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Neurostimulation for Pain

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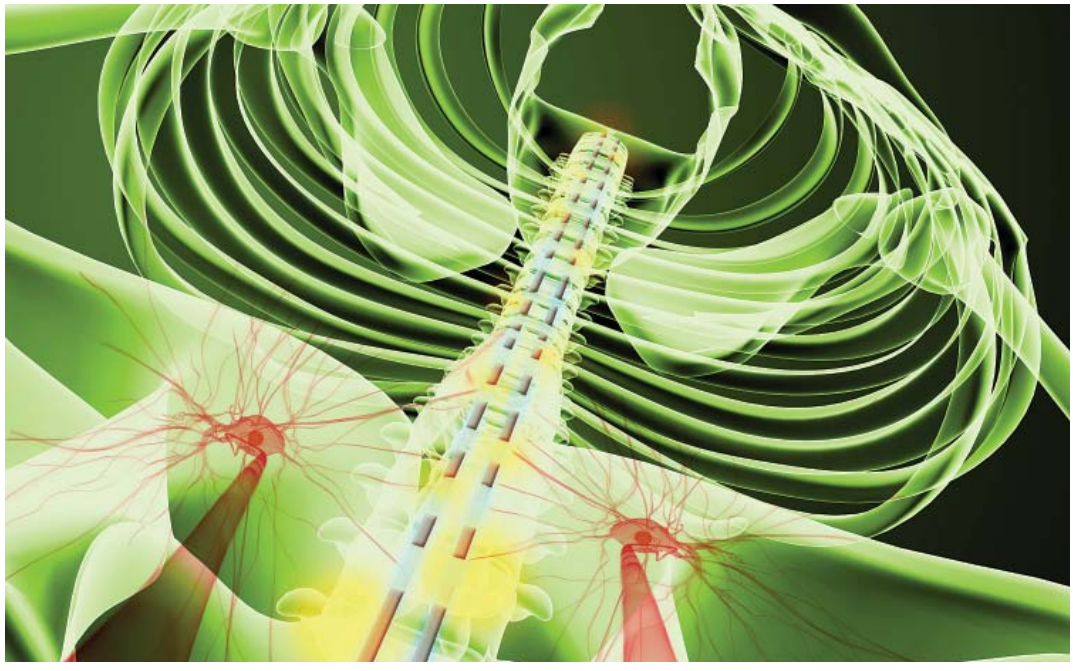

Chronic pain is a pandemic that affects approximately 11% of people in the United States, and is estimated to cost the nation $100 billion per year in medical expenses, lost income, and decreased productivity.[1,2] Chronic pain interferes with all aspects of life, including personal enjoyment, work, and relationships. Although pain is universal, the etiology of many painful conditions is not well understood, making treatment difficult.

Neuromodulation

Forms of neuromodulation were used long before the discovery of electricity. The Egyptians first attempted electric stimulation to treat pain as early as 2,500 BC, as seen on stone carvings depicting electric catfish being placed on people.[3] The torpedo fish, which also generates electric currents, was used to treat pain and common maladies like headaches and arthritis during the time of Socrates.[4] Electric shocks from these animals can reach 220 volts, enough to kill a human adult. In ancient Greece and Rome, the shocks from the species *Torpedo nobiliana* were used as a treatment for gout, headache, and other sources of pain.[4]

Grounded in the theory that non-noxious stimuli can reduce noxious pain perception, modern neuromodulation works by introducing an electric current near the source of chronic pain impulses or along pain pathways. In 1967, Shealy introduced neuromodulation into contemporary medicine; however, the approach did not gain popularity for the treatment of pain until the mid-1980s.[5,6]

Stimulation is becoming increasingly popular for the treatment of refractory pain conditions. It is reversible, safe, cost-effective, and nonpharmacologic. The most common forms of stimulation offered to treat pain are spinal cord stimulation (SCS), peripheral nerve stimulation (PNS), motor cortex stimulation, and deep brain stimulation. This review focuses on SCS and PNS.

Most implantable pulse generators (IPGs) are rechargeable, programmable, and can connect to 1 or 2 leads. The IPG produces a low-voltage current, which creates a sensation that blocks the ability of the brain to sense previously perceived pain. The intensity of the stimulator can be changed, the pattern of the electrical field can be varied, and the system can be turned on and off as necessary to provide optimal pain relief as experienced by the patient. Currently available IPG devices are listed in Table 1. Fluoroscopic images of device leads are shown in the Figure.

A stimulator trial is performed prior to permanently implanting the IPG and leads. In a stimulator trial, 1 or 2 leads containing varying amounts of electrodes are implanted percutaneously into the epidural space (SCS) or close to pain-generating nerves (PNS) with local anesthetic and IV drug sedation. If pain and function improve by a margin of 50% or more (assessed on a visual analog scale [VAS] and through careful monitoring of the patient over 3-7 days), the patient can receive permanent electrodes and the IPG can be surgically implanted.

Spinal Cord Stimulation

Spinal cord stimulation has proven to be an effective treatment modality in improving daily function and quality of life for many patients suffering from severe neuropathic pain of various causes, most commonly chronic back and limb pain[7] (Table 2). However, treatment of chronic neuropathic pain in the region of the face, neck, head, and low back are challenging for pain specialists. The pain is typically refractory to many of the conventional treatment options, including medical therapies (nonsteroidal anti-inflammatory drugs [NSAIDs], anticonvulsants, local anesthetics, antidepressants, and opiates), physical therapy, and nerve blocks or ablations.[8]

Table 1. Comparison of Small, Rechargeable IPG Devices

Device, Manufacturer	Size	FDA Battery Life	Days Between Recharge	Power Delivery
Eon Mini St. Jude Medical	18 cc	10 yr	121	Constant current
Precision Boston Scientific	22 cc	5 yr	61	Constant current
RestoreULTRA Medtronic	22 cc	9 yr	54	Constant voltage

IPG, implantable pulse generator

Source: Clinician's manual for Eon Mini Neurostimulation System. Plano, TX: St. Jude Medical Neurostimulation; 2008.
Precision IPG [product brochure]. Valencia, CA: Boston Scientific; 2007.
RestoreULTRA [product brochure]. Minneapolis, MN: Medtronic; 2008.

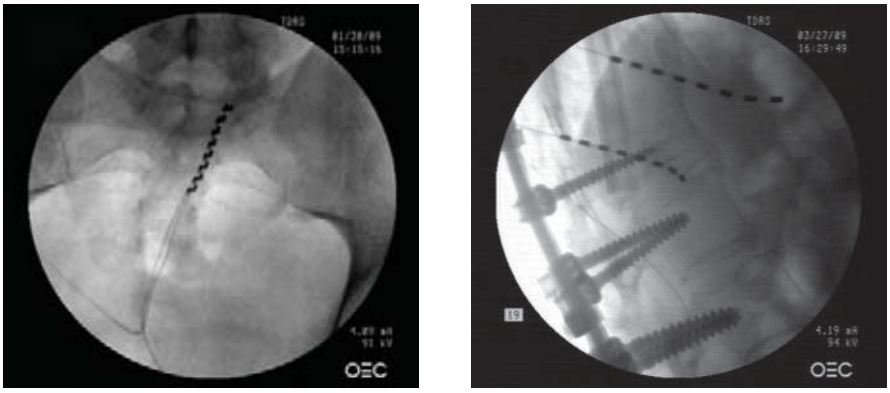

Figure. Fluoroscopic images of leads.

Images provided by ArizonaPain.com.

Peripheral Nerve Stimulation

Peripheral nerve stimulation is a type of neuromodulation that is becoming increasingly popular for the treatment of many causes of chronic pain and peripheral neuralgias (Table 3). This innovative treatment works by delivering low-level electric impulses close to pain-generating nerves that interfere with the perception of nociceptive pain.[9]

Peripheral nerve stimulation can be further divided into 2 entities. The first is PNS of an identifiable pain-generating nerve (such as the sciatic nerve in a patient with foot pain or the occipital nerves in a patient with occipital neuralgia). The second type of PNS, peripheral nerve field stimulation (PNfS), involves the subcutaneous placement of electrical leads over the generalized area of pain (eg, lumbar leads for axial lumbar pain). An advantage of PNS over SCS is the ability to place the lead directly adjacent to an affected nerve or in the area of pain, and the ability to provide relief to areas that may be difficult to reach with SCS.

Head, Neck, and Facial Pain

The first through third cervical nerve roots are commonly involved when a patient presents with head, neck, and facial pain. Spinal nerve roots are not always the cause of these cephalad neuralgias and muscle contractures. Patients who have failed other treatments for their pain have responded positively to PNS. In 2007, Melvin et al conducted a study of patients with occipital headaches. After 4 weeks of receiving PNS for their headaches, 46% of the patients rated the relief as *excellent*, and at 12 weeks no patients enrolled in the study reported *poor* pain relief.[10] Percutaneous implantation of peripheral stimulator leads has been shown to provide good to excellent results in treating intractable occipital neuralgia, which has been a suggested trigger for migraines.[8] In a clinical investigation of patients receiving PNS for craniofacial pain, 73% of the participants experienced significant improvement in pain intensity in the first 3 months.[10]

Table 2. Conditions Effectively Managed With Spinal Cord Stimulation[7]

Ischemic vascular
Peripheral vascular disease
Refractory angina
Emerging uses
Chronic pancreatitis
Chronic pelvic pain
Facial pain (nucleus caudalis stimulation)
Idiopathic neuropathic foot pain
Neuropathic pain
Brachial plexus neuropathy
Complex regional pain syndrome
Peripheral neuropathy
Postherpetic neuralgia
Post-laminectomy syndrome
Post-thoracotomy syndrome
Phantom limb pain
Radiculitis (cervical, thoracic, lumbar, sacral)

Table 3. Conditions That May Be Effectively Treated by PNS and PNfS

Axial pain (cervical, thoracic, lumbar, sacral)
Cervicogenic headaches
Chronic pelvic/testicular pain
Complex regional pain syndrome (I & II), RSD
Migraines/chronic daily headaches (C1-C3 PNS)
Post-laminectomy syndrome
Occipital neuralgia (C1 PNS)

PNfS, peripheral nerve field stimulation; **PNS,** peripheral nerve stimulation; **RSD,** reflex sympathetic dystrophy

Case Report

Chief Complaint: Chronic Low Back Pain (Without Radiculopathy)

History of present illness: The patient is a 68-year-old man with a long history of lower back pain. The patient had been treated with NSAIDs, narcotics, and physical therapy, as well as epidurals and facet injections. The patient underwent spinal fusion 2 years ago without significant pain relief.

On presentation, the patient describes the pain as 5 out of 10 on the VAS, continuous and dull, without lower extremity radiation.

Review of Systems: Negative

Past medical history: Back pain, hip pain, and osteoporosis

Past surgical history: Lumbar fusion at L4-L5 in 2006. Hip replacement in 2004. T7 vertebroplasty several years ago; patient could not remember exact year.

Family history: noncontributory

Allergies: No known drug allergies

Relevant Abnormal Physical Examination Findings

Lumbar spine: Tenderness to palpation over facet joints with lumbar extension and rotation. Some paraspinous musculature spasm. No gross anatomic abnormalities. Decreased range of motion with lumbar extension and flexion. Two focal and discrete vertical areas of pain about the size of a palm just lateral to midline at L4-S1. Well-healed midline vertical incision from previous lumbar spinal surgery.

Assessment

Lumbar post-laminectomy syndrome

Chronic degenerative disease of the lumbar spine

Chronic axial low back pain

Plan

SCS trial with 2 lumbar epidural leads compared with PNS trial with 2 lumbar axial percutaneous leads.

Trial

The patient underwent implantation of a trial spinal cord stimulator with 2 epidural leads in the thoracolumbar region, as well as 2 peripheral field leads in the lumbar region. Two SJM Octrode (St. Jude Medical) leads were advanced from the 14-gauge Tuohy needles at the L2-L3 epidural interspace to the inferior border of the T7 vertebral body (covering the entire midline of the T8 and T9 vertebral bodies). Stimulation was initiated and the patient had coverage over his low back in the area of pain, as well as over both legs. These leads were then anchored to the skin.

Attention was turned toward placement of the percutaneous peripheral leads. Several 14-gauge St. Jude Medical Tuohy needles were advanced subcutaneously in a vertical fashion beginning at the L4 level and going straight down on either side of L4, L5, and S1. The leads were placed through the needles and the needles were subsequently withdrawn, leaving the leads in place.

The patient had coverage over his low back and legs via his SCS leads, but did not feel the stimulation was beneficial. He did report an 80% reduction in painful symptoms from the peripheral leads during his 5-day trial.

Permanent Implant

Permanent implantation was performed 3 weeks after the successful trial. The patient presented at a 1-week follow-up appointment with no pain. The patient stated that he had a 70% reduction in pain and complained only of discomfort at the site of incision. He reported receiving 100% coverage of the area of pain with the permanent PNS and was very happy with the results.

Chronic Back Pain

The evaluation and treatment of back pain, either acute or chronic, poses economic hardship on society, as well as an emotional and physical destitution to the patient.[11] Back pain can arise from a number of structures causing irritation to central and/or peripheral nerves. Localizing a specific offending structure (nerve root, facet joint, disc, ligament, muscle) as the cause of the pain can be difficult. In PNS, the electrode is placed to the nerve causing the pain, improving the likelihood of sufficient nociceptive blockade.

A study of PNfS for chronic lower back pain after failed back surgery syndrome found a significant reduction in mean VAS scores of 4.18±1.42 in patients who reported a successful outcome (1 of 13 patients reported a poor outcome).[9] Leads were placed subcutaneously over the area of worst pain. Patients had axial low back pain without a radicular component.

Abdominal, Pelvic, and Ilioinguinal Pain

Abdominal, pelvic, and ilioinguinal pain are common, and research on the efficacy of pain relief from PNS in these conditions is insufficient. However, a peripheral nerve likely is implicated and, if identified or if the patient has a discrete and focal area of pain, PNS may prove beneficial.

Lead migration has been a constant complication for some patients following implantation in SCS. When leads migrate in the epidural space from an SCS, the

Case Report

Chief Complaint: Right Lower Extremity Pain

History of present illness: The patient is a 35-year-old man diagnosed with chronic right lower extremity pain that began after sustaining a tibial fracture in a motor vehicle accident. The patient underwent a number of corrective surgeries and recently has been given the diagnosis of reflex sympathetic dystrophy. The patient describes pain, increased perspiration, temperature changes, swelling, burning sensations, and increased sensitization extending from the lateral tibia region into the foot. On physical examination, a decreased amount of hair on the right leg compared with the left leg was noted.

The patient also describes throbbing, shooting, sharp, and burning lower back pain that also developed after the accident. He stated that rising from a sitting position, climbing stairs, and driving exacerbate the pain, whereas sitting improves it.

In the past, the patient has tried opiates, acupuncture, steroid injections, and chiropractic manipulations for pain relief; all have proven to be only moderately effective.

Since becoming a patient at our clinic, the patient underwent right-sided L2 to L4 sympathetic chain radiofrequency ablation from which he received excellent, but temporary, pain relief. Although pain control was achieved acutely, the patient still required a moderate amount of opiates and was experiencing significant pain. At this point, the option of SCS was discussed.

Review of Systems: Negative

Allergies: Cephalexin, Aureomycin (Lederle), penicillin, Lyrica (Pfizer)

Past medical history: Reflex sympathetic dystrophy in the left lower extremity, chronic pain syndrome

Past surgical history: Multiple surgeries to the right lower extremity after car accident

Relevant Abnormal Physical Examination Findings

Sensation: Over the anterior shin and the lateral shin, the patient has numbness and "electrical"type pain radiating down into his right foot on light touch and pressure. He has some hair loss over the right anterior shin compared with the left side, as well as some shiny skin. There is a lack of variance in temperature with touch. The patient does not have pain on light touch. Straight-leg raise is positive on the right side, which may be indicative of some pathology in the lumbar spine. Straight-leg raise is negative on the left side.

Assessment

Reflex sympathetic dystrophy of the right lower extremity

Axial low back pain with right lower extremity radiculopathy

Plan

SCS trial with dual electrode leads

Trial

The patient underwent implantation of a trial SCS with 2 epidural leads. A 14-gauge St. Jude Medical Tuohy needle was advanced to the T12-L1 interspace on the left side and then on the right side. The 8-contact electrode was advanced through the Tuohy needle. The first lead was placed over the midline of the entire T9-T10 vertebral body with the tip at the inferior aspect of the T8 vertebral body. The second 8-contact electrode was placed through the right-sided needle. This was advanced up just to the right of midline in the same distribution with the tip at the inferior border of the T8 vertebral body covering the entire T9 and T10 vertebral body. Stimulation was then initiated. The patient had coverage over all of his painful symptoms, including his low back and into the entire right lower extremity including his foot. The needles were withdrawn, pressure was held over the needle entry site, and a sterile bandage was applied.

At the 5-day follow-up, the patient noted 80% improvement in his overall pain symptomatology. He felt the SCS significantly decreased his overall pain and increased his daily function and quality of life.

Permanent Implant

Permanent implantation was performed 4 weeks after the successful trial. The patient presented at a 1-week follow-up appointment with no pain. At 1- and 2-month follow-up visits, the patient reported a 90% reduction in pain, adding that he was feeling better than he had in 15 years. The patient reported decreased opiate use and increased quality of life.

stimulation coverage changes and may no longer provide adequate pain relief. Although peripheral leads are prone to migration, they are more accessible and easier to manipulate in order to receive sufficient stimulation coverage. However, the most evident benefit of PNS over SCS is that in the former technique the leads are placed outside of the epidural space, thus reducing the risk for epidural neurologic insult and epidural hemorrhage.[1,3]

Table 4. Contraindications for Spinal Cord and Peripheral Nerve Stimulation

Cardiac pacemaker/defibrillator (relative contraindication)
Systemic infection (absolute contraindication)
Pregnant or lactating women (relative contraindication)

Future Considerations

The number of centers using PNS for craniofacial pain and other peripheral nerve syndromes is increasing. In the future, a wider acceptance of this treatment is expected because it is minimally invasive, can be trialed, is reversible, and has adjustable settings. These unique qualities may eventually make PNS the preferred modality for otherwise intractable conditions.[9]

Spinal cord stimulation can reduce pain by approximately 50% in the near term; however, controversy exists as to whether it provides adequate long-term pain relief.[9] Peripheral nerve stimulation is a relatively new treatment. As a result, little evidence-based medicine supports its long-term efficacy. Nevertheless, it has relatively few contraindications (Table 4), and the majority of patients who undergo PNS report a significant decrease in pain and the use of pain medication 12 months after implantation.[9] Therefore, PNS may be considered an effective means of relieving pain and decreasing the use of pain medication, particularly opioids.

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