

R E V I E W

When to perform vertebroplasty? A retrospective analysis from a single center and a review of the literature

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Abstract. *Background and aim:* To establish an optimal timing for vertebroplasty in order to obtain a clinically important pain reduction and improving quality of life in patients with osteoporotic or traumatic vertebral fractures. *Methods:* This study includes 22 vertebroplasty procedures performed from October 2018 to July 2020 in 21 patients with traumatic or osteoporotic vertebral fractures (19 female, two men; age between 53 and 89 years). All treatments were executed under fluoroscopic guidance using 11 or 13 G needle through transpedicular or costovertebral unilateral approach. Each patient underwent conscious sedation, continuously monitored by an anesthesiologist. Preoperative MRI images, obtained by 3T or 1.5T MRI scanner, always showed bone marrow edema. The VAS scale and Roland Morris disability questionnaire (RMdq) were administered to patients before and after the treatment to evaluate pain and life quality. *Results:* 7 patients were treated in the first month after the injury, one was treated twice; 8 patients in the second month, 6 in the third. We observed a reduction of: 5.5 points in the vas scale, 10.3 in the RMDq in the first month; 5.6 points vas, 11.6 points RMDq in the second month; 4 points vas and 9.75 points RMDq in the third month. *Conclusions:* This study demonstrated that, in our preliminary experience, vertebroplasty has the best outcome if performed at 2 months from injury.

Key words: vertebroplasty, vertebral fractures, interventional radiology

Introduction

Considering the increasing aging of the population, the incidence of pathologies such as osteoporosis has grown in recent years, with osteoporotic vertebral fractures affecting 1-4 million patients per year worldwide (1). In addition to osteoporosis, either primary in postmenopausal women or secondary to the prolonged use of steroids, traumas and cancers may represent a relatively common substrate of vertebral fractures (2-5). In traumatic vertebral fractures, the thoracolumbar junction and the lumbar vertebral bodies of L1/L2 are most frequently affected (6, 7).

Vertebral compression fractures are a common cause of severe debilitating back pain and can negatively affect quality of life, leading to limited mobility, impaired physical function, and mood disorders (8). Although the conservative approach, including bed rest, analgesic medications, braces, and physiotherapy, is often regarded as a first-line treatment, it may result in physical deconditioning, poor nutrition, deep venous thrombosis, and decubitus ulceration, thus leading to a prolonged recovery period (9-14).

Percutaneous vertebroplasty (PV) is a widely used, minimally invasive procedure introduced in 1984 in France and performed for the first time by Galibert

and Deramond to treat an aggressive vertebral heman-gioma (15). This fast-emerging technique has proved effective for managing painful vertebral compression fractures (VCF) secondary to osteoporosis or malignancies (16).

The procedure consists of injecting radio-paque bone cement, usually polymethylmethacrylate (PMMA), into the fractured vertebral body, thus enabling fracture stabilization and providing pain relief.

PV is indicated in painful osteoporotic VCF refractory to medical treatment administered for at least three weeks or when it requires a high dosage of narcotics for acceptable pain sedation. The procedure may be performed earlier in specific cases, such as cases with high risk related to prolonged immobilization. Other indications include benign and malignant bone tumors or palliative therapy in cases of extensive osteolysis, in Kummel's disease, in symptomatic vertebra plana, before posterior surgical stabilization, and in traumatic fractures classified as acute stable A1, A3 according to Magerl's classification.

PV should not be performed on asymptomatic or unstable VCF or in case of improvement after medical therapy. Similarly, given osteomyelitis or systemic infections, severe coagulopathy, or allergies, PV is contraindicated. Furthermore, radicular pain, involvement of the vertebral canal or cord compression, and fracture of the posterior column are considered relative contraindications to performing PV.

As mentioned above, current guidelines recommend performing this procedure in case of inadequate response after at least three weeks of conventional medical therapy (17); nevertheless, the optimal timing to perform the procedure is still widely debated (18).

Indications and Contraindications

PV is generally indicated in all cases of vertebral body fractures with persistent non-radicular pain and unresponsive to traditional medical therapy; this generally consists in the administration of analgesics (from NSAIDs to opiates, depending on the pain intensity) and immobilization by positioning a brace or, depending on the severity of the injury and symptoms, by bedding the patient. The use of opiates and prolonged

immobilization can cause increased risks, especially in elderly patients, including pharmacological side effects, venous thrombosis, infections, worsening of osteoporosis, and, last but not least, psychological depression. For a correct indication of the procedure, from the objective evaluation of the patient, a focal, intense pain, localized along the midline, with evidence of a fracture of the body on the radiograph of the column should emerge; acupressure on the spinous process should reproduce the patient's pain. It is important to remember that the primary purpose of PV is to reduce pain and, secondarily, to stabilize the fractured vertebra.

PV is indicated in the following clinical conditions:

- painful vertebral fracture from osteoporosis refractory to medical therapy;
- painful vertebral fracture, or osteolysis at risk of fracture, due to benign tumors or malignant (angioma, metastasis, myeloma, lymphoma);
- painful vertebral fracture with associated osteonecrosis (Kummell's disease);
- patients with multiple fractures for whom further fractures would cause respiratory compromise;
- chronic traumatic fracture in healthy bone, with non-consolidation of the fragments or cystic degeneration.

PV is not indicated for stable asymptomatic fractures, in subjects where radicular pain prevails, in those who benefit from medical therapy in less than a month, in patients with tumors that extend to the epidural and foraminal space, in case not correctable coagulopathies or allergy to the components used and as prophylaxis in osteopenic subjects without radiological signs of fracture.

Absolute contraindications are spondylitis and spondylodiscitis, as well as a septic state of the patient. Instead, the planar vertebrae (collapse > 90%) and an invasion of the vertebral canal of more than 20% are relative contraindications, where the operator's manual skills and experience in the VP procedure also count.

In selecting patients is the collegial approach in which doctors of different disciplines (orthopedists, radiologists, anesthesiologists, oncologists, etc.) must participate is fundamental. It is, in fact, necessary a correct classification of the patient with collection of anamnestic data, neurological examination, and adequate

radiological documentation. An x-ray of the spine is generally sufficient in the case of a single vertebral failure with spinal symptoms attributable with certainty to the fracture, while an MRI may be necessary in subjects with multiple collapses or with neoplastic pathology. MRI has the dual purpose of allowing a differential diagnosis for the various possible causes of back pain and identifying, in the context of multiple fractures, the soma, or somes, on which it is indicated to proceed with the VP. The “signal” provided by the examination makes it possible to distinguish chronic and stabilized failures from acute or otherwise unstabilized fractures, susceptible to treatment. It is possible to identify intrasomatic fissures with gaseous or fluid content and in particular the fat-suppressed T2W sequences show a more or less diffuse hyperintensity of intrasomatic signal in the case of recent fractures (Figure. 1, 2).

In the case of neoplastic pathology, MRI accurately identifies the vertebrae involved and, at times,



Figure 1. Pre-operative 3T MRI STIR sagittal plane image. Single vertebral fracture at L1 level. The image demonstrates bone marrow edema (arrow).

with the integration of CT, defines the presence and possible extra-vertebral extension of the neoplastic tissue, as well as the degree of impairment and lysis of the vertebral cortex. The latter data could contraindicate the VP procedure if it suggests a safe extra-vertebral extravasation of cement.

Finally, it is good clinical practice to inform the patient of the risks of the surgery and submit him to the necessary preoperative investigations. In particular, the patient's respiratory function must be carefully evaluated, considering that during the maneuver he must remain in the prone position for a long time and that its respiratory function could be aggravated by the possible toxicity of the volatile monomeric component of the cement.

Single center experience

In our experience, patients are hospitalized the day before the procedure and coagulation parameters are carefully evaluated before performing PV; in particular a platelet count of at least 50.000 per microliter and an international normalized ratio (INR) \leq



Figure 2. Pre-operative 3T MRI - T1-weighted sagittal plane image. Single vertebral fracture at lumbar level. Presence of bone marrow edema (arrow).

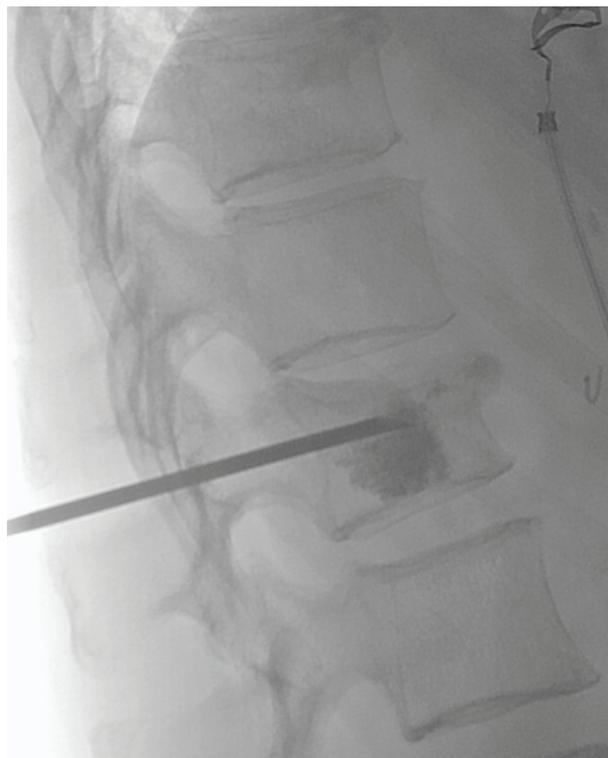


Figure 3. Intra-procedural lateral view during the injection of PMMA.

1.5 were considered as fundamental prerequisites. Antiplatelet drugs were suspended 5 days before procedure. Treatments are generally carried out under fluoroscopic and dyna-CT guidance through biplane angiographic equipment (Siemens Artis Zee; Erlangen, Germany) using an 11 or 13G bevel-shaped needle with a transpedicular or costovertebral unilateral approach (Figure 3).

All procedures are performed under anesthesiologist assistance, performing spinal or peridural anesthesia, or, when not technically feasible, through conscious sedation. The procedure lasts a maximum of two hours, with the patients being conscious and cooperative for the entire time frame. A maximum of 3 levels were treated in a single session. Patients were followed up 24 hours after the intervention performing dorsal or lumbar spine X-rays examination (Figure. 4) and discharged after 2 or 3 days, depending on their general conditions and encouraged to briefly stand up and walk a few steps during the hospital stay.



Figure 4. 24-hours AP follow-up examination.

Discussion and Conclusion

The mechanism by which the intrasomatic injection of cement can determine the analgesic effect in a vertebral fracture is not yet adequately known. The most accredited hypothesis identifies the stabilization of the fracture as an analgesic mechanism; the thermal effect with consequent necrosis of adjacent nerve fibers and the toxic effect of cement have been proposed by some authors.

The most important factor for the successful outcome of the maneuver is the correct selection of patients in which focal type pain must prevail, localized along the midline, which is accentuated on acupuncture and with evidence of vertebral body fracture on radiological examination. A collegial approach in which specialists from different disciplines must participate is therefore indispensable for the selection of patients.

Complications are a rare event, especially if the maneuver is performed in the appropriate location,

by expert hands and under combined CT and digital fluoroscopy guidance. In fact, the only guide of the fluoroscopy for the upper dorsal levels may not allow to find anatomical reference points suitable for the introduction of the needle, references with which the spiral CT is equipped, thanks to the axial vision and for the possibility to perform two-dimensional and three-dimensional reconstructions. On the other hand, fluoroscopy is essential for monitoring when the cement is injected.

At present, PV is a well-established minimally invasive procedure widely used in the treatment of acute VCF because of its favourable clinical effects, safety, and short bed rest time required after on, in patients with evidence of edema on magnetic resonance imaging.

Nowadays, increasing attention is paid to interventional radiology thanks to the most recent innovations in the field of clinical imaging and the progressive and rapid development of technology (19-32), both for diagnostic and interventional purposes (33-52).

These new therapeutical possibilities and the increase in the number of patients suffering from VCF because of the gradual ageing of population make it necessary to optimize and exploit the maximum potential of an already tried-and-tested treatment such as PV.

Our personal experience aimed to assess the suitable timing to perform PV to improve patients' quality of life affected by VCF by swiftly recovering mobility and rapidly returning to normal daily activities.

Current guidelines set by CIRSE in 2017 recommend to perform PV after at least three weeks of conventional pharmacological therapy, although a specific timing is not indicated, merely suggesting that the treatment should ideally be executed within four months from the onset of pain.

Several authors illustrated their own experience in assessing the ideal timing to perform this procedure.

In particular, a study conducted by Nieuwenhuijse et al in 2012 on 115 patients, confirmed the significant improvement in back pain obtained after performing PV, independently of the time from fracture. This evidence allowed the authors to identify an appropriate moment to perform PV between two and twelve months from the clinical onset. Indeed,

according to the authors, no worsening of the pre-operative conditions nor of the vertebral deformity, nor intravertebral cleft were associated with a delayed PV (53).

On the other hand, a multicentre, randomised, double-blind, placebo-controlled trial of 2016, known as the VAPOUR study by Clark et al., reported a superiority of PV compared to placebo for pain reduction in patients with acute VCF of less than 6-weeks in duration. Moreover, in this study, the possibility of injecting a larger amount of PMMA in VCF within 6-weeks of onset was reported (18).

Additionally, with regards to the possible complications, a study conducted by Yang et al in 2018 highlighted that PV performed within 30 days from the occurrence of CVF, is associated with a lower risk of adjacent fractures mainly thanks to a better integration of the bone-cement interface and to the chance of preventing the inactivity-related paravertebral muscle degeneration. On the opposite, according to this analysis, delayed treatment may lead to increased kyphosis, exacerbated pain and increased rate of adjacent VCFs (54, 55).

The present study shows that, in our experience, percutaneous vertebroplasty seems to ensure a better outcome if performed at two months from the injury, especially regarding the improvement in the daily activities measured by RMDq.

In particular, many patients have reported a remarkable improvement in sleep quality and a significant enhancement of daytime wellbeing. Furthermore, several people experimented heightened mood immediately after the PV thanks to restoring their independence in simple activities such as dressing autonomously.

Moreover, the promising results obtained in terms of pain relief and improvement in daily activities, observed in patients who performed the procedure within 30 days, seems to support the option to perform this treatment in an «earlier» phase in order to prevent extended bed rest with prolonged immobilization, avoid long drug therapies and increase patient independence. These findings are consistent with the results from other studies (56-58).

A more in-depth knowledge of the biomechanics of vertebral fractures and of the organic effects of

PMMA within the bone structures will allow, in the future, a better classification of the patient undergoing VP, with the possibility of more accurate assessments of the repercussions on the entire spine and development of new cements and materials that could broaden the indications and make the execution and outcome of this procedure easier, and at a lower risk.

However, our experience indicates that PV could be performed in selected cases in an earlier phase to obtain a more rapid pain relief and a faster return to normal daily activities, especially in patients with tendency to hyper coagulability and struggling with prolonged drug therapies.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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