VERTEBRAL AUGMENTATION (KYPHOPLASTY OR VERTEBROPLASTY)

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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*.

/// PERSONNEL

- Only physicians trained in vertebral augmentation should perform this procedure.
- Appropriately trained personnel are needed to operate the fluoroscopy unit or assist the physician.

/// CONTRAINDICATIONS

ABSOLUTE

- An active systemic or localized infection within the procedural field
- Uncooperative patient or inability to obtain informed consent
- Allergy to medication(s) that cannot safely be mitigated by pre-treatment
- Uncorrectable coagulopathy
- Hypotensive emergency/urgency
- Anatomical derangements that compromise the safe and successful conduct of the procedure

RELATIVE

- Pregnancy: Vertebral augmentation (VA) is usually contraindicated. There may be exceptional situations in which benefits could prevail over risks. Radiation exposure to the fetus should be minimized.
- Coagulopathy [normalize/correct clotting function (INR <1.5)]: The risk of bleeding should be balanced against the complications associated with bed rest. Caution in patients with thrombocytopenia (platelets less than 100,000/µl).
- Asymptomatic blood pressure >180/110

- Fracture retropulsion/canal compromise: Bony retropulsion is generally not considered a contraindication unless there is a neurologic deficit. VA may worsen any neurologic compromise and should only be considered in unusual circumstances. A CT scan may determine the integrity of the posterior wall before the procedure. If the fracture is causing spinal cord compression and/or neurologic deficit, then surgical decompression and stabilization are indicated. In this scenario, VA may worsen the neurologic compromise and should only be considered in unusual circumstances.
- The presence of an unstable spinal fracture, depending on the degree of instability and fracture level: Surgical intervention is likely needed to address instability and may be performed during the same session as vertebral augmentation.
- Allergies to bone cement or other agents used in the procedure, depending on the severity of allergy: If prior reactions were not associated with anaphylaxis, the risk of an allergic reaction may be mitigated by pretreatment with antihistamines and steroids. The physician may also choose a different fill material.
- Inadequate fluoroscopic visualization of bony structures secondary to severe osteoporosis or malignant process: CT guidance may be helpful.
- Metastasis or primary tumor extending into the epidural space

/// 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.
- The bleeding risk is classified as intermediate-high for vertebral augmentation procedures.

/// PROCEDURAL SEDATION

- VA may be performed under local anesthesia alone; however, given the associated procedural pain, these cases (especially kyphoplasty) are often performed under conscious sedation or monitored anesthesia care (MAC).
- General anesthesia may also be used at the discretion of the anesthesia team and the performing physician.
- The decision to use sedation should be made on a case-by-case basis.
- If the physician performing the procedure decides that sedation is indicated, a separate healthcare provider must administer the medications and monitor the patient.
- Resuscitation drugs, appropriate monitoring equipment, and oxygen must be available if sedation is utilized.

ANTIBIOTIC PROPHYLAXIS

- Because of the nature of the fracture and the frailty of patients who typically develop fractures requiring treatment, antibiotic prophylaxis is recommended to decrease the risk of perioperative 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:
  - Skin overlying the target region should be prepared for an aseptic procedure, preferably using chlorhexidine in alcohol. The area should then be draped to create a sterile field.
  - Barriers, including sterile gloves, sterile gowns, caps, and masks, should be utilized during
  - the procedure.
  - Sterile equipment should be utilized, including a sterile C-arm cover.
  - 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.

IMAGING

- Appropriate imaging (MRI, CT, or bone scan) or recent prior study comparison is highly recommended to confirm a recent or unhealed fracture.
- Use of image guidance and live fluoroscopy is critical for appropriate needle placement and monitoring polymethylmethacrylate (PMMA) placement.
- Fluoroscopic guidance has been used in the primary literature; if alternative imaging guidance is to be used (*e.g.*, CT), it must be utilized to exclude vascular uptake or flow of PMMA into other areas outside the vertebral body.
- The fluoroscopic technique should follow the ALARA (As Low As Reasonably Achievable) protocols to minimize X-ray exposure for the patient and the healthcare team.

INJECTIONS

- The ultimate choice of approach or technique (vertebroplasty vs. kyphoplasty vs. other augmentation technique) should be made by the treating physician by balancing the potential risks and benefits of each technique for each patient.
- When a transpedicular approach is used, the needle should be advanced with AP or oblique viewing to allow visualization of the medial border of the pedicle. The needle should not violate the medial border of the pedicle. The needle should not be advanced in lateral view until it has crossed the posterior margin of the vertebral body in lateral views.
- When an extrapedicular or parapedicular approach is required, the physician should carefully review available cross-sectional imaging to ensure an extrapedicular approach will not violate venous or arterial structures which lay lateral to the pedicle.
- Most reported complications are related to PMMA leakage or placement in unintended structures. Such complications include spinal cord injuries from leakage into the spinal canal and pulmonary emboli of PMMA. Sufficient time should be allowed for the PMMA to cure and become sufficiently viscous before administration to minimize the risk of these complications. In addition:
  - If PMMA is seen filling a tubular structure, the injection should be stopped because placement is likely intravenous.
  - Injection should be stopped when PMMA is seen approaching the posterior margin of the vertebral body (within approximately 5 mm) to avoid PMMA leaking into the spinal canal.
- When treating a fracture due to malignancy, an approach minimizing needle trajectory through the tumor is preferred to reduce the risk of seeding the tumor. For example, if a tumor is present in one pedicle, a transpedicular approach on the opposite side or a parapedicular approach is preferred.

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-injection period
  - potential common side effects that may occur immediately post-injection and in the days following the procedure (*e.g.*, pain at the injection site)
  - symptoms that merit immediate medical attention
  - 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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