PERIPHERAL NERVE STIMULATION (TRIAL AND PERMANENT)

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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*.

/// GENERAL

- The physician must assess region-specific anatomical considerations that may influence the procedure's safety.

/// PERSONNEL

- Only physicians trained in peripheral nerve stimulation (PNS) should perform these procedures.

/// CONTRAINDICATIONS

ABSOLUTE

- Any 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
- Anatomical derangements that compromise the safe and successful conduct of the procedure

RELATIVE

- Immunosuppression
- Pregnancy - the risk of an elective procedure and the location of the stimulator hardware in relation to the fetus
- Asymptomatic blood pressure >180/110
- Uncorrected coagulopathy
- Certain occupations and hobbies may increase the potential for interference with or hazard associated with PNS.
- Severe psychiatric/psychological pathology
- Inability to communicate the sensation of paresthesias in the distribution of the targeted nerve with stimulation testing

- Need for future MRI depending on PNS technology and MRI compatibility
- PNS 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.
- 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.
- PNS has a variable bleeding risk depending on the location where the stimulator hardware is implanted.

/// PROCEDURAL SEDATION

- In certain cases, moderate sedation or monitored anesthesia care (MAC) may be needed during trial lead placement for PNS. The use of sedation needs to be assessed and discussed on a case-by-case basis.
- Depth of sedation needs to be discussed with the anesthesiologist, considering the ability to wake the patient to get reliable feedback during the procedure.
- MAC may be used for permanent PNS implantation in selected cases.
- 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.)
- Second dose if the procedure goes beyond 4 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 permanent PNS placement procedure.
  - Peripheral nerve 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.
  - A cap and face mask must be worn by all personnel in the operating room, and sterile gloves and sterile surgical gown must 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 for any injections, and single-dose vials should be utilized when available.
  - Acquisition, storage, and utilization of medications should adhere to relevant governmental guidelines.
  - An adherent, iodinated dressing may be placed over the sterile field, provided the patient does not have an iodine allergy.

PROCEDURE

- Careful hemostasis before closure of the incisions and pockets is recommended.
- 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 the following:
  - o restrictions and recommendations for the immediate post-procedure perio
    - the location of the leads should dictate the duration of time for which activity should be restricted
  - o potential common side effects that may occur immediately post-procedure and in the days following the procedure
  - o symptoms that merit immediate medical attention
  - o requirement to take analgesics only for moderate or severe pain during trial
  - o timing for resumption of usual medications and anticoagulants if discontinued for the procedure
- Ensure patients have a follow-up plan to monitor progress and for lead removal, as needed.

SOURCES

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