SPINE INTERVENTION SOCIETY

SAFETY PRACTICES FOR INTERVENTIONAL PAIN PROCEDURES

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

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.

PERSONNEL

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

CONTRAINDICATIONS

ABSOLUTE

- An active systemic and non-systemic (e.g. sinus, urinary tract) infection or a localized infection within the procedural field
- Uncooperative patient
- Allergy to medication(s) that cannot safely be mitigated by pre-treatment
- Pregnancy
- Severe central canal stenosis for SCS and DRGS if the leads need to be passed cranial to or placed at the level of stenosis. While severe central stenosis is defined as less than 1/3 of the spinal canal occupied by cerebrospinal fluid in axial MRI views, central or foraminal stenosis sufficient to disallow the passage of the stimulator lead should be considered a contraindication.
- Severe foraminal stenosis for placement of DRGS

RELATIVE

- Concurrent treatment with anticoagulants is a contraindication for epidural access for SCS and DRGS. The risks and benefits of discontinuing anticoagulants (as per Neurostimulation Appropriateness Consensus Committee recommendations) and antiplatelet drugs should be discussed with the patient in consultation with the patient's prescribing physician.
- In the presence of a pacemaker and/or automated implantable cardioverter defibrillator, SCS and DRGS can be safely performed with prior approval from the cardiologist/electrophysiologist and through close collaboration with their team.
- Spinal surgery at the levels where stimulator lead should be advanced for SCS and DRGS
- Immunosuppression
- Chronic coagulopathy and chronic anticoagulation therapy are considered by many as relative contraindications to long-term SCS/DRGS therapy. In both trial and permanent placements, the patient's coagulation has to be within normal range.
- Need for repeat MRI depending on SCS/DRGS technology and MRI compatibility
- Occupational issues: if patients need to be around powerful electromagnetic fields for work (e.g. welding)

SEDATION

- In certain cases moderate sedation or monitored anesthesia care (MAC) may be needed during trial lead placement for SCS and DRGS. This needs to be assessed and discussed on a case-by-case basis.
- Depth of sedation needs to be discussed with the anesthesiologist, taking into consideration the ability to wake the patient to get reliable feedback during the procedure.
- MAC is recommended for permanent placement of SCS and DRGS, which should only be performed in the ambulatory surgery center (ASC) or hospital setting.
- Resuscitation drugs, monitoring equipment, and oxygen must be available if sedation is utilized.

ANTIBIOTIC PROPHYLAXIS

- Preoperative antibiotic administration: 1 dose within 30 to 120 minutes prior to incision/start of procedure (cephalosporin 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.)
- Second dose if the procedure goes beyond 4 hours

SAFE, ASEPTIC PRACTICES

- Strict aseptic technique should be followed at all times as they pertain to the facilities, materials, patient preparation, physician preparation, personnel, and injectate/syringe preparation. Examples include, but are not limited to:
  - Patients should be advised to shower with chlorhexidine gluconate soap the night before and morning of the procedure.
  - Surgical hand scrub for physician and scrub assistants
  - 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.
  - The fluoroscope must be draped.
  - A cap, face mask, sterile gloves, and sterile gown must be worn during the procedure. Frequent glove changes and double-gloving are advised.
  - Sterile single-use syringes and needles are required for any injections, and single-dose vials should be utilized when available. Centers for Disease Control and Prevention (CDC) guidelines for safe injection practices must be followed.
  - Acquisition, storage, and utilization of medications should be in accordance with relevant governmental guidelines such as those of the CDC in the United States.
  - Single-use or reusable probes are appropriate if proper sterilization techniques are employed between patients and procedures.
  - An adherent, iodinated dressing should be placed over the sterile field provided that the patient does not have an iodine allergy.

FLUOROSCOPIC IMAGING FOR SCS AND DRGS PLACEMENT

- Reviewing the CT/MRI before the procedure is recommended for all spinal levels at which the leads will traverse.
- Use of image guidance is necessary to establish segmentation in SCS and ensure appropriate lead placement.
- The imaging technique should follow the ALARA protocols (as low as reasonably achievable) to minimize x-ray exposure for both 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, contralateral oblique view. Ensure appropriate landmarks are visible in the images (e.g. last rib in the image in relation to lead position for SCS).

PROCEDURE

- For cervical SCS lead placement, the level of entry into the epidural space at or below C7/T1 is strongly advised, as at more cephalad levels the 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 where bipolar electrocautery can 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:
  - activity restrictions for the immediate post-procedure period (e.g. do not operate a motor vehicle or machinery for the remainder of the day),
  - activity restrictions for up to six weeks following permanent placement procedure (e.g. avoid bending, twisting, and heavy lifting),
  - potential expected side effects that may occur immediately post-procedure and in the first few days following the procedure (e.g. pain at procedure site),
  - symptoms that merit immediate medical attention,
  - requirement to take analgesics only for moderate or severe pain during trial, and
  - when to resume usual medications and anticoagulants if discontinued for the procedure.
- Ensure patients have a follow-up plan.

SOURCES

Deer TR, Narouze S, Provenzano DA, et al. The Neurostimulation Appropriateness Consensus Committee (NACC): recommendations on bleeding and coagulation management in neurostimulation devices. Neuromodulation. 2017;20:51–62.

Solomkin JS, Mazuski JE, Baron EJ, et al. Guidelines for the selection of anti-infective agents for complicated intra-abdominal infections. Clin Infect Dis 2003;37(15):997–1005.

DISCLAIMER

While these Safety Practices are intended to identify elements critical to the safe performance of interventional spine procedures, they are not intended to be inclusive of all proper methods relevant to the safe performance of spine procedures, or exclusive of other methods of care reasonably utilized to obtain the same results. Nothing contained in these documents is intended to be used as a substitute for the care and knowledge of the individual clinician. They are guidelines based on evidence-informed expert consensus. SIS makes no representation and assumes no responsibility for the accuracy of the information contained or available through this website, and such information is subject to change without notice. The clinician's independent medical judgment, given the individual patient's clinical circumstances and preferences, should always determine patient care and treatment. Practitioners are advised to consider management options in the context of their own training and background and institutional capabilities when selecting recommended treatment options. SIS is not responsible nor does it assume any legal liability or responsibility for the accuracy, completeness, clinical efficacy, or value of any such information or any apparatus, product, or process described or referenced through this website or the information contained therein.

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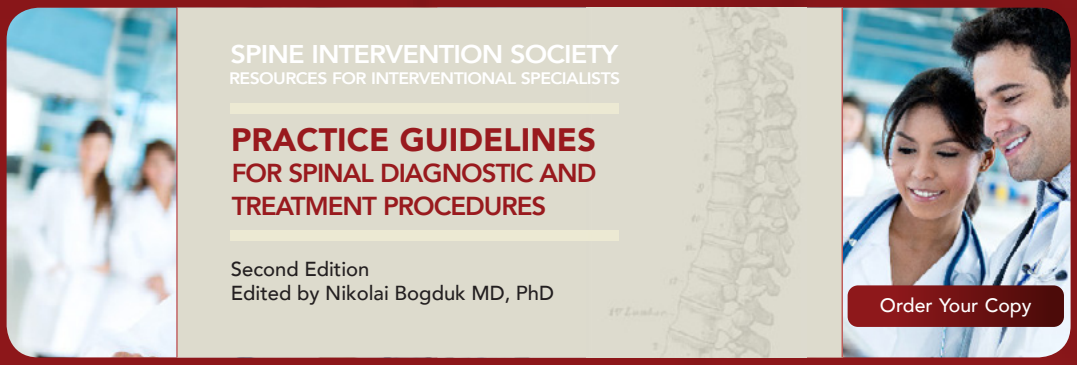
MODULE 1 EPIDURAL STEROID INJECTIONS
MODULE 2.1 FACET INTERVENTIONS: MEDIAL BRANCH BLOCKS
MODULE 2.2 FACET INTERVENTIONS: INTRA-ARTICULAR (ZYGAPOPHYSIAL) JOINT INJECTIONS
MODULE 2.3 FACET INTERVENTIONS: MEDIAL BRANCH RADIOFREQUENCY NEUROTOMY
MODULE 2.4 FACET INTERVENTIONS: LATERAL ATLANTO-AXIAL JOINT INJECTIONS
MODULE 3.1 SACROILIAC INTERVENTIONS: SACRAL LATERAL BRANCH BLOCKS
MODULE 3.2 SACROILIAC INTERVENTIONS: SACROILIAC JOINT INJECTIONS
MODULE 3.3 SACROILIAC INTERVENTIONS: SACRAL LATERAL BRANCH RADIOFREQUENCY NEUROTOMY
MODULE 4.1 NEUROSTIMULATION: SPINAL CORD AND DORSAL ROOT GANGLION STIMULATION
MODULE 4.2 NEUROSTIMULATION: PERIPHERAL NERVE STIMULATION
MODULE 5 PROVOCATION DISCOGRAPHY
MODULE 6 VERTEBRAL AUGMENTATION

THE INTERVENTIONAL SPECIALISTS' FREE RESOURCE TO HELP DECREASE THE RISK OF PREVENTABLE COMPLICATIONS

For additional information about the indications and technical aspects that yield improved treatment outcomes, refer to the *SIS Practice Guidelines for Spinal Diagnostic and Treatment Procedures*.



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