

## CIRSE GUIDELINES

# Quality Assurance Guidelines for Percutaneous Vertebroplasty

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Vertebral compression fracture (VCF) is an important cause of severe debilitating back pain, adversely affecting quality of life, physical function, psychosocial performance, mental health and survival [1, 2]. Its diverse etiology encompasses osteoporosis, neoplastic vertebral involvement (myeloma, metastasis, lymphoma, hemangioma), and osteonecrosis. There are more than 700,000 osteoporotic VCFs per year in the United States [3], but there are no published data available as to the incidence of VCFs in the European Union.

The lifetime risk of VCF is 16% for women and 5% for men, and the incidence of osteoporotic fractures is anticipated to increase fourfold worldwide in the next 50 years [3]. In addition, patients with VCFs have a 23% risk of mortality compared to age-matched controls without VCFs. This is primarily related to compromised pulmonary function as a result of thoracic as well as lumbar fractures [4, 5].

Irrespective of etiology, treatment has largely been conservative, with bed rest, narcotic analgesics, biphosphonates, and back bracing for several weeks. Percutaneous vertebroplasty (PVP) is a minimally invasive technique, in which a painful fractured vertebral body is internally splinted with image-guided percutaneous injection of polymethyl methacrylate (PMMA) cement.

Originally described by Deramond et al. in 1987 for the treatment of an aggressive vertebral hemangioma [6], the technique has evolved to become a standard of care for VCFs.

## Definition

Vertebral compression fracture is the reduction in individual vertebral body height by 20% or 4 mm [7]. PVP is a therapeutic, image-guided procedure that involves

injection of radio-opaque cement into a partially collapsed vertebral body, in an effort to relieve pain and provide stability.

## Indications [8–37]

- Painful osteoporotic VCF refractory to medical treatment. Failure of medical therapy is defined as minimal or no pain relief with the administration of physician-prescribed analgesics for 3 weeks or achievement of adequate pain relief with only narcotic dosages that induce excessive intolerable sedation, confusion, or constipation [24].
- Painful vertebrae due to aggressive primary bone tumors like hemangioma and giant cell tumor [25, 26]. In hemangiomas, treatment is aimed at pain relief, strengthening of bone, and devascularization. It can be used alone or in combination with sclerotherapy, especially in cases of epidural extension causing spinal cord compression [27, 28].
- Painful vertebrae with extensive osteolysis due to malignant infiltration by multiple myeloma, lymphoma, and metastasis [10, 12, 29–35]. Because PVP is only aimed at treating the pain and consolidating the weight-bearing bone, other specific tumor treatment should be given in conjunction for tumor management.
- Painful fracture associated with osteonecrosis (Kummel's disease) [36].
- Conditions in which reinforcement of the vertebral body or pedicle is desired prior to a posterior surgical stabilization procedure [37].
- Chronic traumatic fracture in normal bone with nonunion of fracture fragments or internal cystic changes.

## Contraindications

### *Absolute*

- Asymptomatic vertebral body compression fracture
- Patient improving on medical treatment

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- Osteomyelitis, discitis, or active systemic infection
- Uncorrectable coagulopathy
- Allergy to bone cement or opacification agents
- Prophylaxis in osteoporotic patients

### *Relative*

- Radicular pain
- Tumor extension into the vertebral canal or cord compression
- Fracture of the posterior column; increased risk of cement leak
- Vertebral collapse >70% of body height; needle placement might be difficult
- Spinal canal stenosis; asymptomatic retropulsion of a fracture fragment causing significant spinal canal compromise
- Patients with more than five metastases or diffuse metastases
- Lack of surgical backup and monitoring facilities [38]

## Patient Selection

A multidisciplinary team consisting of a radiologist, spine surgeon, and referring physician (rheumatologist or oncologist) must come to a consensus on which patients should undergo this procedure and to ensure appropriate adjuvant therapy and follow-up [39]. A detailed clinical history and examination, with specific emphasis on the neurological signs and symptoms, should be performed to confirm the underlying VCF as the cause of debilitating back pain and rule out other causes like degenerative spondylosis, radiculopathy and neurological compromise. This should be correlated with the imaging findings [1, 9]. In osteoporosis and metastatic disease, fractures might be present at multiple levels, not all of which require treatment with PVP. Manual examination under fluoroscopy localizes and identifies the painful vertebral body [9].

## Time of Intervention

The ideal candidate for PVP is one who presents within 4 months of a fracture and has midline nonradiating back pain that increases with weight bearing and that is exacerbated by manual palpation of the spinous process of the involved vertebra [8]. Ideally patients should have at least 3 weeks of conservative treatment, failure of which should prompt one to consider PVP. Intervention within days of a painful VCF is considered in patients at high risk for decubitus complications like thrombophlebitis, deep vein thrombosis, pneumonia, and decubitus ulcer [9, 40]. There is increasing clinical data now available on the usefulness of PVP in the treatment of chronic osteoporotic fractures more than a year old [41–43].

## Imaging

Preoperative planning requires radiographic studies to identify the fracture, estimate the duration of fracture, define fracture anatomy, assess posterior vertebral body wall deficiency [1], and exclude other causes of back pain like facet arthropathy, spinal canal stenosis, or disc herniation [2] and to determine the relevant level(s) in cases of multiple fractures.

Radiographs of the spine give an overview of multilevel involvement of the vertebral column by the disease process, help assess the extent of vertebral collapse (grading of fracture), and guide further imaging investigation.

Magnetic resonance imaging (MRI) is a must in all patients considered for PVP, as it provides both functional and anatomical information. T1, T2, and STIR sequences in axial and sagittal planes are required.

Acute, subacute, and nonhealed fractures are hypointense on T1W images and hyperintense on T2W and STIR sequences because of marrow edema [2, 40]. Further, MRI helps differentiate benign from malignant infiltration and infection [1]. Bone scans are useful in determining the age of a fracture. An increased uptake of tracer “hot scan” is highly predictive of a positive clinical response following PVP [2, 44].

If there is any doubt regarding the intactness of the posterior vertebral wall, a limited computed tomography (CT) scan through the intended level(s) should be performed [2]. It will also provide information regarding the location and extent of the lytic process, the visibility and degree of involvement of the pedicles, and the presence of epidural or foraminal stenosis caused by tumor extension or retropulsed bone fragment, which can increase the likelihood of complications.

In addition, if the MRI is suggestive of healing of a compression fracture by sclerosis, a confirmatory CT scan should be performed, as needle placement and injection of PMMA in such cases will be difficult and yields suboptimal radiological and clinical results [2].

## Preprocedure

The treating radiologist should arrange for a preprocedural consultation with the patient and family (if so desired by the patient). The procedure, intended benefits, complications, and success rates must be discussed in detail with the patient and informed consent obtained.

Anesthesia consult should be arranged prior to the procedure date. A complete blood count, coagulation screen, and inflammatory markers (C-reactive protein) should be performed.

## Technique

The procedure can be performed under local anesthesia and sedo-analgesia [24, 45–47] or general anesthesia [48, 49].

Intraoperative antibiotic cover (e.g., Cefazolin, 1 g) is mandatory in immunocompromised patients; however, at present, in other patient groups, there is no clear consensus. Pulse, oxygen saturation, and blood pressure are monitored throughout the procedure. Strict asepsis is maintained. A prone position is used for the thoracic and lumbar vertebrae and a supine position for the cervical region.

The classical transpedicular route is preferred in the thoracic and lumbar vertebrae, as it is inherently safe. This can be performed either by a unipedicular or bipedicular approach. An intercostovertebral route is useful in the thoracic spine when the pedicle is too small or destroyed. It is associated with a higher risk of pneumothorax and paraspinous hematoma. The posterolateral approach is an alternative in the lumbar vertebrae but is seldom used. In the cervical vertebrae, the anterolateral approach is used. The needle path should avoid the carotid jugular complex.

Using dual guidance or biplane fluoroscopy, the needle is tapped into position using a hammer, as it provides better control [37].

### *Biplane Fluoroscopy Guidance*

The appropriate radiographic profile for the pedicular approach is a straight anteroposterior (AP) view with 5°–10° angulation, in which the pedicle appears oval. For an optimal approach, the entry point and its distance from the midline can be measured on the axial CT or MR images. Using AP and lateral screening, the needle is advanced through the upper and lateral aspect of the pedicle because a breach in these locations is less significant than along the inferior or medial margin, where there is greater risk of injury to the spinal cord and nerve roots. The tip is positioned in the anterior part of the vertebral body using lateral fluoroscopy, with the shaft of the needle maintained parallel to the superior and inferior endplates. With this technique, the tip is positioned in the ipsilateral half of the vertebral body, resulting in a bipedicular approach for optimal filling of the vertebrae.

The use of a beveled needle allows for precise placement. After penetration of the cortex within the pedicle, the bevel of the needle is rotated toward the midline, allowing medial positioning. This allows bilateral filling of the vertebral body, obviating the need for the bipedicular approach.

### *Dual Guidance*

The combination of CT and fluoroscopy allows for precise needle placement (particularly in upper thoracic vertebrae, tumor cases, and difficult cases), reduces complications, and increases the comfort of the operator, as it allows for visualization in three dimensions with exact differentiation of anatomic structures. Fluoroscopy is provided by placing a mobile C-arm in front of the CT gantry. Use of CT allows for precise medial positioning of the needle tip in the anterior third of the vertebral body, thus allowing complete

vertebral fill and no need for a contralateral access. Once satisfactory positioning of the needle is obtained, the imaging mode is switched to fluoroscopy for real-time visualization of cement injection.

### *Value of Vertebral Venography*

Vertebral venography has been advocated for the identification of potential routes of cement extravasation. However, as the physical properties of the cement are different from those of iodinated contrast media, this objective is not always achieved. Therefore, for routine cases, it is not generally performed and is reserved for hypervascular lesions with overflow of blood [50].

### *Cement Injection*

The older-generation cements were not sufficiently radio-opaque for good visualization during PVP and, hence, barium sulfate, tungsten, or tantalum was added to increase the radio-opacity. This addition was noted to interfere with the polymerization of the cement and alter its chemical properties.

Radio-opacity is an important feature of cement because it allows for good visualization of the cement during injection and, hence, early and easy detection of leaks. The new generation of cements are intrinsically radio-opaque.

Cement is prepared once the needle is in position [50]. A closed mixing system is advocated, as it avoids cement contamination, and excludes the inclusion of air bubbles in cement, which can reduce its strength and provides homogenous mixing [47]. During the first 30–50 sec, the cement is very thin in consistency [50]. It then becomes pasty and thick. It is in this pasty polymerization phase that the cement is injected, as that reduces the risk of venous intravasation.

Injection should be performed either using a dedicated injection set (e.g., from Optimed; Allegiance; Cook; Stryker) or a 2-mL Luer lock syringe. The injection sets allow aspiration and direct injection of cement in continuous flow and with minimal effort [50]. Although the use of the injection sets increases the expense of the procedure, it is safer than free-hand injection.

Injection of cement is done under continuous lateral fluoroscopic control. The lateral projection is preferred, as it allows for early detection of epidural leak. Intermittent AP screening should be done to rule out lateral leaks. If biplane fluoroscopy is available, the injection can be monitored in AP and lateral projection simultaneously.

The risk of cement leakage is particularly high at the beginning of cement injection. The operator should be very careful during the injection of the first drops of cement. If a leak is detected, the injection is immediately stopped, and using the injection set, the pressure can be reversed. Waiting for 30–60 sec will allow the cement to harden and seal the leak. If, on further injection, the leak persists, the needle

position and/or the bevel direction should be modified. If the leak still continues, the injection is terminated and the needle removed. If incomplete fill of the vertebral body is obtained, the contralateral pedicle is accessed and completion of fill achieved.

The cement injection is stopped when the anterior two-thirds of the vertebral body is filled and the cement is homogeneously distributed on both sides and between both endplates. The mandarin of the needle is replaced under fluoroscopy control before the cement begins to set and the needle is then carefully removed [50].

The effective working time with the cement is 8–10 min after mixing (room temperature, 20°C) following which it begins to set [50]. However, some new cements have longer setting times.

In patients with osteoporosis or hemangiomas, 2.5–4 mL of cement provide optimal filling of the vertebra and achieves both consolidation and pain relief. In tumor disease, where the aim of vertebroplasty is relief of excruciating pain, smaller volumes (1.5–2.5 mL) are usually sufficient [50].

## Postprocedure Care

Before removing the patient from the table, the operator should wait for cement hardening, which is indicated by the setting of the rest of the cement in the mixing bowl.

The patient is maintained in the recumbent position for 2 h following the procedure and can then be mobilized. (Ninety percent of the cement's ultimate strength is obtained in 1 h).

Vital signs and neurological evaluations (focused on the extremities) are monitored every 15 min for the first hour, then half-hourly for the next 2 h. An immediate evaluation of the patient's condition must be undertaken if there is any increase in pain, change in vital signs, or deterioration of the neurological condition. If neurological deterioration occurs, a detailed neurological examination carried out by a specialist is followed by a thin-section CT scan of the level(s) treated to look for spinal cord or nerve root compression by extravasated cement, which might require urgent neurosurgical decompression.

Non-steroidal or steroidal anti-inflammatory drugs can be used for 2–4 days after vertebroplasty to minimize the inflammatory reaction to the heat of polymerization of acrylic bone cement.

## Complications

Complications can be grouped into minor and serious adverse reactions. Minor adverse reactions are defined as unexpected or undesirable clinical occurrences that require no immediate or delayed surgical intervention [9, 24]. Serious adverse reaction is the occurrence of an unexpected

or undesirable clinical event, which requires surgical intervention or results in death or significant disability.

Published data have placed the complication rates in osteoporotic fractures treated with PVP at <1% and in malignant fractures at <10% [36].

Centers planning to start a PVP program should aim at keeping their complication rates below the published rates. A procedure threshold for all complications for PVP performed for osteoporotic indications is 2% and for malignant indications is 10% [36].

### *Cement Leakage*

Leakage is often asymptomatic [51]. Transient neurological deficit has an incidence of 1% in osteoporotic patients and 5% in patients with malignant etiology and seldom persists beyond 30 days or require surgery.

Permanent neurological deficit is defined as symptoms lasting >30 days and requires surgery. It has not been reported in patients treated for osteoporosis, but in neoplastic etiology, it has an incidence of 2% [36].

The routes of cement leakage are as follows:

- **Epidural space and neural foramina:** It can produce radiculopathy and paraplegia as a result of nerve root and cord compression, respectively. Radiculopathy is a minor adverse reaction. It occurs as a result of cement contact with the emergent nerve root and heating of the nerve tissue during polymerization of the cement. To avoid this complication, a spinal needle should be immediately positioned in the foramina and normal saline injected slowly to cool the nerve root. This radiculopathy might require a brief course of nonsteroidal anti-inflammatory agents, oral steroids, or local steroid injection in the affected area. Cord compression is a serious complication and requires urgent neurosurgical decompression to prevent neurological sequelae.
- **Disc space and paravertebral tissue:** It is usually of no clinical significance. However, in severe osteoporosis, large disc leaks could lead to collapse of the adjacent vertebral bodies.
- **Perivertebral venous plexus:** It can result in pulmonary embolism, which is usually peripheral and asymptomatic [45] and rarely central, causing infarction [52, 53]. Paradoxical cerebral embolization has been reported.

### *Infection*

It occurs in less than 1% of cases.

### *Fracture of Ribs, Posterior Elements, or Pedicle*

Incidence is <1%. It is considered a minor complication.

### *Risk of Collapse of the Adjacent Vertebral Body*

It has a reported incidence of 12.4% [46] and an odds ratio of 2.27 [54].

**Table 1.** Criteria for measuring the success rate

Criteria	Success rate
1. Pain relief	
• Acute osteoporotic fracture (within 72 h)	90% [13, 14, 24, 55, 56]
• Chronic osteoporotic fractures (onset is delayed)	80% [42]
• Malignant fractures	60–85% [12, 14, 30, 33, 34]
• Hemangiomas	80% [14, 57]
2. Increased mobility	
• Acute osteoporotic fracture	93% [24]
• Chronic osteoporotic fracture	50% [42]
3. Reduced requirement for analgesics	91% [24]

*Note.* References given in brackets.

### Allergic Reaction

The reaction is to the cement and is characterized by hypotension and arrhythmias.

### Bleeding from the Puncture Site

This is associated with localized pain and tenderness, which resolves in 72 h. It is minimized by 5 min of compression once the needle is removed.

The complications reported have usually resulted from poor technique and patient selection, namely due to the following:

- Injection of cement in its liquid phase resulting in venous intravasation and bony extravasation
- Injection at multiple levels (It is advised not to treat more than three to four levels at one sitting [40, 45]).
- Incorrect positioning of the needle tip (e.g., in a basivertebral vein or close to the posterior wall)
- Treatment of highly vascular lesions like metastasis from thyroid and renal cancer

### Outcome Measures

The measures determine the success rate of the procedure and are based on the criteria presented in Table 1.

### Qualification and Responsibilities of Personnel

An experienced operator who has been adequately trained in the procedure should perform PVP. In addition, it is the responsibility of the operator to monitor the progress of patients, report adverse effects and conduct audit [38]. A PVP program should be set up and run in an institute that has a spine surgery unit, to deal with any procedure-related complications. A multidisciplinary team approach is the key to the success of the program, resulting in good patient selection, postprocedural care, and follow-up with fewer complications.

### Equipment Specifications

The procedure is best performed in the interventional radiology suite rather than in the operative theater, as the fixed fluoroscopic equipment is of better imaging quality than the mobile C-arm. High-quality fluoroscopy should be available for adequate visualization of the cement during injection, for early detection of leaks.

It is feasible and safe to use a single plane system as long as the operating physician recognizes the necessity of visualization in multiple planes, to ensure a safe procedure [47].

In addition, some radiological suites may have access to biplane fluoroscopy equipment, which permits rapid alternation between imaging planes without complex equipment moves and projection realignment [47].

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