

# The Team Approach to Spinal Cord and Dorsal Root Ganglion Stimulation: A Guide for the Advanced Practice Provider

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ecause of shortages in the US primary care workforce in the 1960s, the role of the nurse practitioner and physician assistant emerged.<sup>1</sup> The tasks of these individuals are often considered similar, and together they are known as advanced practice providers (APPs). The nurse practitioner is an advanced practice registered nurse who has completed additional training and education, earning a master's or doctoral degree. Physician assistants train for an additional 2 years beyond a Bachelor of Arts or Science degree to earn a physician assistant degree.<sup>1</sup> Many APPs have become more specialized through APP residency programs or specific on-the-job training. Most states allow all APPs to have full or partial prescribing capabilities, including controlled substances.

Given the expanding population of individuals with chronic pain, some practices have begun using APPs to properly care for increasing numbers of patients. This has allowed patients improved access to specialized evaluation and chronic pain treatment options. One such therapy that has grown tremendously during the past 2 decades is neuromodulation, specifically spinal cord stimulation (SCS) and dorsal root ganglion stimulation (DRGS). Multiple randomized controlled trials have proven SCS to produce more cost-effective and superior patient outcomes compared with repeated surgery or conventional medical management.<sup>2-5</sup> A newer technology, DRGS, was shown to be more effective than SCS for certain patients.<sup>6</sup> Together, these 2 advanced treatment modalities have helped countless patients live a better and more fulfilling life.

To date, the role of the APP in the care of the neuromodulation patient has not been defined in the literature. Throughout this paper, we

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aim to clarify the role of the APP in the care of patients with chronic pain by neuromodulatory techniques and offer a reference for these providers to safely manage neuromodulation patients.

## SELECTION OF PATIENTS

As APPs evaluate patients, they have the important role of correctly identifying appropriate neuromodulation candidates. Proper selection of patients is vital in pursuing any therapy and particularly crucial in considering neuromodulatory techniques, such as SCS and DRGS. The initial step begins with the APP's eliciting a comprehensive medical history and relevant physical examination. The Neurostimulation Appropriateness Consensus Commit-(NACC) tee recommends considering neuromodulation for patients who have failed to respond to conservative medical management or those who have experienced adverse effects from their treatment regimen. Spinal cord stimulation is indicated for failed back surgery syndrome with persistent axial low back pain or radicular pain, neuropathic pain syndromes affecting the upper or lower extremities, complex regional pain syndrome type 1 and type 2, and mixed neuropathic-vascular conditions.<sup>7</sup> Dorsal root ganglion stimulation is indicated for complex regional pain syndrome and focal pain syndromes.<sup>6</sup> However, SCS and DRGS have been proven effective for pain syndromes beyond the typical indications and should be considered for any patient who has failed to respond to conservative options and would otherwise be an appropriate stimulation candidate.8-11 Proper inspection of the surgical site to evaluate for any signs of skin infection or skin breakdown is recommended.

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As critical as identifying appropriate candidates, determining poor candidates is of utmost importance. The APP must be able to correctly identify these individuals as well. Contraindications include uncontrolled psychiatric disorders, such as severe depression and untreated anxiety; inability to adhere to therapy or poor compliance; persistent systemic or local infection; immunosuppression; and inability to obtain clearance to cease anticoagulation therapy before, during, and after the SCS trial. In addition, the APP should assess for the patient's mental and physical capacity to operate a patient programmer for an SCS device and social support systems and potential challenges.<sup>7</sup> An abnormality in any of these areas may by itself not be considered an absolute contraindication but at minimum requires additional investigation and consideration.

# THERAPY EDUCATION

Therapy education for the patient and any family members is imperative, and APPs are well prepared to deliver this information. Education should include appropriate goal setting (both pain and functional improvements); a thorough explanation of the trial procedure, including trial duration, lead removal, and postremoval process; and an explanation of the chosen device manufacturer. To be deemed a successful trial, the following outcome measures must be achieved: pain relief of at least 50% along with objective improvements, such as improved walking tolerance, sleep habits, and ability to complete activities of daily living.<sup>7</sup> In some severely disabled persons, the ability to recognize functional improvement during the brief trial period and pain relief may be the only variable that produces a meaningful measurement of success. Preoperative discussion should encourage the patient to be cognizant of procedure site pain vs the typical baseline pain.

In addition, the trial procedure must be explained. In the United States, most SCS trials last for 3 to 10 days, with many insurers requiring 72 hours of evaluation. On the last day of the trial, the leads are removed in the office, and the insertion sites are covered with a simple bandage. A final discussion of the patient's response to the therapy is sought, and a decision to progress to SCS implantation may be determined. However, if the patient desires, a follow-up phone call may be necessary. In some medical conditions, the trial may be shortened because of increased risks, such as infection or blood clotting.

Last, an in-depth discussion of the selected device manufacturer is warranted. The APPs should be trained on evolving waveforms, frequencies, feedback response, and energy delivery offerings and any potential benefits over prior technologies.<sup>12-15</sup> In doing so, APPs can properly inform patients about device nuances as each manufacturer provides slightly different experiences for the patient. This includes paresthesia production, magnetic resonance imaging (MRI) conditionality, recharge requirements, battery size, and expected battery life. Providing this education can potentially minimize the risk of an unsuccessful trial and improve long-term outcomes.

## SURGICAL PREPARATION

## Health Optimization

Obtaining a thorough past medical history is essential. Every patient should undergo optimization of his or her baseline health status before the SCS trial. Optimization includes adequate control of glucose concentration, smoking cessation, anticoagulation management, psychological screening, control of dermatologic issues, exploration of history of prior infections (if applicable), and ensuring that the patient is not immunocompromised. The patient should be deemed an appropriate candidate per psychological screening, and any emotional barriers, such as uncontrolled depression or anxiety, should be stabilized before SCS is undertaken. In addition, review of the past medical history for any conditions that require serial MRI is important because this may affect device selection. The MRI properties of available devices were recently published and should serve as a guide.<sup>16</sup> Documentation of any allergies to adhesives or cleansers is critical. Improving the health status may require a multidisciplinary approach, and APPs should work closely with the other medical teams involved to optimize each patient's health. In doing so, complications are minimized and outcomes improved.

## Imaging

Updated neuraxial imaging, such as radiography, computed tomography, or MRI, should be considered within 12 months of pursuing SCS if there has been a change in neurologic status or if there is a need to evaluate anatomic structure before the placement of a device. This will allow proper evaluation of potential pain generators and rule out any need for corrective surgical intervention but also ensure that there is adequate epidural space for the traversing SCS leads. Stenosis from large disk herniation, ligamentum flavum hypertrophy, epidural fibrosis, and adhesions from previous surgery can adversely affect the epidural space and make placement difficult or inadvisable.<sup>17</sup> This is particularly important if a paddle (surgical) lead is planned in the preoperative treatment decision-making.

## Anticoagulation Management

Guidelines recommend that the SCS implanter and his or her team should discuss anticoagulation cessation and management with the prescribing provider.<sup>18,19</sup> The NACC and the American Society of Regional Anesthesia and Pain Medicine guidelines provide recommendations on the length of cessation of each specific anticoagulant and antiplatelet medication before, during, and after each neuromodulation procedure.<sup>19,20</sup> The NACC recommends that anticoagulation and antiplatelets should be avoided during the entire length of the trial and should not be resumed until at least 12 to 24 hours after the trial period is complete.<sup>18,19</sup> The length of an SCS trial period may be lessened by a patient's inability to cease anticoagulation therapy for the recommended time frame because of potential increased risk of adverse events, and this should be adjusted to each individual patient. In addition, should the patient inadvertently use anticoagulation during the trial, appropriate care must be followed.<sup>21</sup>

## Infection Prevention

Surgical site infections (SSIs) are a significant contributor to individual morbidity and mortality as well as increased health care costs. The APPs play a vital role in assessing patients who may be at a higher risk for postoperative SSI and instituting best practice measures to mitigate SSI risk. Those characteristics that place the patient at an increased risk include advanced age, poor nutritional status, poor oral hygiene, immunocompromised state, preoperative use of steroids, preoperative use of high-dose opioids, uncontrolled diabetes, obesity, history of methicillin-resistant Staphylococcus aureus colonization, and smoking.<sup>22-25</sup> The APPs should familiarize themselves with the current best practice guidelines for infection control measures for the prevention of SSI. The NACC critically appraised the literature as well as reviewed recommendations provided by the National Institute for Health Care and Excellence, the Centers for Disease Control and Prevention, and the Surgical Care Improvement Project to produce a best practice guideline for the neuromodulation arena in an effort to reduce the risk of SSI.<sup>25</sup> Patients should be instructed to perform an antimicrobial shower 24 hours before surgery, preferably with a chlorhexidine wash, which has been shown to decrease the risk of SSI by decreasing microbial colony counts.<sup>26</sup>

Instructions should be clearly communicated to keep the SCS site clean, dry, and intact. Advise the patient that submersion and wetting of the area are not permissible during the trial period or for 2 weeks after implantation. Patients should be educated that it is not uncommon to have mild saturation on their dressings during the trial and after the implantation, and the dressings may be reinforced; however, if significant saturation or soiling should occur, the patient should return for evaluation.

#### Activity Restrictions

Patients should be instructed that while the SCS trial system is in place and for a few months after SCS implantation, it is acceptable to perform routine activities, but patients should take caution and avoid excessive bending, lifting, or twisting to mitigate potential for lead migration.<sup>18</sup> Over time, restrictions are lifted, and a full return to activities is expected after 2 to 3 months.

## POSTOPERATIVE CARE

The APPs are essential in assisting with the postoperative course, including immediate postoperative pain management, surgical site care, and signs of infection. The postoperative care is similar for the SCS trial and implantation, but nuances exist between them; APPs need to understand these differences.

### Trial

At termination of the SCS trial, the stimulator lead should be removed by use of appropriate

hand hygiene and aseptic technique after outcome measures have been obtained. If the patient is receiving anticoagulation, verify with the patient the last dose taken. If the patient has remained off anticoagulation as instructed, trial SCS leads may be removed. Provide post-trial removal instructions, which would include removal of the dressing after 24 to 48 hours, resumption of anticoagulant medications per NACC and American Society of Regional Anesthesia and Pain Medicine guidelines, resumption of showering (but full submersion of the area should be avoided until the puncture site is healed), and return to normal activity.<sup>19,20</sup> Previous failed conservative treatments along with trial outcome measures should be clearly documented in the medical record. After a successful trial, the length of time between trial system removal and permanent implant placement may be individual to each implanter, facility, and insurance carrier. Education of the patient about the authorization approval process time and preoperative screening process will aid in setting the patient's expectation while moving toward a permanent implant.

# Implantation

In the recovery area, patients should be given a short course of pain medications to help with the immediate postoperative pain. Postoperative antibiotics beyond 24 hours and routine use of topical antibiotics to the surgical incision site are not recommended.<sup>25,27</sup> Similar to the trial process, patients should be instructed on timing of resumption of any blood thinners that were halted before the procedure, and avoidance of nonsteroidal anti-inflammatory drugs is recommended in the immediate postoperative period. The surgical site should have an occlusive dressing placed, and it should remain in place up to 48 hours after SCS implantation.<sup>25</sup> After this time, showering is allowed, but submersion of the incision under water is not advisable.

Approximately 2 weeks after implantation, the patient should be seen for a follow-up visit for surgical site care. The APPs should use aseptic technique while performing this postoperative care and evaluation.<sup>25</sup> Removal of any sutures or staples would be expected if wound healing is sufficient. If the incisions are well healed, the patient can be allowed to submerge the incisions under water at this time.

# FOLLOW-UP CARE

# Complications

The APPs must be able to promptly recognize postoperative complications and to intervene. The incidence of device infection is approximately 2% to 5%, and the pulse generator is usually the most common site.<sup>28-30</sup> It may be challenging, but it is paramount that the APP be able to differentiate normal postoperative discomfort from a postoperative complication. Postoperative discomfort and mild swelling at the pulse generator site are not uncommon in the immediate postoperative period. Use of ice packs may help with swelling, and an abdominal binder may be beneficial in aiding with postoperative pain control as well as with mitigation of seroma development. When evaluating the implantable pulse generator site postoperatively, the APP should examine the area for signs of infection, which may include worsening pain and tenderness, erythema, swelling, or drainage.<sup>31</sup> If fever or chills are present, this may be indicative of a deeper or more widespread infection. When there is concern for either superficial or deep infection, the APP should obtain expert consultation from the implanting surgeon. For superficial infections, treatment with oral antibiotics should commence with close monitoring of symptoms. If signs or symptoms are worsening or there is a lack of response to the oral antibiotics, this could be indicative of a deeper infection, and admission to the hospital with a thorough work-up should ensue. If left undetected, these conditions may result in devastating consequences for the patient, such as meningitis or epidural abscess formation. In these instances, clinical symptoms may include new or worsening neurologic signs, such as limb weakness, paralysis, or loss of bowel or bladder control. Spinal epidural abscess is definitively diagnosed by obtaining advanced imaging to evaluate for abscess formation in the epidural space. The preferred imaging modality is MRI with and without contrast enhancement or computed tomography with intravenous administration of contrast material if MRI is not readily available or is contraindicated.<sup>32</sup>

Suggested laboratory studies that may be crucial to move forward with treatment include complete blood count, erythrocyte sedimentation rate, C-reactive protein level, blood cultures, and wound cultures. Consultation with an infectious disease specialist may be warranted. If work-up is positive for deep device infection, the appropriate antibiotic regimen should be initiated, and there should be a low threshold for device explantation.<sup>25</sup>

There are other complications to consider as well. Accumulation of fluid around the implantable pulse generator pocket site may indicate the presence of a seroma or local hematoma. Patients complaining of postprocedure headache must be evaluated for symptoms of post—dural puncture headache. Nerve injury is rare, but documentation of normal neurologic examination findings at follow-up is important.<sup>18</sup>

## **Therapy Maintenance**

Another key role for APP involvement is ongoing evaluation and maintenance of therapy. Tracking and monitoring of routine outcomes after SCS implantation are important. The APPs should document the patient's improvement in pain, improvement in functionality, and any reduction in dosage or frequency of use of chronic pain medication.

During these routine SCS therapy followup visits, patients may report loss of system efficacy. The APPs should have a uniform approach to addressing this concern (Table). First, APPs should assess and evaluate the pain pattern, including any changes compared with the initial description of pain and the associated aggravating factors, and the APP should also elicit any history of new incidents, such as falls or accidents. Second, the APPs should survey the patient for painful areas no longer covered by the system. They should work in collaboration with SCS therapy specialists to provide a complete system interrogation to assess for malfunction and abnormal impedances in addition to reprogramming of the stimulation settings. Obtaining this crucial information will allow the APP to quickly move the patient toward reestablishing therapy or addressing additional pain generators that may have arisen.

When SCS system impairment is suspected, the APP should evaluate both the

#### TABLE. Work-up for Continued Pain After SCS Implantation

A. Loss of coverage or ineffective pain relief

Steps:

- $\ensuremath{\mathsf{I}}$  . Schedule an office visit to interview and to examine the patient.
- 2. Perform an SCS interrogation with a device representative, including an impendence check and dermatomal coverage.
- Obtain a spine radiograph of the appropriate levels to assess for SCS lead migration.
- 4. If SCS interrogation shows device failure or spine radiograph shows migration, notify surgeon and prepare patient for revision surgery.

B. Continued pain from common parallel pain generators

- May include:
- Spondylosis
- Sacroiliac joint dysfunction
- Spinal stenosis
- Myofascial pain

#### Steps:

- I. Schedule an office visit to interview and to examine the patient (may need to turn off the device to properly assess the pain generator).
- $\ensuremath{\mathsf{2.}}$  Obtain any imaging or additional studies that may assist with proper diagnosis.
- Treat parallel pain generator, which may include a new medication or specific interventional procedure.

## C. Battery site pain reported

- Steps:
- I. Schedule an office visit to interview and to examine the patient.
- 2. Assess for signs of infection at both the lead and battery surgical sites.
- 3. Reassure patient that battery site pain will often resolve with time.
- Commence early conservative management, including local anesthetic creams and patches.
- 5. If pain continues, may need to consider prescribing a neuropathic pain medication.
- 6. If pain is intolerable and continues despite local and systemic treatments, prepare patient for SCS device explantation, if desired.

SCS, spinal cord stimulation.

generator and the leads. Obtaining spine radiographs of the known anatomic location of initial lead placement can elucidate proper lead placement vs migration. If migration is identified or system warnings reveal lead microfracture or generator failure, the APP should notify the physician and prepare the patient for SCS lead revision or replacement, depending on the extent of system malfunction.<sup>18</sup> If interrogation does not reveal any system cautions to warrant revision or replacement, the SCS system may be suspended to provide proper assessment of other potential pain generators. The APPs should consider the need for complementary

interventional treatment of these new pain generators in an effort to reestablish or to enhance the efficacy of the patient's neuromodulation therapy. If stimulation was suspended during this time, it is important to reintroduce it as the evaluation is completed.

# CONCLUSION

As the landscape of health care across all medical specialties continues to demand larger volumes of patients to be treated during shorter periods of time, the role of APPs will continue to grow. In the interventional pain space, this will result in increased involvement of the APP, particularly in the implementation and management of neuromodulation therapies. The use of and contributions from APPs could be even greater as interventional pain physicians are spending more of their valuable time dedicated to caring for patients in the operating room and procedural suite. The APPs working in interventional pain should have an understanding of where neuromodulation therapies fit in the treatment continuum and have the ability to properly identify patients who may benefit from this option. The APPs can discuss the expectations and goals of the trial and implantation, provide education on the therapy, and optimize the patient's health in preparation for surgery. Last, with proper training, they can be important for postoperative wound care and ongoing device management. The APPs equipped with these skill sets regarding neuromodulation therapies allow more patients the opportunity to be introduced to nonopioid chronic pain options and an improvement in their quality of life.

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