



## Advanced Innovations for Pain

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**Statement of Need:** General internists and primary care physicians must maintain an extensive knowledge base on a wide variety of topics covering all body systems as well as common and uncommon disorders. *Mayo Clinic Proceedings* aims to leverage the expertise of its authors to help physicians understand best practices in diagnosis and management of conditions encountered in the clinical setting.

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**Learning Objectives:** On completion of this article, you should be able to (1) recognize that intrathecal analgesia via an intrathecal drug delivery device provides equivalent or superior analgesia and the advantage of fewer adverse cognitive and gastrointestinal adverse effects when compared with systemic opioid pain medication in patients with cancer related pain; (2) give examples of pain syndromes or indications that are amenable to advanced interventional options such as spinal cord stimulation and intrathecal analgesia; and (3) list key patient selection criteria for patients being considered for treatment with spinal cord stimulation or intrathecal analgesia.

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In their editorial and administrative roles, William L. Lanier, Jr, MD, Terry L. Jopke, Kimberly D. Sankey, and Nicki M. Smith, MPA, have control of the content of this program but have no relevant financial relationship(s) with industry. Dr Lamer receives research funding from Boston Scientific Corporation and Medtronic.

Dr Deer is a consultant for Bioness Inc, Nevro Corp, St. Jude Medical, Inc, Medtronic, Flowonix Medical Inc, Jazz Pharmaceuticals, Saluda Medical, Axonics Modulation Technologies, Vertos Medical Inc, and Nuvector Corporation; has minority shares in Axonics Modulation Technologies, Bioness Inc, and Nevro Corp; was previously a shareholder in Spinal Modulation Inc; and receives research funding from St. Jude Medical, Inc, and Nevro Corp.

Dr Hayek serves as a consultant or medical advisory board member for Boston Scientific Corporation's Neuromodulation Division, Neuros Medical Inc, and Flowonix Medical Inc; is a consultant for Nuvector Corporation, Globus Medical, Inc, and Micro Systems Engineering, Inc; receives research funding from Boston Scientific Corporation; has applied for research funding from Medtronic, Boston Scientific Corporation, Medtronic, and St. Jude Medical, Inc; and receives support from University Hospitals' fellowship program for pain medicine, where he serves as program director.

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**Abstract**

Chronic pain represents one of the most important public health problems in terms of both the number of patients afflicted and health care costs. Most patients with chronic pain are treated with medications as the mainstay of therapy, and yet most medically treated patients continue to report ongoing pain. Additionally, adverse effects from pain medications represent a major challenge for clinicians and patients. Spinal cord stimulation and intrathecal drug delivery systems are well-established techniques that have been utilized for over 25 years. Intrathecal drug delivery systems have proven efficacy for a wide variety of intractable pain conditions and fewer adverse effects than systemic medical therapy in patients with refractory cancer-related pain. Spinal cord stimulation is cost-effective and provides improved pain control compared with medical therapy in patients with a variety of refractory pain conditions including complex regional pain syndrome, painful diabetic neuropathy, and chronic radiculopathy. Patients who have intractable pain that has not responded to reasonable attempts at conservative pain care measures should be referred to a qualified interventional pain specialist to determine candidacy for the procedures discussed in this article.

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Chronic pain, chronic low back pain, chronic neuropathic pain, and opioid use or misuse related to chronic pain represent important public health problems in the United States and abroad. Despite numerous advances in treatments, many patients with spine and/or limb pain do not have improvement with standard conservative medical therapy. A recent evidence-based review of medical therapy for neuropathic pain concluded that “existing pharmacologic treatments for [neuropathic] pain are limited, with no more than 40-60% of patients obtaining partial relief of their pain.”<sup>1</sup> Put into practical terms, this means that roughly half of all patients who present to their physician with common painful conditions such as diabetic peripheral neuropathy (DPN), postherpetic neuralgia, complex regional pain syndrome (CRPS), failed back surgery syndrome (FBSS) with a neuropathic component, and chronic radiculopathy (sciatica) will not have sufficient improvement with conservative pain care measures.

Advanced pain care options should be considered for many, if not most, of these patients with refractory pain. Yet studies indicate that most clinicians are not familiar with these options.<sup>2-5</sup> Accordingly, many patients who could benefit from such treatment are not referred to a pain specialist who can identify and implement the appropriate advanced interventional pain therapies (AIPTs). Because many of these chronic painful conditions are lifelong problems, failure to refer patients for appropriate therapy potentially subjects them to needless long-term suffering. Another important consideration regarding AIPT is that it offers an alternative to oral opioid therapy for patients with intractable or complex pain problems. Many patients with chronic pain are treated with long-term opioid therapy despite a paucity of evidence for long-term efficacy. Opioid-related adverse effects are common, and opioid misuse has reached epidemic proportions in the United States. In the past, AIPT was considered by many physicians to be a late-stage pain therapy, mainly because of the invasive nature of the therapy. More recently, because of the limited efficacy and the myriad problems associated with long-term opioid therapy, many pain specialists rightfully consider AIPT earlier in the

treatment algorithm for patients with intractable pain.<sup>3,6</sup> Unlike other interventions that may afford only temporary improvement in pain such as nerve blocks and injections, neuromodulation addresses chronic pain problems by continuous application of electrical stimulation or pharmacological treatment delivered to targeted nerves. In this review, we will discuss spinal cord stimulation (SCS) and intrathecal drug delivery systems (IDDSs), 2 advanced neuromodulation interventional therapies that have been proved to be effective treatments for patients with refractory chronic pain. Each of these techniques involves a surgically implanted pain-relieving device, as described in the subsequent sections.

## SPINAL CORD STIMULATION

### SCS Devices

For most patients, the placement of an SCS device is a 2-stage process: stage 1 is a trial or temporary implant, and stage 2 is the implantation of the long-term unit. The use of the trial procedure imparts a substantial advantage for SCS over many other invasive or interventional spinal procedures in that it allows both the patient and the medical team to assess the likelihood that SCS will be helpful for the patient's painful condition. The trial involves placing short-term or temporary SCS leads into the epidural space. It is a minimally invasive outpatient surgical procedure. In most cases, an incision is not required because the leads are placed via epidural needles. Once the leads are successfully placed, the needles are removed and the leads are sterilely taped and secured to the skin surface and then connected to an external battery or generator. The patient is instructed in the proper use of the SCS trial generator and is then dismissed and allowed to assess the amount of relief over the course of the trial period, which usually lasts from 3 to 10 days. At the end of the trial period, the temporary SCS leads are removed, and a decision is made regarding the success of the SCS trial. In most cases, if the patient experiences 50% or greater pain relief as well as notable functional improvement, the decision will be made to implant a long-term SCS system.

There are 2 main components to an implanted SCS system, the generator and the leads (Figure 1). The lead or leads are placed

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