SPINAL CORD STIMULATORS – The Basics And The Buzz

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Chronic pain, spinal cord stimulation, dorsal column stimulation, neuromodulation, neurostimulation, failed back syndrome,

Introduction

Chronic pain is depressing and debilitating. Spinal cord stimulators (SCS), also called dorsal column stimulators, are often considered as an alternative or adjunct treatment when conservative treatments are not an option or have been ineffective. Nurse life care planners (NLCP) should understand how SCS works, its indications and contraindications, procedures and equipment involved, and associated care.

A dorsal root ganglion (DRG) stimulator can be effective in treating pain in areas difficult to treat with traditional SCS. Traditional SCS involves stimulation of the dorsal columns resulting in broad electrical stimulation of multiple dermatomes. DRG stimulation is more precise, directly activating the cell bodies of the very neurons that innervate the painful regions. (Gupta, 2018; Mayo Clinic, 2019)

An SCS uses electrical impulses to interrupt pain sensation as it travels to the brain. The person feels paresthesia, a light tingling, or buzzing. Patients can control its intensity and turn it on and off with a wireless remote controller. The goal of treatment is to improve quality of life and physical function by reducing pain and pain medication.

Decreased medication use varies from person to person: some people can eliminate opioids. (Gupta, 2018) The advantages are obvious.

Indications, contraindications and risks

FDA-approved indications include pain from:

- failed back surgery syndrome (FBSS)
- radiculopathy
- neuropathic pain
- phantom limb pain,
- arachnoiditis,
- complex regional pain syndromes (CRPS)
- postherpetic neuralgia

There are also off-label applications undergoing investigation (Gupta, 2018). This article will focus on SCS used for neck, back and/or extremity pain, but the general principles apply to all.

Contraindications include:

- untreated infection
- implanted cardiac pacemaker or defibrillator
- anticoagulant or antiplatelet therapy
- unstable comorbidities
- psychogenic factors that suggest a somatoform pain disorder
- cognitive impairment that interferes with evaluation or operation

The safety and effectiveness has not been established for pediatric use (under the age of 18) or pregnant women. (Gupta, 2018)

As with any surgery, infection, bleeding and surgical site pain are

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1. Chronic pain (Domain 12, Comfort; Class 1, Physical Comfort);

2. Acute pain postoperatively (Domain 12, Comfort; Class 1, Physical Comfort);

3. Risk for infection at surgical sites (Domain 11, Safety/Protection; Class 1, Infection);

4. Risk for infection of implanted device (Domain 11, Safety/Protection; Class 1, Infection);

5. Impaired skin integrity (Domain 11, Safety/Protection; Class 2, Physical Injury);

6. Risk for bleeding postoperatively (Domain 11, Safety/Protection; Class 2, Physical Injury).

potential risks. As with most spinal surgical procedures, adverse events may include epidural hemorrhage, seroma, CSF leakage, or paralysis. There is also potential for lead migration, hardware malfunction, allergic response to hardware, undesirable change in stimulation and loss of pain relief. (Gupta, 2018) Hardware-related complications are more common than biological complications. "Serious adverse events such as neurological damage are uncommon." (Eldabe, et al., 2016)

Permanent restrictions

The NLCP should keep these restrictions in mind when assessing the patient's plan for future activities. Note that SCS technology changes frequently so restrictions are also subject to change.

- Do not use diathermy.
- SCS should not be on while driving or operating heavy machinery.
- The generator / battery should not be charged while sleeping.
- Avoid sources of strong electromagnetic interference (e.g., defibrillation, electrocautery, MRI, radiofrequency ablation, and therapeutic ultrasound)
  - However, most neurostimulation devices are now "MR Conditional," i.e., the person can have an MRI scan within approved parameters (refer to manufacturer for details regarding a specific model).
- Do not scuba dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmosphere absolute (ATA).
- Consult the surgeon before any chiropractic manipulation because it might cause lead migration.
- Avoid excessive twisting or stretching and other activities that may put undue stress on the implanted components. (Mehta, 2016; Orlando, T., et al., 2019; Medtronic, 2019; Boston Scientific, 2019)

Components

SCS systems are manufactured by Medtronic Inc., Abbott (FKA St. Jude Medical Inc.), Boston Scientific Corp., and Nevro Corp. A system consists of implanted components and external components.

There are two implanted components:

- Neurostimulator / Implanted Pulse Generator (IPG) - rechargeable or non-rechargeable implanted power source that generates electrical pulses according to programmable neurostimulation parameters and features
- Lead - a set of thin wires with a protective coating and electrodes near the tip (percutaneous lead) or on a paddle (surgical lead). The electrodes transmit the electrical pulses to the stimulation site. (Medtronic, 2019)

External components allow the therapy to be customized:

- Clinician Programmer - used to program the implanted neurostimulator;

Figure 1: The Intellis™ implantable neurostimulator by Medtronic (Medtronic, 2019)

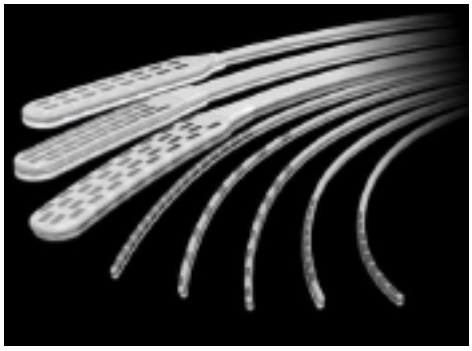

Figure 2: Boston Scientific surgical leads (paddle leads) and percutaneous leads (cylindrical leads). Paddle leads are available with 16 or 32 contacts in an array of 2 or 4 columns, respectively. Percutaneous leads are available with 8 or 16 contacts. The more contacts, the greater the area of coverage. (Boston Scientific, 2019)

- Patient Programmer - the patient can adjust the settings within preset physician parameters and turn stimulation on and off.
- Charger - for rechargeable devices; the charger also shows IPG battery level
- Wireless External Neurostimulator – used for the trial SCS; mimics the therapy delivered by the implantable neurostimulator. (Medtronic, 2019)

Figure 3: Precision Spectra remote control programmer by Boston Scientific (Boston Scientific, 2019)

Figure 4: The Boston Scientific Precision Spectra charger - lightweight, wireless, and portable. (Boston Scientific, 2019)

Procedures

Trial SCS

A trial assesses neurostimulation effectiveness before permanent SCS placement. The plan should include an office visit for evaluation by the pain management physician (anesthesiologist or physiatrist) who will perform the trial SCS procedure, if not already done. Psychological evaluation is recommended to determine the patient's suitability and evaluate the likelihood of successful outcomes: Somatization, depression, anxiety, and poor coping are important predictors of poor outcome (Blackburn, et al, 2014).

The trial is performed in an outpatient surgery setting, e.g., an ambulatory surgical center or hospital outpatient surgery department. Some physicians have the equipment and staff to perform it as an office procedure. Other than those noted above, no preoperative diagnostic tests are needed for a trial.

The physician places two leads in the spinal canal percutaneously under fluoroscopy. These attach to a wireless external stimulator, worn usually on a belt. (Gupta, 2018; Orlando, et al., 2019; Medtronic, 2019; Abbott, 2019; Boston Scientific, 2019) Dorsal root stimulator implantation is similar, but leads are threaded through the epidural space into the intervertebral foramen and directly overlie the dorsal root ganglion.

Inserting trial leads requires awake patient interaction. Local anesthesia and conscious sedation are typically administered by the same physician who performs the procedure or conscious sedation nurse with no other duties than monitoring the patient; some physicians prefer a separate physician/anesthesiologist/nurse anesthetist. A manufacturer's representative is present to help adjust settings and troubleshoot device issues that might arise. There is no additional charge for the manufacturer's representative; this service is included in the cost of the device. The trial procedure can take 30 minutes to 2 hours. (Orlando, et al., 2019; Medtronic, 2019; Boston Scientific, 2019)

After 3 to 7 days, the patient returns to the physician's office for removal of the temporary trial leads and to discuss a permanent implant. If the physician prefers percutaneous leads, the trial leads might be used and not removed (Gupta, 2018; Orlando, et al., 2019; Medtronic, 2019; Abbott, 2019; Boston Scientific, 2019). Charges for the postoperative follow up visit and possible removal of the trial leads is included in the physician's surgical fees. A manufacturer's representative may also attend these visits with no additional charge.

The trial is considered successful pain decreases by at least 50%. Results also help determine the optimal permanent lead placement, best IPG model and settings, and the most comfortable IPG placement. (Gupta, 2018; Orlando, et al., 2019; Medtronic, 2019; Abbott, 2019; Boston Scientific, 2019)

Permanent SCS Implantation

Remember that until a *successful* trial has been completed, permanent placement and replacement IPG procedures are possible, but not definite. The NLCP, therefore, should note the permanent placement and replacement IPG procedures as potential.

The primary care provider (PCP) usually opines on preoperative clearance. Preoperative diagnostic studies vary with the patient's general health status, age and medical history, commonly:

- electrocardiogram (EKG),
- hest x-ray
- complete blood count (CBC)
- comprehensive metabolic panel (CMP)
- coagulation panel: prothrombin time (PT) / partial thromboplastin time (PTT)

Wechter, 2018; Orlando, et al., 2019)

Implantation procedure

- An incision is made over thoracic spine area. A portion of the bony vertebral arch is removed (laminotomy) to allow room to place the leads.
- The leads are placed into the epidural space of the spinal cord and advanced under fluoroscopy to the level where pain relief can best be achieved.
- A second incision creates a pocket under the skin large enough to hold the IPG, the size of a stopwatch or smaller, in the lower abdomen, buttocks or upper chest, depending on where the leads are placed and the comfort of the patient.
- The leads are connected to the neurostimulator.

(Orlando, et al., 2019; Mehta, 2016)

Permanent implantation of percutaneous leads is performed in outpatient surgery by the pain management physician using local anesthesia and conscious sedation.

Permanent paddle leads have more electrodes than percutaneous leads, require a laminotomy or laminectomy, and are placed by a neurosurgeon. Lead placement via a laminotomy takes 1 to 2 hours. This procedure is considered minimally invasive and most patients are discharged home the same day or the following morning, but an inpatient stay might be needed. (Orlando, et al., 2019; Gupta, 2018; Boston Scientific, 2019) A manufacturer's representative is routinely present in the operating room to assist with the equipment, settings and any issues that might arise during surgery. There is no additional charge from the manufacturer for the representative's service.

Charges for leads, IPG, and other equipment are included in the hospital charges. Hospitals typically add a variable handling fee. The NLCP should not use the manufacturer's list price in the plan, but should confirm with the hospital that the SCS equipment is included in the charge quoted.

Follow-up

Follow-up office visits up to 90 days are generally included in surgical fees. After successful programming, follow up appointments are often every 6 to 12 months and as needed (Medtronic, 2019). A manufacturer's representative is often present at no charge at physician follow up office visits to determine the need for recalibration or reprogramming for improved pain coverage. The physician will ordinarily include SCS evaluation with overall patient status evaluation. It is uncommon for the physician to charge for more than an office visit, but this varies with the physician. Remember that the patient might need to be seen by the pain management physician more often for other reasons, e.g., medication management.

Postoperative restrictions

Patients are advised to avoid bending, twisting and reaching above the shoulders for the first six to eight weeks after surgery to prevent lead movement while the area around them heals. (Mehta, 2016; Medtronic, 2019)

IPG replacement and battery life

Neurostimulator replacement is usually short. The IPG goes in the original pocket, and the original leads are left in place and connected. Fluoroscopy is not typically necessary. (Abbott, 2019)

A rechargeable neurostimulator battery needs to be recharged regularly to stay effective. A recharge-free (non-rechargeable) neurostimulator need not be recharged, so requires less effort to maintain (Abbott, 2019). The pain management physician should discuss this with the patient and consider the patient's lifestyle when making this decision.

The NLCP should know the manufacturer and model of the SCS system because this affects the replacement frequency of the IPG / battery, thus the overall cost in the life care plan. Specific individual usage affects IPG battery life. Discuss battery life with the pain management physician, recognizing that physicians can often only estimate a range.

The literature varies, but there is general agreement that the rechargeable IPG will last longer than the non-rechargeable IPG. How long an IPG will last depends on its settings and how often it is used (Abbott, 2019). "Systems with a non-rechargeable battery need to be surgically replaced every 2 to 5 years, depending on the frequency of use. Rechargeable battery systems may last 8 to 10 years or longer (Orlando, et al., 2019)." Boston Scientific rechargeable IPGs have a five-year warranty, but may last much longer (Boston Scientific, 2019). Medtronic has rechargeable IPGs that do not need to be replaced for 9 years independent of the settings or recharge preferences (Medtronic, 2019). "The lifespan of a rechargeable IPGs can vary with manufacturers, but are usually 9 years or more. Theoretically, as the need for battery change is decreased, the number of surgical complications of these procedures should be minimized. To the best of our knowledge however there is no data and we can only speculate (Eldabe, et al., 2016)."

Size matters. Abbott has two different IPGs for the BurstDR™ system. The smaller would need replacement within 5 years; the larger could remain effective for 7 years, but might not fit in a small, thin person (Abbott representative, personal communication, 2018).

The NLCP will therefore have to use a range regarding replacement frequency. If the specific model is unknown, it would help to know if the system has a rechargeable or non-rechargeable IPG. The literature suggests that rechargeable systems are used more often. Review technological advances that could affect the frequency of replacement.

SCS Manufacturers, Models

Manufacturers of spinal cord stimulators are a good source of information. Manufacturers are continuously trying to improve their products with smaller IPGs that require shorter recharging time, have longer battery life and decreased loss of efficacy over time. Newer neurostimulators allow for upgradable technology, when available, with no surgical revision.

CASE STUDY

To protect the identity of the subject of the life care plan, the names and locations of the providers were not noted. For this case study, only the services related to the spinal cord stimulator were noted below. See the information regarding medical codes in this issue on page 36. Note that dollar amounts are for example purposes only; the NLCP should perform the usual cost research for a given case.

In this case, the initial office visit with the pain management physician had been completed. The preoperative office visit with the pain management physician can be done at one of the planned office visits in the year 2019; see below. The number of office visits was recommended by the treating pain management physician. The charges for permanent SCS implantation were for percutaneous placement, recommended by the pain management physician. Opioid use decreased; further weaning was attempted.

Item / Service & Purpose	Age / Year	Frequency of Replacement	Charge	Data Source
Pain Management Physician, Office Visit	Beginning: Age 58 Year 2018 Ending: Age 59 Year 2019	1-2x/month	Per Unit: $125 Per Year: $1,500 – $3,000	Medical Fees 2018 50th%ile

99213: $125

Item / Service & Purpose	Age / Year	Frequency of Replacement	Charge	Data Source
Trial Spinal Cord Stimulator (SCS), to assess efficacy of SCS	Beginning: Age 69 Year 2019 Ending: Age 59 Year 2019	One time	Per Unit: $20,515.56 Per Year: $20,515.56	Medical Fees 2018 50th%ile; American Hospital Directory (AHD), ahd.com

Physician: $8,546.56 (includes conscious sedation)
Facility & SCS equipment: $11,969 (2017 Dollars, latest data)

Total: $20,515.56

Item / Service & Purpose	Age / Year	Frequency of Replacement	Charge	Data Source
Pain Management Physician, office visit 99213: $125	Beginning: Age 59 Year 2019 Ending: Age 84 Year 2044	1x every 6-12 months	Per Unit: $125 Per Year: $125 - $250	Medical Fees 2018 50th%ile

Physician: $1,918.74 (includes conscious sedation)
Facility & SCS Equipment: $46,926 - $47,937 (2017 Dollars, latest data)

Total: $48,844.74 - $49,855.74 (range includes non-rechargeable & rechargeable IPG; manufacturer not specified)

Item / Service & Purpose	Age / Year	Frequency of Replacement	Charge	Data Source
Permanent Implantation of Spinal Cord Stimulator (SCS), to treat chronic pain	Beginning: Age 59 Year 2019 Ending: Age 59 Year 2019	One time	Per Unit: $76,137.58 - $99,924.58 Per Year: $76,137.58 - $99,924.58	Medical Fees 2018 50th%ile; American Hospital Directory (AHD), ahd.com

Physician: $1,918.74 (includes conscious sedation; percutaneous approach)
Facility & SCS Equipment: $46,926 - $47,937 (2017 Dollars, latest data)

Total: $48,844.74 - $49,855.74 (range includes non-rechargeable & rechargeable IPG; manufacturer was not specified)

Item / Service & Purpose	Age / Year	Frequency of Replacement	Charge	Data Source
Replacement IPG for Spinal Cord Stimulator (SCS), to replace expired SCS battery (IPG)	Beginning: Age 67 Year 2027 Ending: Age 84 (life expectancy) Year 2044	Every 7-9 years, or an average of every 8 years	Per Unit: $48,844.74 - $49,855.74 Per Year: $6,105.59 - $6,231.97	Medical Fees 2018 50th%ile; American Hospital Directory (AHD), ahd.com

Physician: $1,918.74 (includes conscious sedation)
Facility & SCS Equipment: $46,926 - $47,937 (2017 Dollars, latest data)

Total: $48,844.74 - $49,855.74 (range includes non-rechargeable & rechargeable IPG; manufacturer not specified)

The latest advances have been related to improved equipment technology, stimulation targets, and how the electrical energy is delivered to the spine and nerves. (Bendel, M., 2018) Remember, however, that they are trying to sell a product.

- Medtronic, Inc., www.medtronic.com
- Abbott (FKA St. Jude Medical, Inc.), www.sjm.com
- Boston Scientific, www.controlyourpain.com
- Nevro Corp. www.nevro.com

The following are examples manufacturers' information about their systems.

Medtronic

- Medtronic SureScanTM systems provide safe access to 1.5 Tesla MRI scans on any part of the body;
- The Medtronic Intellis™ with AdaptiveStim™ automatically adjusts with body movement. AdaptiveStim™ is powered by proprietary Overdrive™ battery technology. With Overdrive™, over 95% battery capacity is retained at 9 years, independent of therapy parameters or recharge preferences. It also recharges faster than traditional lithium ion batteries, taking about 1 hour to recharge from empty to full. Medtronic claims that Intellis, weighing one ounce and measuring 2.2"x1.9," is the "smallest fully implantable spinal cord neurostimulator (Medtronic, 2019)."

Abbott

- Abbott claims that their Prodigy MRI™ IPG with BurstDR™ stimulation has the longest projected battery life, 10 years of practical recharging.
- Several products feature settings that can be charged with Apple™ mobile digital devices and Bluetooth® wireless technology. Approved technologies are easily delivered via software updates.
- With traditional SCS neurostimulation, pain signals are replaced with what some describe as a tingling or buzzing sensation. BurstDR™ stimulation works similarly, but mimics natural patterns found in the brain; modifying pain signals and changing the way the body perceives pain. Most people feel no sensation with BurstDR stimulation. (Abbott, 2019)

Boston Scientific Corp.

- The Spectra WaveWriter SCS system combines both paresthesia and paresthesia-free therapy simultaneously in a single device. With multiple therapy options, treatment can adapt to changes in pain over time.
- Boston Scientific has an adapter that will connect compatible Abbott/St. Jude, Medtronic and Nevro leads to a Boston Scientific IPG. (Boston Scientific, 2019)

Nevro Corp.

- The Nevro Senza and Senza II have rechargeable IPGs designed to have at least a 10-year battery life. Theses IPGs use HF10 (high-frequency) that does not create a tingling sensation / paresthesia. HF10 does not have driving restrictions. It is MR conditional, approved for MRI scan of the head and extremities with 1.5 Tesla or 3.0 Tesla (Note: Tesla describes the strength of the magnet used in an MRI scanner). (Nevro Corp., 2019; Al-Kaisy,. et al., 2014)

Costs vary with the manufacturer and model. Providers, however, rarely specify such variations in their estimated charges ad are rarely aware of them.

Summary

Spinal cord stimulation may be an effective alternative or adjunct when conventional treatment provides inadequate pain relief or intolerable side effects. The goals are to improve the quality of life and increase function by reducing pain severity. A 50% decrease in pain is considered successful. The need for pain medication is often decreased. There are numerous models and ongoing technological advances. Charges vary with the manufacturer and model. Charges will also vary depending on the surgical approach, percutaneous or laminectomy. Both variables are determined by the treating physician.

The NLCP should remember that until a successful trial SCS has been completed, the need for permanent placement and replacement IPG procedures is not established, and that permanent and replacement procedures are properly projected as potential needs.

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entered the world of legal nurse consulting, nurse case management, and life care planning following a clinical nursing career in intensive care, cardiovascular intensive care, and heart transplant care. She serves on the peer review committee for JNLCP and on the board of directors of the Phoenix Chapter of AALNC. She is also a member of the International Association of Rehabilitation Professionals (IARP) and the International Academy of Life Care Planners (IALCP). She can be contacted at gerries@vocationaldiagnostics.com

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