Introduction

Chronic pain affects approximately one-third of the US population and is the leading cause of adult disability. Chronic pain also has a significant effect on health care expenditures and quality of life (QoL), including physical, emotional, and social functioning.

Treatment options for individuals suffering from chronic pain include over-the-counter medications, physical therapy, prescription drugs, and invasive surgeries. However, some individuals may respond poorly to conventional treatments. An alternative may be spinal cord stimulation (SCS), a reversible therapy that delivers electrical pulses from an implantable pulse generator to electrodes implanted in the posterior epidural space, representing a viable option to long-term medication therapy. SCS masks pain signals that travel to the brain and does not result in the side effects commonly associated with analgesic medications. As a result, properly selected patients can experience improved QoL and may regain the ability to function on all levels.

This monograph provides an overview of a roundtable discussion moderated by Pain Medicine News that brought together experts from a diverse set of health care fields, including anesthesiology, neurosurgery, pain management, and radiology during the 2013 North American Neuromodulation Society (NANS) Annual Meeting to discuss the use of SCS in clinical practice.

Selecting Patients for SCS Trial

SCS is approved to treat individuals with chronic pain of the trunk and limbs associated with failed back surgery syndrome (FBSS), intractable low back pain, and leg pain. It is important to consider several factors when selecting patients with chronic pain who will respond positively to SCS treatment. "In my practice, eligibility for SCS rests on several criteria," noted Giancarlo Barolat, MD, director of Barolat Neuroscience. "First, patients must have severe pain rather than mild or moderate pain. Second, the patient must have failed other reasonable treatments, or the risk of alternative treatment must be deemed too high to attempt. Third, the severe pain has to be chronic—say, for a period of at least 6 months. Finally, the patient has to have a stable social and psychological situation."

Given the detrimental effects of chronic pain and a failed response to less invasive treatment, clinicians should consider the likelihood of achieving improved function and QoL when considering SCS implantation for patients. According to James North, MD, a pain specialist at the Carolinas Pain Institute, the decision to use SCS is 3-fold. "When considering the use of the SCS device, my number 1 goal is for the patient to be more functional and to be able to do things they couldn't do prior to [SCS treatment]," he said. "Second, we want to reduce their pain scores to as low as we can. Third, we want to minimize the amount of medications needed to improve functionality and to relieve pain."

Imaging Options for the Patient With an SCS Device

As with other implanted metallic devices, such as pacemakers, implanted SCS devices can preclude the use of magnetic resonance imaging (MRI) because of device labeling restrictions, or the patient not meeting all of the eligibility requirements for MR conditional devices. According to Garry Gold, MD, professor of radiology at Stanford University School of Medicine and co-author of the guidelines...
on MRI imaging of the spine for the American College of Radiology, there are numerous imaging options available to SCS patients that can depict different parts of the body, including soft tissue, and can be used to achieve a confident diagnosis without using MRI. These include x-ray, fluoroscopy, CT [computed tomography] scans, ultrasound, nuclear medicine, and positron emission tomography CT, which work quite well for almost every indication," explained Dr. Gold.

In some cases, alternative modalities such as CT may provide better imaging results than MRI. “CT with contrast is often an acceptable substitute for MRI, and in some cases, it can be even better than MRI,” Dr. Gold said. “For example, a CT myelogram is just as accurate for looking for disk herniation, nerve root compression, and canal stenosis as MRI, and it’s better than conventional MRI around the metallic fusions that you often find in patients with FBSS.” Additionally, Dr. Gold confirmed that clinicians can use CT with or without IV contrast and CT perfusion studies in the evaluation of stroke; CT perfusion, nuclear medicine study, and stress echocardiography in the evaluation of the coronary arteries and cardiac function; and CT arthrography or ultrasound for rotator cuff tears and for labral tears.

“There are a few conditions for which MRI is clearly the superior imaging choice. The best example is probably MS (multiple sclerosis), where the soft tissue contrast provided by MRI allows you to see white matter lesions in the brain that you can’t easily see on any other imaging modality,” said Dr. Gold. “Another example would be primary spinal cord lesions like spinal cord tumors or spinal cord infarct.” In the case of MS, several manufacturers, including Boston Scientific, offer SCS devices that allow for conditional MRI scans of the head for patients who meet specified eligibility requirements.

Given the available alternatives to MRI, explanting an SCS device should be a rare occurrence. “If you get a request from another clinician to explant an SCS device to obtain an MRI, it’s important to discuss with that provider whether there’s another imaging modality that would suffice because there almost always is, or, in some instances, the MRI is not really indicated,” said Dr. Barolat. Dr. Gold agreed with this assessment, stating that “many options are available, so if you’re limited by the lack of MRI, you can almost always find another way to get the diagnosis. It’s almost never appropriate to have someone’s device explanted in order to obtain an MRI.”

Dr. Gold and his colleagues noted that data from one manufacturer of an MRI-conditional SCS system stated that the majority of patients who have indications for SCS would need an MRI scan at least 5 years down the line. "These data, however, overstate the need for MRI because the researchers used a cohort of all individuals indicated for SCS (ie, those with low back pain or any kind of nerve pain or those with various conditions who might at some point get an SCS). This cohort, for example, would have included anyone with low back pain who had an MRI but would have never had an SCS implanted. Furthermore, the study ignored the fact that almost all of these individuals, if they had an SCS system in place, could get alternative imaging options. “A more appropriate measure would
have been to assess how many people with an SCS had their device explanted in order to get an MRI—and that annual prevalence rate is estimated to be less than 0.5% from the Boston Scientific complaint database and less than 1.5% from an analysis of the CMS [Centers for Medicare & Medicaid Services] database,” explained Dr. Gold. Corroborating these figures, Dr. Hayek co-authored an analysis of 241 implanted SCS patients at Case Western over 8 years, and the annualized explant rate due to MRI was found to be less than 1% (6 total explants to obtain an MRI over 8 years).

“Patients do not need MRI scans. Patients need to have accurate diagnosis that will enhance their clinical care, and such diagnosis may be achieved by MRI scans as well as other diagnostic imaging tools,” said Nagy Mekhail, MD, PhD, director of evidence-based pain management research at the Cleveland Clinic Spine Center. “The imaging study should give me the needed information to optimize clinical care; however, it does not have to be an MRI scan.”

Experience With the Boston Scientific Precision Spectra™ SCS System

In the past, SCS systems have offered a maximum of 16 contacts and 2 lead ports, with each lead port allowing the placement of one lead. The Precision Spectra SCS system has 32 contacts and 4 lead ports to offer more coverage of the spinal cord and greater flexibility, respectively, for the management of chronic pain (Figure 1). The system uses the advanced Illumina 3D™ Programming Algorithm, a 3-dimensional anatomy-driven computer model that generates advanced anode/cathode configurations to target the selected central points of stimulation, allowing the physician to create a customized stimulation field.

According to Dr. North, the Precision Spectra SCS system offers an efficient approach through the ability to try numerous combinations of anodes and cathodes. “It stands to reason that the more combinations you’re able to try on a patient, the more likely you are to find good paresthesia coverage that works well to control pain,” said Dr. North. “The way that you program this device is so radically different than any other device that’s on the market; that sort of speed and efficiency I think is going to change outcomes.” The Precision Spectra SCS system uses LeadSync™ Technology to detect lead location, account for lead offset, and refocus the stimulation field to ensure precision in targeting affected areas. I have found that this system provides more flexibility and programmability than most systems around,” Dr. Barolat said. “I believe that this system has many features that allow you to be more precise in how you deliver the current, how you pinpoint the areas of the pain, and how you program the device. As a result, it is easier to use, it allows you to be more precise and effective, and it increases your success rate.”

In the Precision Retrospective Outcomes study recently presented at NANS 2013, Dr. North and his colleagues designed a multi-site assessment that looked at 213 consecutive patients at 13 sites undergoing SCS trial of the Precision Spectra SCS System. Of those 213 trials, 200 were deemed successful, meaning the physician intended to proceed with permanent implant. “That correlates into a 94%
success rate for a trial, which is a remarkable result,” Dr. North said.11

In addition to coverage and flexibility, the Precision Spectra SCS system also simplifies the patient experience using FreeLink™ Technology, which provides the patient with more control.10 “It uses a wireless remote control, so that patients who might have restricted mobility can control the SCS well rather than having to reach around in an awkward manner, making it also easy to read,” said Joshua Rosenow, MD, director of functional neurosurgery at Northwestern University Feinberg School of Medicine.

Conclusion

Chronic pain is a highly prevalent condition that can be difficult to manage. SCS can be a safe and effective treatment option for properly selected patients. Although all SCS systems have restrictions and/or strict eligibility requirements with respect to MR imaging, there are many imaging options available for SCS patients that in all but rare cases can provide the needed diagnosis. Furthermore, data indicate that physicians using the Precision Spectra SCS System are achieving high trial success and significant relief for low back pain.

References


Important Prescribing Information

The Precision Spectra™ SCS system is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain. The Precision Spectra System is contraindicated for patients who are unable to operate the Precision Spectra System, have failed trial stimulation by failing to receive effective pain relief, are poor surgical risks, or are pregnant. Refer to the Instructions for Use provided with the Precision Spectra System or ControlYourPain.com for potential adverse effects, warnings, and precautions prior to using this product. The Precision Spectra SCS System with ImageReady™ Technology is “MR Conditional” only when exposed to the MRI environment under the specific conditions defined in the ImageReady MRI Guidelines for Precision Spectra Spinal Cord Stimulation System.

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

The NANS roundtable discussion was sponsored by Boston Scientific Corporation. Faculty participated in the roundtable as paid consultants of Boston Scientific Corporation. Dr. Barolat reported that he is a consultant for Boston Scientific and a consultant and equity owner for QIG Group. Dr. Gold reported that he is a consultant for Boston Scientific, ISTO Technologies, Medical Metrics, and Samumed, Inc., and has received research support from GE Healthcare. Dr. Hayek reported that he is a consultant for and is on the medical advisory board for Boston Scientific and Flowonix. Dr. Mekhail reported that he is on the medical advisory board for Boston Scientific. Dr. North reported that he is a consultant for Boston Scientific, kaléo, Inc., and SPR Therapeutics. Dr. Rosenow reported that he is a consultant for and has received grant support from Boston Scientific.

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