SPINAL CORD AND DORSAL ROOT GANGLION STIMULATION (TRIAL AND PERMANENT IMPLANTATION)

Ameet Nagpal, MD, MS, MEd, MBA; Yakov Vorobeychik, MD, PhD

These safety practices have been developed to highlight the important elements in the safe performance of interventional pain procedures. Adherence to these practices will help decrease the risk of preventable complications. For additional information about the indications and technical aspects that yield improved treatment outcomes, refer to the *IPSIS Technical Manual and Atlas of Interventional Pain and Spine Procedures*.

/// PERSONNEL

- Only physicians trained in spinal cord stimulation (SCS) and/or dorsal root ganglion stimulation (DRGS) should perform these procedures.
- Appropriately trained personnel are needed to operate the fluoroscopy unit or assist the physician.

/// CONTRAINDICATIONS

ABSOLUTE

- An active infection
- Uncooperative patient or inability to obtain informed consent
- Allergy to medication(s) that cannot safely be omitted or mitigated by pre-treatment
- Hypertensive emergency/urgency
- Pregnancy
- Coagulopathy: For SCS/DRGS lead placement and removal, coagulopathy increases the risk of epidural hematoma formation with consequent neurologic compromise.
- Central spinal canal (severe narrowing or obliteration of the posterior epidural space) or laminectomy that includes the levels from the planned epidural access to the final lead tip position
- Severe foraminal stenosis for placement of DRGS
- Anatomical derangements that compromise the safe and successful conduct of the procedure

RELATIVE

- Asymptomatic blood pressure >180/110
- Spinal surgery at the levels where stimulator lead advancement is anticipated for SCS and DRGS
- Immunosuppression
- Certain occupations and hobbies may increase the risk of lead migration or the potential for interference with or hazard associated with SCS or DRGS.
- Need for future MRI depending on SCS/DRGS technology and MRI compatibility
- SCS/DRGS may be safely performed in the presence of a pacemaker or automated implantable cardioverter defibrillator. In this scenario, collaboration with the cardiologist or electrophysiologist is advised.

/// ANTITHROMBOTICS AND BLEEDING DISORDERS

- The decision to continue or how to temporarily discontinue anticoagulation/antiplatelet (AC/AP) therapy must take into account potential complications in each scenario.
- There is a quantifiable risk of life-threatening thrombotic events associated with discontinuation of therapeutic AC/AP agents for spine interventions.
- The decision to temporarily discontinue AC/AP therapy and whether to employ a bridging strategy should include the patient and the physician prescribing the AC/AP therapy.
- Consistent with the IPSIS *Technical Manual and Atlas of Interventional Pain and Spine Procedures*, the bleeding risk is classified as intermediate-high for SCS/DRGS procedures.

/// PROCEDURAL SEDATION

- In certain cases, moderate sedation or monitored anesthesia care (MAC) may be needed during trial lead placement for SCS and DRGS. The use of sedation needs to be assessed and discussed on a case-by-case basis.
- Spinal cord injury (cord transgression) during interlaminar epidural access has been associated with deep sedation or general anesthesia, which is unnecessary for interlaminar access and should not be used. If moderate sedation is used for interlaminar access, the patient must always remain conscious and be able to communicate.
- Resuscitation drugs, appropriate monitoring equipment, and oxygen must be available if sedation is utilized.

/// ANTIBIOTIC PROPHYLAXIS

- Optimization of hyperglycemia in diabetic patients decreases the risk of infection. While no specific hemoglobin A1C and/or point-of-care blood glucose levels are known to prevent infection, some data suggest that hemoglobin A1C levels above 8.0% and FSBG levels above 200 increase the possibility of infection.
- Cessation of nicotine products for 30 days has been shown to decrease the risk of infection.
- Preoperative antibiotic administration: 1 dose within 30 to 120 minutes before incision/start of the procedure (cephalosporins such as cefazolin 1-3 g or cefuroxime 1.5 g intravenously. If allergic to beta-lactams, give clindamycin 600 mg. If the patient is colonized with MRSA, use vancomycin 1 g.)
- An additional dose is indicated if the procedure duration exceeds four hours.

SAFE, ASEPTIC PRACTICES

- Strict aseptic technique should always be applied to the facility, patient, physician, assisting personnel, injectate/syringe, and other procedural materials. Examples include, but are not limited to:
  - Patients should be advised to shower with chlorhexidine gluconate soap the night before and on the morning of the procedure.
  - Spinal cord stimulator implant procedures should be performed in operating rooms with positive pressure and/or laminar flow with HEPA filters. Limiting in-and-out traffic from the operating room also decreases the risk of infection.
  - Surgical hand scrub for physicians and scrub assistants
  - If hair removal is necessary, an electric clipper should be used immediately prior to the procedure.
  - Skin overlying the target region should be prepared for an aseptic procedure, preferably using chlorhexidine in alcohol.
  - The patient's body should be draped entirely to create a sterile field, not only for the physician's hands but also for the leads and devices that will be brought into the field.
  - Placing a sterile cover over the image collector
  - A cap and face mask must be worn by all personnel in the operating room; sterile gloves and a sterile surgical gown must also be worn by the physician during the procedure.
  - Double-gloving has been shown to reduce infection rates in the case of an inadvertent needle-stick injury. Glove changes before handling the pulse generator have been shown to reduce infection rates during procedures involving implanted pulse generators.
  - Sterile single-use syringes and needles are required, and single-dose vials should be utilized when available.
  - Acquisition, storage, and utilization of medications should adhere to relevant regulatory guidelines.
  - An adherent, iodinated dressing may be placed over the sterile field, provided the patient does not have an iodine allergy.

FLUOROSCOPIC IMAGING FOR SCS AND DRGS PLACEMENT

- MRI sagittal and axial images should be reviewed to assess the geometry and size of the posterior epidural fat at the planned level of epidural access and along the intended path of lead placement to its target position.
- Use of fluoroscopic guidance is necessary to establish segmentation and ensure appropriate lead placement.
- The fluoroscopic technique should follow the ALARA (As Low As Reasonably Achievable) principles to minimize X-ray exposure for the patient and the healthcare team.
- Obtain image(s) showing final SCS and DRGS lead placements in a lateral and AP view and, if indicated, a contralateral oblique view. Ensure appropriate landmarks are visible in the images (*e.g.*, the last rib in the image in relation to the lead position for SCS).

PROCEDURE

- For cervical SCS lead placement, the entry level into the epidural space at or below C7/T1 is strongly advised, as at more cephalad levels, the dorsal epidural space and spinal canal diameter can be diminished.
- Extensive irrigation of incisions and careful hemostasis before closure of the incisions and pockets is recommended.
- Tunneling during the SCS/DRGS implantation should be done carefully in stages to avoid deep penetration into the abdominal or pleural cavity.
- Avoid monopolar electrocautery near electrical equipment. Bipolar electrocautery or manual hemostasis should be utilized instead.

POST-PROCEDURE MONITORING/FOLLOW-UP

- Patients should be monitored for an appropriate time following the procedure, depending upon the nature of the intervention and the agents utilized.
- Provide detailed oral and written discharge instructions to patients that outline the following:
  - restrictions and recommendations for the immediate post-procedure
  - activity restrictions for six weeks following the permanent placement procedure (*e.g.*, avoid bending, twisting, and heavy lifting)
  - potential common side effects that may occur immediately post-procedure and in the days following the procedure [*e.g.*, pain at the procedure/surgical site(s)]
  - symptoms that merit immediate medical attention
  - requirement to take analgesics only for moderate or severe pain during trial
  - timing for resumption of usual medications and anticoagulants if discontinued for the procedure.
- Ensure patients have a follow-up plan.

SOURCES

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