COX) inhibition thus reducing prostaglandin (PG) and thromboxane (TXA2) synthesis	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	Updated ASRA guidelines pending
Time to wait after catheter is placed before RESTARTING MEDICATION	Updated ASRA guidelines pending
Time to wait after last dose before REMOVING CATHETER	Updated ASRA guidelines pending
Time to wait after catheter is removed before RESTARTING MEDICATION	Updated ASRA guidelines pending
Comments	Used alone, possible risk of spinal hematoma (guidelines pending). Recommend against neuraxial techniques if concurrent use of other anti-coagulants in the early postoperative period due to potential increased risk of bleeding complications.
Thrombolytic Therapy (tPA, urokinase, streptokinase)	
Mechanism of Action: Activation of plasminogen to plasmin, which dissolves cross-linked fibrin clots	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	Neuraxial technique not recommended. Data are not available to define the length of time neuraxial puncture should be avoided after discontinuation of thrombolytics.
Time to wait after catheter is placed before RESTARTING MEDICATION	Avoid medication with indwelling catheter
Time to wait after last dose before REMOVING CATHETER	In unexpected situations in which patients who have a neuraxial catheter in place receive thrombolytics, there is no definitive recommendation. Measurement of fibrinogen level (one of the last clotting factors to recover) is suggested.
Time to wait after catheter is removed before RESTARTING MEDICATION	No recommendation offered
Neuraxial block during Thrombolytic therapy	In these rare instances, limit epidural infusion to drugs minimizing sensory and motor blockades. Perform neurological monitoring every 2 hours or less
GP IIb/IIIa Inhibitors (abciximab, eptifibatide, tirofiban)	
Mechanism of Action: Binds to platelet glycoprotein IIb/IIIa receptors thus reducing platelet aggregation	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	24–48 hours for abciximab. 4–8 hours for eptifibatide and tirofiban
Time to wait after catheter is placed before RESTARTING MEDICATION	Avoid medication with indwelling catheter

(*continued*)

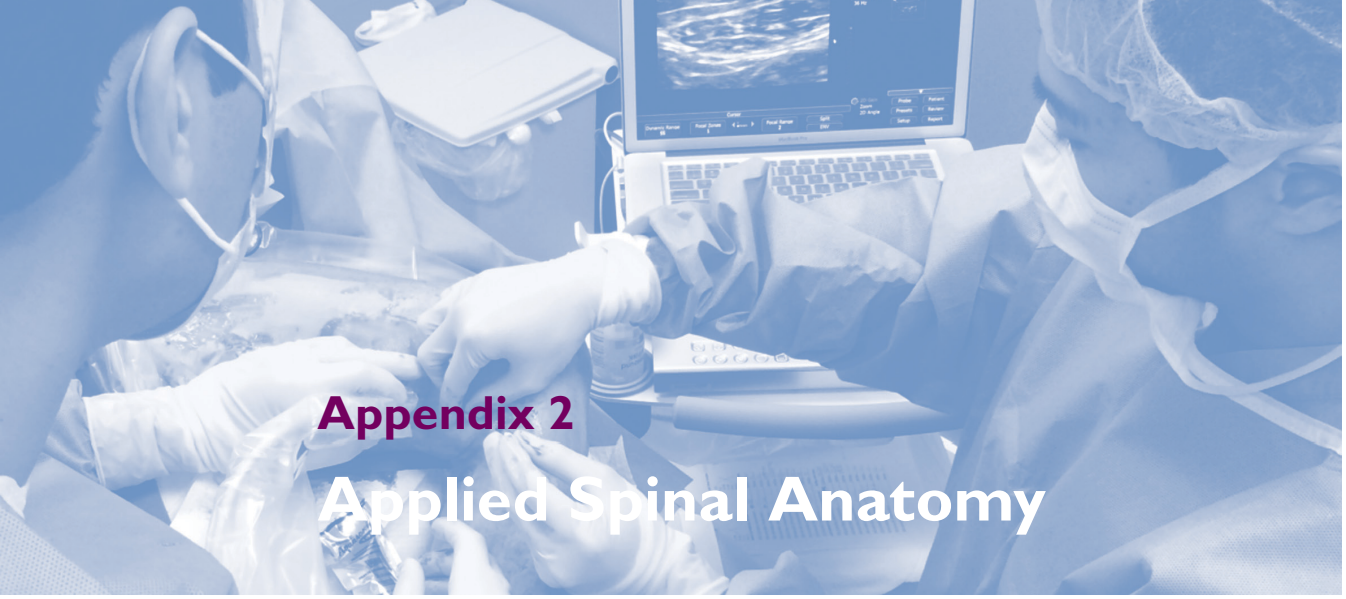
Table A1.1 Continued

Time to wait after last dose before REMOVING CATHETER	Avoid medication with indwelling catheter
Time to wait after catheter is removed before RESTARTING MEDICATION	No recommendation offered
Comments	GP IIb/IIIa inhibitors are contraindicated within 4 weeks of surgery. However, should one be administered in the postoperative period after (neuraxial technique), the patient should be carefully monitored neurologically.
Thienopyridine Derivatives (ticlopidine and clopidogrel)	
Mechanism of Action: Irreversible and noncompetitive inhibition of platelet P2Y12 adenosine diphosphate receptors thus reducing platelet activation and aggregation	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	14 days for ticlopidine; 7 days for clopidogrel—if neuraxial block indicated between 5–7 days of discontinuation, normalization of platelet function should be documented
Time to wait after catheter is placed before RESTARTING MEDICATION	Avoid medication with indwelling catheter
Time to wait after last dose before REMOVING CATHETER	Avoid medication with indwelling catheter
Time to wait after catheter is removed before RESTARTING MEDICATION	No recommendation offered
Comments	Actual risk of spinal hematoma is unknown. Recommendations based on labeling precautions and clinical experience.
Thrombin Inhibitors (Desirudin, Lepirudin, Bivalrudin, Argatroban)	
Mechanism of Action: Direct inhibitors of free and clot-bound thrombin. Effect monitored by aPTT. No reversal agent available. Effect lasts for 1–3 hours after administration.	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	Neuraxial technique not recommended
Time to wait after catheter is placed before RESTARTING MEDICATION	Neuraxial technique not recommended
Time to wait after last dose before REMOVING CATHETER	Neuraxial technique not recommended
Time to wait after catheter is removed before RESTARTING MEDICATION	Neuraxial technique not recommended

Table A1.1 Continued

Fondaparinux (Arixtra)	
Mechanism of Action: Factor Xa inhibitor, more selective than Lovenox. Plasma half-life is 21 hours. No reversal agent available.	
Intervention	**ASRA Guidelines/Recommendations**
Time to wait after last dose before SPINAL/EPIDURAL CATHETER PLACED	No recommendation offered
Time to wait after catheter is placed before RESTARTING MEDICATION	Avoid medication with indwelling catheter
Time to wait after last dose before REMOVING CATHETER	Avoid medication with indwelling catheter
Time to wait after catheter is removed before RESTARTING MEDICATION	No recommendation offered
Comments	Unknown risk of spinal hematoma formation due to lack of evidence. Any neuraxial techniques should occur under clinical trial conditions (single-needle pass, atraumatic needle placement, avoidance of indwelling neuraxial catheters).
Herbal Medications	
Comments	Ginseng, ginko, garlic, etc., inhibit platelets and can indirectly potentiate antiplatelet actions of NSAIDs. No increased risk of spinal hematoma. Recommend against mandatory discontinuation of medication for neuraxial placement or regional techniques. Best discontinued one week prior to surgery.
Anticoagulated Parturient	
Comments	No large series of evidence regarding neuraxial techniques in the parturient receiving anticoagulation. Recommend that ASRA guidelines be applied to parturient as well
Plexus or peripheral nerve block	
Comments	Recommend that guidelines regarding neuraxial techniques be similarly applied to patients undergoing plexus or peripheral nerve blocks

Horlocker T, Wedel DJ, Rowlingson JC, et al. Regional anesthesia in the patient receiving antithrombic or thrombolytic therapy: American Society of Regional Anesthesia and Pain Medicine Evidence-Based Guidelines (3rd Edition). *Region Anesth Pain Med.* 2010;35(1):64–101.



Appendix 2
Applied Spinal Anatomy

J. Tasker Gundy and Sanjeet Narang

Introduction

Sir William Osler notoriously opined that to study medicine without books was to embark upon a sailing expedition over uncharted sea. Despite the routine use of radiographic-image guidance by today's interventional pain physician, the successful application of surgical techniques requires a studied and sound knowledge of spinal anatomy; without this we are no less ill-fated: lost and adrift, navigating a complex landscape without map or chart. From the topography and coordinates of bony surface landmarks we palpate to the elegant patterning and geometry of the vertebral spaces our needle penetrates, we are intimately involved with the spine in our daily practice. Therefore the safety of our patients and the success of our interventions will begin and end with the fundamentals of neuraxial anatomy.

Embryology

Embryologic Origins and Organization

From the third week of embryogenesis (gastrulation) through the eighth week (collectively, the embryonic period), an organized series of events occur that culminate in the characteristic segmental arrangement of the vertebral column and its contents (1, 2, 3). With the process of gastrulation during week 3, the implanted blastocyst transforms from a 2-layer bilaminar disc (epiblast and hypoblast) into a trilaminar germ disc via a well-choreographed sequence of cell migration, tissue induction, and response. Condensing epiblast cells form the linear primitive streak along the dorsal midline of the embryo posteriorly (permanently establishing dorsal-ventral, left-right, and cranio-caudal axes), which subsequently elongates and condenses into a primitive groove as migrating cells converge at the streak and dive ventrally in a process known as invagination. Initially these inward-moving cells displace hypoblast to become endoderm, and the migrating cells that follow form a definitive intervening layer of mesoderm between epiblast and the newly formed layer of endoderm. Cells that remain behind dorsally in the epiblast become ectoderm, and these three primary germ layers—each of which originated as epiblast—are the foundation of all tissues and organs in the developing embryo.

Other important events occur simultaneously during gastrulation. Certain epiblast cells entering the primitive streak via the anterior most aspect (a well-demarcated area of cell invagination known as the primitive node) will migrate cranially, forming a longitudinal cord of cells in the midline between endoderm and ectoderm called the notochord. This structure, which forms cranially at first and extends caudally thereafter (following the regression of the primitive streak), forms the basis for the development of the axial skeleton. Neurulation signals from the notochord induce changes in the overlying (dorsal) ectoderm cells, which thicken responsively into a neural plate whose lateral edges then elevate as neural folds. Union of these bilateral folds as they curl medially and fuse in the midline results in formation of the neural tube and the genesis of the central nervous system.

Closure of the neural tube occurs in the cervical region initially, with midline fusion of the neural folds progressing both cranially and caudally thereafter. The broad cranial region next undergoes a series of subdivisions as it organizes into the fundamental components of the brain, while distal and contiguous to this the spinal cord begins forming with continued inductive signals from the ventral notochord. Mesodermal cells along either side of the notochord proliferate into a thickened cell mass known as paraxial mesoderm, which then develops a series of transverse indented pleats that separate this longitudinal cell mass into paired segments or somites. A total of 42–44 paired somites will form by the end of the fifth week of development, representing 4 occipital, 8 cervical, 12 thoracic, 5 lumbar, 5 sacral, and 8–10 coccygeal pairs (1 occipital and 5–8 coccygeal somites will later regress). As cells shift within each somite into ventromedial and dorsolateral clusters, ventromedial cells known as sclerotome disperse about the notochord and neural tube, merging with cells from the contralateral somite to form the primordia of the vertebral bodies; remaining somitic cells (the dermomyotome) go on to form muscle and dermis. Importantly, dispersing sclerotome cells from the cranial aspect of one somite aggregate with condensing cells from the caudal half of the somite above in a process known as resegmentation. Individual vertebrae are therefore formed intersegmentally, via the fusion of two adjacent somites, to ultimately create the centrum (body) of a vertebra ventromedially and a neural arch dorsally. Segmental muscles will extend across the intervertebral joints—innervated by spinal nerves growing out between the cranial and caudal aspects of each somite—and this "out-of-phase" development of trunk muscles will permit them to move the vertebral column laterally when they contract (see Figure A2.1).

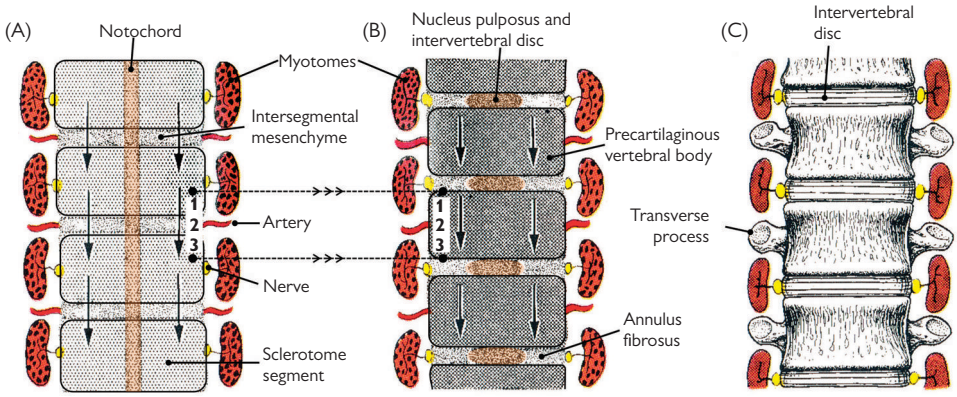


Figure A2.1 Formation of the vertebral column in the embryonic period.
A. At the fourth week of development, sclerotomic segments are separated by less dense inter-segmental tissue. Note the position of the myotomes, inter-segmental arteries, and segmental nerves. **B**. Condensation and proliferation of the caudal half (1) of one sclerotome proceeds (*solid vertical arrows* in A and B) into the inter-segmental mesenchyme (2) and the cranial half (3) of the subjacent sclerotome to form a vertebral body. Note the presence of the notochord in the primitive intervertebral disc as the future nucleus pulposus. **C**. Pre-cartilaginous vertebral bodies are formed by the upper and lower halves of two successive sclerotomes and the inter-segmental tissue (*broken horizontal arrows* between A and B).
*Myotomes bridge the intervertebral discs and, therefore, can move the vertebral column. The blood supply of each vertebral body enters at its mid-point and spinal nerves emerge between them.

The remaining components that will eventually complete the segmented vertebral column are also taking shape at this time. Sclerotome cells remaining in place between their dispersing cranial and caudal brethren condense as precursors of cartilaginous intervertebral discs. Mesenchymal cells between developing neural arches (not yet fused dorsally) become the ligaments of the neural arch. Within the neural tube, neuroblast cells and their progeny are organizing the spinal cord and sending out spinal nerves, which themselves divide into dorsal and ventral rami during the fifth week of development. Chondrification centers appear in the centrum and neural arches of the vertebrae during week 6, and the arches closes at this time, forming characteristic dorsal and lateral projections (spinal and transverse processes, respectively) and zygapophysial joints with adjacent vertebrae. With chondrification, the cells of the notochord, which have maintained a midline axis within the developing vertebral bodies and intervertebral discs, are expulged from the vertebral bodies into the discs (eventually forming the nucleus pulposus). As the embryonic period ends, the ossification of the vertebral column begins, with ossification centers forming in the bodies and arches of vertebrae and beginning to transform these structures from cartilaginous to bone. Ossification continues for the remainder of gestation and beyond birth, as the vertebral column continues to increase in size with growth through puberty. The spinal cord, on the other hand, will not increase in length: it extends the length of the entire vertebral column at three months of fetal life, but remains that length as the vertebrae continue growing (hence the expected level of cord termination being L3 in the newborn and L1–2 in the adult). The concave curvature of the fetus will also reconfigure with the milestones of early life, adopting a cervical lordosis when the head is held upright and a lumbar lordosis when sitting and standing begin.

Developmental Anomalies

The potential for anatomic variation due to developmental anomaly must be considered; the majority of malformations, when they occur, are found in the lumbosacral spine. Failure of the neural arch to close dorsally can result in a spectrum of conditions from myelomeningocele to spina bifida occulta; clinically the observant practitioner may be alerted to the possibility of spina bifida occulta by a tuft of hair or dimple overlying the region of malunion. Failure of ossificaiton centers in the vertebral bodies to fuse may result in wedge-shaped malformation of individual vertebral bodies (predisposing to scoliosis) or anterior spina bifida. Adjacent vertebrae may become partially or completely fused (as in sacralization of L5, where L5 incorporates completely or partially into the sacrum), and elements that normally fuse during development may fail to do so (as in lumbarization of S1, where fusion between S1 and S2 is incomplete and S1 is potentially mobile). Anatomic variation in the sacrum can also involve incomplete closure of the vertebral canal (either segmentally or the along the entire bony roof of the canal), narrowing or obliteration of the canal itself, defects in the posterior midline congruous with the hiatus, bony defects obscuring the hiatus, and absence of cornu (making palpation and identification of the hiatus a challenge). Among the nerve roots, aberrations may include anomalous courses, multiple or absent roots within individual intervertebral foramen, and anastomoses between nerve roots; this has potential clinical significance, as a lesion causing root compression to an anomalous nerve may not be located at the expected level, and in these cases, foraminal injection might not elicit the intended effect.

Spinal Anatomy

Anatomy of the Vertebral Column and Spinal Cord

The anatomic organization of the adult neuraxis reflects a complex interplay between form and function: an architecture of bony components, columns, and curvatures designed for axial load-bearing and upright posture, stabilizing support ligaments, joint articulations whose angles and synovial interplay permit us the heterogeneity of our movements, and compartments and spaces whose boundaries we must understand before we breech them with our needle or catheter.

The surface of the back bears several palpable bony prominences that are described as landmarks despite their established variability and the potential for clinical inaccuracy when they are used in isolation to predict vertebral level (4). When imaging is unavailable, however, it is important that one's locus along the 33 vertebrae composing the normal adult spine (7 cervical, 12 thoracic, 5 lumbar, 5 fused sacral, and 4–5 fused coccygeal vertebrae) be estimated using surface anatomy. Grossly, curvatures of the spine provide a general idea of location along its length, via the cervical/lumbar lordoses and the thoracic/sacral kyphoses. Landmarks marking specific vertebral levels include the prominent spinous process of C7 (vertebra prominens), the inferior angles of the scapulae (an imaginary line between which approximates the T7 level when the arms are adducted), the inferior margins of the ribcage (approximately L1), the superior portion of the iliac crests (which when joined by the imagined intercristal or Tuffier's line are used to approximate the L4 vertebral body and the L3/L4 interspace above), and the posterior superior iliac spines, which correspond to the S2 level and therefore approximate the termination of the dural sac. The depression palpated between sacral cornua marks the sacral hiatus.

The basic patterning and structure of typical individual vertebrae was evident embryologically and is fully realized in the normal adult spine. Weight is borne along the length of the column by the stacked bony vertebral bodies, which increase in size from the cervical to the lumbar region as their weight-bearing role becomes more substantive. Dorsal projections from the vertebral bodies form the individual vertebral arches, each composed of stout bilateral base columns known as pedicles, which support paired laminae as they arc elliptically, forming dorsal spinous processes where they meet in the midline. Each anterior body with its posterior arch encircles a vertebral foramen, and assembled collectively these osseous components encapsulate and protect the spinal cord and nerve roots within a vertebral canal formed by sequential foramina. Width of this canal is variable: it is narrowest in the thoracic region, and widens in the cervical and lumbar regions to accommodate the cervical (C4–T1) and lumbosacral (T11–S1) cord enlargements that reflect an increased nerve density supplying the nerve plexuses of the arms and legs (5). Notches on the superior and inferior surfaces of each pedicle form intervertebral foramen between adjacent vertebrae, through which the segmental spinal nerves pass (see below). Laterally, transverse processes project from the juncture of each lamina and its associated pedicle, along with superior and inferior articular processes (facets) that articulate with those of adjacent vertebra to form zygapophysial joints.

Along with variation in size among the vertebral bodies themselves, other characteristic differences between cephalad and caudad regions of the vertebral column are present. The cervical spine is home to a heterogeneous assortment of vertebrae, including two that are unique (C1, known as atlas, and C2, known as axis) and designed to support and maneuver the head. The nearly axial orientation of the facet joints here permits rotatory movement in addition to flexion and extension. Transverse processes originate more anteriorly on the cervical vertebrae than in other segments, and from C6 upward to C1 also contain transverse foraminathat provide safe passage for the vertebral vessels as they approach the foramen magnum.

Thoracic vertebrae, in turn, are most notable for the steep caudad angulation of their spinous processes, which accounts for the favorability of paramedian over midline approaches to the epidural space in this region. Transverse processes here are large and bear demi-facets for articulation with the ribs; flexion is limited by a near-vertical alignment of joint surfaces of the facets. In the lumbar region, spinous processes re-establish a more perpendicular orientation, and sagittal opposition at the facet joints limits rotation. Notably, the interlaminar gap between adjacent vertebrae increases in this region (becoming even more pronounced with flexion of the spine), which, along with the favorably oriented vertebral spines, accounts for the popularity of a lumbar approach to the epidural space (6). The 5 vertebrae forming the sacrum in adulthood are nearly indistinguishable as vertebrae, forming as they do a single fused structure. Intervertebral foramina are no longer present; instead, anterior and posterior primary rami of sacral nerves exit via anterior and posterior sacral foramina, respectively. Posteriorly on the sacrum, the first four vertebral arches typically fuse to form the roof of a sacral canal, while the fifth is typically unfused and open, forming the sacral hiatus that lies in a depression between the sacral cornua on either side (roofed by the posterior sacrococcygeal ligament in most cases). Finally, 4–5 fused remnants make up the triangular coccyx, which articulates with the lower border of the sacrum and is angled anteriorly.

The articulated spine is linked by a number of important support structures and ligaments in addition to the facet joints. Intervertebral discs sit as cushions between adjacent vertebral bodies, composed of a stiff outer layer of fibrocartilaginous rings (annulus fibrosus) surrounding an inner core of soft, gelatinous tissue (nucleus pulposus, a notochord remnant, as noted previously). As these discs dehydrate and stiffen with age, fissures may form in the annulus fibrosus that permit contents of the nucleus pulposus to track into the intervertebral foramen, irritating spinal nerve roots traversing there (disc herniation, more common in cervical and lumbar regions, will usually affect the nerve root corresponding to the lower of two adjascent vertebrae) (7). Anteriorly and posteriorly, the units of vertebral bodies and intercalated intervertebral discs are well supported by the anterior and posterior longitudinal ligaments, respectively. Posterior elements are joined by the interspinous ligament linking adjacent spinous processes in the midline, the supraspinous ligament that also runs in the midline connecting the dorsal ends of each spinous process, and the thick ligamentum flavum ("yellow ligament") that spans the laminae of adjacent vertebrae, defining the posterolateral boundaries of the epidural space. Of note, the ligamentum flavum posteriorly is composed of left and right "halves" that converge in the midline, occasionally leaving a gap.

Within the spinal canal lies the cord itself, beginning at the foramen magnum as a cylindrical continuation of the medulla oblongata and terminating caudally as the tapered conus medullaris roughly 45 cm later (typically at the interspace between the first two lumbar vertebrae, as noted previously). Three meningeal layers that protect the brain in the calvarium also envelop and protect the cord: the tough outer dura mater, the delicate arachnoid mater, which lines the inside of the dura (enclosing the subarachnoid space and CSF in which the cord floats suspended), and the fine pia mater, which adheres to the surface of the cord itself. Beneath the conus, the dural (thecal) sac continues as the lumbar cistern, typically to the level of S2, containing lumbosacral nerve roots of the cauda equina traveling toward their respective IV foramina (which lie distally as a result of the differential growth between cord and canal, noted previously), as well as a thread-like projection of pia mater known as filum terminale, which courses within the dural sac and subsequently extends beyond it, tethering the cord caudally to the coccyx. Transverse section reveals the composition of the cord as external white matter (myelinated nerve axons in ascending and descending tracts) surrounding a butterfly-shaped area of grey matter (nerve cell bodies) and a CSF-filled central canal. Vascular supply to the cord occurs via the paired posterior spinal arteries originating at

the posterior inferior cerebellar arteries, as well as the larger, discontinuous anterior spinal artery supplying the anterior two-thirds of the cord.

Along the length of the cord, 31 pairs of spinal nerves emerge, each composed of fused ventral (motor) and dorsal (afferent sensory) spinal roots, which themselves form via the aggregation of smaller dorsal and ventral rootlets. At each vertebral level bilaterally, a pair of roots merge and pierce the dura as they approach their associated inferolateral intervertebral space, carrying along an extension of dura and arachnoid known as the dural sleeve, which ultimately merges with epineurium as the converged roots become a completed spinal nerve in the foramen itself. These nerve roots are believed to represent the principal sites of action for neuraxial blockade. Exiting spinal nerves are numbered according to the vertebra beneath which they emerge, with the exception of nerves C1–C7, which exit above their associated vertebrae. Just before merging with the ventral root at the intervertebral foramen, the dorsal root forms an enlarged dorsal root ganglion that houses the cell bodies of afferent sensory nerve fibers. Dorsal and ventral roots merge in the foramen, and in the paravertebral space each completed nerve immediately divides into anterior and posterior primary rami (rendering the spinal nerves proper quite short). The anterior ramus, which is the larger of the two and contains the majority of both motor and sensory fibers at any given level, gives off a small branch known as the sinuvertebral nerve, which re-enters the foramen and courses in a network along the posterior longitudinal ligament, supplying the outer layers of the IV discs. The afferent sensory axons within the anterior ramus at each level are associated with a specific cutaneous surface or dermatome (with the exception of C1, for which no sensory dermatome has been identified), although some degree of overlap among dermatomes is expected. The smaller posterior primary ramus sends out a lateral branch posteriorly (innervating the paraspinous muscles and overlying skin), as well as a medial branch that carries afferent sensation from the corresponding facet joint. Of note, each facet joint receives dual innervation from two medial branch nerves: one from its own level and another descending from the level above (8). Two nerves must therefore be blocked to adequately anesthetize a facet joint.

Soft Tissue Spaces and Anatomic Considerations in Interventional Pain

The epidural space is of paramount interest to the pain interventionalist, not only as a locus for injection of therapeutic local anesthetic or steroid solution, but also as a conduit for cord stimulator lead advancement/positioning and epiduroscopy. All that lies outside the dural sheath but within the confines of the vertebral canal constitutes the epidural space, and as such it is bordered anteriorly by the posterior longitudinal ligament (running along the backs of the vertebral bodies and IV discs), laterally by the pedicles and IV foramina, and posterolaterally by the ligamentum flavum and laminae. This arrangement contributes to a characteristic series of encounters as one advances an epidural needle past skin and subcutaneous tissue in the midline: first the supraspinous ligament (which offers minimal resistance, except when calcified in the elderly), followed by the increasing resistance of the interspinous ligament (potentially a confounding area if lateral exit from the ligament is falsely perceived as "loss" of resistance), and finally the firm crunch of the ligamentum flavum, beyond which the needle enters the epidural space (9). The distance a needle must travel from skin to space is variable (ranging from 2–8 cm), but averages about 5 cm; likewise the distance from ligamentum flavum to dural sac will vary with spinal level, but averages 2–8 mm and is greatest in the midlumbar region at the cephalad aspects of the intralaminar spaces.

The epidural space itself is roughly triangular in cross section, filled mostly with loose, non-concentric fatty tissue (along with a venous plexus dispersed throughout, and nerve

roots found laterally at the intervertebral foramen); anteriorly the epidural space is largely potential, with the dural sheath lying in close approximation with the posterior longitudinal ligament, attaching to it directly on occasion (10). The proportion of epidural fat increases caudally, where it surrounds the dural sac beyond the conus. Imaging studies investigating causes for asymmetric epidural anesthesia have found that uniform distribution of injectate within the epidural space is uncommon: solution spreads circumferentially around the cord, longitudinally within the space, and out into the paravertebral space via the intervertebral foramina (significant not only because fluid may exit the epidural space here, but also because solution injected in proximity to the intervertebral foramen—as in a paravertebral block—may take an unintended course and enter). Though hypothetical fibrous elements forming barriers within the epidural space have not been discovered, movement of a catheter inserted into the space is nonetheless inconsistent, often tracking laterally (even exiting the space through the intervertebral foramen) rather than rostrally in the midline as imagined. Fortunately, adequate clinical effect can usually be achieved despite this variability in solution spread and catheter tip positioning (11). Similar inconsistency is possible when dorsal column stimulator leads are placed in the epidural space, as an advancing electrode may course ventrally into the anterior space, resulting in pain or unwanted motor stimulation when pulse is generated (12).

Between the closely approximated dura and arachnoid mater lies a potential subdural space, which may occasionally receive an aberrantly placed catheter. The subarachnoid space is located between the arachnoid and pia mater, filled with CSF. Roughly 500 cc of this clear fluid is produced by the choroid plexuses in the cerebral ventricles each day and subsequently is reabsorbed into venous circulation by the arachnoid villi, such that approximately 150 cc bathes the central nervous system at any given time. Within this fluid floats the cord (and spinal nerve roots), suspended and supported by the filum terminale distally, a series of tooth-like fibrous elements (denticulate ligaments) connecting the pia to the arachnoid surface of the dura laterally, and an interrupted, fenestrated membrane known as the septum posticum connecting pia to arachnoid in the posterior midline. Within the contiguous subarachnoid spaces of the brain and spinal cord, CSF does not lie stagnant but rather oscillates with arterial pulsations; amplitude of this oscillation varies with position along the cord, highest in the cervical region and lowest distally in the lumbar cistern. This variation may contribute to non-uniform distribution of injectate within the CSF depending upon level of injection, as may the unpredictable presence of loculated subarachnoid cysts (13).

Conclusion

Comfort and facility with neuraxial anatomy are essential to the daily efforts of the interventional pain physician. This material will maintain its relevance as new interventions, therapies, and techniques are developed in the future.

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Appendix 3

Pharmacology of Intrathecal Medications

Michele L. Matthews

Introduction

Intrathecal drug administration involves the delivery of medication directly into areas within the spinal cord that are essential to pain processing. This method of drug delivery has several advantages over epidural administration, including lack of absorption phase, 100% bioavailability, and high concentration of drug in the cerebrospinal fluid (CSF) (1). Medications must diffuse from the CSF and enter the spinal cord to produce analgesia; therefore, an understanding of the characteristics of the intrathecal space, as well as the pharmacology of drugs to be administered through this route, is important to ensure analgesia while minimizing toxicity.

The intrathecal space separates the arachnoid mater and pia mater and contains CSF, arteries, and veins (2). The arachnoid mater has cellular architecture that creates a high level of resistance to drug diffusion, and its permeability is dependent upon the lipid solubility of the drug administered. The pia mater, located on the surface of the spinal cord, is composed of only one cell layer and generally does not confer resistance to drug diffusion (1, 2). The choroid plexus produces the majority of CSF. The volume of CSF within the intrathecal space is typically 75 mL, and it is replaced 3–4 times per day at a rate of 0.3–0.4 mL/min; however, it is unknown how the renewal of CSF impacts drug pharmacokinetics (3, 4). CSF circulates through cerebral ventricles and then into the subarachnoid space and is reabsorbed into venous blood through arachnoid villi (4). The spread of drug within the CSF is directly related to its movement, which is caused by pulsatile blood flow into the CNS (3, 5). Once in the CSF, a drug must penetrate into the spinal cord to exert its effect. White matter within the spinal cord is composed mostly of lipids, and lipophilic drugs (e.g. fentanyl) move preferentially into this area and are subsequently cleared into the plasma (6). The dorsal horn is found within the gray matter of the spinal cord and is saturated with opioid receptors. Hydrophilic drugs (e.g., morphine) will preferentially partition to this area. Furthermore, the lipid solubility of a drug will determine the extent of rostral ascent. Concentrations of hydrophilic drugs within the CSF decline more slowly in comparison to lipophilic drugs, which accounts for a greater degree of rostral spread (7). Lipophilic drugs often do not produce significant cisternal concentrations and therefore can be effective for segmental analgesia that lacks supraspinal

effects (7). Other factors that may affect the intrathecal spread of drugs include characteristics of the injected solution (e.g., baricity, volume/dose/concentration, temperature of the solution, viscosity, and additives), clinical technique (e.g., patient position, level of injection, needle type/alignment, use of an intrathecal catheter, and fluid currents), and characteristics of the patient (e.g., age, height, weight, gender, spinal anatomy, and CSF volume) (8).

Medications

Opioids

The effect of intrathecal opioids is multifaceted. They exert a direct effect on opioid receptors in the spinal cord and on cerebral opioid receptors after cephalad transport and have peripheral and central effects following vascular absorption (9). The differences between opioids when administered intrathecally includes their duration of analgesic effect, rate of redistribution to brainstem sites, and the mechanism by which the drug reaches such sites (10). Lipophilic opioids have a rapid onset and shorter duration of action than hydrophilic opioids after intrathecal administration (11). Hydrophilic opioids have a slower onset and delayed elimination, which can be attributed to their ability to spread widely throughout the CSF. Late cephalad CSF spread with the use of hydrophilic opioids can cause delayed yet undesired clinical effects, such as respiratory depression (12).

Morphine is a hydrophilic opioid that is commonly used as first-line intrathecal therapy and is 100 times more potent than when administered intravenously (13, 14). A continuous intrathecal infusion of morphine achieves steady state within 72 hours and is eliminated via absorption through the spinal cord vasculature. Optimal dosing of intrathecal morphine is considered to be dependent upon the clinical indication, and the incidence of adverse effects increases in proportion to the dose (15, 16). The slow rostral spread of intrathecal morphine, resulting in delayed respiratory depression, necessitates low starting doses and close monitoring, particularly in those patients with risk factors such as underlying respiratory dysfunction. Intrathecal hydromorphone is slightly more lipophilic than morphine but exerts similar effects. It is approximately 6 times more potent than morphine and is generally associated with fewer adverse effects (17). Intrathecal hydromorphone is recommended as first-line therapy for nociceptive pain but is considered second-line therapy alone or in combination with bupivacaine or clonidine for neuropathic pain (13). Fentanyl is highly lipid soluble with a rapid onset and short duration of action following intrathecal administration. It has greater intrinsic activity compared to morphine and interacts with fewer opioid receptors to produce an analgesic response (14). Fentanyl produces segmental analgesia, which warrants proper placement of the intrathecal catheter to ensure adequate concentration of drug at the appropriate site. For nociceptive pain, fentanyl is considered a first-line option for intrathecal therapy due to long-term safety data but should be reserved as a third-line option for neuropathic pain (13). The use of sufentanil, a more potent derivative of fentanyl, is often reserved for patients with refractory nociceptive pain (13). The role of intrathecal methadone is currently limited by the lack of long-term safety and stability data. Table A3.1 summarizes the doses, concentrations, and recommendations for various intrathecal medications.

Adverse effects associated with the intrathecal administration of opioids vary based on pharmacologic properties, dose, and duration of use. Although the risk of respiratory depression with intrathecal opioid use is low, it may occur as a delayed response with the use of hydrophilic drugs such as morphine. Patients who are elderly, opioid-naïve, receiving large opioid doses, and/or taking concomitant centrally acting medications may be more susceptible to opioid-induced respiratory depression (18). Single intrathecal injections are commonly associated with gastrointestinal symptoms such as nausea, urinary retention, and pruritus. Gastrointestinal adverse effects occur at a lower incidence rate in comparison to systemic opioids and are responsive to antiemetics. Urinary retention is usually self-limiting and often resolves within 48 hours. Pruritus may be caused by central mechanisms and typically responds to treatment with an opioid antagonist (e.g., naloxone) or a mixed agonist-antagonist (e.g., nalbuphine) (19).

Table A3.1[13, 36] Summary Guidelines for the Management of Pain by Intrathecal Drug Delivery***

Drug	Starting Dose Range	Maximum Concentration available on formulary at BWH *	Maximum Concentration used clinically at BWH **	Guidelines	
				Nociceptive Pain	Neuropathic Pain
Morphine	0.1–0.5 mg/day	70 mg/mL	30 mg	1st line alone; 2nd line + bupivacaine; 3rd line + clonidine; 4th line + clonidine and bupivacaine	1st line ± bupivacaine; 2nd line + clonidine
Hydromorphone	0.02–0.5 mg/day	50 mg/mL	40 mg	1st line alone; 2nd line + bupivacaine; 3rd line + clonidine; 4th line + clonidine and bupivacaine	2nd line ± bupivacaine or clonidine
Fentanyl	25–75 mcg/day	10,000 mg/mL	2000 mcg/ml	1st line alone; 2nd line + bupivacaine; 3rd line + clonidine; 4th line + clonidine and bupivacaine	3rd line ± bupivacaine or clonidine
Sufentanil	10–20 mcg/day	500 mg/mL	500 mcg/ml	3rd line alone; 4th line + bupivacaine or clonidine; 5th line + bupivacaine and clonidine	Not recommended
Bupivacaine	1–4 mg/day	40 mg/mL	35 mg/ml	2nd line + opioid; 4th line + opioid and clonidine; 5th line + sufentanil and clonidine	1st line + morphine; 2nd line + hydromorphone; 3rd line + fentanyl; 4th line + clonidine ± opioid
Clonidine	20–100 mcg/day	2000 mcg/mL	1000 mcg/mL	3rd line + opioid; 4th line + opioid and bupivacaine OR + sufentanil; 5th line + sufentanil and bupivacaine	2nd line + morphine or hydromorphone; 3rd line ± fentanyl; 4th line + bupivacaine ± opioid
Ziconitide	0.5–2.4 mcg/day	100 mcg/mL	100 mcg/ml	1st line alone; 2nd line + opioid	1st line alone; 3rd line + opioid
Baclofen	50–100 mcg/day	5000 mg/mL	5000 mcg/ml	Not recommended	5th line alone

13 -Deer TR, Levy R, Prager J, Buchser E, Burton A, Caraway D, Cousins M et al. Polyanalgesic Consensus Conference—2012: recommendations for the management of pain by intrathecal (intraspinal) drug delivery: report of an interdisciplinary expert panel. *Neuromodulation*. 2012;15(5):436–466.

36- Ghafoor VL, Epshteyn M, Carlson GH, Terhaar DM, Charry O, Phelps PK. Intrathecal drug therapy for long-term pain management. *Am J Health Syst Pharm*. 2007;64(23):2447–2461.

* Maximum concentrations are per the Brigham and Women's Hospital Intrathecal Drug Formulary

** Maximum concentration used clinically, risks increase at higher concentration (granuloma, pump failure, solution pH and tonicity etc.)

*** The use of the majority of medications mentioned is 'off label' and not approved by the FDA. It may also void the warranty of the device manufacturer.

In addition to the aforementioned effects, long-term intrathecal opioid administration via continuous infusion can also result in tolerance, hyperalgesia, neuroendocrine dysfunction, granuloma formation, withdrawal, and overdose (20). The proposed mechanisms for tolerance involve the down-regulation and desensitization of opioid receptors (21). There is inter-patient variability with regard to the development of tolerance. Dose titrations may restore analgesia; however, this may be limited by the volume of the infused opioid, thereby necessitating opioid rotation or modification of the drug formulation. Increased activity of excitatory neurotransmitters has been theorized to cause opioid-induced hyperalgesia, which manifests as abnormal pain processing that extends beyond the original location of pain (21). Management includes the discontinuation of therapy, dose reduction, or supplementation with an N-methyl-D-aspartate (NMDA) receptor antagonist. Opioids have been shown to cause neuroendocrine dysfunction that can result in decreased cortisol and testosterone levels, as well as alterations in antidiuretic hormone function (22). Intrathecal granulomas may develop as a result of high concentrations or high daily opioid doses and can lead to irreversible neurological dysfunction (23).

Local Anesthetics

Local anesthestics cause blockade of sodium channels, inhibiting the transmission of pain signals. The lipid solubility of a local anesthetic is related to its potency, while its duration of action is dependent on protein binding at the site of action. Local anesthetics that are more lipid-soluble require lower CSF concentrations. The acid dissociation constant (pKa) of a local anesthetic is important to the rate at which the neurological block occurs (12). The relationship between pKa and physiologic pH determines the availability of the local anesthetic in a non-ionized form (12). Within nerves, the drug becomes ionized so that it can interact with sodium channels.

Lidocaine has a rapid onset of action and intermediate duration of action due to its hydrophilic nature and poor protein binding. Its use has been associated with the development of transient neurologic symptoms, which has limited its role in long-term pain management (24). Bupivacaine has high lipid solubility and protein binding, resulting in higher potency and longer duration of action in comparison to other local anesthetics. It has been recommended as first-line therapy in combination with morphine for the management of neuropathic pain and second-line therapy in combination with an opioid for nociceptive pain (13). Bupivacaine is a racemic mixture, and the R-(+)-enantiomer is associated with central nervous system toxicity and cardiotoxicity (25). These effects can be prolonged and difficult to manage. Ropivacaine is a long-acting amino-amide local anesthetic that is structurally similar to bupivacaine but with lower lipid solubility and reduced likelihood of causing cardiotoxicity (26). Evidence to support long-term intrathecal use of ropivacaine is lacking.

Alpha-2 Agonists

The intrathecal administration of alpha-2 agonists results in spinally mediated analgesia involving the inhibition of pre- and postsynaptic receptors on afferent nociceptors within the central nervous system (27, 28). Clonidine is rapidly absorbed and eliminated from the CSF. It has high lipid solubility, which can lead to systemic absorption; however, it is believed to have higher potency after neuraxial administration. When used in combination with local anesthetics, clonidine can improve the extent and duration of analgesia but may also increase the degree of motor blockade. Clonidine appears to work synergistically with opioids, thereby producing a greater magnitude of analgesia than either drug alone, and this combination has been recommended as second-line therapy for neuropathic pain (13). Dose-dependent hypotension, bradycardia, and sedation can occur with the intrathecal administration of clonidine, although its use has not been associated with causing or potentiating respiratory depression

(28). The therapeutic dose range for clonidine is 150–300 mcg. Malignant hypertension has been reported with abrupt clonidine withdrawal; it is recommended to use the lowest dose possible. Blood pressure monitoring is considered a mandatory monitoring parameter; abrupt withdrawal, particularly in situations such as intrathecal pump failure or catheter leak, should be considered a medical emergency. Other alpha-2 agonists that have been evaluated for intrathecal use include tizanidine, dexmedetomidine, and epinephrine. Dexmedetomidine has significantly more affinity for alpha-2 receptors in comparison to clonidine and produced spinally mediated antinociception in animal models (29). Systemic use of dexmedetomidine is associated with tolerance, tachyphylaxis, and dose-related increase in adverse effects; the implications for intrathecal use are not yet known.

Calcium Channel Antagonists

Calcium is involved in pain processing and interacts with cells via voltage-sensitive calcium channels (VSCCs), which regulate the release of neurotransmitters that control synaptic transmission. These channels are abundant within the dorsal horn of the spinal cord where A-delta and C fibers terminate, and 6 sub-types of the VSCCs have been identified. Ziconotide is a selective, reversible antagonist of the N-type VSCC and is derived from the venom of the marine snail (30). It has been approved for intrathecal use in the United States and Europe for the management of severe refractory chronic pain; however, ziconotide has a narrow therapeutic window and can cause adverse effects such as dizziness, constipation, mental confusion, nystagmus, gait imbalance, and psychosis. Several psychological symptoms should be monitored during ziconotide therapy, including depression, anxiety, energy level, eating behavior, sleep cycle, sexual functioning, memory and concentration, and perception (e.g., hallucinations) (13). A psychological assessment should be performed prior to therapy to assess for a history of significant psychiatric history, as this might predispose the patient to worsening disease and increased risk of suicidality. Ziconotide is recommended as a first-line therapeutic option for the management of neuropathic and nociceptive pain but can also be formulated in combination with an opioid; however, this may potentiate the development of gastrointestinal-related adverse effects, specifically constipation.

Gamma-Aminobutyric Acid (GABA) Agonists

Among the three subtypes of GABA receptors that have been identified, the GABA-A and GABA-B receptors are found pre- and postsynaptically throughout the spinal cord. The presynaptic activation of these receptors results in diminished release of neurotransmitters, whilst postsynaptic activation causes hyperpolarization and decreased VSCC opening (31). Baclofen is a GABA-B agonist that is widely used for spasticity, and preclinical studies have suggested that it may also induce antinociception, although further clinical studies are needed to elucidate its role in other pain models. Adverse effects associated with intrathecal baclofen include drowsiness, cognitive impairment, and sexual dysfunction. Baclofen withdrawal can be a life-threatening complication and involves symptoms such as increased spasticity, respiratory depression, and acute organ failure (32). Abrupt withdrawal, particularly in situations such as intrathecal pump failure or catheter leak, should be considered a medical emergency, and the use of oral baclofen should be considered as a safety measure. Midazolam is a benzodiazepine with activity at GABA-A receptors that has shown to possess antinociceptive properties in animal models; however, intrathecal use is associated with neurotoxicity and should be avoided.

NMDA-Receptor Antagonists

NMDA receptors contain binding sites for glutamate and other excitatory neurotransmitters and, when activated, can lead to wind-up and central sensitization (e.g., allodynia).

These receptors are also believed to be involved in the development of opioid tolerance and opioid-induced hyperalgesia. The use of NMDA receptor antagonists, such as ketamine, is limited due to adverse psychiatric and cardiovascular effects. Additionally, these drugs have been implicated in the development of neurotoxicity and are not recommended for intrathecal use.

Miscellaneous

There are several medications that have been studied in animal models or have limited efficacy data in humans that are possibly safe after intrathecal administration; these include gabapentin and octreotide. Gabapentin is structurally related to GABA but does not bind to GABA receptors. Although its actual mechanism is unknown, it may prevent thrombospondin from binding to receptors involved in excitatory synapse formation. Octreotide is a somatostatin analogue that may inhibit neuronal response to noxious stimulation and increase pain thresholds. Factors limiting the use of intrathecal octreotide include tolerance and cost of therapy (33). Drugs that have demonstrated neurotoxicity and are not recommended for intrathecal use include droperidol, methylprednisolone, ondansetron, and tramadol (13).

Intrathecal Drug Formulations

Many medications administrated through the intrathecal route are not available in formulations that are preservative-free or in concentrations needed for patient-specific therapy. Therefore, intrathecal drug formulations can be compounded by specialty pharmacies; however, this process carries the risk of contamination and/or adulteration. The United States Pharmacopeia (USP) implemented regulations for sterile compounding in 2004, which were then updated in 2008 with Chapter 797, which was intended to further stratify risk classifications for sterile compounds and provide guidance on methods to prevent microbial contamination, excessive bacterial endotoxins, variability in the intended strength of ingredients, unintended physical contaminants, and ingredients of inappropriate quality (34). Noncompliance with USP regulations can lead to serious complications, including death (35). In addition to proper sterile compounding techniques, other factors such as drug concentration, isotonicity, and stability must be considered as the intrathecal product is formulated (36). Pharmacies have implemented technologies that offer safeguards that result in decreased errors as well as other advantages that include decreased waste, operational efficiency, and increased employee safety through reduced exposure to hazardous materials. For example, robotics can be used for sterile compounding (see Figure A3.1). Important considerations when selecting pharmacies for the compounding of intrathecal drug formulations include training of personnel, space and air quality, certification and calibration of equipment, and implementation of a quality assurance program (37). Table A3.2 depicts a sample audit survey for compounding pharmacies.

Figure A3.1 Robotics used for sterile compounding at Brigham and Women's Hospital.

Table A3.2 Sample Audit Survey for Compounding Pharmacies

Vendor Audit Survey Form		
Vendor/Company Name:		
Address:		
Telephone:	Fax:	
Notice: I (we) certify that the information containers in this survey form is accurate and complete as of the date indicated. All information obtained will be kept confidential. This survey has been completed with the permission of the company surveyed.		
Signature:	Title:	
Signature:	Title:	
Part 1: General Information		
Licensed by:		
Board of Pharmacy; State(s) =	License #	Exp.
Food and Drug Administration	License #	Exp.
Drug Enforcement Agency (DEA)	License #	Exp.
DEA Manufacturer	License #	Exp.
Other:		
Other:		
Accredited by:		
Pharmacy Compounding Accreditation Board (PCAB)	Accreditation #	Exp.
Joint Commission	Accreditation #	Exp.
Other:	Accreditation #	Exp.
Other:	Accreditation #	Exp.
Inspections:	Copy of inspection provided	Date(s)
Board of Pharmacy; State(s) =	Yes or No	
Food and Drug Administration	Yes or No	
Drug Enforcement Agency (DEA)	Yes or No	
DEA Manufacturer	Yes or No	
Pharmacy Compounding Accreditation Board (PCAB)	Yes or No	
Joint Commission	Yes or No	
Other:	Yes or No	
Disciplinary Actions: Any adverse change in status of accreditation, including by not limited to withdrawal, discontinuance, termination, revocation, suspension, probation, or warning.		Date(s)
Board of Pharmacy; State =	Yes or No	
Food and Drug Administration	Yes or No	

(*continued*)

Table A3.2 Continued

Drug Enforcement Agency (DEA)	Yes or No
DEA Manufacturer	Yes or No
Pharmacy Compounding Accreditation Board (PCAB)	Yes or No
Joint Commission	Yes or No
Other:	Yes or No
Other:	Yes or No

Complaints: Any complaints registered with a state or federal agency.		Date(s)
Board of Pharmacy; State(s) =	Yes or No	
Food and Drug Administration	Yes or No	
Drug Enforcement Agency (DEA)	Yes or No	
DEA Manufacturer	Yes or No	
Pharmacy Compounding Accreditation Board (PCAB)	Yes or No	
Joint Commission	Yes or No	
Other:	Yes or No	
Other:	Yes or No	

Annual sales:	$
Privately owned:	Yes or No
Years in business:	
Subsidiary division of:	
Other plant locations:	

List of Major Customers:

1.

2.

3.

List of Company Management

Name	Title
1.	
2.	
3.	

Table A3.2 Continued

Services to be performed for Brigham and Women's Hospital:	
Total # of Employees:	
Work Schedule Hours:	
Number of Shifts:	
Day per Week:	
Are training programs for personnel utilized?	Yes or No
Proficiency Based?	Yes or No
Certifications Provided?	Yes or No
Recertification Period:	
Describe training program:	

Part II: Facility	
Number of Buildings On-Site:	
Type of Structure:	Single, Multiple, Wood, Brick, Block, Steel
Location:	Industrial Park, Urban, Suburban, Rural
Equipment:	Owned or Leased
Square Footage:	
List Process Capabilities and/or Services Provided	
1.	
2.	
3.	
4.	
5.	
Do you have Liability Insurance?	Yes or No; Coverage amounts:
Are written compounding procedures (SOPs) in place?	Yes or No
How often are procedures reviewed?	
Are procedures under change control?	Yes or No
	Describe revision process:
	How is training of newly revised documents handled?

(*continued*)

Table A3.2 Continued

Are calibration records kept on file?	Yes or No
Are calibration standards traceable?	Yes or No
	Describe:
Part III: Quality Control and Assurance:	
Formal Quality Unit	Yes or No
Does the Quality Unit report directly to the top management?	Yes or No
Does the Quality Unit have full authority to reject CSPs?	Yes or No
Are the Quality Unit procedures in a formal written document?	Yes or No
Are procedures revised on a periodic based?	Yes or No
Training and education of the Quality Unit	Describe:
Is there a formal quality assurance program involving the performance testing of equipment used for testing?	Yes or No
Part IV: Customer Complaints	
Is there an organization compliant file?	Yes or No
Does each compliant state:	
Nature of compliant	Yes or No
Response to customer	Yes or No
Further corrective/preventative action	Yes or No
Complaint file kept for how long?	Years
Is there a specific review of compliant files for trends?	Yes or No
Is the review filed with a written summary?	Yes or No
Is there a group or individual assigned to handle customer inquires and follow-up on complaints?	Yes or No
Do you perform 'in-house" audits?	Yes or No
Have any companies performed audits on your company/ pharmacy in the last year?	Yes or No
	If so who?

Table A3.2 Continued

	1.
	2.
	3.

Part V: USP <797> Quality Compliance	
Describe gowning process of preparing CSPs:	
Who is responsible for cleaning/sanitization programs?	
Rotation of sanitizers?	Yes or No
Frequency of cleaning cleanroom	
Number of cleanrooms	
Environmental Monitoring Performed?	Yes or No
	Surfaces: Yes or No; Type =
	Air: Yes or No; Type =
	Personnel: Yes or No; Type =
	Trending program: Yes or No
	Particle Counts: Yes or No
	Cleanroom Certificates: Yes or No; Frequency =
CSP Testing USP <71> Sterility	Yes or No
	Validation of sterility tests: Yes or No
CSP Testing USP <85> Endotoxin	Yes or No
Inhibition Testing Performed	Yes or No
USP Testing Performed by	
	Have you audited your testing facility? Yes or No
CSP Proficiency Pharmacist/Technician Testing	Yes or No
	Pharmacist: High, Medium, Low
	Technician: High, Medium, Low
	Frequency:
USP <797> Compliance Program	Yes or No
	Do you supply your customers with a report? Yes or No
	If so how often is it supplied? Monthly, Quarterly, Bi-Annual, Annually

(*continued*)

Table A3.2 Continued

Part VI: Tour of Facility	
General cleanliness of facility:	
Cleanliness of garbing area	
Cleanliness of ante room	
Cleanliness of cleanroom	
Cleanliness of hoods	
Cleanliness of equipment	
Cleanliness of medication storage areas	
Cleanliness of medication receiving and shipping areas	
Part VII: Product Audit (if applicable)	
Name of product prepared for BWH:	
Lot # of product:	
View preparation log or batch record? Yes or No	
	Preparation log or batch record complete? Yes or No
Prepared by:	
	View employee training documents: Yes or No
	Training documents complete? Yes or No
View test results of product? Yes or No	
	Accuracy? Yes or No; Pass or Fail
	Potency? Yes or No; Pass or Fail
	Sterility? Yes or No; Pass or Fail

Summary

The use of intrathecal medications for pain management has evolved significantly due to an improved understanding of drug pharmacokinetic and pharmacodynamic interactions within the spinal cord after neuraxial administration. An abundance of clinical evidence continues to support this method of drug delivery for various pain models, and enhanced regulations surrounding the compounding of drug formulations have improved the safe use of these products. Nonetheless, appropriate patient selection, choice of drug therapy, administration technique, and clinical monitoring continue to be paramount in the successful implementation of intrathecal medication delivery.

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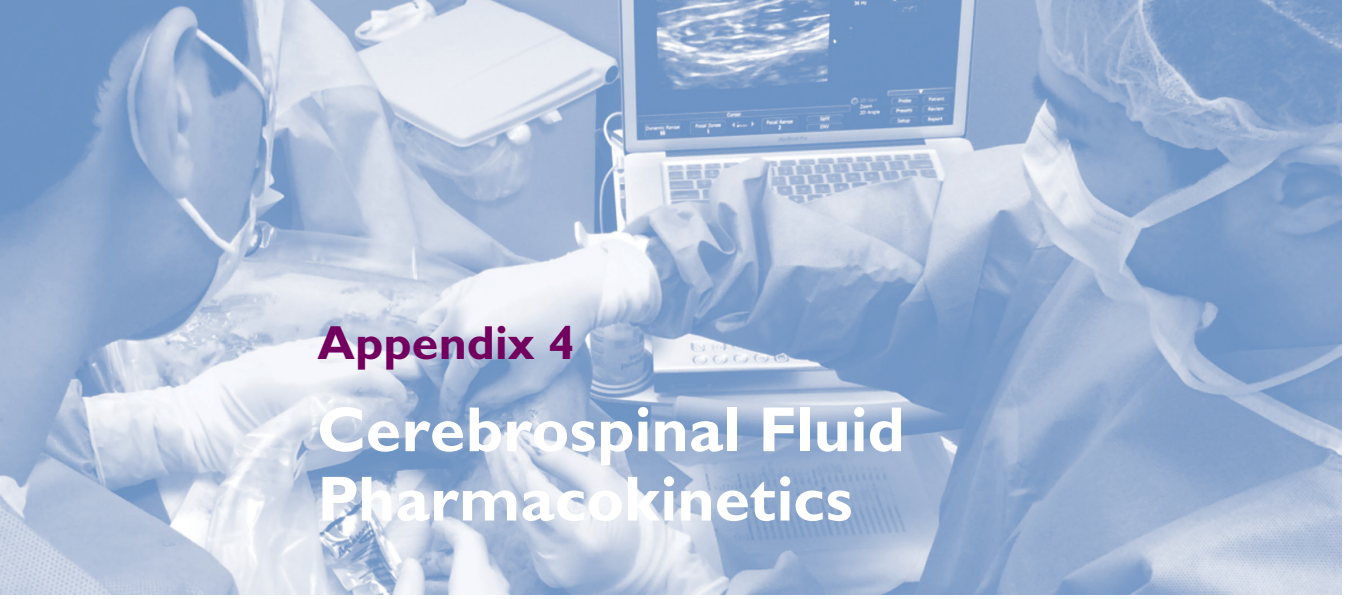
Online Resources

- United States Pharmacopeia (USP). Chapter 797—Sterile Compounding. Available at http://www.usp.org/usp-healthcare-professionals/compounding/compounding-general-chapters
- American Society of Health-System Pharmacists Foundation. Outsourcing Sterile Products Preparation: Contractor Assessment Tool. Available at http://www.ashpfoundation.org/SterileProductsTool



Appendix 4

Cerebrospinal Fluid Pharmacokinetics

Ankur Dave and Punam Narang

Introduction

The advent of neuraxial analgesia can be traced to the late 1800's with the work of Leonard Corning and the first spinal anesthetic in 1898 by August Bier. Subsequently, in 1907, Arthur E. Barker studied the effects of different local anesthetics in spinal anesthesia and found that baricity and position of patient were two contributing factors in determining the level of the spinal blockade (1). For many years thereafter, the primary theory about cerebrospinal (CSF) pharmacokinetics revolved around uniform distribution of CSF and medications throughout the intrathecal space, despite many 'failed spinals'.

More recent studies have transformed our understanding of the spinal space and CSF circulation. In 2002, Hogan discovered the distribution of solution in the epidural space is non-uniform (2). Further studies since then have supported that the movement of medication in both the epidural and subarachnoid spaces is complex and variable.

Properties Affecting Intrathecal Medications

Anatomic Considerations

Numerous factors have been postulated to affect spinal anesthetic block height, including: site of injection, direction of needle, volume, and density. (3) Most of these factors assume that spinal fluid flow is equally distributed. However, variability in CSF distribution, CSF oscillations, and drug clearance play a role in the heterogenous spread of both opioids and local anesthetics in the subarachnoid space.

Of the 500 mL of CSF produced daily, less than 10% flows through the subarachnoid space. It was previously thought that this limited pool of CSF acts to bathe the delicate neuraxial structures uniformly (4). However, more recent studies have demonstrated that this volume of CSF is not distributed equally throughout the subarachnoid space. Carpenter et al (5) demonstrated that the lumbosacral region holds more CSF than the cervical and thoracic spine; their study concluded that this variability was the most important factor contributing to a lower than expected level of sensory block during spinal anesthesia. This was confirmed by Higuchi et al (6) who showed that larger CSF volume in the lumbosacral region was associated with a lower sensory block and less time for regression of the block. They also observed that CSF oscillated vigorously with arterial pulsations and created local pressure gradients, leading to alterations in the velocity of CSF flow (6).

Practical Applications

Anesthesiologists use a variety of measures to help determine the dose of spinal anesthetic to administer to a patient. However, based on the aforementioned studies, lumbosacral CSF volume seems largely responsible for the variable spread of spinal anesthesia. Clinically, this parameter is neither predictable nor controllable in the selected patient. One option is the placement of a spinal catheter instead of a single shot approach. Spinal anesthetic dose can then be adjusted based on patient response. However, the risks associated with placement of a short-term spinal catheter must be compared to the benefits for an individual patient. Another consideration is the effect of systemic circulation on CSF velocity. CSF pulsations might be an important factor in the clearance of spinal agents through the epidural venous plexus, which is closely coupled to CSF movement (8). CSF oscillation is also amplified with increased intra-abdominal pressure, which may explain the extended anesthetic effect in pregnant and obese patients (9).

Intrathecal Infusions

CSF flow heterogeneity is an important concept to consider when working with intrathecal infusions in the chronic pain patient. As the infusion continues over time, it is believed that intrathecal drug solution will eventually equally distribute throughout the spine. Further, decisions regarding drug dose, rate, and concentration are often based solely on patient symptoms and refill convenience. However, many studies have shown this not to be entirely true, and that other factors may be important.

Intrathecal Catheter Placement

The concept of CSF flow homogeneity has been used to obviate the importance of intrathecal catheter tip placement. Current dogma asserts that by increasing the dose of medication, analgesia can be achieved at rostrally located dermatomes, even if the catheter is placed lower in the spine. Kuttler et al showed via biosimulation of drug distribution in the CSF space that this was likely not true in practice. Figures A4.1 and A4.2 show the extent of drug heterogeneity once a solution is injected into the intrathecal space. Kuttler et al go on to mention it is more likely to achieve a higher dermatomal level after single injection than a

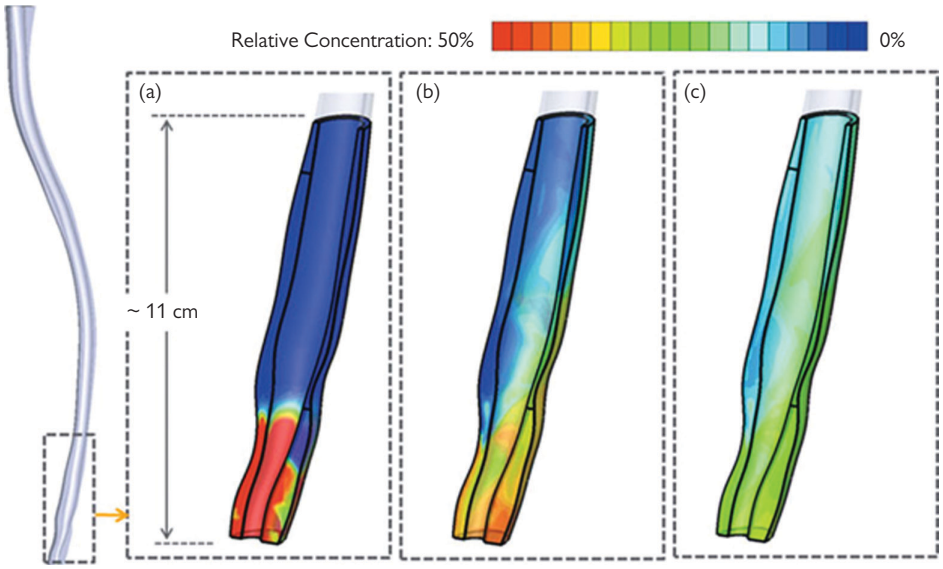


Figure A4.1 Three-dimensional drug propagation in the lower thoracic lumbar region starting from a concentration distribution simulated in a separate injection analysis (a). The contour plots (scaled to 50% of the initial concentration) after 10 minutes (b) and 20 minutes (c) show decreased and homogenized drug concentration levels.

slow infusion (10). Thus, the amount of heterogeneity may be increased in chronic infusions, according to this model. Another study by Flack et al (11) examined the distribution of morphine in the spinal cord after chronic infusions. As shown in Figure A4.3, morphine distribution is limited during chronic intrathecal delivery and there are significant spinal cord drug concentration gradients as a function of distance from the infusion point. Flack concludes that catheter tip position may be critical, particularly when infusing isobaric solutions (11).

Techniques for intrathecal drug delivery vary between individual physicians, in regards to catheter tip placement and analgesic drug mixtures. Some practitioners will place the catheter tip at a predetermined spinal segment, regardless of the patient's symptoms, others may place above the affected area or will determine the position based on the analgesic solution. In our practice the level where the catheter tip is situated relative to the patient's pain is important; our ideal placement is approximately in the middle of the symptomatic spinal segments. As Figure A4.3 proposes, intrathecal opioids reliably cover a limited number of segments, possibly six to eight. This stresses the need for appropriate patient selection and accurate physical examination; patients with widespread or non-continuous pain may only achieve partial benefit from intrathecal drug administration. By carefully selecting the level of intrathecal catheter tip placement, patients will achieve maximal benefit while reducing the risk of higher dosing of drug solutions.

Drug Distribution

Decisions on intrathecal drug doses, mixtures, and concentrations are made for various reasons, including symptom management and patient convenience. As mentioned above, precise placement of the intrathecal catheter tip will lower the spread required to achieve adequate analgesia and maximize symptom control. Patient independence is another important factor that may influence the physician to select a higher concentration and lower rate of medication;

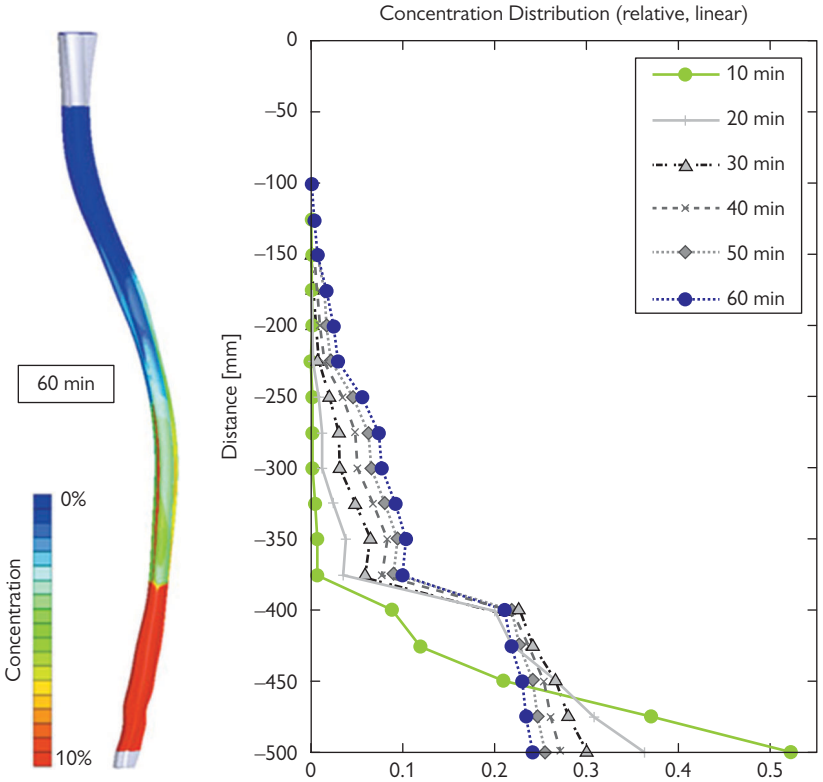


Figure A4.2 Steady streaming-based transport simulation of an initial concentration distribution (determined in a separate injection analysis) in the spinal CSF (left: contour plot of the local concentration levels 60 minutes after the injection (scaled to 10% of the initial concentration); right: averaged drug concentration profiles from L2 to C4 within the first hour postinjection.

patients with higher concentrations and lower rate of intrathecal drug infusion will require less frequent pump refills. However, this may not sufficiently cover a patient's pain. Further, a higher concentration of intrathecal medications may cause local spinal cord toxicity. High concentrations of local anesthetics in the intrathecal space (such as lidocaine, bupivacaine, and dibucaine) have been shown to cause demyelination and loss of axons; intrathecal opiates (such as morphine, hydromorphone, and methadone) have been associated with aseptic granulomatous masses, which may require neurosurgical intervention (12).

The daily dose of intrathecal drug, its concentration, and the rate of flow are inter related and are linked to the formation of intrathecal catheter tip inflammatory masses. Allen et al, while exploring this relationship found that increasing the concentration while administering the same dose(thereby reducing the rate) reliably led to the formation of these granulomas (7). In addition, the size of the masses regressed when the drug was removed from the infusion and replaced with saline. At this time, the precise combinations of medications and their behavior in CSF have not been elucidated. Precise placement of the intrathecal catheter tip in patients with a well-defined area of pain reduces the variability for many patients receiving chronic intrathecal infusions; these individuals will likely require a lower rate and lower concentration to achieve maximal analgesia. However, many patients may have surgical limitations to precise

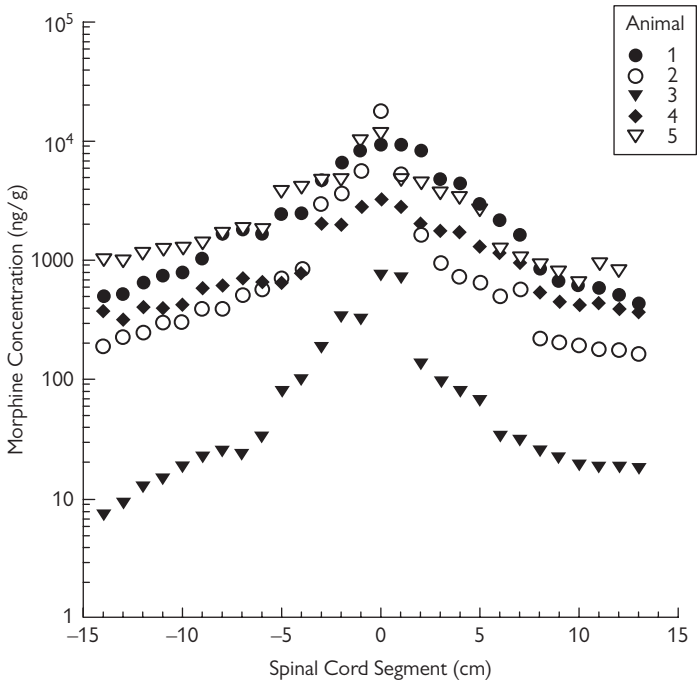


Figure A4.3 Morphine concentration (log scale) in each spinal cord segment from each animal. Animal 3 received one-tenth of the morphine dose (1 mg/mL at 2 μL/h) in comparison with the other animals (1 mg/mL at 20 μL/h); n = 4 animals.

placement of the intrathecal catheter tip or may not have adequate analgesia despite apparently optimal catheter placement. Adjusting the intrathecal medications in these settings must be done on a patient-by-patient basis.

Opiate Ceiling Effect

One of the indications for intrathecal drug pumps is to reduce the total opioid consumption in a patient. However, there is a subset of intrathecal pump patients who do not achieve satisfactory analgesia despite sufficient doses of intrathecal opiates. Gradual up-titration of intrathecal opioids, with the hope of either increasing the spinal block height or increasing the opiate exposure to the involved spinal segments, may not always have the desired effect. As Figure A4.3 suggests, simply increasing the concentration of intrathecal opiate does not translate to higher spinal segment blockade and/or pain relief. Further, continually increasing doses of intrathecal opioids contributes to increasing side effects like opioid tolerance, neurotoxicity, and aseptic granuloma formation.

Conclusion

CSF flow and drug distribution were thought to be uniformly and evenly distributed throughout the spinal space; however, recent evidence seems to indicate otherwise. Several factors have been shown to affect the extent and rate of redistribution of drug in the lumbar spinal space. These include: bolus versus infusion, volume, rate, baricity, local CSF dilution, and CSF pulsations. (7)

Patient selection is the most important criteria to placing an intrathecal drug pump; patients with an anatomically defined pain syndrome are more appropriate candidates for this procedure. The location of the intrathecal catheter tip is crucial to provide maximal benefit to patients, as drug concentration seems to rapidly decrease with distance from the point of delivery. The intrathecal drug concentration and rate of delivery must be adjusted while weighing the risks and benefits as higher concentration and lower rate of intrathecal drug solutions may increase the risk of local drug toxicity.

While this multi-factorial variability provides unclear layers of complexity to chronic intrathecal infusions, appropriate management can provide significant improvement in patients' pain relief and quality of life.

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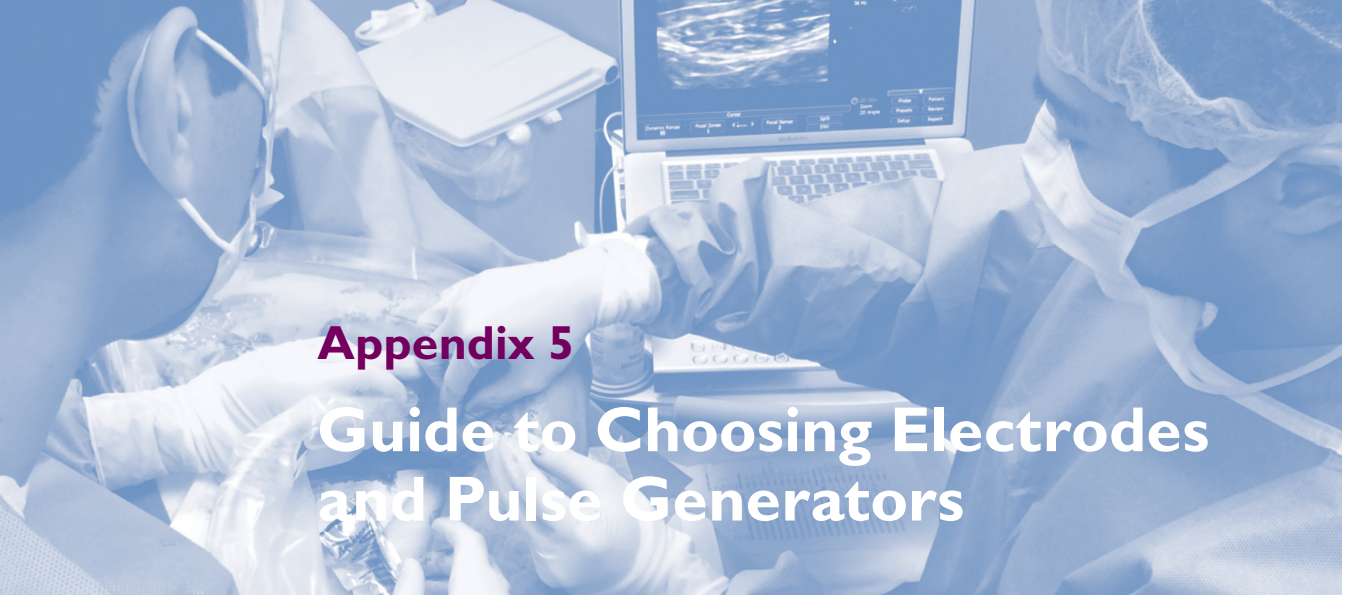


Appendix 5

Guide to Choosing Electrodes and Pulse Generators

Edgar L. Ross

Introduction

Stimulation technology has dramatically improved since its first use in the late 1970s. This steady improvement in treatment options, sophistication, and reliability has led to new clinical applications and more treatment options, flexibility, and innovative approaches to the treatment of chronic pain. The fundamental advantage of stimulation is the potential to effectively treat very difficult end-stage patients who have failed many other therapies with significant reductions or even elimination of supplemental analgesics. Optimal use of this treatment approach requires careful patient selection, as well as an understanding of electrophysiology and the appropriate system to use. Patient selection requires not only clearance by a psychologist but also an understanding of how much complexity the patient or the patient's family can effectively manage.

Factors Affecting Stimulation

- Anatomical location of the electrode
- Electrode array spacing and size of the electrodes
- Amplitude, pulse width, frequency, and number and polarity of active electrodes.

Anatomical Location of the Electrode

The fundamental governing principle for analgesia in using neuromodulation is the overlap of paresthesias with either the perceived or actual anatomical area of pain while minimizing unwanted stimulation in unaffected dermatomal areas. Location of the electrode is the principal means of delivering stimulation to the appropriate area. All other variables are used to focus and optimize analgesia. Active electrodes can either be cathodes (negative) or anodes (positive). Current flows from the anode to the cathode. In order for an electrical circuit to be complete and current to flow, at least one cathode and one anode must be active and close enough to overcome electrical resistance. Spinal cord stimulation leads are placed in the epidural space. In order for stimulation to occur, the electrical field must penetrate through epidural fat tissue, dura, and cerebral spinal fluid (CSF) covering the spinal cord. Each of these layers has unique electrical properties. The principal target of epidural stimulation is the dorsal column of the spinal cord, which is thought to house the large longitudinal myelinated afferent fibers. When placed over the dorsal columns, medial electrodes tend to cover more distal dermatomes, while lateral placements tend to cover more proximal dermatomes. More lateral placement over the dorsal root entry zone or elements of spinal nerve will focus the stimulation to adjacent dermatomes and reduce the amount of dermatomes covered.

Cerebrospinal Fluid Properties and Effects on Stimulation

The conductivity of CSF is such that epidurally generated electrical fields tend to be distributed laterally. CSF volume varies significantly by anatomical location and postural changes. The hourglass configuration of the spinal cord leaves relatively more CSF volume in the mid-thoracic area and high cervical levels. Increased volume of CSF decreases the selectivity between motor and sensory fibers because of the need to increase amplitude to achieve therapeutic stimulation. Increases in the number of electrodes in the desired area can overcome this. Spinal pathology can change CSF volumes. A review of spinal imaging before a stimulator trial is recommended.

Postural Changes

Optimal neuromodulation requires sufficient stimulation intensity to block the pain. However, stimulation intensity can vary widely with postural changes, causing an increase in intensity and painful paresthesia, which can significantly limit relief. If postural changes lead to a painful paresthesia, the patient will reduce stimulation intensity, compromising analgesia. Less commonly, some patients adjust stimulation intensity in anticipation of these postural changes. These changes in amplitude are related to changes in the distance between the targeted tracts and the active electrodes. This applies equally to either voltage- or amplitude-controlled systems. Generators that sense position changes can adapt to this movement, leading to a reduction of suboptimal stimulation and reliance on patient personal programmers.

The Electrode Programmer

Once the stimulator is placed, the electrode programmer is the only variable available to the implanter. Variables affecting stimulation are found in Table A5.1. Ideally, the active electrodes that cover the pain should be in the center of the leads. Ensuring adequate redundancy with active electrodes above and below the ideal location is an important characteristic for long-term success. Inadequate coverage secondary to electrode movement or changes in pain location can lead to revision surgery, which is usually much more difficult than the primary

Table A5.1 Variables Affecting Stimulation

Variable	Parameter	Effect
Amplitude	Volts or milliamps	Affects size of electrical field, leading to increased surface area covered and intensity of stimulation.
Pulse width	Duration of stimulus measured in microseconds	Increases recruitment of nerve fibers, spreads the stimulation for more neural elements.
Rate	Hertz or cycles per second	Changes perception of stimulation and patient preference. Changes selectivity of nerve fiber recruitment.
Electrode spacing and size	Millimeters between contacts and size of contacts	Smaller spacing leads to increased penetration of spinal cord and number of dermatomes covered and selectivity of dorsal column fibers. Wider spacing of electrodes will lead to less penetration of current but will cover a greater span of vertebral bodies

procedure. Program adjustments affecting electrode spacing, number of electrodes in the ideal area, amplitude, rate, and pulse width can be used to improve the selectivity of which nerve fibers are stimulated. Electrode programming choices for electrodes and rationals are found in Table A5.2. Table A5.3 reviews electrode choices by manufactor.

Implantable Pulse Generators

Implantable pulse generators (IPG) can be categorized into 2 basic types, rechargeable or non-rechargeable. In general, rechargeable generators are more cost-effective in high-energy applications. The rechargeable units are smaller because of their battery size. In high-energy applications, these smaller units can require very frequent or even potentially daily recharge

Table A5.2 Programming Options for Various Electrodes

Electrode Programming					
Anode—cathode	Simple monopole				Increased coverage with increased amplitude. Limited by lateral spread of current and resulting painful stimulation.
Guarded cathode (transverse or longitudinal)		Lead 3	Lead 2	Lead 1	
	Longitudinal guarded cathode single lead	N/A	N/A	+	Focused stimulation on a localized area. allowing higher amplitudes with less lateral spread and deeper penetration and wider coverage. Provides for wider therapeutic window between pain relief and painful stimulation
				–	
				+	
	Transverse guarded cathode 2 leads	N/A		+	
		N/A	–		
		N/A		+	
	Transverse guarded cathode 3 leads	+	–	+	
Energy consumption	Increase in approximate rank order, increased amplitude, number of active electrodes, increasing pulse width, increased rate				

Table A5.3 Electrode Choices by Manufacturer

Manufacturer	Type	Electrode name/model	Diameter or dimensions/ length(s)	Electrode number	Electrode size/ spacing edge to edge	Electrode distribution/array length
Medtronic	Percutaneous	Pisces Compact 3887	1.3/33, 45, 56	4	3.0/4.0	Symmetric/24.0
		Pisces Standard 3887A	1.3/28, 33, 45, 56	4	3.0/6.0	Symmetric/30.0
		Pisces Plus 3888	1.3/33, 45, 56	4	6.0/12.0	Symmetric/60.0
		3776 1 x 8 SC	1.3/45, 60, 75	8	3.0/1.5	Symmetric/34.5
		37781 x 8 Compact	1.3/45, 60, 75	8	3.0/4.0	Symmetric/52.0
		3777 1 x 8 Standard	1.3/45, 60, 75	8	3.0/6.0	Symmetric/66.0
	Paddle	Resume II 3587A	8 x 1.8/25	4	4.0/6.2	Circular in-line/34.6
		Resume TL 3986A	6.6 x 1.4/25, 45, 60, 70	4	4.0/6.2	Circular in-line/34.6
		On-Point 3987A	6.6 without mesh x 1.4/25, 60	4	4.0/6.2	Circular in-line/34.6
		Specify 3998	7.9 x 1.8/21	8	2.0/6.0	Rectangle 2 rows of 4 symmetric/30
		2 x 4 Hinged Specify 3999	9.9 x 1.8/30, 45, 60	8	2.0/3.3	Rectangle 2 rows of 4 asymmetric/28.2
		Specify 2 x 8 39286	7.6 x 1.8/30, 65	16	1.5/1.0	Rectangle 2 rows of 8 symmetric/43.0
		Specify 39565 5-6-5	10.0 x 2.0/30, 65	16	1.5/4.5	Rectangle 3 rows of 5-6-5 center row offset/49.0
Boston Scientific	Percutaneous	Linear	1.3/30, 50, 70	8	3.0/1	Symmetric/31.0
		Linear ST	1.3/30, 50, 70	8	3.0/1	Symmetric/31.0
		Linear 3-4	1.3/30, 50, 70	8	3.0/4	Symmetric/52.0
		Linear 3-6	1.3/30, 50, 70	8	3.0/6	Symmetric/66.0
	Paddle	Artisan 2 x 8	8 x 2/45.7	16	3 x 2/1	Symmetric/Oblong 5.7 x 31

St. Jude Medical	Percutaneous	Quattrode 3/4 3143/3146 3149/3141	1.4/30, 60, 90, 110	4	3 x 4	Symmetric/24
		Quattrode 3/6 3153/3156 3159/3151	1.4/30,60,90,110	4	3 x 6	Symmetric/30
		Wide Spaced Quattrode 3066	N/A60	4	3 x 11 and 18	Symmetric/52
		Octrode 3183/3186 3189/3181	1.4/30, 60, 90, 110	8	3 x 4	Symmetric/52
		Axxess 3/4 4143/4146	0.84/30, 60	4	3 x 4	Symmetric/24
		Axxess 3/6 4153/4156	0.84/30, 60	4	3 x 6	Symmetric/30
	Paddle	Lamitrode S4 3243/3246/3266/3267		4		
		Lamitrode 4 3240/3254/3255		4		
		Lamitrode 22 3222		4		
		Lamitrode S8 3283/3286/3268/3269		8		
		Lamitrode 8 3280		8		
		Lamitrode 44 3244/3262/3263		8		
		Lamitrode 44C 3245/3264/3265		8		
		Lamitrode Exclaim 3224/3225		12/8 Channel		
		Lamitrode Tripole 8 3208		14/8 Channel		
		Lamitrode Tripole 8C 3210		14/8 Channel		
		Lamitrode 88 3288		16		
		Lamitrode 88C 3289		16		
		Lamitrode Tripole 16C 3214		16		
		Penta 3228		20		

(*continued*)

Table A5.3 Continued

Manufacturer	Type	Electrode name/model	Diameter or dimensions/ length(s)	Electrode number	Electrode size/ spacing edge to edge	Electrode distribution/array length
Medtronic	Percutaneous	Pisces Compact 3887	1.3/33, 45, 56	4	3.0/4.0	Symmetric/24.0
		Pisces Standard 3887A	1.3/28, 33, 45, 56	4	3.0/6.0	Symmetric/30.0
		Pisces Plus 3888	1.3/33, 45, 56	4	6.0/12.0	Symmetric/60.0
		3776 1 x 8 SC	1.3/45, 60, 75	8	3.0/1.5	Symmetric/34.5
		3778 1 x 8 Compact	1.3/45, 60, 75	8	3.0/4.0	Symmetric/52.0
		3777 1 x 8 Standard	1.3/45, 60, 75	8	3.0/6.0	Symmetric/66.0
	Paddle	Resume II 3587A	8 x 1.8/25	4	4.0/6.2	Circular in-line/34.6
		Resume TL 3986A	6.6 x 1.4/25, 45, 60, 70	4	4.0/6.2	Circular in-line/34.6
		On-Point 3987A	6.6 without mesh x 1.4/25, 60	4	4.0/6.2	Circular in-line/34.6
		Specify 3998	7.9 x 1.8/21	8	2.0/6.0	Rectangle 2 rows of 4 symmetric/30
		2 x 4 Hinged Specify 3999	9.9 x 1.8/30, 45, 60	8	2.0/3.3	Rectangle 2 rows of 4 asymmetric/28.2
		Specify 2 x 8 39286	7.6 x 1.8/30, 65	16	1.5/1.0	Rectangle 2 rows of 8 symmetric/43.0
		Specify 39565 5-6-5	10.0 x 2.0/30, 65	16	1.5/4.5	Rectangle 3 rows of 5-6-5 center row offset/49.0
Boston Scientific	Percutaneous	Linear	1.3/30,50,70	8	3.0/1	Symmetric/31.0
		Linear ST	1.3/30,50,70	8	3.0/1	Symmetric/31.0
		Linear 3-4	1.3/30,50,70	8	3.0/4	Symmetric/52.0
		Linear 3-6	1.3/30,50,70	8	3.0/6	Symmetric/66.0
	Paddle	Artisan 2 x 8	8 x 2/45.7	16	3 x 2/1	Symmetric/Oblong 5.7 x 31

St. Jude Medical	Percutaneous	Quattrode 3/4 3143/3146 3149/3141	1.4/30,60,90,110	4	3 x 4	Symmetric/24
		Quattrode 3/6 3153/3156 3159/3151	1.4/30,60,90,110	4	3 x 6	Symmetric/30
		Wide Spaced Quattrode 3066	N/A60	4	3 x 11 and 18	Symmetric/52
		Octrode 3183/3186 3189/3181	1.4/30,60,90,110	8	3 x 4	Symmetric/52
		Axxess 3/4 4143/4146	0.84/30,60	4	3 x 4	Symmetric/24
		Axxess 3/6 4153/4156	0.84/30,60	4	3 x 6	Symmetric/30
	Paddle	Lamitrode S4 3243/3246/3266/3267	4	4	3	25
		Lamitrode 4 3240/3254/3255	4	4	6	34
		Lamitrode 22 3222	4	4	3.6	12(x2)
		Lamitrode S8 3283/3286/3268/3269	4	8	3	53
		Lamitrode 8 3280	4	8	3.5	56
		Lamitrode 44 3244/3262/3263	4	8	3	28
		Lamitrode 44C 3245/3264/3265	4	8	3	28
		Lamitrode Exclaim 3224/3225	R:5.8 C:2.2	12/8 Channel	1.6	21
		Lamitrode Tripole 8 3208	Ctr:4 Out:6	14/8 Channel	Ctr:3 Out:1	39
		Lamitrode Tripole 8C 3210	Ctr:4 Out:6	14/8 Channel	Ctr:3 Out:1	39
		Lamitrode 88 3288	4	16	3	56
		Lamitrode 88C 3289	4	16	3	56
		Lamitrode Tripole 16C 3214	Ctr:4 Out:6	16	Ctr:3 Out:1	40
		Penta 3228	4	20	3	25

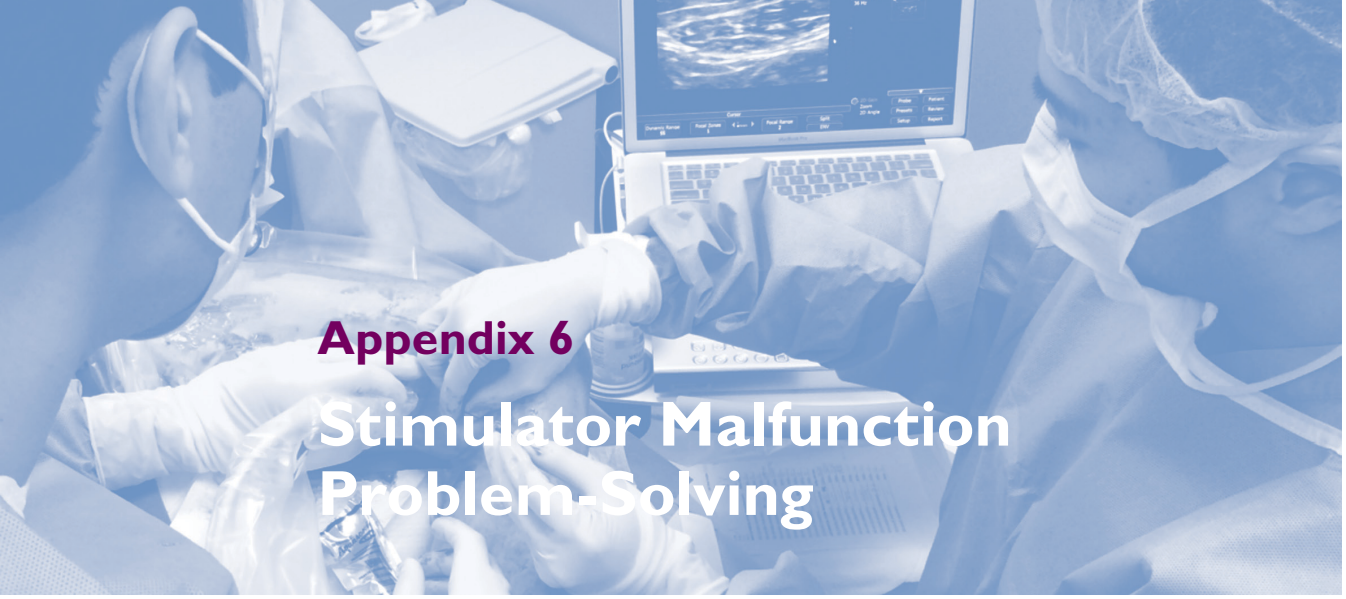
* Check with each manufacturer's specific requirements for details regarding MRI safety, preparation, and use.

Table A5.4 IPG Features by Manufacturer

Manufacturer (MRI safety)*	IPG type	Features	Rechargeable?	Size(ccs)	Electrode capacity	FDA approved lifespan
Medtronic (Full body MRI safe, requires newly introduced electrode types and IPGs and epidural use only.)	Restore Sensor	Programmable accelerometer that responds to position changes automatically and "learns" optimal stimulation parameters and activity monitor. This feature only approved for lumbar applications.	Yes	22	16	9 years
	Restore Ultra	Same size and Restore sensor, but without accelerometer	Yes	22	16	9
	Restore Advanced	Larger battery capacity for high-current applications	Yes	39	16	9
	Restore Prime	Basic cost-effective solution	No	39	16	Variable
	Prime Advanced	Same as Restore Advanced with more programming options	No	39	16	Variable
	Itrel 4	Updated Itrel 3 replacement	No	28	4	Variable
Boston Scientific (conditional approval for head only)	Precision Spectra	Multiple independent current control, electronically generated lead location without need for imaging. Near field programming	Yes	22	32 with 4 ports to accommodate 8 electrodes	≥ 5
	Precision Plus	Multiple independent current control, electronically generated lead location without need for imaging. Near field programming	Yes	22	16	≥ 5
St. Jude Medical (Not MRI compatible)	Eon Mini	Small and light weight	Yes	18	16	10 Years
	EonC	Prime cell, cost-effective	No	49	16	Variable
	Eon	Large rechargeable battery	Yes	42	16	10
	Protégé	Upgradable software and smallest rechargeable IPG	Yes	17.7	16	Variable

sessions. This frequency can require significant time and has the potential to run counter to goals of chronic pain therapy.

Planning for the type of generator should begin with the trial. If high amplitudes, multiple active electrodes, and long pulse width are required initially, one can anticipate only further increases, and large capacity IPGs should be considered. The technical expertise needed to recharge these IPGs is minimal, but for some patients it is a difficult concept. In these situations, consideration should be given to prime cells or non-rechargeable devices. In lower energy applications, the prime cells are much cheaper over the long run and need much less maintenance. The current IPG choices are found in Table A5.4.



Appendix 6
Stimulator Malfunction Problem-Solving

Edgar L. Ross

Introduction

The growing sophistication of stimulators has resulted in the use of this modality in many more clinical applications than ever before. With these new applications and device sophistication, a successful implant program must have the resources to investigate and correct stimulator malfunctions. A methodical approach to troubleshooting can often solve stimulator problems very quickly without the need for further surgery or procedures. The history provided by the patient is the first and most important step in this process. A list of questions to ask is found in Table A6.1. The flow chart depicted in Figure A6.1 can be used to determine most of the common causes of stimulator malfunctions.

Table A6.1 Approach to Troubleshooting Stimulator Malfunction

Questions to ask patient	Yes	No
1. Is the painful area in the same location as always, is the character of the pain same as usual?		
2. Does the patient feel paresthesias?		
3. If the patient feels paresthesias, are they painful?		
4. If the paresthesiais are not painful, are they overlapping with the painful area?		
5. If the paresthesias are overlapping the painful area, are they providing analgesia?		
6. If the paresthesias are not providing analgesia, did the stimulator work at some point?		
7. Have you fallen, participated in unusual activity, or injured yourself in any way since the stimulator last worked?		

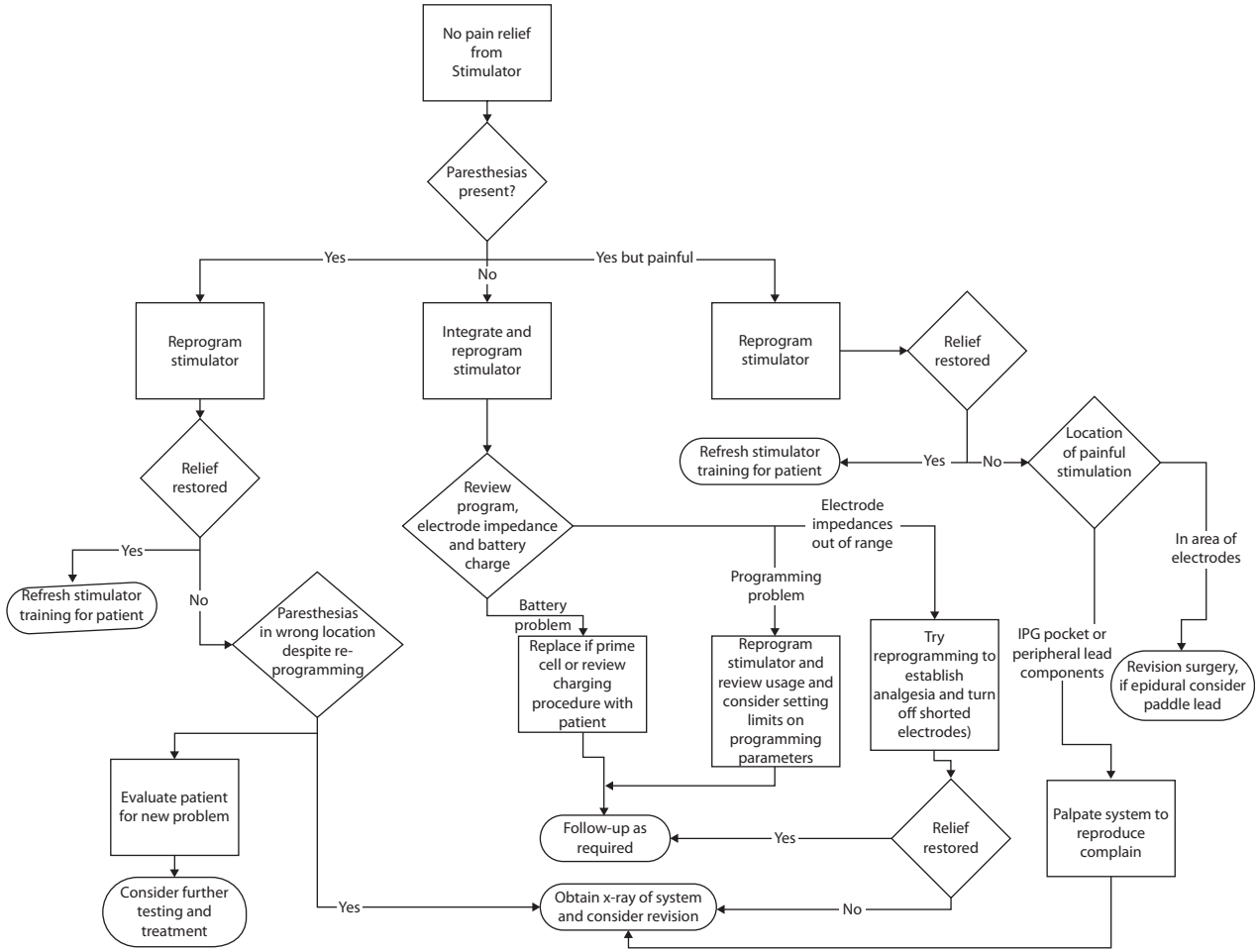


Figure A6.1 Flow chart to help determine common causes of stimulator malfunction.

Case Studies

Case 1

A 42-year-old woman reports that her stimulator suddenly has stopped functioning and that there is a painful spot along the path of her stimulator whenever she turns it on. Questions 1 through 7 are answered as follows: 1-yes, 2-yes, 3-yes, 4-no, 5-no, 6-yes, 7-no. Based on the answers and following the flow chart, the next step is measurement of impedances. These are found to be out of normal range. An X-ray is then obtained; diagnosis is lead extension fracture requiring revision, noted by the yellow oval in Figure A6.2.

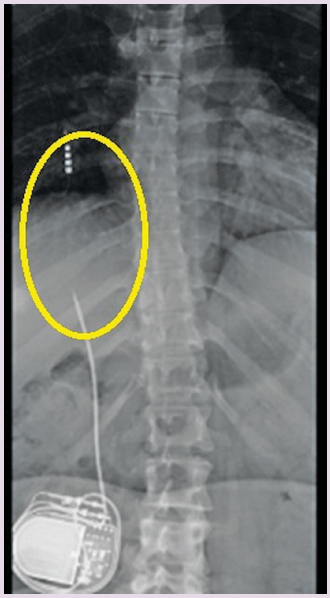


Figure A6.2 Fluoroscopic image showing lead extension fracture.

Case 2

A 36-year-old car mechanic returns with loss of pain relief from his stimulator. Reprogramming is not effective in restoring effective stimulation. ; He reports stimulation only in his back. Questions 1 through 7 are answered as follows: 1-yes, 2-yes, 3-no, 4-no, not completely, 5-yes, 6-yes, 7-no, other than returning back to work. Impedances are in the normal range. X-ray obtained reveals complete retraction of leads out of the epidural space for one lead circled by the yellow oval, while the second remains in place (see Figure A6.3). Patient's job requires significant bending, which is likely the cause of the electrodes being pulled out. Placement of generators was also moved, to avoid a traction point on the electrodes, thus reducing the risk of the electrodes being displaced again.

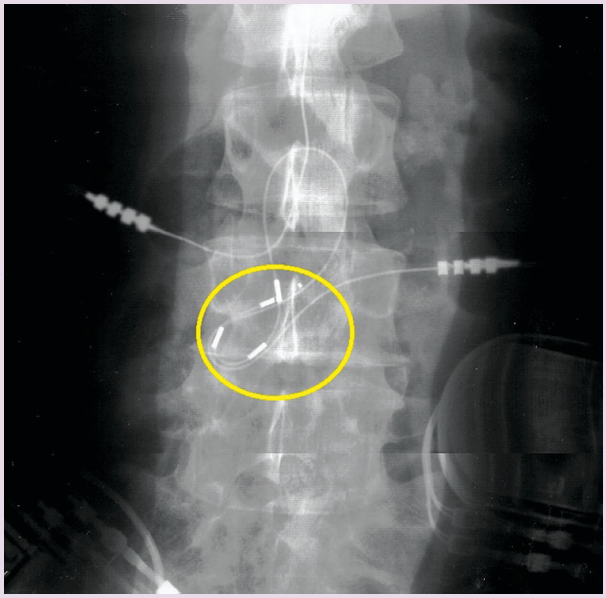


Figure A6.3 Fluoroscopic image of one lead outside the epidural space and one lead remaining in the epidural space.

Appendix 7

Implantable Devices and Equipment

Michael Vaninetti and Edgar L. Ross

This appendix displays various models of implantable devices and equipment for spinal cord stimulation, targeted drug delivery therapy, and percutaneous lumbar decompression (Figures A7.1).

Medtronic

Figure A7.1 Medtronic Synchromed II Implantable Intrathecal Pump. Reprinted with the permission of Medtronic, Inc. © 2008.

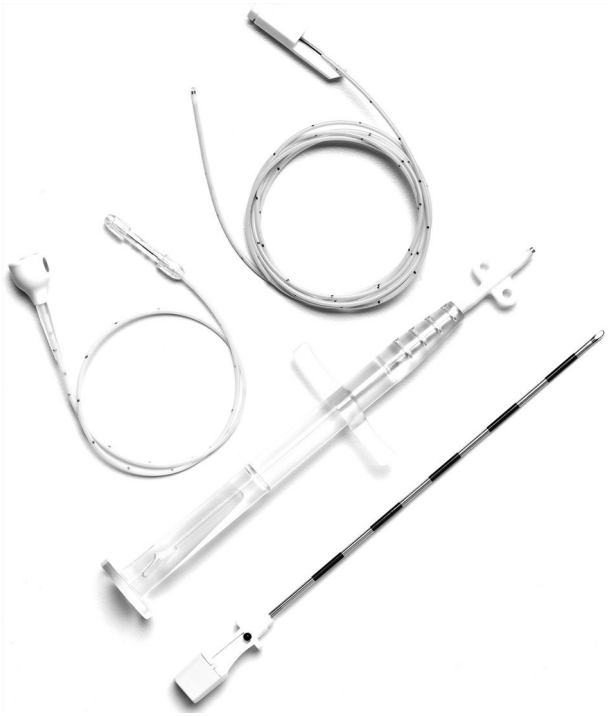


Figure A7.2 Medtronic Intrathecal Catheter, Introducer Needle, and Anchoring Device. Reprinted with the permission of Medtronic, Inc. © 2008.

Figure A7.3 Medtronic IT Pump Catheter Access Port Kit. This example Medtronic Catheter Access Port (CAP) Kit includes a sterile drape, templates for transcutaneously locating the CAP, noncoring needles, tubing, filter, and syringe. Reprinted with the permission of Medtronic, Inc. © 2008.

Figure A7.4 Medtronic Personal Therapy Manager, Clinician Programmer, and Intrathecal Pump. Reprinted with the permission of Medtronic, Inc. © 2010.

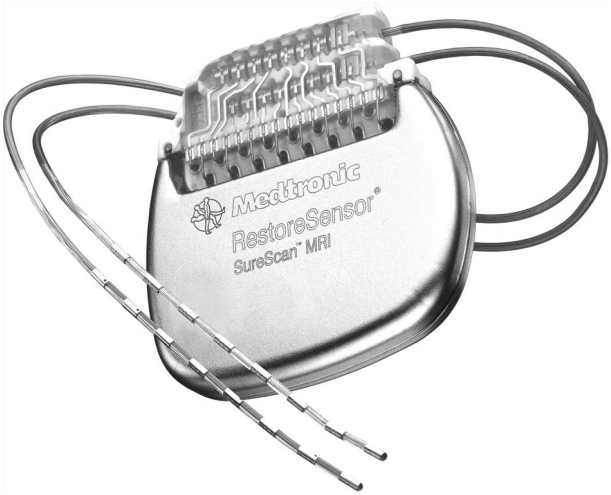


Figure A7.6 Medtronic RestoreSensor Neuromodulation Generator with Percutaneous Leads. Reprinted with the permission of Medtronic, Inc. © 2013.

Boston Scientific

Figure A7.7 Boston Scientific Precision Spectra Spinal Cord Stimulator Generator. Reprinted with the permission of Boston Scientific.

Figure A7.8 Boston Scientific Spinal Cord Stimulator Generator, close-up of ports. Reprinted with the permission of Boston Scientific.

Figure A7.9 Boston Scientific Precision Spinal Cord Stimulator Set. Reprinted with the permission of Boston Scientific.

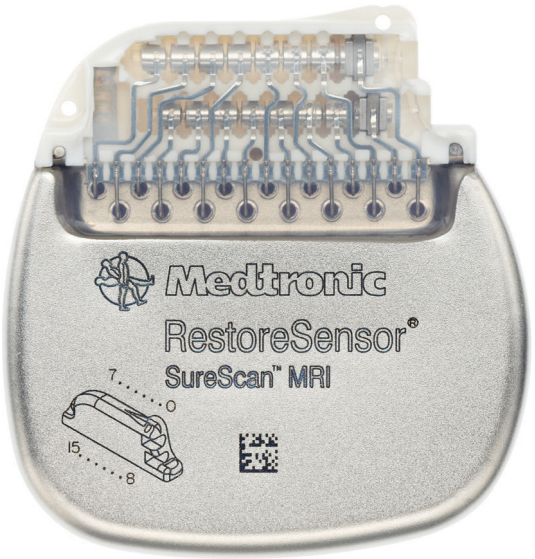


Figure A7.5 Medtronic RestoreSensor Neuromodulation Generator. Reprinted with the permission of Medtronic, Inc. © 2013.

Figure A7.10 Boston Scientific Spinal Cord Stimulator Remote. Reprinted with the permission of Boston Scientific.

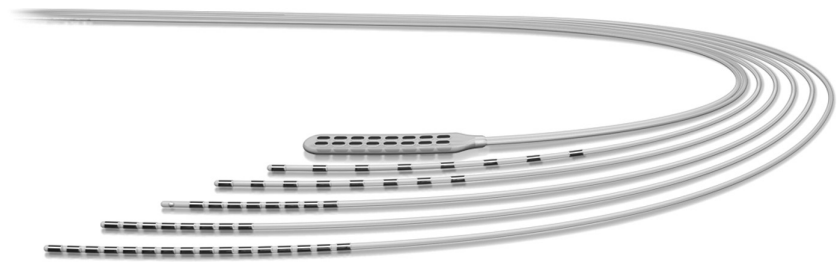


Figure A7.11 Boston Scientific Spinal Cord Stimulator Leads. Reprinted with the permission of Boston Scientific.

St. Jude Medical

Figure A7.12 St. Jude Medical Protégé Spinal Cord Stimulator Generator. Reprinted with the permission of St. Jude Medical.

Figure A7.13 St. Jude Medical Prodigy Spinal Cord Stimulator Generator. Reprinted with the permission of St. Jude Medical.

Vertos Medical

Figure A7.14 Complete MILD kit. Reproduced with the permission of Vertos Medical.

Appendix 8

Food and Drug Administration Medical Device Reporting

Edgar L. Ross

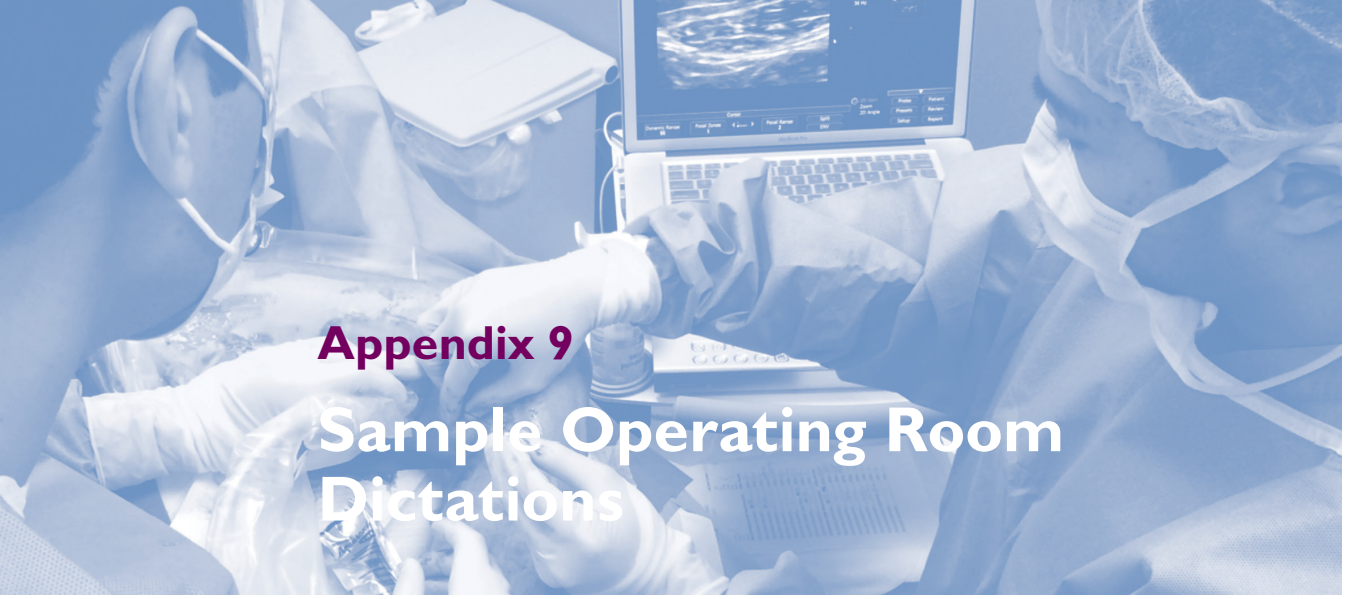
Implantable device recalls and advisories are prompted by patterns found from the hundreds of thousands of reports that the US Food and Drug Administration (FDA) receives each year. These reports can come from multiple sources, including healthcare professionals, patients and their caregivers, manufacturers, facilities where the devices are implanted, and importers of these devices. Mandatory reporting is required for manufactures, importers, and end-user facilities where serious harm or death has occurred that potentially can be attributed to a device. This information is an important part of post-marketing surveillance that improves both the quality and safety of implantable devices. Forms received from manufacturers should be filled out as completely as possible. Human-device interfaces are an important source of possible medical errors. When a medical error occurs, a Quality Assurance (QA) discussion should be held under an umbrella of peer review process, even when no harm comes to a patient. In addition, where a human-device interface problem is identified, a volunteer report using the MedWatch Form FDA 3500 should be used. The FDA has published a guidance document for facility device users (see "Medical Device Reporting for User Facilities," available online, for details regarding these standards).

The FDA has mechanisms in place that facilitate voluntary medical device reporting. These mechanisms are available for healthcare professionals, patients, caregivers, and consumers when significant adverse events occur. Access is through "MedWatch" or even through "MedWatcher mobile application."

One of the most important tasks that implanting physicians have is to remain current regarding any advisories or recalls for the devices they use. These reports can be accessed through the Manufacturer and User Facility Device Experience (MAUDE) database. This website contains all the mandatory reporting filed by manufacturers and importers from August 1996, all mandatory user facility reports from 1991 to present, and all the voluntary reports filed after June 1993 to present.

Implanting physicians are a key resource for quality improvement. The FDA provides the framework that facilitates and organizes this process.

For online references see http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.



Appendix 9

Sample Operating Room Dictations

Raheel Bengali and Alison Weisheipl

Overview

Sample procedure dictations are provided in this appendix. Note that each section should be based on the actual procedure performed and techniques used. The templates should serve as a guide to the implanter, but should be tailored to each individual case. The sample dictations discussed in this appendix include the following: intrathecal pump placement (see Box A9.1); intrathecal pump replacement (see Box A9.2); spinal cord stimulator placement for percutaneous leads (see Box A9.3); spinal cord implantable pulse generator replacement (see Box A9.4); peripheral nerve stimulation (see Box A9.5); field stimulation (see Box A9.6); and epidural port-a-cath (see Box A9.7).

BOX A9.1 DICTATION FOR INTRATHECAL PUMP PLACEMENT

DATE OF PROCEDURE:

SURGEON:

ASSISTANT:

PREOPERATIVE DIAGNOSIS:

POSTOPERATIVE DIAGNOSIS:

OPERATION: Intrathecal pump placement.

ANESTHESIA: General or Spinal

ESTIMATED BLOOD LOSS:

SPECIMENS: No specimens were removed.

INDICATIONS FOR PROCEDURE:

Include brief HPI discussing patient history and indications for procedure.

Example: This is a 52-year-old woman <*age/sex*> with chronic chest and left shoulder pain not controlled with conventional management who presents for intrathecal pump implant after successful epidural catheter trial.

DESCRIPTION OF PROCEDURE:

The patient was seen in the preoperative holding area. All of her questions were answered and her consent was signed. We discussed pump placement located at the <*left/right anterior abdomen just above the belt line*> and her skin was marked. A <*Insert device company*> <*insert size (40 mL or 20 mL)*> pump was interrogated in the box and the serial number was matched along with calibration constant.

The patient was brought to the operating room. <*Antibiotics 2 grams of Ancef*> were given 30 minutes prior to the incision. The patient was then induced with general anesthesia with an endotracheal tube.

The patient was then placed in the <*insert position*> position. With C-arm guidance, AP, lateral, and contralateral oblique views were obtained of the lumbar and thoracic spine. The patient was then prepped and draped in a sterile fashion. The skin over the target area was anesthetized and an incision was made. A 15-gauge introducer needle was then placed in the subarachnoid space at the <*insert level*> under direct fluoroscopy. The intrathecal catheter was then guided cephalad and midline approximately to the <*insert desired level*> vertebral body level. The needle was partially pulled back, approximately 1 cm, out of the subarachnoid space. Incision was made down to lumbodorsal fascia. A purse-string suture was placed with 0 Ethibond around the needle, and stay sutures for the anchor loops.The anchor was placed and secured with the stay sutures. The stylet from the intrathecal catheter and the needle were then removed and direct CSF flow was noted from the end of the catheter.The anchor was deployed and the purse string suture tightened. CSF flow was again reconfirmed. The pump was prepped as instructed and drained of its water and filled with <*insert drug mixture concentration here*>.

The skin overlying the desired pump pocket was anesthetized with 2% lidocaine plus epinephrine 1:200,000 and 0.5% bupivacaine solution in equal volumes. The skin was incised and the pocket formed by blunt dissection. A tunneling device was used to tunnel from the posterior back incision to the pump pocket incision. The intrathecal catheter and an epidural catheter were then passed through the tunneling device. The tunneling device was then removed and the intrathecal catheter and epidural catheter were held in place. Once

BOX A9.1 CONTINUED

the tunneling device was removed, the epidural catheter was withdrawn while injecting approximately 6 mL of 0.5% bupivacaine to anesthetize the track. The intrathecal catheter was then connected to the pump using the sutureless connector. <*To aid in stability, 2-0 silk suture was used to secure the catheter to the pump.*> The pump was placed in the pouch and sutured to the fascial layer using 0 Ethibond.

At this time, both the midline back and the pump incisions were irrigated copiously with antibiotic solution. The midline back incision and pump pocket were both closed using interrupted sutures, first the deep layer with 2-0 vicryl, followed by 3-0 vicryl, and finally a running subcuticular stitch with 4-0 monocryl. The wound sites were dressed with Dermabond and steri-strips, and covered with a Telfa gauze and Tegaderm. The pump was interrogated and set to deliver a priming bolus of <*insert dose of bolus here*> and the pump was set at a rate of <*insert rate here*>.

The patient was returned to the supine position. The patient emerged from anesthesia without event. The patient tolerated the procedure well. There were no complications and the patient had minimal pain and did well in the recovery room.

BOX A9.2 DICTATION FOR INTRATHECAL PUMP REPLACEMENT

DATE OF PROCEDURE:

SURGEON:

ASSISTANT:

PREOPERATIVE DIAGNOSIS:

POSTOPERATIVE DIAGNOSIS:

OPERATION: Intrathecal pump replacement.

ANESTHESIA: General vs MAC

ESTIMATED BLOOD LOSS:

SPECIMENS: Old pump sent to Pathology for ID only.

INDICATIONS FOR PROCEDURE:
Include brief HPI discussing patient history and indications for procedure.

Example: This is a 52-year-old woman <*age/sex*> with chronic chest and left shoulder managed with intrathecal medications who presents for intrathecal pump replacement as her current pump has reached end-of-life.

DESCRIPTION OF PROCEDURE:
The patient was seen in the preoperative holding area. All of her questions were answered and her consent was signed. We discussed pump replacement located at the <*left/right anterior abdomen just above the belt line*> and her skin was marked. A <*Insert device company*> <*insert size (40 mL or 20mL)*> pump was interrogated in the box and the serial number was matched along with calibration constant.

The patient was brought to the operating room and placed supine. <*Antibiotics 2 grams of Ancef* > were given 30 minutes prior to the incision. The patient was then administered general anesthesia with an endotracheal tube.

The patient was prepped and draped in a sterile fashion. Preliminary fluoroscopy was done to ensure the relative position of the pump and catheter such that it may not be accidentally cut. The skin overlying the desired pump pocket was anesthetized with 2% lidocaine

BOX A9.2 CONTINUED

plus epinephrine 1:200,000 and 0.5% bupivacaine solution in equal volumes. The skin was incised and the pocket explored by blunt dissection until the old pump was exposed. The catheter was disconnected from the pump, and the pump was removed. The new pump was placed in the pocket and connected to the catheter after free flow of CSF confirmed and dead space volume of catheter was free of drug. The pump was placed in the pouch and sutured to the fascial layer using 0 ethibond.

The pump incision was irrigated copiously with antibiotic solution. The incision was closed using interrupted sutures, first the deep layer with 2-0 vicryl, followed by 3-0 vicryl, and finally a running subcuticular stitch with 4-0 monocryl. The wound sites were dressed with Dermabond and steri-strips, and covered with a Telfa gauze and Tegaderm. The pump was interrogated and set to deliver the original rate of medication to the patient.

The patient emerged from anesthesia without event. The patient tolerated the procedure well. There were no complications and the patient had minimal pain and did well in the recovery room.

BOX A9.3 DICTATION FOR SPINAL CORD STIMULATOR PLACEMENT: PERCUTANEOUS LEADS

DATE OF PROCEDURE:

SURGEON:

ASSISTANT:

PREOPERATIVE DIAGNOSIS:

POSTOPERATIVE DIAGNOSIS:

OPERATION: Spinal Cord Stimulator Placement

ANESTHESIA: General vs MAC

ESTIMATED BLOOD LOSS:

SPECIMENS: No specimens were removed.

INDICATIONS FOR PROCEDURE:

Include brief HPI discussing patient history and indications for SCS device.

Example: This is a 52-year-old woman with chronic bilateral lower extremity pain who has failed conventional treatment and has had successful spinal cord stimulator trial and is here for permanent implantation of spinal cord stimulator.

DESCRIPTION OF PROCEDURE:

The patient was seen in the preoperative holding area. All of her questions were answered and her consent was signed. We discussed spinal cord stimulator generator placement located at the <*left/right upper and outer buttocks below the belt line*> and her skin was marked.

The patient was brought to the operating room. <*Antibiotics 2 grams of Ancef* > were given 30 minutes prior to the incision. The patient was then placed in the prone position and given conscious sedation by the anesthesia team.

With C-arm guidance, AP, lateral, and contralateral oblique views were obtained of the lumbar and thoracic spine. The patient was then prepped and draped in a sterile fashion. The skin over the target area was anesthetized and an incision was made. A 14-gauge introducerneedle was then placed paramedian at the <*insert level*> under direct fluoroscopy and

BOX A9.3 CONTINUED

the epidural space was identified by loss of resistance technique to <*saline/air*>. The spinal cord stimulator lead was then guided cephalad and midline approximately to the <*insert desired interspace*> interspace. The position of the lead was confirmed by fluoroscopy and through test stimulation. No cerebro-spinal fluid or heme was noted on the lead placement. The patient reported good response covering the area of pain. The introducer needle was then removed and the lead was anchored to the paraspinal muscles and fascia using the manufacturer's anchoring device. This was held in place by two 0 ethibond sutures. The procedure was then repeated for the second lead, and the final placement was confirmed with fluoroscopy.

The skin overlying the desired generator pocket was anesthetized with 2% lidocaine plus epinephrine 1:200,000 and 0.5% bupivacaine solution in equal volumes. The skin was incised and the pocket formed by blunt and sharp dissection using electrocautery. A tunneling device was used to tunnel the leads from the pocket to the posterior spineincision. The leads and an epidural catheter were then passed through the tunneling device. The tunneling device was then removed and the leads and epidural catheter were held in place. Once the tunneling device was removed, the epidural catheter was withdrawn while injecting approximately 6 mL of 0.5% bupivacaine to anesthetize the tract. Lead connections were then wiped clean and dried prior to connection and connected to the generator by tightening the device screws with the manufacturer supplied screwdriver. Telemetry confirmed correct placement with impedances. The leads were then coiled beneath the generator, creating loops to relieve any strain. The generator was placed in the pouch in the correct orientation and sutured to the fascial layer using 0 ethibond.

At this time, both the midline back and the generator incisions were irrigated copiously with antibiotic solution. The midline back incision and pocket were both closed using interrupted sutures, first the deep layer with 2-0 vicryl, followed by 3-0 vicryl, and finally a running subcuticular stitch with 4-0 monocryl. The wound sites were dressed with Dermabond and steri-strips, and covered with a Telfa gauze and Tegaderm.

The patient tolerated the procedure well. There were no complications and the patient had minimal pain and did well in the recovery room.

BOX A9.4 DICTATION FOR SPINAL CORD STIMULATOR IMPLANTABLE PULSE GENERATOR REPLACEMENT

DATE OF PROCEDURE:

SURGEON:

ASSISTANT:

PREOPERATIVE DIAGNOSIS:

POSTOPERATIVE DIAGNOSIS:

OPERATION: Spinal Cord Stimulator Replacement

ANESTHESIA: General vs MAC

ESTIMATED BLOOD LOSS:

SPECIMENS: Old IPG sent to Pathology for ID only

BOX A9.4 CONTINUED

INDICATIONS FOR PROCEDURE:

Include brief HPI discussing patient history and indications for procedure.

Example: This is a 48-year-old man with chronic bilateral lower extremity pain who has had a spinal cord stimulator placed previously and the battery IPG is nearing end of life and requires replacement.

DESCRIPTION OF PROCEDURE:

The patient was seen in the preoperative holding area. All of her questions were answered and her consent was signed. We discussed spinal cord stimulator generator replacement located at the <*left upper buttocks below the belt line*> and her skin was marked.

The patient was brought to the operating room. <*Antibiotics 2 grams of Ancef*> were given 30 minutes prior to the incision. The patient was then placed in the prone position and given conscious sedation by the anesthesia team.

The patient was then prepped and draped in a sterile fashion. The skin overlying the desired generator pocket was anesthetized with 2% lidocaine plus epinephrine 1:200,000 and 0.5% bupivacaine solution in equal volumes. The skin was incised and the pocket dissected by blunt dissection to the original generator. The leads were carefully removed from the generator, which was then taken off the field, and the new generator was placed in its pocket. The leads were reconnected after careful drying and wiping of the ends, and device telemetry showed normal impedances. The leads were then coiled beneath the generator, creating loops to relieve any strain. The generator was placed in the pouch in the correct orientation and sutured to the fascial layer using 0 ethibond.

At this time, the generator incision was irrigated with copious antibiotic solution. The incision was closed using interrupted deep sutures, first with 2-0 vicryl, followed by 3-0 vicryl, and finally a running subcuticular stitch with 4-0 monocryl. The wound site was dressed with Dermabond and steri-strips, and covered with a Telfa gauze and Tegaderm.

The patient tolerated the procedure well. There were no complications and the patient had minimal pain and did well in the recovery room.

BOX A9.5 DICTATION FOR PERIPHERAL NERVE STIMULATOR PLACEMENT

DATE OF PROCEDURE:

SURGEON:

ASSISTANT:

PREOPERATIVE DIAGNOSIS:

POSTOPERATIVE DIAGNOSIS:

OPERATION: Peripheral Nerve Stimulator Placement

ANESTHESIA: General vs MAC

ESTIMATED BLOOD LOSS:

SPECIMENS: No specimens were removed.

BOX A9.5 CONTINUED

INDICATIONS FOR PROCEDURE:

Include brief HPI discussing patient history and indications for peripheral nerve stimulator placement.

Example: This is a <*age/sex*> with chronic bilateral anterior abdominal cutaneous nerve pain who has failed conventional treatment and has had successful peripheral nerve stimulator trial and is here for permanent implantation of peripheral nerve stimulator.

DESCRIPTION OF PROCEDURE:

The patient was seen in the preoperative holding area. All of her questions were answered and her consent was signed. We discussed peripheral nerve stimulator generator placement located at the <*left lower abdomen*> and her skin was marked.

The patient was brought to the operating room. <*Antibiotics 2 grams of Ancef* > were given 30 minutes prior to the incision. The patient was then placed in the supine position and given conscious sedation by the anesthesia team.

The patient was then prepped and draped in a sterile fashion. The skin over the target area was anesthetized and an incision was made. The trial images were examined for reference. A 14-gauge introducer needle was then placed subcutaneously over the <*anterior abdominal cutaneous nerve with ultrasound guidance and/or neurostimulation*>. The stimulator lead was then guided through the introducer to the appropriate position. The position of the lead was confirmed by fluoroscopy/ultrasound and through test stimulation. The patient reported good response covering the area of pain. The introducer needle was then removed, skin incision was made, and the lead was anchored to the area and fascia using the manufacturer's anchoring device. This was held in place by two 0 ethibonds sutures. The procedure was then repeated for the second lead, and the final placement was confirmed with fluoroscopy.

The skin overlying the desired generator pocket was anesthetized with 1% lidocaine plus epinephrine 1:200,000 and 0.5% bupivacaine solution in equal volumes. The skin was incised and the pocket formed by blunt and sharp dissection using electrocautery. A tunneling device was used to tunnel the leads from the pocket to the leads insertion sites. The leads and an epidural catheter were then passed through the tunneling device. The tunneling device was then removed and the leads and epidural catheter were held in place. Once the tunneling device was removed, the epidural catheter was withdrawn while injecting approximately 6 mL of 0.5% bupivacaine to anesthetize the tract. Lead connections were then wiped clean and dried prior to connection and connected to the generator by tightening the manufacturer's screws. Telemetry confirmed correct placement with impedances. The leads were then coiled beneath the generator, creating loops to relieve any strain. The generator was placed in the pouch in the correct orientation and sutured to the fascial layer using 0 ethibond.

At this time, both incisions were irrigated with copious antibiotic solution. The incisions were both closed using interrupted sutures, first the deep layer with 2-0 vicryl, followed by 3-0 vicryl, and finally a running subcuticular stitch with 4-0 monocryl. The wound sites were dressed with Dermabond and steri-strips, and covered with a Telfa gauze and Tegaderm.

The patient tolerated the procedure well. There were no complications and the patient had minimal pain and did well in the recovery room.

BOX A9.6 DICTATION FOR FIELD STIMULATOR PLACEMENT

DATE OF PROCEDURE:

SURGEON:

ASSISTANT:

PREOPERATIVE DIAGNOSIS:

POSTOPERATIVE DIAGNOSIS:

OPERATION: Field Nerve Stimulator Placement

ANESTHESIA: General vs MAC

ESTIMATED BLOOD LOSS:

SPECIMENS: No specimens were removed.

INDICATIONS FOR PROCEDURE:

Include brief HPI discussing patient history and indications for procedure.

Example: This is a 42-year-old woman<*age/sex*> with chronic axial back pain following lumbar post laminectomy syndrome who has failed conventional treatment and has had successful field nerve stimulator trial and is here for permanent implantation of field nerve stimulator.

DESCRIPTION OF PROCEDURE:

The patient was seen in the preoperative holding area. All of her questions were answered and her consent was signed. We discussed field nerve stimulator generator placement located at the <*left upper buttocks below the belt line*> and her skin was marked.

The patient was brought to the operating room. <*Antibiotics 2 grams of Ancef*> were given 30 minutes prior to the incision. The patient was then placed in the prone position and given conscious sedation by the anesthesia team.

The patient was then prepped and draped in a sterile fashion. The skin over the target area was anesthetized and a stab incision was made. A 14-gauge introducer needle was then placed subcutaneously over the <*tissue overlying the sacroiliac joint*>. The stimulator lead was then guided through the introducer needle to the appropriate position. The position of the lead was confirmed by fluoroscopy and through test stimulation. The patient reported good response covering the area of pain. The introducer needle was then removed and incision made down to the lead. This was anchored to the fascia in the area using the manufacturer's anchoring device by two 0 ethibonds sutures. The procedure was then repeated for the second lead, and the final placement was confirmed with fluoroscopy.

The skin overlying the desired generator pocket was anesthetized with 2% lidocaine plus epinephrine 1:200,000 and 0.5% bupivacaine solution in equal volumes. The skin was incised and the pocket formed by blunt and sharp dissection using electrocautery. A tunneling device was used to tunnel the leads from the pocket to the leads insertion sites. The leads and an epidural catheter were then passed through the tunneling device. The tunneling device was then removed and the leads and epidural catheter were held in place. Once the tunneling device was removed, the epidural catheter was withdrawn while injecting approximately 6 mL of 0.5% bupivacaine to anesthetize the tract. Lead connections were then wiped clean and dried prior to connection and connected to the generator by tightening the manufacturer's screws. Telemetry confirmed correct placement with impedances. The leads were then coiled beneath the generator, creating loops to relieve any strain. The

BOX A9.6 CONTINUED

generator was placed in the pouch in the correct orientation and sutured to the fascial layer using 0 ethibond.

At this time, both incisions were irrigated copiously with antibiotic solution. The incisions were both closed using interrupted sutures, first the deep layer with 2-0 vicryl, followed by 3-0 vicryl, and finally a running subcuticular stitch with 4-0 monocryl. The wound sites were dressed with Dermabond and steri-strips, and covered with a Telfa gauze and Tegaderm.

The patient tolerated the procedure well. There were no complications and the patient had minimal pain and did well in the recovery room.

BOX A9.7 DICTATION FOR EPIDURAL PORT-A-CATH INSERTION

DATE OF PROCEDURE:

SURGEON:

ASSISTANT:

PREOPERATIVE DIAGNOSIS:

POSTOPERATIVE DIAGNOSIS:

OPERATION: Epidural Port-A-Cath Insertion

ANESTHESIA: General vs MAC

ESTIMATED BLOOD LOSS:

SPECIMENS: No specimens were removed.

INDICATIONS FOR PROCEDURE:
Include brief HPI discussing patient history and indications for procedure.

Example: This is a 52-year-old woman <*age/sex*> with chronic refractory cancer pain who has failed conventional treatment and has had a successful epidural catheter trial and is here for permanent implantation of an epidural portacath.

DESCRIPTION OF PROCEDURE:
The patient was seen in the preoperative holding area. All of her questions were answered and her consent was signed. The intended location of the port-a-cath was marked on the 7th rib roughly 5 cm directly below the infra mammary line and lateral to mid clavicular line. The patient was brought to the operating room. <*Antibiotics 2 grams of Ancef* > were given 30 minutes prior to the incision. The patient was then placed in the <*left/right lateral decubitus*> position and given conscious sedation by the anesthesia team.

With C-arm guidance, AP, lateral, and contralateral oblique views were obtained of the lumbar and thoracic spine. The patient was then prepped and draped in a sterile fashion. The skin over the target area was anesthetized and a stab incision was made. A 17-gauge introducer needle was then placed paramedian at the <*insert level*> under direct fluoroscopy and the epidural space was identified by loss of resistance technique to <*saline/air*>. The epidural catheter was then guided cephalad and midline approximately to the <*insert desired interspace*> interspace. The position of the catheter was confirmed by fluoroscopy. No cerebro spinal fluid or heme was noted on the lead placement. The stab incision was widened perpendicular to the direction of the introducer needle and dissected down to

BOX A9.7 CONTINUED

paravertebral fascia. The introducer needle was then removed The designated site for the port-a-cath was anesthetized with local anesthetic 2% Lidocaine with epinephrine 1:200 k and incised with a #15 scalpel and hemostasis was achieved. Dissection was down to about 1 cm below the skin surface. A manufacturer tunneling device was used to pass the catheter from the spine to the left anterolateral chest at the pocket site of the port-a-cath.

The epidural catheter was trimmed to allow only a small amount of slack before connecting it to the port-a-cath and securing with the manufacturer supplied connector. The port-a-cath was primed with normal saline and placed in the pocket, and the four suture holes secured using 0 Ethibond.

Next, hemostasis was achieved and both the midline spine and the port-a-cath incisions were irrigated copiously with antibiotic solution. The midline spine stab incision was closed in one layer and the pocket was closed using interrupted sutures, first the deep layer with 2-0 vicryl, followed by 3-0 vicryl, and finally a running subcuticular stitch with 4-0 monocryl. The wound sites were dressed with Dermabond and steri-strips, and covered with a Telfa gauze and Tegaderm. The epidural portacath was accessed with a Gripper plus needle 19 G *<0.75 / 1.0/ 1.25 inch>* with Huber tip and the appropriate epidural analgesic solution was started.

The patient tolerated the procedure well. There were no complications and the patient had minimal pain and did well in the recovery room

Appendix 10
Surgeon's Preference Cards

Christopher Sears and Edgar L. Ross

When one is designing an implant service, it is helpful to have preference cards for commonly performed procedures. This can aid the nurse or scrub technician in setting up the room in an efficient manner. This appendix provides a list of surgical items commonly used for intrathecal pump placement (see Table A10.1) and revisions (see Table A10.2), spinal cord stimulator and peripheral or field simulator implantation (see Table A10.3), and the MILD™ procedure (see Table A10.4).

Table A10.1 Surgeon's Preference List for Intrathecal Pump Placement

Soft Goods (Disposable Items)							
Item (Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
[ ]	1	Pack custom basic general					
[ ]	1	Transverse laparotomy sheet					
[ ]	2	Half sheet					
[ ]	1	Scrub pack					
[ ]	2	Ioban drape					
[ ]	1	Grounding pad					
[ ]	1	C-arm drape					
[ ]	1	Steristrip closures					
[ ]	1	60ml Luer lock syringe					
[ ]	1	3ml Luer lock syringe					
[ ]	2	20ml Juer lock syringe					
[ ]	1	27G 1.5-in needle					
[ ]	1	Incise drape					
[ ]	8	Towel drapes					
[ ]	1	#11 blade knife					
[ ]	1	Sterile camera cover					
Metal Ware/Reusable Linen							
[ ]	1	Basin					
[ ]	1	Absorbent towel					
CPD Instruments List							
[ ]	2	Kocher clamp					
[ ]	1	#7 Fr suction					
[ ]	1	#9 Fr suction					
[ ]	1	Iris single skin hook					
[ ]	1	Iris double skin hook					
[ ]	1	Regular skin hook single					
[ ]	1	Regular skin hook double					
[ ]	1	Ragnell retractor					
[ ]	1	Senn retractor					
[ ]	1	Army/Navy retractor					
[ ]	1	Small rakes					
[ ]	1	Vein retractor					
[ ]	1	Weitlander retractor					
[ ]	1	Nancy retractor					
[ ]	4	Small towel clamps					
[ ]	2	Webster needle holder					
[ ]	2	French needle holder					
[ ]	2	General needle holder					
[ ]	4	Straight Halstead mosquitoes					
[ ]	4	Curved Halstead mosquitoes					
[ ]	4	Straight mosquitoes					
[ ]	4	Curved mosquitoes					

Table A10.1 Continued

CPD Instruments List							
Item (Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
[ ]	4	Straight snaps					
[ ]	4	Curved snaps					
[ ]	2	Schnidt					
[ ]	6	Kelly clamps					
[ ]	6	Allis clamps					
[ ]	2	Right angle clamps					
[ ]	2	Vulsellum clamps					
[ ]	1	Straight Mayo scissor					
[ ]	1	Curved Mayo scissor					
[ ]	1	Regular Metz					
[ ]	1	Plastic Metz					
[ ]	1	Straight Iris					
[ ]	1	Curved Iris					
[ ]	1	Stevens scissor					
[ ]	2	Iris toothed forceps					
[ ]	2	Iris smooth forceps					
[ ]	2	Adson toothed forceps					
[ ]	2	5-in toothed forceps					
[ ]	2	Neuro toothed forceps					
[ ]	2	Adson-Brown forceps					
[ ]	2	Adson-Smooth forceps					
[ ]	2	5-in Depakey forceps					
[ ]	2	#3 knife handle					
[ ]	1	Mini Beaver					
[ ]	1	Probe					
[ ]	1	Groove director					
[ ]	2	Kockers 8 in					
[ ]	2	DeBakey forcep 7 in					
[ ]	2	Sharp Senns					
[ ]	2	Adson-Beckman retractor					
[ ]	2	Weitlaner baby retractor					
[ ]	1	Extras per surgeon					
Soft Goods (Disposable Items) located in OR							
[ ]	1	Adhesive: Dermabond					
[ ]	1	Abdominal binder					
[ ]	1	Bootie suture					
[ ]	1	120 mL specimen container					
[ ]	1	Device catheter fixation percustay					
[ ]	2	4 in x 4.75 in Tegaderm dressing					
[ ]	1	Surgical glove liner (in surgeon's size)					

(*continued*)

Table A10.1 Continued

Soft Goods (Disposable Items) located in OR							
Item (Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
[ ]	1	Surgical glove (in surgeon's size)					
[ ]	3	Surgical gowns					
[ ]	1	Shunt passer					
Sutures							
[ ]	1	2-0 silk 12–16 in					
[ ]	1	0-0 ethibond 18 in					
[ ]	2	3-0 vicryl 27 in					
[ ]	1	2-0 vicryl 27 in					
[ ]	1	2-0 silk ties 60 in					
[ ]	2	4-0 monocryl 18 in					
Equipment in OR							
[ ]	1	Bair Hugger warming unit					
[ ]	1	Compression boots and console					
[ ]	2	Padded sitting stool non-rolling					
[ ]	1	Bipolar box					
[ ]	6	Lead aprons					
[ ]	1	Hair clipper					
[ ]	1	Pain service travel cart					
[ ]	1	Electrosurgical generator (Bovie)					
[ ]	1	Jackson table					
Solutions							
[ ]	1	Bacitracin or Polymixin irrigation					

Table A10.2 Surgeon's Preference List for Intrathecal Pump Reservoir Replacement

Soft Goods (Disposable Items)							
Item(Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
[ ]	1	Pack custom basic general					
[ ]	1	Transverse laparotomy sheet					
[ ]	2	Half sheet					
[ ]	1	Scrub pack					
[ ]	2	Ioban drape					
[ ]	1	Grounding pad					
[ ]	1	Steristrip closures					
[ ]	1	60ml Luer lock syringe					
[ ]	1	3ml Luer lock syringe					
[ ]	2	20ml Juer lock syringe					
[ ]	1	27G 1.5-in needle					
[ ]	1	Incise drape					

Table A10.2 Continued

Soft Goods (Disposable Items)							
Item(Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
[ ]	8	Towel drapes					
[ ]	1	#11 blade knife					
[ ]	1	Sterile camera cover					
Metal Ware/Reusable Linen							
[ ]	1	Basin					
[ ]	1	Absorbent towel					
CPD Instruments List							
[ ]	2	Kocher clamp					
[ ]	1	#7 Fr suction					
[ ]	1	#9 Fr suction					
[ ]	1	Iris single skin hook					
[ ]	1	Iris double skin hook					
[ ]	1	Regular skin hook single					
[ ]	1	Regular skin hook double					
[ ]	1	Ragnell retractor					
[ ]	1	Senn retractor					
[ ]	1	Army/Navy retractor					
[ ]	1	Small rakes					
[ ]	1	Vein retractor					
[ ]	1	Weitlander retractor					
[ ]	1	Nancy retractor					
[ ]	4	Small towel clamps					
[ ]	2	Webster needle holder					
[ ]	2	French needle holder					
[ ]	2	General needle holder					
[ ]	4	Straight Halstead mosquitoes					
[ ]	4	Curved Halstead mosquitoes					
[ ]	4	Straight mosquitoes					
[ ]	4	Curved mosquitoes					
[ ]	4	Straight snaps					
[ ]	4	Curved snaps					
[ ]	2	Schnidt					
[ ]	6	Kelly clamps					
[ ]	6	Allis clamps					
[ ]	2	Right angle clamps					
[ ]	2	Vulsellum clamps					
[ ]	1	Straight Mayo scissor					
[ ]	1	Curved Mayo scissor					
[ ]	1	Regular Metz					
[ ]	1	Plastic Metz					

(*continued*)

Table A10.2 Continued

CPD Instruments List							
Item(Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
[ ]	1	Straight Iris					
[ ]	1	Curved Iris					
[ ]	1	Stevens scissor					
[ ]	2	Iris toothed forceps					
[ ]	2	Iris smooth forceps					
[ ]	2	Adson toothed forceps					
[ ]	2	5-in toothed forceps					
[ ]	2	Neuro toothed forceps					
[ ]	2	Adson-Brown forceps					
[ ]	2	Adson-Smooth forceps					
[ ]	2	5-in Depakey forceps					
[ ]	2	#3 knife handle					
[ ]	1	Mini Beaver					
[ ]	1	Probe					
[ ]	1	Groove director					
[ ]	2	Kockers 8 in					
[ ]	2	DeBakey forcep 7 in					
[ ]	2	Sharp Senns					
[ ]	2	Adson-Beckman retractor					
[ ]	2	Weitlaner baby retractor					
[ ]	1	Extras per surgeon					
Soft Goods (Disposable Items) located in OR							
[ ]	1	Adhesive: Dermabond					
[ ]	1	Abdominal binder					
[ ]	1	120 mL specimen container					
[ ]	1	Device catheter fixation percustay					
[ ]	2	4 in x 4.75 in Tegaderm dressing					
[ ]	1	Surgical glove liner (in surgeon's size)					
[ ]	1	Surgical glove (in surgeon's size)					
[ ]	3	Surgical gowns					
Sutures							
[ ]	1	2-0 silk 12–16 in					
[ ]	1	0-0 ethibond 18 in					
[ ]	2	3-0 vicryl 27 in					
[ ]	1	2-0 vicryl 27 in					
[ ]	1	2-0 silk ties 60 in					
[ ]	2	4-0 monocryl 18 in					

Table A10.2 Continued

Sutures							
Item(Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
Equipment in OR							
[ ]	1	Bair Hugger warming unit					
[ ]	1	Compression boots and console					
[ ]	2	Padded sitting stool non-rolling					
[ ]	1	Bipolar box					
[ ]	1	Hair clipper					
[ ]	1	Pain service travel cart					
[ ]	1	Electrosurgical generator (Bovie)					
Solutions							
[ ]	1	Bacitracin or Polymixin irrigation					

Table A10.3 Surgeon's Preference List for Spinal Cord Stimulator, Peripheral Nerve Stimulator, and Field Stimulator Implantation

Soft Goods (Disposable Items)							
Item(Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
[ ]	1	Pack custom basic general					
[ ]	1	Transverse laparotomy sheet					
[ ]	2	Half sheet					
[ ]	1	Scrub pack					
[ ]	2	Ioban drape					
[ ]	1	Grounding pad					
[ ]	1	C-arm drape					
[ ]	1	Steristrip closures					
[ ]	1	60ml Luer lock syringe					
[ ]	1	3ml Luer lock syringe					
[ ]	2	20ml Juer lock syringe					
[ ]	1	27G 1.5-in needle					
[ ]	1	Incise drape					
[ ]	8	Towel drapes					
[ ]	1	#11 blade knife					
[ ]	1	Sterile camera cover					
Metal Ware/Reusable Linen							
[ ]	1	Basin					
[ ]	1	Absorbent Towel					

(*continued*)

Table A10.3 Continued

Metal Ware/Reusable Linen							
Item(Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
CPD Instruments List							
[ ]	2	Kocher clamp					
[ ]	1	#7 Fr suction					
[ ]	1	#9 Fr suction					
[ ]	1	Iris single skin hook					
[ ]	1	Iris double skin hook					
[ ]	1	Regular skin hook single					
[ ]	1	Regular skin hook double					
[ ]	1	Ragnell retractor					
[ ]	1	Senn retractor					
[ ]	1	Army/Navy retractor					
[ ]	1	Small rakes					
[ ]	1	Vein retractor					
[ ]	1	Weitlander retractor					
[ ]	1	Nancy retractor					
[ ]	4	Small towel clamps					
[ ]	2	Webster needle holder					
[ ]	2	French needle holder					
[ ]	2	General needle holder					
[ ]	4	Straight Halstead mosquitoes					
[ ]	4	Curved Halstead mosquitoes					
[ ]	4	Straight mosquitoes					
[ ]	4	Curved mosquitoes					
[ ]	4	Straight snaps					
[ ]	4	Curved snaps					
[ ]	2	Schnidt					
[ ]	6	Kelly clamps					
[ ]	6	Allis clamps					
[ ]	2	Right angle clamps					
[ ]	2	Vulsellum clamps					
[ ]	1	Straight Mayo scissor					
[ ]	1	Curved Mayo scissor					
[ ]	1	Regular Metz					
[ ]	1	Plastic Metz					
[ ]	1	Straight Iris					
[ ]	1	Curved Iris					
[ ]	1	Stevens scissor					
[ ]	2	Iris toothed forceps					
[ ]	2	Iris smooth forceps					
[ ]	2	Adson toothed forceps					
[ ]	2	5-in toothed forceps					

Table A10.3 Continued

CPD Instruments List							
Item(Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
[ ]	2	Neuro toothed forceps					
[ ]	2	Adson-Brown forceps					
[ ]	2	Adson-Smooth forceps					
[ ]	2	5-in DeBakey forceps					
[ ]	2	#3 knife handle					
[ ]	1	Mini Beaver					
[ ]	1	Probe					
[ ]	1	Groove director					
[ ]	2	Kockers 8 in					
[ ]	2	DeBakey Forcep 7 in					
[ ]	2	Sharp Senns					
[ ]	2	Adson-Beckman retractor					
[ ]	1	Lead hand					
[ ]	2	Weitlaner baby retractor					
[ ]	1	Extras per surgeon					
Soft Goods (Disposable Items) located in OR							
[ ]	1	Adhesive: Dermabond					
[ ]	1	Abdominal binder					
[ ]	1	Shunt passer					
[ ]	1	120 mL specimen container					
[ ]	1	Device catheter fixation percustay					
[ ]	2	4 in x 4.75 in Tegaderm dressing					
[ ]	1	Surgical glove liner (in surgeon's size)					
[ ]	1	Surgical glove (in surgeon's size)					
[ ]	3	Surgical gowns					
Sutures							
[ ]	1	0 Silk CT-1 Needle 18 in					
[ ]	1	2-0 silk 12–18 in					
[ ]	1	0 ethibond CT-2 Needle 18 in					
[ ]	2	3-0 vicryl 27 in					
[ ]	1	2-0 vicryl 27 in					
[ ]	1	2-0 silk ties 60 in					
[ ]	2	4-0 monocryl 18 in					

(*continued*)

Table A10.3 Continued

Sutures							
Item(Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
Equipment in OR							
[ ]	1	Bair Hugger warming unit					
[ ]	1	Compression boots and console					
[ ]	2	Padded sitting stool non-rolling					
[ ]	1	Bipolar box					
[ ]	1	Hair clipper					
[ ]	1	Pain service travel cart					
[ ]	1	Electrosurgical generator (Bovie)					
Solutions							
[ ]	1	Bacitracin or Polymixin irrigation					

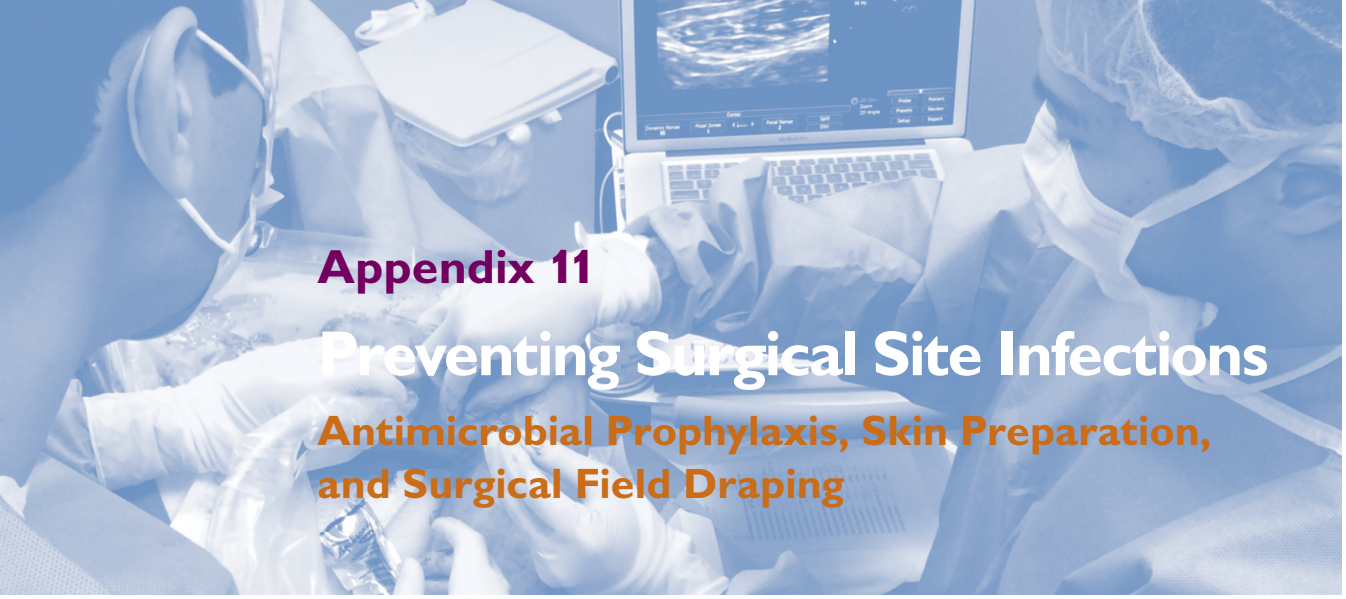
Table A10.4 Surgeon's Preference List for MILD® Procedure

Soft Goods (Disposable Items)							
Item(Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
[ ]	1	Pack custom basic general					
[ ]	1	Transverse laparotomy sheet					
[ ]	2	Half sheet					
[ ]	1	Scrub pack					
[ ]	2	Ioban drape					
[ ]	1	Mayo stand cover					
[ ]	1	C-arm drape					
[ ]	1	Steristrip closures					
[ ]	2	10ml Luer lock syringe					
[ ]	1	22G 3.5-in spinal needle					
[ ]	2	18G 1.5-in needle					
[ ]	1	27G 1.5-in needle					
[ ]	1	Incise drape					
[ ]	1	20 in sterile tubing					
[ ]	8	Towel drapes					
[ ]	1	#11 blade knife					

(*continued*)

Table A10.4 Continued

Soft Goods (Disposable Items)							
Item(Chk)	QTY	Description	Reference #	PS #	Location	Hold	Not Used?
[ ]	1	MILD® kit and labels					
[ ]	1	Epidural needle					
Metal Ware/Reusable Linen							
[ ]	1	Basin					
[ ]	1	Absorbent Towel					
Soft Goods (Disposable Items) located in OR							
[ ]	1	120 mL specimen container					
[ ]	2	Anesthesia spinal needle 22G 7 in					
[ ]	1	Surgical glove liner (in surgeon's size)					
[ ]	1	Surgical glove (in surgeon's size)					
[ ]	3	Surgical gowns					
[ ]	1	Epidural tray					
Equipment in OR							
[ ]	1	Bair Hugger warming unit					
[ ]	6	Lead aprons					
[ ]	1	Pain service travel cart					
[ ]	1	Jackson table					



Appendix 11

Preventing Surgical Site Infections

Antimicrobial Prophylaxis, Skin Preparation, and Surgical Field Draping

Robert M. Chow, Brendan McGinn, and Alison Weisheipl

Background

Surgical site infections (SSI) are a feared complication in the postoperative period. As such, antimicrobial prophylaxis was developed to target specific bacterial flora implicated in SSIs for different surgical procedures. In addition, preoperative skin antiseptics and specialized skin and surgical field draping have been used in an effort to decrease the amount of skin flora in the vicinity of the incision site.

Prior to any surgical pain procedure, the skin is thoroughly prepared with antiseptic solution, sterile drapes are placed around the surgical site, and appropriate antibiotics are administered within a specific window of time to optimize pre-incision blood levels. Applied strictly and consistently, these steps—in combination with a conscientious surgical team—will help reduce the risk of surgical site infection.

Antimicrobial Prophylaxis

Antimicrobial prophylaxis is utilized in various surgical procedures to reduce the incidence of SSI in the postoperative period. Implementation of the Surgical Care Improvement (SCIP) guidelines has standardized this practice. The choice of antibiotic is dependent on the type of procedure. For most surgical pain procedures, a first generation cephalosporin (such as cefazolin) or clindamycin (in the case of *b*-lactam allergy) is commonly used, as they are effective against both the *Staphylococci* and *Streptococci* species that are found in normal skin flora (1, 2). This antibiotic is typically administered within 60 minutes prior to surgical incision with no need for postoperative prophylactic antibiotics (1, 2).

If the patient has a known history of methicillin-resistant *Staphylococcus aureus* (MRSA) and has not been documented to have cleared colonization, a single dose of vancomycin is added to the first-generation cephalosporin or clindamycin, but again, no postoperative antibiotics are needed (1, 2). The vancomycin should be given less than 2 hours prior to incision (ideally starting to infuse at a minimum of greater than 15 minutes before incision). The longer time period allowed prior to incision is to account for the longer infusion time required for vancomycin administration (1).

In the case of paddle lead implantations for dorsal column stimulation (DCS) (inserted via incision over the spinal cord with laminectomy), our institution's guidelines recommend vancomycin and ceftriaxone for spine neurosurgical operations where hardware is used and the dura mater is entered.

Though it has not been studied specifically for surgical pain procedures, the application of vancomycin powder to surgical wounds holds promise in reducing SSIs. Chang et al. (3) performed a meta-analysis investigating the use of vancomycin powder to prevent SSIs in spinal surgeries. After reviewing 10 studies (7 quasi-experimental, 2 cohort, one randomized-controlled trial), vancomycin powder appeared to decrease the incidence of SSIs. At this point, larger, randomized-controlled studies should be performed to better investigate this modality.

Although the efficacy of antimicrobial prophylaxis has not been validated for most surgical pain procedures in large-scale studies, Follett et al. postulated that perioperative antibiotics should result in lower infection rates for intrathecal drug delivery system and spinal cord stimulation system implantations, based on data gathered from the literature pertaining to CSF shunts (4).

Surgical Preparation and Draping

Surgical preparation involves proper use of an antiseptic solution to clean the surgical site as well as the area immediately surrounding it. In accordance with the SCIP protocol, hair removal should be done with clippers, which prevent skin abrasions that could become nidi for infection (2).

There have been few studies to determine the optimal preoperative antiseptic solution. Some studies, however, have shown that during clean-contaminated surgery, chlorhexidine-alcohol scrub is superior to povidone-iodine scrub in reducing surgical site infections (5, 6). In addition, the Centers for Disease Control and Prevention (CDC), in collaboration with various other medical organizations, cite chlorhexidine-alcohol as the preferred antiseptic for prevention of intravascular catheter-related infections (6, 7).

Prior to surgical antiseptic preparation, an area significantly wider than the intended surgical site should be demarcated with water impermeable drapes, preferably with an adhesive edge. Next, the area demarcated by the plastic drapes is prepped with the surgeon's antiseptic of choice. After appropriate cleansing of the surgical site, sterile towels should be placed around the prepped areas, making sure to fully cover the edges of the plastic drapes that were placed prior. An antimicrobial surgical incise drape can be placed over the sterile towels, covering the surgical site and surrounding area. Although iodine impregnated surgical incise drapes are commonly used, they do not cause a statistically significant reduction in surgical site infection rates (8). The patient can be further draped with half sheets, followed by a transverse laparotomy drape that is fluid repellant and forms a sterile protective barrier. The laparotomy drape can be cut in order to fit properly around the surgical site. A chest drape could be used for its larger opening, or two split sheets if the area to be prepped is very large. Since fluoroscopy is commonly used in pain procedures, the C-arm should also be appropriately draped with a sterile plastic barrier. If an ultrasound is used, care should be taken to drape the probe in a sterile fashion.

Additional Considerations

Thoroughfare through the operating room should be limited to essential personnel. In studies of CSF shunt infection rates, this has been shown to decrease SSIs (4).

References

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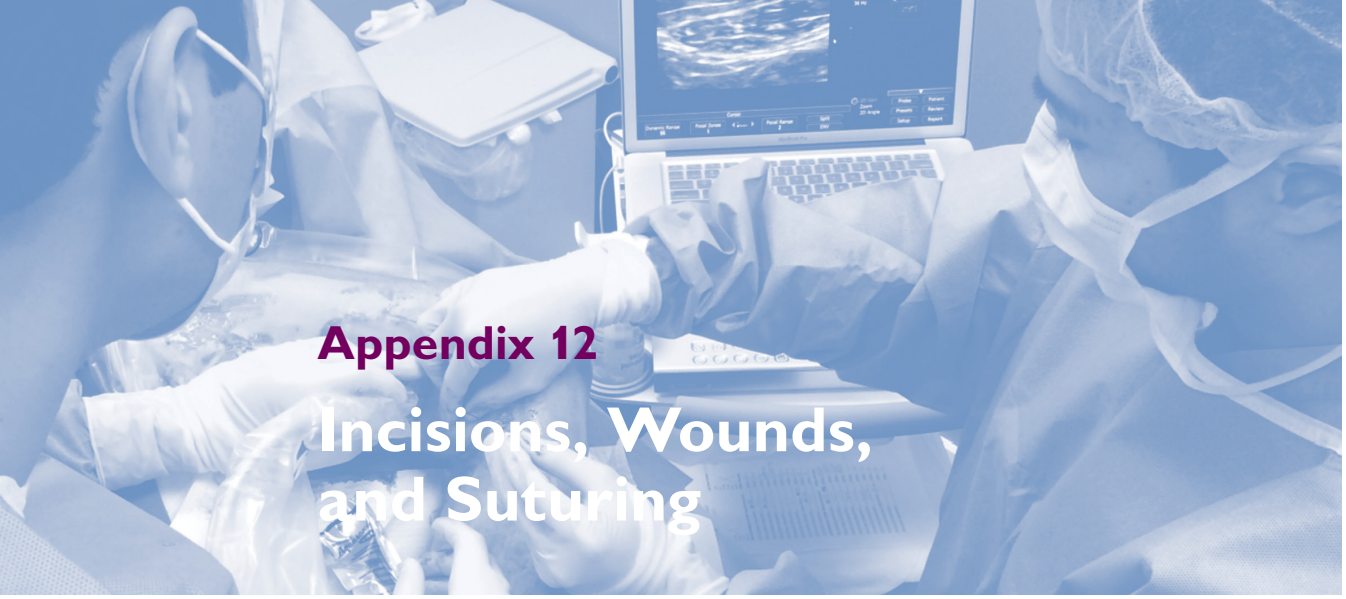

Appendix 12

Incisions, Wounds, and Suturing

Christian Sampson

Introduction

This appendix will discuss the techniques and basic surgical principles required for the safe implantation of implantable pulse generators (IPG), pumps, and their leads and catheters. Of particular importance in the preoperative assessment is the need to assess the individual patient's body habitus. Patients at either extreme of the body mass index (BMI) scale can present particular challenges. In patients with a low BMI, placement of either pumps or IPGs can be complicated by bony prominences and the lack of adequate soft tissues coverage. Although somewhat controversial, in patients with high BMIs, there is data to suggest that surgery is associated with a higher incidence of wound-healing complications (1). In addition, shifting of the implant, causing tension and potential displacement of the device and/or the catheters or leads, is of greater concern in this patient population. This appendix will also discuss site selection technique based on these issues and on the presence of any pre-existing scars. In female patients of childbearing age, particular attention must be given to the possibility of a future pregnancy. We will also discuss the preoperative, intraoperative, and postoperative management of these patients. Finally, we will discuss potential complications and their management.

Preoperative Assessment

The preoperative assessment of patients who are to undergo IPG or pump placement is the critical step in the patient's overall management, and begins with direct communication between the pain management team and surgeon. The first step is deciding upon optimal placement of the device. Once this is done, the best routing of the lead(s) or catheter from the device to the target is planned. In addition to a careful history and physical examination, particular attention must be paid to comorbidities that could impact successful implantation of the devices. This includes a history of diabetes and smoking history. Both of these can lead to wound-healing complications, and can negatively affect a successful outcome. In diabetics, glycosylated hemoglobin (HbA1c) levels should ideally be no higher than 5%–7%, as higher levels are associated with higher postoperative infection (2). Smoking cessation should be attempted 3–6 months prior to surgery. In addition, the patient's body mass index should be determined. Patients with very low BMIs or very high BMIs can present unique surgical challenges. In extremely thin patients, adequate soft tissue coverage can be difficult to attain. In these patients, the abdomen, thighs, or buttocks can often provide greater opportunity for obtaining adequate soft tissue coverage, rather than placing the device in the chest region. These sites need to be considered in relation to where the lead(s) or catheter is to be routed; in general, choosing a site that will minimize lead and/or catheter length is desirable. In patients with very high BMI, care must be taken to be certain that the implant and/or lead(s) or catheter will not shift in position with changes in body position. The operative procedure is typically performed with the patient in a horizontal position. When the patient is upright, the soft tissues may shift, and in so doing significantly change the position of the implant, lead(s), or catheter, causing displacement. Such displacement may render the device inoperative and may cause significant discomfort to the patient. Revision of the system is then required. The patient must be examined for the presence of any pre-existing scars, which could impact site selection for the device placement and/or lead or catheter tunneling. Finally, darker skinned individuals (black, Latino, Indian, Malaysian, Asian, Caribbean) should be counseled that they may have a 15%–20% higher risk of developing a surgical site keloid. Keloids can be very disturbing to patients and are difficult to manage, so patients must be made aware of this possibility (3). Patients should be instructed to have a Hibiclens shower the evening before surgery.

Intraoperative Management

The operative plan must be discussed ahead of time regarding patient positioning and whether changes in patient position intraoperatively will be needed. This is often the case, especially for spinal forward catheters or lead placement where the generator or pump will be placed in the anterior abdominal region. The operative plan for how to handle this transition is critical in maintaining sterility. For posterior lead(s) or catheter placements, the patient is usually first placed in the prone position, with pressure points and eyes protected. Once proper placement of the leads or catheter has been obtained, the catheter or lead is left in a lateral incision with the wound closed. All wounds are dressed, and the patient is then placed in the supine position. The dressing is removed from the incision, which would allow access to the generator lead or catheter, and the patient is re-prepped. In general, all prepping should be performed with chlorhexidine-based skin preparation products. Numerous studies and evidence-based medicine suggest lower infection rates with chlorhexidine-based products (4). The selected site is injected with local anesthetic with epinephrine. Typically, it is prudent to allow 5–10 minutes for the epinephrine to be effective. The skin incision is made with a 15-blade scalpel, and precise hemostasis is achieved with forceps and unipolar cautery. Toothed Adson forceps are used for handling the tissues, and care must be taken to only grasp the dermal elements, not the epidermis of the skin. Grasping the epidermis can traumatize the skin, leading to breaks in the skin, which can potentially lead to wound-healing complications. The subcutaneous tissues are divided with both sharp and blunt dissection to create the pocket necessary for the device being used. When possible, an amount of adipose tissue equal in volume to the implant should be removed from the pocket. This maneuver will help conceal the device by helping to provide a more normal external contour. Typically, these devices are placed no deeper than one inch below the skin surface. This is to allow easy access to the pump and also proper charging for battery-operated devices. Once the pocket is created, the leads are tunneled into this pocket using a variety of techniques. There are various wire passers and tunneling devices that can be used to route the lead(s) or catheter into the pocket. Counter-incisions are used judiciously. As they are brought into the pocket, the introducer can be simultaneously injected with local anesthetic for postoperative pain management in the tunneled area. The lead or catheter is then connected to the pump according to the manufacturer's guidelines. In the case of IPGs, impedance can be checked to ascertain whether the leads are properly connected. In high BMI patients, greater care must be taken to securing the device and lead(s) or catheter anchor points, as well as having enough lead or catheter slack, in order to minimize lead or catheter migration with changes in body position. Once this is done, the pocket is irrigated a final time with antibiotic-containing solution and assessed for hemostasis. If the device is over muscle fascia, it is anchored to the muscle fascia with 0 ethibond sutures. If the device is within subcutaneous tissue only, then it should be anchored to Scarpa's fascia also using 0 ethibond sutures. The skin incision is closed meticulously using either 2-0 or 3-0 vicryl sutures for the deep dermal closure and a running intracuticular 4-0 monocryl suture for skin closure. Dermabond can then be used for the final skin closure, followed by steristrips, Telfa and Tegaderm.

Postoperative Care

The patients typically do not require any additional antibiotics other than the single dose received in the operating room. For patients with occipital or frontal leads, a cervical collar is used for protection of the cervical spine for the first week. Scalp incisions are typically closed with nylon sutures, which would need to be removed in approximately 10–14 days. All surgical sites should be kept dry for at least 5 days. Scalp incisions can be exposed to water in 48 hours with only a simple bacitracin gauze or band-aid dressing. Patients may resume usual daily activities, but not engage in workout activities or sports. These activities may be resumed in 4–6 weeks as long as there are no wound-healing issues.

Complications

The most worrisome complication in the postoperative period is infection. Hardware-related surgical site infection rates in the neurosurgical literature are as high as 4.5%–12% (5, 6). Superficial infections can often be managed conservatively with local wound care and antibiotics. These patients need to be monitored very carefully for potential development of a deeper infection, which could jeopardize keeping the implant and/or catheters. The presence of fevers, elevated white blood cell count, erythema, drainage, and pain are the key signs of a potential implant infection. If this is verified, the implant and its associated lead(s) and/or catheter must be removed. Cultures are taken and appropriate antibiotics are utilized. Other complications can be pain or discomfort due to the site of the implant impinging adjacent structures. This is usually in very thin individuals where the device is very near a bony prominence, either in the chest, abdomen, or hip regions. If these cannot be managed conservatively, revision of the implant site may be needed. Other complications can occur if the implant is not adequately secured to the surrounding tissues. This can lead to the implant shifting within the pocket and even rotating 180 or more degrees. These problems are more evident in high BMI individuals, in whom adequately securing the device is more difficult, and because of greater movement of the device with changes in the patient's position. Other complications would include device failure (1%–2%).

Conclusion

The implantation of IPGs and pumps and their associated lead(s) and catheters requires careful preoperative planning and meticulous surgical technique. With proper coordination and communication between the pain management and surgical teams, complications can be reduced and a successful outcome can be anticipated.

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Appendix 13
Surgical Instruments

James Bell, J. Tasker Gundy and Edgar L. Ross

Introduction

Surgical techniques and the surgeon's armamentarium have evolved substantially over time, but the fundamental roles for which we employ our instruments—cut, grasp, retract, repair—are remarkably constant (1, 2). A familiarity with appropriate surgical instrumentation facilitates both fluidity and safety in the operating room; despite the fact that many operative interventions in pain management qualify only as "minor" surgical procedures, a fair number of instruments will still be used. The appropriate use of instruments will help to reduce infection and tissue trauma, facilitate procedures, improve healing and reduce total operating times. The following images and accompanying captions represent the standard instrument sets utilized during surgical pain procedures at our institution.

Standard Instruments

Cutting: Scalpels and Scissors

The standard scalpel consists of a handle attached to one of several interchangeable, disposable blades. Pictured in Figure A13.1o are three of the more commonly used blades: the #10 blade (top) whose large sloping body is utilized for primary skin incision, the #11 blade (middle) which bears a pointed tip for stab incisions, and the multipurpose #15 blade (bottom). Most scalpel work can be suitably performed using the standard #3 handle (Figure A13.1m), although the slender, elongated #7 handle (Figure A13.1n) may be preferred for more precise or deeper cutting.

Often the dissection required in surgical pain procedures involves superficial tissue planes only, and thus is well served by blunt finger dissection (as in preparation of a subcutaneous pocket for an implantable infusion pump). When necessary, a variety of scissor styles and sizes abound, and should be selected in accord with the type of tissue being divided or dissected. Instruments with curved blades and blunt tips are considered best for gentle shearing dissection, such as the lightweight Metzenbaum scissor (Figure A13.2b and f) or the heftier curved Mayo scissor (Figure A13.2e) for tougher tissue. The smaller Iris scissor is appropriate for delicate tissues (Figure A13.2a). A straight scissor is intended for cutting suture (see straight Mayo, Figure A13.2d), though some kits contain dedicated stitch scissors for this purpose.

Cutting: Electrosurgical Devices

The "Bovie" electrosurgical device is a popular instrument for cutting, coagulating, and dessicating tissue in the operating room. It was developed by William T. Bovie and debuted at the Peter Bent Brigham Hospital in 1926, when it was used by Dr. Harvey Cushing to remove a

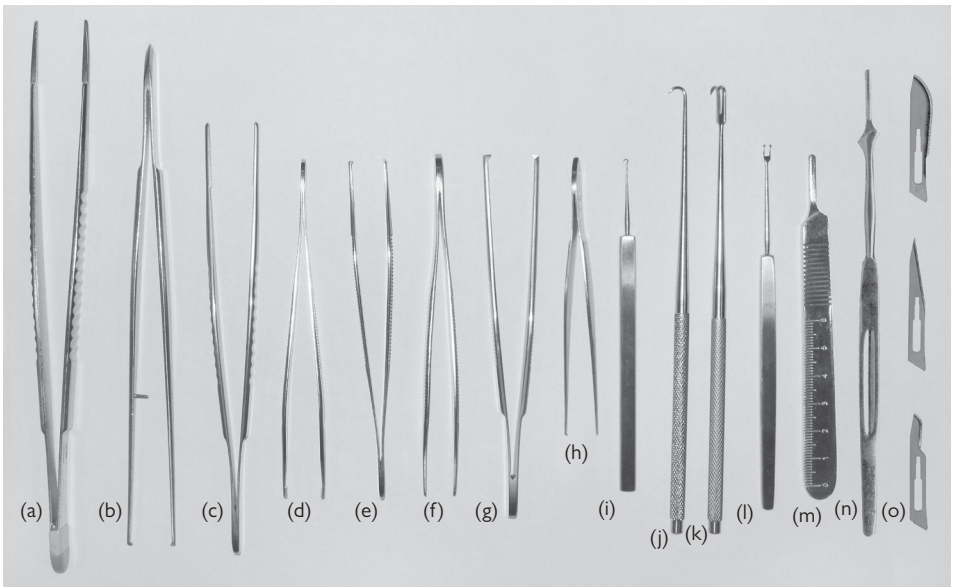

Figure A13.1 Forceps, Hooks, Scalpels. a. Debakey forceps (7 in); b. Toothed Iris forceps; c. Debakey forceps (5 in); d. Adson-Brown tissue forceps; e. Adson toothed forceps; f. Adson smooth forceps; g. Reguar rat tooth forceps; h. Small rat tooth forceps; i. Small single skin hook; j. Regular single skin hook; k. Regular double skin hook; l. Small double skin hook; m. #3 Scalpel handle; n. #7 Scalpel handle; o. Scalpel blades: #10 (top), #11 (middle), #15 (bottom).

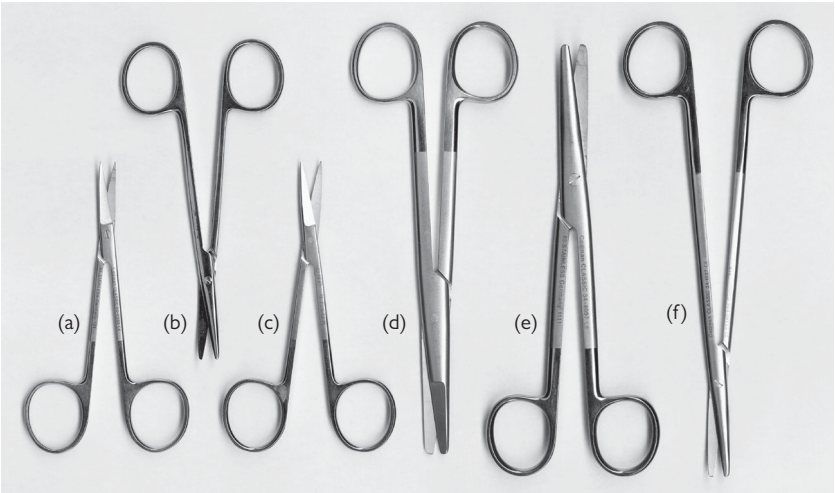

Figure A13.2 Scissors. a. Curved Iris. b. Metzenbaum (5 in); c. Straight Iris; d. Straight Mayo; e. Curved Mayo; f. Metzenbaum (7 in).

complex vascular malformation from the head of a 64-year-old patient (3). With this device (held like a pencil), high-frequency electrical current delivered through an electrode generates heat in tissues, generally in one of two modes selected via a manual switch on the instrument. Continuous current output in the "cut" mode creates high temperatures that cut (vaporize) tissue, while interrupted current delivery in the "coag" mode results in coagulation. Of note, electrosurgical cuts are generally reserved for deeper tissues only, as these are believed to create more scarring than a scalpel blade if used to divide the epidermis. In the subcutaneous plane though, where most pain related surgery occurs, only the "coag" mode need be used, where it decreases tissue trauma, blood loss, and postoperative pain when compared to blunt dissection.

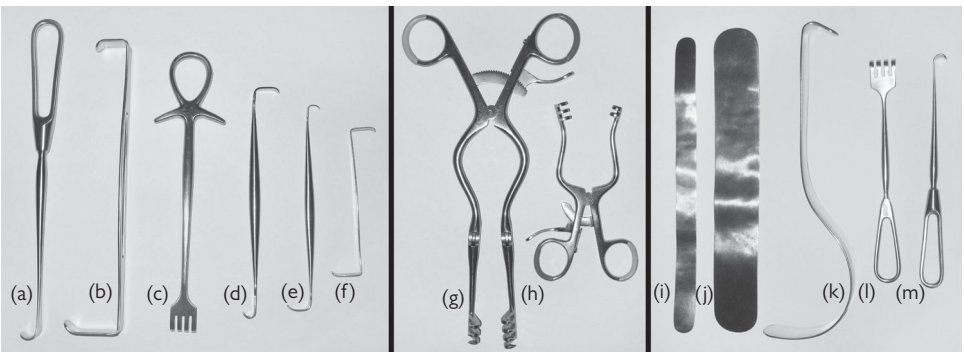

Figure A13.3 Retractors. a. Cushing vein retractor (large); b. Army Navy retractor; c. Murphy rake retractor; d. Senn sharp, retractor (large); e. Senn sharp retractor (small); f. Ragnell retractor (small); g. Weitlaner; h. Baby Weitlaner; i. Malleable retractor (small); j. Malleable retractor (large); k. Deaver retractor; l. Rake retractor; m. Cushing vein retractor (regular).

Retracting

A variety of retractors may be utilized to provide or enhance exposure in the operative field. Manual retractors are held by their operator, and according to the tissue retracted may be either smooth (see the Army Navy, Figure A13.3b, or the smaller Ragnell, Figure A13.3f), toothed (see the Murphy rake, Figure A13.3c) or sharp (Senn sharp, Figure A13.3d and e). Jointed or self-retaining retractors (Weitlaner, Figure A13.3g and h) have a locking

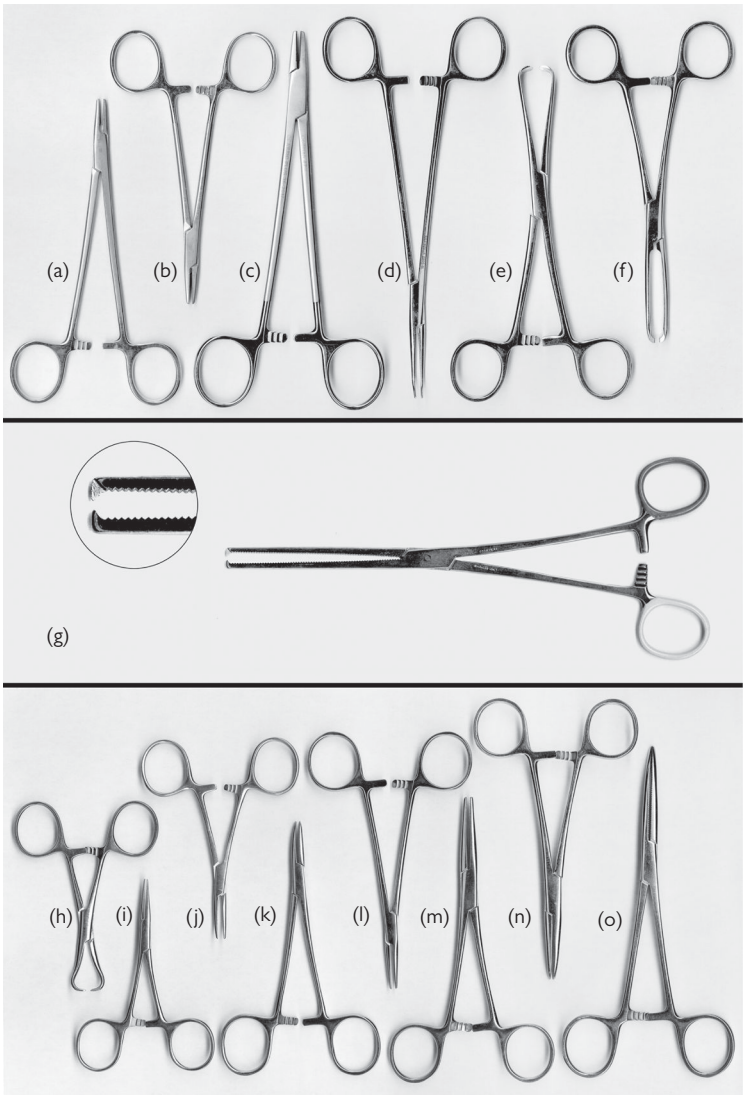

Figure A13.4 Clamps, Hemostats, Needle Holders. a. Webster needle holder (smooth); b. Webster needle holder (regular); c. Mayo-Hegar needle holder (7 in); d. Large 7-in snap (hemostat); e. Allis clamp (large); f. Allis clamp (regular); g. Kocher clamp; h. Towel clamp; i. Straight mosquito; j. Curved mosquito; k. Straight 5-in snap (hemostat); l. Curved 5-in snap (hemostat); m. Straight snap; n. curved snap; o. Kelly clamp.

mechanism, which offers the added advantage of hands-free use, while Malleable retractors (Figure A13.3i and j) can be contorted into the angle desired.

Grasping: Forceps, Clamps and Needle Holders

Simple thumb forceps are used to grasp and immobilize tissue during dissection and suturing. Forceps with teeth (such as the Adson, Figure A13.4e, or rat tooth, Figure A13.4g) prevent slippage and are typically used for skin, muscle, and fascia, while smooth (tooth-less) forceps are preferred for more delicate tissues (see Figure A13.4f) but are ineffective at holding skin. Scissor-style grasping forceps ("clamps") hold tissue firmly with traction, aided by ratcheting locks near the finger rings. Observe the serrated teeth of the Allis clamp, used for moderate traction (Figure A13.4e), and the powerful interlocking teeth of the Kocher clamp, used for strong traction (Figure A13.4g). Hemostatic forceps bear fine jaws, well suited to control bleeding when tissue is grasped gently; these come either curved or straight and in varying sizes, the larger of which are known as hemostats or snaps (Figure A13.4d, k, and l) and the smaller of which are called mosquitos (Figure A13.4i, j). Needle holders, used while suturing (Figure A13.4a, b and c) bear characteristically stout jaws, which transmit maximal pressure to a grasped needle. Towel clamps (Figure A13.4h) are helpful in securing towels in the surgical field, when necessary, though may obscure the radiographic view.

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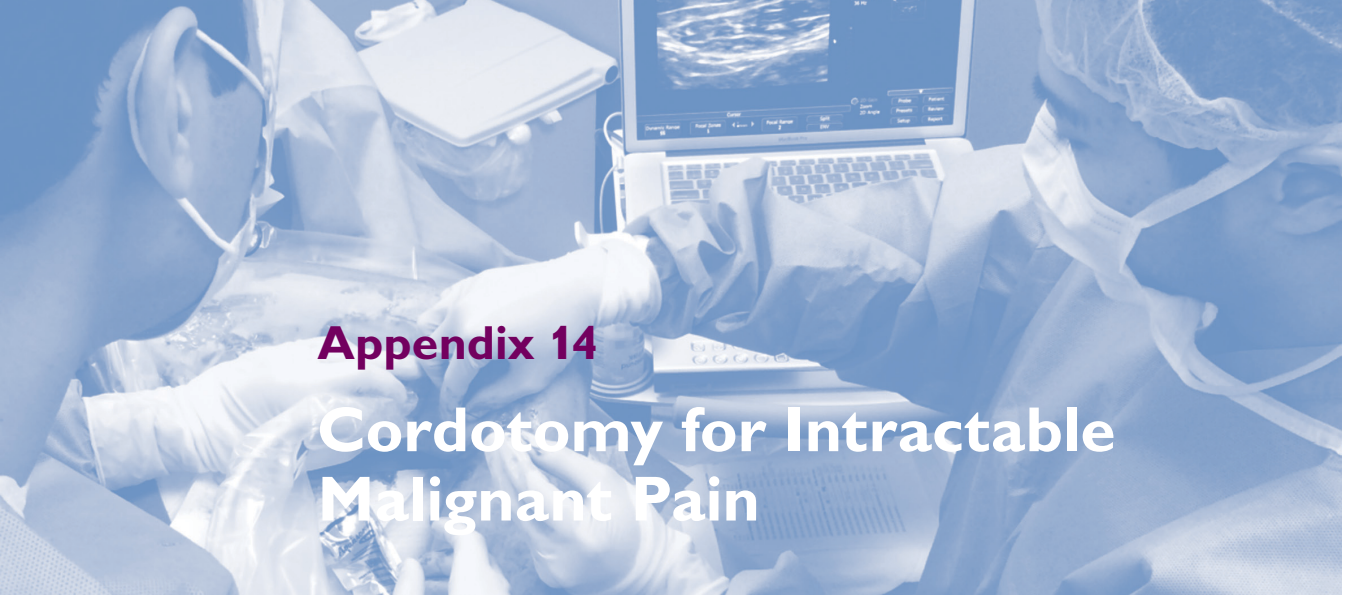

Appendix 14

Cordotomy for Intractable Malignant Pain

William S. Rosenberg

Introduction

The modification of pain perception through lesioning of the nervous system has been practice since Napoleonic surgeons performed battlefield nerve transections. During more modern times, multiple targets have been used, including cingulotomy, thalamotomy, mesencephalotomy, trigeminal nucleotractotomy, myelotomy, and cordotomy (1). One of the more effective procedures has been the sectioning of the lateral spinothalamic tract in the spinal cord. Initially, this was performed as an open procedure with extensive exposure, manipulation of the spinal cord, and no real-time patient feedback as to location of the lesion (2). More recently, the procedure has been improved with the introduction of fluoroscopic targeting for percutaneous targeting of a radiofrequency lesion, with further development through the introduction of CT guidance (3). This outpatient, percutaneous procedure, performed with local anesthetic and real-time patient feedback, is an important tool in the treatment of refractory pain, particularly when cancer-related.

Indications

Cordotomy is indicated for the treatment of severe, refractory pain, located contralateral to the proposed side of lesioning and entirely below the clavicle. It is most effective for nociceptive pain, although it has been used to treat neuropathic pain as well. There has been suggested a time limitation in the efficacy of analgesia of up to 2 years, and for that reason, often cordotomy is reserved for neoplasm-related pain with a limited life expectancy. However, long-term pain control has been reported (4, 5), and therefore one must carefully weigh risk versus potential benefit. Severe pulmonary dysfunction has been listed as a relative contraindication, because of the possibility of disruption in automatic breath control pathways and, in the case of bilateral lesions, Ondine's Curse (potentially life-threatening complete apnea during sleep) (6). However, these recommendations are based on the open procedure; clinical evidence on the percutaneous procedure seems to indicate that it is much less likely to cause respiratory dysfunction, if at all (3). The procedure may be performed while the patient is on chemotherapy and requires only a short window off anticoagulation for the actual procedure itself.

Technique

A myelogram is performed through lumbar puncture and the intrathecal dye is allowed to flow into the cervical spine. The patient is brought to the CT scanner and positioned supine in the gantry. A metallic skin marker is positioned 2 cm caudal to the mastoid, and its position is refined, initially using scout images and then axial CT images, until it is positioned in the anterior 1/3 of the C1/2 interspace, just anterior to the equator of the spinal cord on axial scans. The distance from skin to dura is measured.

After prepping and draping, local anesthetic is infiltrated, both superficially and deeply, and a small stab incision is made. A special, thin-walled 20 gauge spinal needle is positioned, using sequential CT scans through the area of interest, until it pierces the dura and CSF is acquired. The tip is then carefully advanced to lie just next to the spinal cord, again under CT guidance. A radiofrequency electrode (0.25 mm diameter, 1.8 mm exposed tip; Cosman Medical, Inc., Burlington, MA) is advanced through the spinal needle. Electrode placement is monitored by tactile feedback and impedance. The impedance at the exposed tip will predictably change, depending on its location (typical: CSF: < 200 Ω; pia: 300–400 Ω; intraparenchymal: 700–900 Ω). It is possible to feel the transition of the electrode across the pia and into the spinal parenchyma. Ideal placement is just within anterolateral quadrant of the spinal cord (Figure A14.1), with attention to the rough somatotopy of the lateral spinothalamic tract (arm: ventromedial; leg: dorsolateral).

Proper neurophysiological positioning is confirmed using stimulation. First, low frequency stimulation (2–5 Hz) is used to verify that the electrode tip is not within the corticospinal tract. While ipsilateral contractions of the neck and shoulder are common, possibly secondary to direct stimulation of the anterior horn motor neurons, there should be no contractions in the arm or leg up to at least 1.0–1.5 V. Then sensory stimulation is conducted using higher

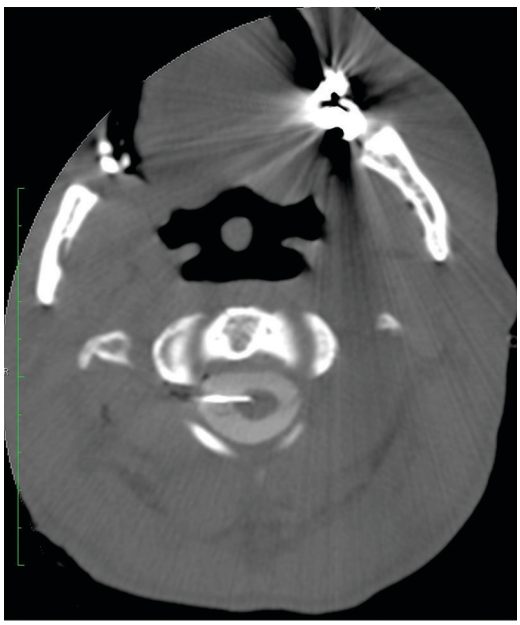

Figure A14.1 Axial CT image with radiofrequency electrode placed through a thin-walled 20 gauge spinal needle from the left and into the lateral spinothalamic tract in the spinal cord parenchyma.

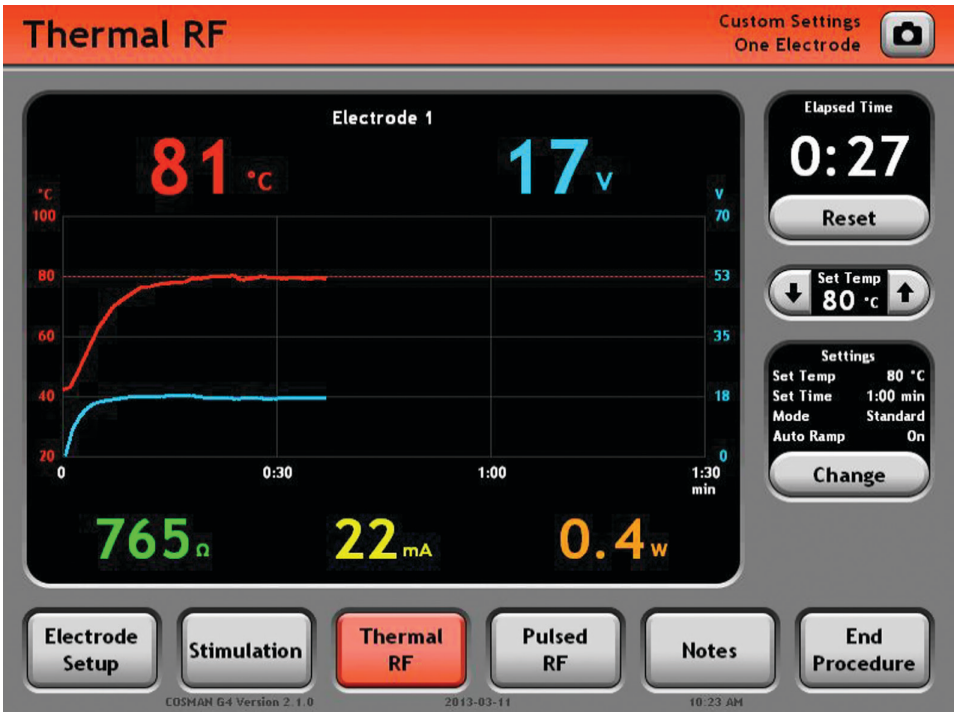

Figure A14.2 Screen shot of radiofrequency generator delivering an 80°C treatment lesion. Note that continued positioning of the electrode within the spinal cord parenchyma is confirmed throughout lesioning by the high impedance maintained (765 Ω).

frequency (50–100 Hz), with placement in the lateral spinothalamic tract confirmed by the report of a contralateral sensory response. While it is desirable to have the sensory response overlap the area of desired analgesia, close approximation is usually adequate for an excellent clinical outcome. After confirmation of spinothalamic tract placement, a test lesion (60°C x 1 minute) is made, followed by a neurological assessment of appendicular sensory and motor function. Then one or two treatment lesions are made (80°C x 1 minute each; Figure A14.2) with neurological assessments in between. The needle and electrode are then removed, and the patient is observed for a few hours before discharge.

Outcomes and Complications

For patients in whom there is proper anatomic and neurophysiological positioning of the electrode, there is usually excellent pain relief, which can be immediate. Kanpolat et al. (3) reported a series of 207 patients, all but 14 with neoplasm-related pain, with 92.5% reporting either complete or partial but satisfactory initial pain relief. Twelve cases were performed bilaterally, with no instances of sleep-induced apnea (Ondine's Curse). The complication rate was extremely low, with no major morbidity or mortality. The few instances of adverse events (slight motor weakness, slight ataxia, mild hypotension, and urinary retention) were all temporary and resolved within days to weeks.

Raslan et al. (7) reviewed the field of neuroablation, concluding that the preponderance of clinical data favored cordotomy. A total of 3601 patients have been reported in the cordotomy literature, with the vast majority enjoying greater than 50% pain relief at 6 months. Even though these citations include both open and percutaneous procedures, the reported complication rate remained extremely low.

Pain care is moving toward a multimodality, "big toolbox" approach, in which CT-guided percutaneous cordotomy fits well. The ability to eliminate a large locus of pain—even though it may not address the entirety of pain—can be very helpful. For example, a patient with multiple metastases who has a severe, dominant area of pain that is driving treatment could have that area addressed by cordotomy, allowing other modalities to more effectively manage overall pain control. A recent multicenter case series (8) reported on the combined use of intrathecal drug delivery and neuroablation in the treatment of complex neoplasm-related pain. As a safe, cost-effective, efficacious, non-pharmacological treatment, CT-guided percutaneous cordotomy deserves consideration in the management of complex, refractory pain.

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