SPINE INTERVENTION SOCIETY
SAFETY PRACTICES FOR INTERVENTIONAL PAIN PROCEDURES

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.

PERSONNEL

- Only physicians trained in the performance of vertebral augmentation should perform this procedure.
- Appropriately trained personnel are needed for the operation of the fluoroscopy unit and to assist the physician.

CONTRAINDICATIONS

ABSOLUTE

- Uncorrectable coagulopathy
- An active systemic or localized infection within the procedural field

RELATIVE

- Pregnancy: Vertebral augmentation is usually contraindicated in pregnancy. There may be exceptional situations in which benefits could prevail over risks. Radiation exposure to fetus should be minimized.
- Coagulopathy [normalize/correct clotting function (INR <1.5)]: Risk of bleeding should be balanced against the complications associated with bed rest. Caution in patients with thrombocytopenia (platelets less than 100,000/µl).
- Bony retropulsion at the fracture to a degree that is causing spinal cord compression and/or neurologic deficit: Decompression and stabilization is the preferred treatment option; vertebral augmentation only to be considered if patient is unable to undergo surgery.
- The presence of an unstable spinal fracture, depending on the degree of instability and level of fracture: Additional intervention is likely needed to address instability and may be performed during the same session as vertebral augmentation.
- Allergies to bone cement or other agent used in procedure, depending on severity of allergy: If prior reactions were not associated with anaphylaxis, the allergy can be pre-treated with steroids and antihistamines. May also choose a different fill material.
- Fracture retropulsion/canal compromise: Generally not a contraindication in the absence of neurologic deficit. CT scan may be used to determine integrity of posterior wall prior to procedure.
- 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

SEDATION/GENERAL ANESTHESIA

- These procedures may be performed under local anesthesia alone; however, given the degree of pain associated with the procedure, these cases, especially kyphoplasty, are often performed under sedation or monitored anesthesia care (MAC).
- General anesthesia may also be used at the discretion of the anesthesia team.
- The decision to use sedation should be made on a case-by-case basis. If the physician performing the procedure decides to administer and supervise the sedation, they should be trained and qualified to do so. In these situations, a separate healthcare provider is required to assist with the administration of the medications and monitoring of the patient.
- Resuscitation drugs, 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.
  - o Cephalosporins (cefazolin or cefuroxime) are the preferred drug due to their low toxicity.
  - o Vancomycin is recommended in patients with an allergy to cephalosporins.

SAFE, ASEPTIC PRACTICES

- Strict aseptic technique should be followed at all times with respect to the facilities, materials, patient preparation, physician preparation, personnel, and injectate/syringe preparation. Examples include, but are not limited to:
  - o 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.
  - o Barriers including sterile gloves, sterile gown, cap, and masks should be utilized during the procedure.
  - o Sterile equipment should be utilized, including a sterile C-arm cover.
  - o Sterile single-use syringes and needles are required, and single-dose vials should be utilized when available. Centers for Disease Control and Prevention (CDC) guidelines for safe injection practices must be followed.
  - o Acquisition, storage, and utilization of medications should be in accordance with relevant governmental guidelines such as those of the CDC in the United States.
- Manage anticoagulation as for neuraxial procedures in consultation with the primary team/cardiologist.

IMAGING

- Appropriate imaging that confirms recent or unhealed fracture such as MRI, bone scan, or recent comparison films prior to fracture occurred are highly recommended.
- Use of image guidance and live fluoroscopy is critical to ensuring 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 so as to exclude vascular uptake or flow of PMMA into other areas outside of the vertebral body.
- 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.

INJECTIONS

- The ultimate choice of approach or technique (vertebroplasty vs kyphoplasty vs other augmentation technique) should be made by the treating physician by balancing potential risks and benefits with 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 medial border of the pedicle should not be violated by the needle. The needle should not be advanced in lateral view until it has crossed the posterior margin of the vertebral body in lateral views.
- The vast majority of 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. In order to minimize the risk of these complications, it is recommended that sufficient time be allowed for the PMMA to cure and become sufficiently viscous prior to administration. In addition:
  - o If PMMA is seen filling a tubular structure, the injection should be stopped because placement is likely intravenous.
  - o 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 tumor is preferred to reduce the risk of seeding the tumor. For example, if 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:
  - o activity restrictions for the immediate post-procedure period (e.g. not to operate a motor vehicle or machinery for the remainder of the day of the procedure),
  - o potential expected side effects that may occur immediately post-procedure and in the first few days following the procedure,
  - o symptoms that merit immediate medical attention, and
  - o when to resume usual medications and anticoagulants if discontinued for the procedure.
- Ensure patients have a follow-up plan.

SOURCES

American College of Radiology. ACR–ASNR–ASSR–SIR–SNIS Practice Parameter for the Performance of Vertebral Augmentation. Available at:
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DISCLOSURES

Kreiner, Scott:
Advisory committees or review panels: Served as a member on a Vertebral Augmentation AUC (relationship with MPW).
Any position in a healthcare, medical, or physician society/association (committee, board, workgroup/taskforce, etc.): NASS Clinical Research Development Chair (Board of Directors), NASS Coverage Committee Co-Chair, NASS Clinical Guidelines Committee Co-Chair.
Travel Expenses: Travel & hotel reimbursement for NASS Board-related travel and for Vertebral Augmentation AUC.

Gill, Jatinder:
No Financial Relationships to Disclose.

Stojanovic, Milan P.:
Any position in a healthcare, medical, or physician society/association (committee, board, workgroup/taskforce, etc.): World Institute of Pain, Education Committee.
Travel Expenses: World Institute of Pain - FIPP Exam Travel Expenses.
Other: Pain Practice Journal - Editorial Work Reimbursement.

Vorobeychik, Yakov:
No Financial Relationships to Disclose.

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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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*.

PRACTICE GUIDELINES
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