

ACR–ASNR–ASSR–SIR–SNIS PRACTICE PARAMETER FOR THE PERFORMANCE OF VERTEBRAL AUGMENTATION

Revised 2022 (Resolution 19)

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), the American Society of Spine Radiology (ASSR), the Society of Interventional Radiology (SIR), and the Society of NeuroInterventional Surgery (SNIS).

Vertebral augmentation encompasses a variety of procedures typically used for treating vertebral compression fractures or other pathologic lesions involving the spine. The more common techniques in current use are vertebroplasty, kyphoplasty (with or without a balloon), sacroplasty, mechanical implant assisted augmentation, and/or adjunctive radiofrequency ablation (RFA). Polymethylmethacrylate (PMMA) is the most commonly used injectate; however, other types of injectate are available. The available devices and techniques for vertebral augmentation continue to evolve. This document should be considered applicable to these emerging devices and techniques including more complex implants and other approaches to ablation.

II. INDICATIONS AND CONTRAINDICATIONS

The major indication for vertebral augmentation is the treatment of one or more symptomatic vertebral body insufficiency macro-or microfracture(s) due to osteoporosis or neoplasia [1-7].

A. Indications

1. Painful osteoporotic vertebral fracture(s) [8]
 - Medically refractory pain (eg, opioid intolerance)
 - Pain requiring reduction in ADLs
2. Vertebral bodies weakened by neoplasm [8]
3. Symptomatic vertebral body microfracture as documented by advanced imaging without obvious loss of vertebral body height [8]
4. Benign painful lesion of bone
5. Rapidly progressive fracture, with or without pseudoarthrosis potentially leading to kyphosis
6. Severe kyphosis resulting in decreased pulmonary function

B. Absolute Contraindications [8]

1. "Septicemia" [8]
2. "Active osteomyelitis of the target vertebra" [8]
3. Infection along the intended trajectory of access
4. "Uncorrectable coagulopathy" [8]

C. Relative Contraindications [8]

1. Radiculopathy, caused by a compressive syndrome unrelated to vertebral body fracture
2. Retropulsion of a fracture fragment with signs and/or symptoms of neurological compromise up to and including myelopathy or cauda equina syndrome [8]
3. "Epidural tumor extension with significant encroachment on the spinal canal" [8]
4. "Ongoing systemic infection" [8]
5. Patient with apparently stable fracture on imaging who is clinically improving [8]
6. Pregnancy

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Core Privileging: This procedure is considered part of or amendable to image-guided core privileging.

Initial Qualifications

In general, the requirements for physicians performing vertebral augmentation may be met by adhering to the recommendations listed below:

1. Certification in Radiology, Diagnostic Radiology, or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec, and has performed (with supervision) a sufficient number of vertebral augmentation procedures to

demonstrate competency as attested by the supervising physician(s).

or

2. Completion of an approved residency or fellowship program by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPS), the Collège des Médecins du Québec, or an American Osteopathic Association (AOA) approved residency program and has performed (with supervision) a sufficient number of vertebral augmentation procedures to demonstrate competency as attested by the supervising physician(s).
or
3. A physician who did not successfully complete an ACGME-approved radiology residency or fellowship program that included the above may still be considered qualified to perform vertebral augmentation provided the following can be demonstrated: the physician must have experience in performing percutaneous image-guided spine procedures, during which the physician was supervised by a physician with active privileges in these spine procedures. During this year, the physician must have performed vertebral augmentations as the primary operator with outcomes within the quality improvement thresholds of this practice parameter.
and
4. Physicians meeting any of the qualifications in 1, 2, or 3 above must have written substantiation that they are familiar with all of the following:
 - a. Indications and contraindications for vertebral augmentation.
 - b. Technical aspects of the procedure, including periprocedural and intraprocedural assessment, monitoring, and management of the patient and particularly the recognition and initial management of procedural complications.
 - c. Appropriate use, operation, and safety of fluoroscopic equipment and other electronic imaging systems.
 - d. Principles of radiation protection, hazards of radiation, and radiation monitoring requirements as they apply to both patients and personnel.
 - e. Anatomy, physiology, and pathophysiology of the spine, spinal cord, and nerve roots.
 - f. Pharmacology of contrast agents and implanted materials and recognition and treatment of potential adverse reactions to these substances.
 - g. The written substantiation should come from the chief of the service that provides vertebral augmentation or the chair of the department of the institution in which the physician will be providing these services^[1]. Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current chief of the service that provides vertebral augmentation or the chair of the department at the institution in which the physician provided these services.and
5. Physicians must possess certain fundamental knowledge and skills that are required for the appropriate application and safe performance of vertebral augmentation:
 - a. In addition to a basic understanding of spinal anatomy, physiology, and pathophysiology, the physician must have sufficient knowledge of the clinical and imaging evaluation of patients with spinal disorders to determine those for whom vertebral augmentation is indicated.
 - b. The physician must fully appreciate the benefits and risks of vertebral augmentation and the alternatives to the procedure.
 - c. The physician is required to be competent in the use of fluoroscopy, CT, and MRI or interpretation of images in the modalities used to evaluate potential patients and guide the vertebral augmentation procedure.
 - d. The physician should be able to recognize, interpret, and act immediately on image findings.
 - e. The physician must have the ability, skills, and knowledge to evaluate the patient's clinical status and to identify those patients who might be at increased risk, who may require additional perioperative care, or who have relative contraindications to the procedure.
 - f. The physician must be capable of providing the initial clinical management of complications of vertebral augmentation, including administration of basic life support, and recognition of spinal cord compression.
 - g. Training in radiation physics and safety is an important component of these requirements.

Such training is important to maximize both patient and physician safety. It is highly recommended that the physician has adequate training in and be familiar with the principles of radiation exposure, the hazards of radiation exposure to both patients and radiologic personnel, and the radiation monitoring requirements for the imaging methods listed above.

Some methods of vertebral augmentation may require specialized training and experience, and such needs should be assessed before a physician contemplates using any method. The vertebral augmentation procedure continues to evolve, and new techniques and equipment can be expected after a physician is in practice. Some advanced methods of vertebral augmentation may require additional specialized training and experience to be performed safely.

Maintenance of Competence

Physicians must perform a sufficient number of overall procedures applicable to the spectrum of core privileges to maintain their skills, with acceptable success and complication rates as laid out in this parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates. Consideration should be given to the physician's lifetime practice experience.

Continuing Medical Education

The physician's continuing education should be in accordance with the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [9].

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#). [9]

The appropriate subfield in medical physics for this practice parameter is Diagnostic Medical Physics (previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

C. Non-Physician Radiology Provider (NPRP)

NPRPs are all Non-Physician Providers (eg, RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term "NPRP" does not include radiology, CT, US, NM MRI technologists, or radiation therapists who have specific training for radiology related tasks (eg, acquisition of images, operation of imaging and therapeutic equipment) that are not typically performed by radiologists.

The term 'radiologist-led team' is defined as a team supervised by a radiologist (ie, diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).

NPRPs can be valuable independently functioning members of the interventional radiology team but may not function as primary procedural operator for vertebral augmentation. See the [ACR-SIR-SNIS-SPR Practice Parameter for the Clinical Practice of Interventional Radiology](#) [10].

D. Radiologic Technologist

The technologist, together with the physician and the nursing personnel, should be responsible for patient comfort. The technologist should be able to prepare and position the patient^[2] for the vertebral augmentation procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform regular quality control testing of the equipment under the supervision of the Qualified Medical Physicist.

The technologist should have appropriate training and experience in the vertebral augmentation procedure and be certified by the American Registry of Radiologic Technologists (ARRT) and/or have an unrestricted state license.

E. Nursing Services

Nursing services are an integral part of the team for perioperative patient management and education and may assist the physician in monitoring the patient during the vertebral augmentation procedure. Working with a licensed provider, nurses may provide sedation for augmentation procedures.

^[1] At institutions in which there is joint (dual) credentialing across departments doing like procedures, this substantiation of experience should be done by the chairs of both departments to ensure equity of experience among practitioners when their training backgrounds differ [43].

^[2] The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available.* There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (ACR Resolution 26, 1987 – revised in 2007, Resolution 12m)

*For the purposes of this parameter, "personally and immediately available" is defined in manner of the "personal supervision" provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001

IV. SPECIFICATIONS OF THE PROCEDURE

A. Technical Requirements

Vertebral augmentation may be performed with either fluoroscopy or CT imaging guidance. The choice is a matter of operator preference and patient characteristics. In either case, there are several technical requirements to ensure safe and successful vertebral augmentations. These include adequate institutional facilities, imaging and monitoring equipment, and support personnel. The following are minimum requirements for any institution in which vertebral augmentation is to be performed:

1. A procedural suite large enough to allow safe transfer of the patient from bed to procedural table, as well as sufficient space for appropriate positioning of patient monitoring equipment, anesthesia equipment, respirators, etc. There should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other staff within the room without contaminating the sterile conditions.
2. Most of these procedures are performed under fluoroscopic guidance. A high-resolution image intensifier or flat-panel detector and video system with adequate shielding, capable of rapid imaging in orthogonal planes, is strongly recommended. Permanently recording and archiving the images from the procedure is required. The fluoroscope should be compliant with IEC 601-2-43 [11]. Imaging findings are acquired and stored either on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the "as low as reasonably achievable" (ALARA) radiation safety guidelines.
3. Prompt access to CT and MRI is necessary to evaluate potential complications. This may be particularly important if vertebral augmentation is planned in patients with osteolytic vertebral metastasis and/or with significant pre-existing spinal canal compromise.
4. The facility must provide adequate resources for observing patients during and after vertebral

augmentation and managing periprocedural pain. Physiologic monitoring devices appropriate to the patient's needs—including blood pressure monitoring, pulse oximetry, and electrocardiography—and equipment for cardiopulmonary resuscitation must be available in the procedural suite.

B. Surgical and Emergency Support

Although serious complications of vertebral augmentation are infrequent, there should be prompt access to surgical, interventional, and medical management of complications.

C. Patient Care

1. Preprocedural care [12]

Perioperative documentation should reflect the mandates of the individual state medical board and involve an electronic medical record, but should include at minimum the below:

- a. The clinical history and findings, including the indications for the procedure, must be reviewed and recorded in the patient's medical record by the physician performing the procedure. Specific inquiry should be made with respect to relevant medications, prior allergic reactions, and bleeding/clotting status. A pain evaluation must be performed prior any interventions. The vital signs and the results of physical and neurological examinations must be obtained and recorded.
- b. The indication(s) for the procedure must be recorded.
- c. The indication(s) for treatment of the fracture should include documentation of imaging correlation and confirmation.

2. Procedural care

- a. Adherence to the Joint Commission's current Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in all treatment settings, including bedside procedures.
- b. Vital signs should be obtained at regular intervals during the course of the procedure, and a record maintained.
- c. Patients must have venous access in place for the administration of fluids and medications as needed.
- d. If the patient receives sedation or anesthesia, physiologic monitoring should be in accordance with the [ACR–SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia](#) [13] or standard institutional anesthesia protocol. A registered nurse or other appropriately trained personnel should be present and have primary responsibility for monitoring the patient. A record of medication doses and times of administration should be maintained.

3. Postprocedural care

- a. A brief operative note should be entered in the patient's medical record summarizing the procedure, any immediate complications, and the patient's status at the conclusion of the procedure. This note should allow for clear understanding of the patient's care until a formal dictation is available.
- b. All patients should be on bed rest and observed during the initial postprocedural period. The length of this period will depend on the patient's medical condition and recovery from procedural sedation and/or anesthesia.
- c. During the immediate postprocedural period, the patient's vital signs, sensorium, and motor strength should be monitored by a nurse or other appropriately trained personnel. Neurological status should be assessed at regular intervals. Initial attempts at ambulation by the patient must be carefully supervised.
- d. For patients in whom osteoporosis might be the suspected etiology, where clinically indicated and if not already performed, during follow-up bone densitometry and appropriate referrals for medical treatment are strongly recommended.
- e. Patients should be followed up per institutional protocol by the provider or their designee who performed the procedure.

V. DOCUMENTATION

Reporting should be in accordance with the [ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures](#) [14].

VI. EQUIPMENT SPECIFICATIONS

For further information, see the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment](#) [15].

RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775_web.pdf

Nationally developed guidelines, such as the [ACR's Appropriateness Criteria](#)[®], should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently[®] for children (www.imagegently.org) and Image Wisely[®] for adults (www.imagewisely.org). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on Quality Control & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

A. Informed Consent and Procedural Risk

Informed consent must be obtained from the patient or their proxy [8]. Informed consent should comply with the [ACR–SIR–SPR Practice Parameter on Informed Consent for Image-Guided Procedures](#) [16].

B. Success and Complication Rates and Thresholds [17-26]

Indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. Complications can be stratified based on outcome. Major complications can result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death [8]. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation, generally overnight [8]. For further information, see the [Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee](#) [27]. The complication rates and thresholds described herein refer to major complications, unless otherwise noted [8].

A review of all instances of death, infection, neurologic complications, or symptomatic pulmonary embolus is recommended.

Success Rates

Presently, successful vertebral augmentation, including when performed for neoplastic involvement, should be reflected by significant pain relief and/or an improvement in disability or quality of life [8]. It is important to acknowledge that with the preponderance of the data demonstrating a mortality advantage in symptomatic patients treated with augmentation rather than conservative therapy, parameters that are not routinely or easily measured (eg, preservation of vertebral body height) may be markers of procedural success that are difficult to recognize. These should be measured by validated measurement tools.

Complications

Overall, major complications from vertebral augmentation are rare, occurring in <1% and <5% of patients treated for compression from osteoporosis and neoplasm, respectively. However, these rates are variable based on patient selection and number of cases performed by the operator.

Specific Complications of Percutaneous Vertebroplasty [8,26,28-44]

Adverse Event Severity	Complication	Published Rate
Patient Death	Death	<1%
Life-Threatening or Disabling	Permanent neurologic deficit · Osteoporosis · Neoplasm	<1% 2%
Moderate or Severe	Vascular injury or significant hemorrhage	<1%
	Pneumothorax or hemothorax (symptomatic)	<1%
	Symptomatic cement pulmonary embolus	<1%
	Infection	<1%
	Additional fracture (ribs, sternum, vertebrae)	1%
	Transient neurologic deficit · Osteoporosis	1% 10%

	· Neoplasm	
	Symptomatic cement leakage*	<5%
	· Osteoporosis	<10%
	· Neoplasm	
Mild	Transient increase in pain	5%
	Asymptomatic cement leakage*	
	· Osteoporosis	15%-76%
	· Neoplasm	Up to 90%
	New vertebral compression fracture [†]	21%
	· Adjacent level	12%
	· Nonadjacent level	

*Factors that increase risk of cement leakage: severe vertebral collapse, highly vascularized lesions, cortical destruction, Kummell disease, or presence of epidural soft tissue mass.

[†]Evidence suggests that there is no significant difference in new vertebral compression fracture between patients that underwent vertebral augmentation and those who were managed without vertebral augmentation [45].

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