Edited by
Sanjeet Narang,
Alison Weisheipl, *and*
Edgar L. Ross

Surgical Pain Management

A Complete Guide to Implantable and Interventional Pain Therapies

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Edited by

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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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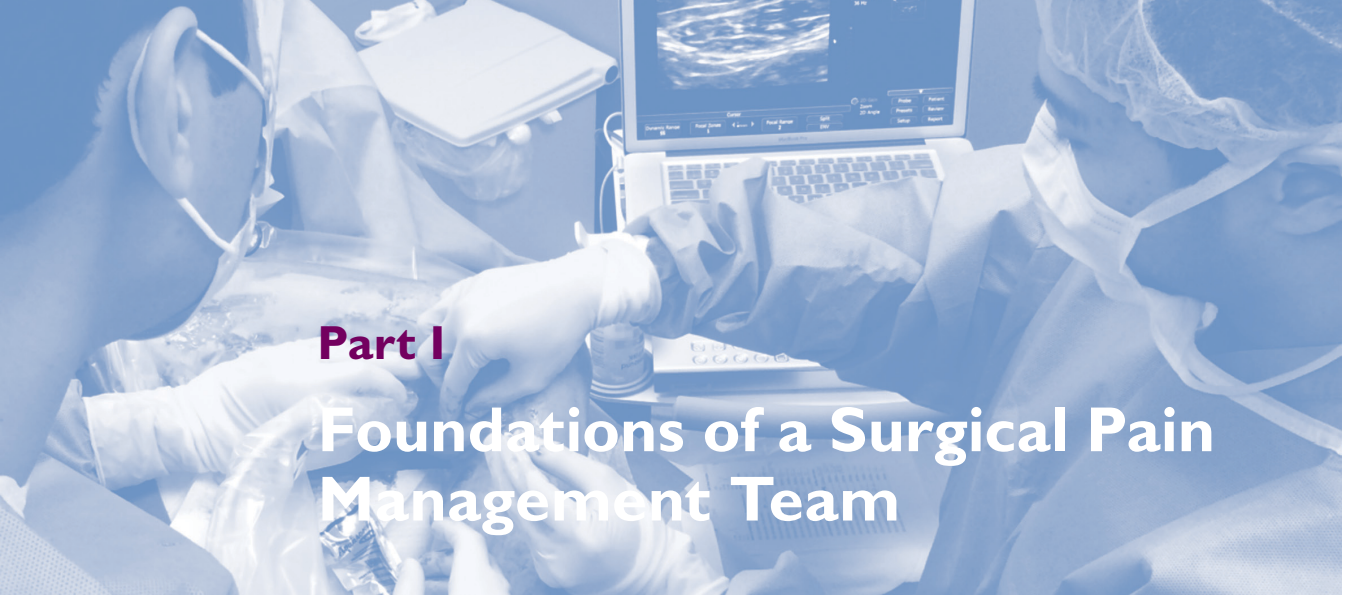

Part I

Foundations of a Surgical Pain Management Team

Chapter 1

Organization of an Implant Service

Daniel Vardeh and Diane Palombi

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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