Original Article

Percutaneous Vertebroplasty in the Management of Osteoporotic Vertebral Compression Fractures: Initial Experience

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Abstract

***Introduction**: Vertebral compression fractures related to osteoporosis may cause persistent pain which impairs mobility and reduces the quality of life. Percutaneous vertebroplasty is a therapeutic interventional radiology procedure which is used in the management of pain relief in such fractures. It involves the injection of bone cement [polymethylmethacrylate (PMMA)] into the collapsed vertebrae under radiological guidance. This provides pain relief as well as increases the strength and stability of the vertebra. **Materials and Methods**: A total of 16 patients with 17 osteoporotic compression fractures which were treated with percutaneous vertebroplasty over an 18-month period were studied. There were all women with the exception of 1 male patient. Their ages ranged from 61 to 87 years. The fracture sites were at the thoracolumbar junction from T12 to L3 levels. The majority of cases only required a unipedicular injection, with bipedicular injections in 3 cases. All cases were performed in the angiographic suite in the radiology departments, with biplanar fluoroscopy in one hospital. PMMA was injected in a semi-solid state under radiological guidance and screening into the collapsed vertebrae. **Results**: All cases showed good technical success with no mortality or major complications. Only 2 cases had minor complications of cement leakage into the soft tissues of the back and adjacent disc space, respectively. There was sufficient pain relief in all patients and they were well enough to be discharged within 1 to 5 days after the procedure. Patients were followed up to evaluate the degree of long-term pain relief as well as analgesic usage. **Conclusion**: Percutaneous vertebroplasty is a new and minimally-invasive modality of treating pain in patients with osteoporotic compression fractures who are refractory to medical therapy. Under adequate imaging guidance, the risks of complications are minimal while the potential benefit to patients and their care-givers are significant.*

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Introduction

With the general increase in life expectancy in the local population, the incidence of osteoporosis is anticipated to rise as well. Even with screening modalities such as bone mineral densitometry and preventive treatment such as hormone replacement therapy, many patients are asymptomatic and are diagnosed with osteoporosis only after they suffer their first osteoporotic fracture. This leads to osteoporosis being known as the "silent disease".

Common sites of fracture include the vertebral column, proximal femur, distal radius, and other sites in the extremities. However, the fractures in the limb bones are amenable to a surgical approach, with either open reduction and internal fixation, or hemiarthroplasty in the case of a proximal femoral fracture. The management of vertebral fractures has been predominantly conservative, with bed rest, analgesia and physiotherapy being the three main modalities. However, in many patients, the pain is persistent despite adequate therapy and is significant enough to limit mobility and activities of daily living. With the development of percutaneous vertebroplasty in many centres in both Europe and North America, it has become an accepted method of treatment for painful osteoporotic compression fractures.

Materials and Methods

This is a prospective study involving 17 cases of percutaneous vertebroplasty done for osteoporotic

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compression fractures in 16 patients. All cases were performed in the angiographic/interventional suite in the radiology department of the three hospitals. The cases were done over an 18-month period beginning from February 2000. Patients with either a known history of malignancy or who were positive for malignancy on biopsy were excluded. All patients included in our study were post-menopausal women, with the exception of 1 male patient. Their ages ranged from 61 to 86 years. The vertebral levels treated were all at the thoracolumbar junction from T11 to L3 (Table I). The degree of anterior wedging ranged from approximately 30% to 80% in comparison to the posterior cortical height. The majority only had a unipedicular injection, with 5 cases necessitating a bipedicular approach.

TABLE I: NUMBER OF OSTEOPOROTIC COMPRESSION FRACTURES AT VARIOUS LEVELS

Level of vertebra	T11	T12	L1	L2	L3
No. of fractures	1	7	6	0	3

Pre-procedure Evaluation

All cases were evaluated by the attending radiologist after initial discussion with the referring physician. Factors assessed included onset and duration of back pain, relation to any fall or minor trauma, current analgesic requirements, and progression of pain despite rest and rehabilitation. A clinical examination focussed on the back was done to identify exact sites and levels of pain, and to evaluate for any neurologic changes in the lower limbs. The patients were also assessed on their ability to lie prone for some period of time.

Recent (within 6 months) radiographs of the level of interest were reviewed (Figs. 1 and 2) and the site of vertebral collapse was correlated with the site of the patient's pain. Osteoporotic compression fractures typically show varying degrees of anterior wedging, with preservation of the posterior height and height of the adjacent disc spaces. Any break in or retropulsion of the posterior vertebral cortex was also noted, as were any definite break in the vertebral end-plates. Magnetic resonance imaging (MRI) of the spine (Fig. 3) was used to identify any other possible cause for back pain, such as degenerative disc disease or nerve root compression, for which vertebroplasty was not indicated. The presence of bone marrow oedema on T2-weighted fat-saturated or STIR (short tau inversion recovery) scans would also indicate that the fracture is of recent onset. Computed tomographic (CT) scan of the fracture site is not routinely indicated, unless delineation of the pedicular anatomy is required due to previous surgery or congenital malformations. Any fracture cleft or pseudoarthrosis was also noted.

Informed consent was obtained for all cases. Blood testing for full blood count, urea/electrolytes and PT/APTT were performed for all cases. Group and cross-matching of blood for stand-by was also done. Easy access to CT imaging and surgical/orthopaedic assessment must be available if complications arise.

Contraindications

Patient selection is crucial as the degree of pain relief is closely related to accurate identification of vertebral collapse as the predominant reason for the back pain, as well as to identify a particular vertebra when there are multiple levels of compression fractures. Absolute contraindications include evidence of active infection and coagulopathy. Posterior retropulsion or fracture of the posterior cortex are relative contraindications, as is if the patient is unable to lie prone for the duration of the procedure.

Technique

The patient is placed in a prone position and the blood pressure, heart rate and oxygen saturation are monitored throughout the procedure. 50 to 100 μg of intravenous fentanyl is usually given for sedation if there are no contraindications. Strict aseptic conditions are observed, and the site of injection is cleaned and draped. Localisation is initially done with a 22G spinal needle through which 1% lignocaine is given as local anaesthetic to the skin and subcutaneous tissues down to the periosteum. The position and direction of injection is checked with biplanar fluoroscopic screening.

An 11G or 13G bone biopsy needle (Cook, Bloomington, IN, USA, or Stryker-Howmedica-Osteonics, Rutherford, NJ, USA) is advanced following the same path, and passed through the pedicle with the aid of a small sterile bone mallet. Extreme care is taken not to penetrate the medial cortex of the pedicle which would encroach into the spinal canal. Once the needle tip is within the body of the vertebra as shown on lateral fluoroscopy, the needle is deviated medially, coming to rest in the midline in the anterior third of the vertebral body (Fig. 4). If there is a question of possible malignancy present, a biopsy is taken at this point in the procedure. All male patients are also biopsied, as the incidence of osteoporosis in males is much lower than in females.

The next step involves mixing of the liquid monomer and polymethylmethacrylate (PMMA) powder to form bone cement (Surgical Simplex P, Stryker-Howmedica-Osteonics, Rutherford, NJ, USA, or Osteobond, Zimmer, Warsaw, IN, USA). Although both have 10% w/v of barium sulphate within, the radio-opacity is inadequate to allow accurate visualisation of cement during administration. We add a sterile inert opacifying agent, either 3 g

Fig. 1. Lateral view showing T12 compression fracture.

Fig. 2. Anteroposterior view showing T12 compression fracture.

Fig. 3. T1-weighted MRI scan showing a low signal intensity area in the T12 vertebral body due to compression fracture.

Fig. 4. Lateral view showing needle in place within the anterior third of the vertebral body.

tantalum or 8 g barium sulphate. The combination is then mixed in a sterile open mixing bowl, or in a vacuum mixer. We prefer the use of a vacuum mixer, as the removal of entrapped air and other gases can improve the strength of the hardened cement. This also helps to reduce the incidence of air-lock in the injection syringe. The cement is mixed until a semi-solid state is achieved, with approximately the consistency of melted ice-cream. This is liquid enough to allow injection through the needle but viscous enough to prevent rapid intravasation into the vertebral venous plexus. The working time before cement hardening is between 6 to 8 minutes.

High-resolution magnified fluoroscopic screening in the lateral position is employed during the critical stage of injection of cement into the vertebral body. This is to ensure that the cement remains contained within the vertebral body, with no extravasation into the spinal canal, disc spaces and para-spinal soft tissues. Also, if there is rapid disappearance of the cement from the injection site, it may indicate that there is vascular embolisation taking place. Continuous fluoroscopic screening is therefore to look for not only the extravasation but also for venous intravasation.

The vertebral body will usually accommodate between 3 to 8 mL of cement, depending on the degree of collapse. When there is adequate and symmetrical filling of the vertebral body, the needle is rotated to prevent fixation within the vertebral body and then removed. The final position of the cement should be in contact with both the superior and inferior end-plates to provide adequate support for weight-bearing (Figs. 5 and 6). The distribution of the cement is checked in both the anteroposterior and lateral planes, and if the contralateral side is deemed to be suboptimally filled, the other pedicle is punctured and the procedure repeated (Figs. 7, 8 and 9). The patient remains in the prone position for another 15 to 20 minutes to allow for complete hardening of the cement.

Post-procedure Care

The patient is nursed in a supine position for the next few hours and gradually allowed to sit up in bed or move out of bed and stand as the degree of pain allows. All mobilisation

Fig. 5. Post-procedure lateral view showing cement conforming to the shape of the fractured vertebral body which is in good contact with both the superior and inferior end-plates.

Fig. 6. Post-procedure anteroposterior view showing good distribution of cement in the midline of the vertebral body.

Fig. 7. Lateral view showing bipedicular needle insertion into a severely collapsed vertebra.

Fig. 8. Anteroposterior view showing bipedicular needle insertion into a severely collapsed vertebra.

Fig. 9. Anteroposterior view showing post-procedure cement distribution after bipedicular injection.

Fig. 10. Lateral view showing extravasation of cement through a fractured inferior end-plate into the adjacent disc space.

should be under direct care and guidance of trained medical personnel. Local pain and soreness at the puncture site is to be expected; this may be treated with either non-steroidal anti-inflammatory drugs (NSAIDs) or narcotic analgesics. Physiotherapy is a vital component of the post-procedure care, especially in patients who have been bed-bound for some time. Simple back care movements, such as rolling over and pushing up with the hands to get up from a supine position, should be taught to both the patient and the care-givers. The patient may be discharged after 1 to 3 days, depending on the rate of recovery and pain relief. In many centres, the procedure is done as a day-surgery case, with the patient going home in the evening of the same day.

Results

The procedure was a technical success in all cases, with deposition of between 2 to 9 mL of cement within each vertebral body. Only 2 minor complications were encountered, with extravasation of a minimal amount of cement through the broken end-plate into the adjacent disc space (Fig. 10). No posterior extravasation into the spinal canal or intervertebral exit foramina was demonstrated. There was also no evidence of vascular embolisation which could result in pulmonary embolism and if in large amounts, subsequent mortality. Up till the time of discharge, all patients showed some degree of improved mobility and were able to at least sit up in bed or move out of bed.

The patients and their care-givers were subsequently contacted by telephone and the degree of pain relief and analgesic requirements were evaluated. The duration of time since the procedure ranged from 1 to 12 months. Eleven patients or their care-givers were reviewed, with 5 being uncontactable either due to change of telephone number or invalid number. With the pre-procedure degree of pain being graded as 10 points, a large majority (9 patients) had relief of more than 50% of their pain, with only 1 patient having slight worsening of pain (Table II). Six patients did not require any analgesia for relief of back pain, while 4 still required occasional doses during episodes of exacerbation. The patient who had increased pain was still on daily analgesia at the time of study.

Discussion

Osteoporosis is one of the critical diseases which confronts an ageing population; the main issue is the increased fracture risk with its potential to alter lifestyle for the worse. This is due to the reduction in the ability of the bone to withstand the loads and stresses of daily living. Osteoporotic fractures are typically associated with minor trauma such as falls to the floor, lifting of heavy objects or during strenuous activities. The common sites of fracture, other than the vertebral column, include the proximal femur, distal radius and, occasionally, in the proximal humerus and the bony pelvis.

Involutional bone loss contributes significantly to the susceptibility of bones to fracture in the elderly person.[1,2] Although osteoporosis is largely attributed to age-related bone loss, particularly in elderly females, other causes can be identified in about 20% of women and 40% of men presenting with osteoporotic fractures.[1] These factors include long-term steroid usage, early oophorectomy or hypogonadism, and premature menopause. Other factors with less well-established associations are smoking, chronic obstructive lung disease, anticonvulsant usage and excessive alcohol intake.

Vertebral compression fractures are the most common osteoporotic fractures[3] and there is an increase in incidence with age, from shortly after menopause to the age of 90 years.[4] However, the exact incidence is often difficult to quantify, due to the gradual and occasionally painless onset of many vertebral fractures. It has been reported that only about one-third of vertebral fractures become clinically apparent.[5] Also, it is estimated that one-quarter of women aged 50 years and above in the general population in the USA have one or more vertebral fractures.[6] Although no comparable figures for our local population are available, a Japanese study showed a similar high prevalence of vertebral fractures among Asians.[7] An analysis of bone mineral density (BMD) readings revealed that Singaporean Chinese females had a 5% lower BMD compared to American white female control subjects.[8]

The site of osteoporotic vertebral compression fractures is typically at the thoracolumbar region, which was evident in our cohort. This is postulated to be due to the loss of the stabilising effect of the thoracic ribs and musculature, as well as to the change in orientation of the facet joints between the thoracic and lumbar spine.[9] Multiple compression fractures of various ages are also a common finding; as after a first collapse, the risk of another fracture is increased by two- to four-fold.[10]

Our results are comparable to previous studies reported in both North America and Europe. These studies report success rates of between 73% and 97%, where patients have complete or significant pain relief. The pain relief was apparent within 24 to 48 hours after the injection, and the pain did not recur for at least several months up to several years.[11-14] Between 50% and 83% of patients were able to reduce the analgesic dose or convert to another class of

TABLE II: POST-PROCEDURE PAIN SCORE BASED ON PRE-PROCEDURE PAIN OF 10 POINTS

Pain score at follow-up	0-1	2-3	4-5	6-7	8-9	10 or more
No. of patients	4	2	3	0	1	1

drugs (e.g. opiates to NSAIDs).[11,15] The exact mechanism of pain relief in patients who have undergone vertebroplasty is not certain, but is probably mainly due to the fracture fusion and mechanical support provided by the bone cement. Other hypothesis also include neurolysis due to extreme heat produced by polymerisation as the cement hardens, which can reach temperatures of up to 60^oC to 70^oC, and also due to toxicity from the liquid monomer.

The variable amount of cement introduced in our patients is probably a reflection of the degree of vertebral collapse, the consistency of the cement-barium or cement-tantalum mixture, and experience with the introduction of the cement. In patients with severe (70% or more) loss of vertebral body height, it is expected that the volume of cement inserted will be less before extravasation begins to occur. However, it has been shown that the degree of pain relief is not related to the amount of cement introduced, neither is it proportional to the percentage of filling of the vertebra.[12,16]

Our 2 cases with extravasation of a small amount of cement into the superior disc space in 1 patient and the inferior disc space in the other remained completely asymptomatic, with no neurological complications. In both cases, cortical disruption of the end-plates was the reason. This gave us a minor complication rate of 12.5%, which again is comparable to other larger studies.[11,12,15]

However, what is more important is that we did not meet with any major or symptomatic complication, such as leakage of cement into the epidural space with cord or thecal sac compression, leakage of cement into the intervertebral exit foramina with nerve root compression and radiculopathy. Perhaps the most feared complication is that of vascular embolisation of cement into the paravertebral venous plexus, which can result in pulmonary embolism. One such case of cement embolisation to the lungs has been reported,[17] and it was attributed to the fact that perivertebral venous migration was not recognised during vertebroplasty. The undetected embolisation of cement into the pulmonary vessels can result in significant morbidity.

In patients with either suspected tumour in the collapsed vertebra, or a known malignancy elsewhere in the body, biopsy for histology can be done from the vertebral body, through the needle before insertion of cement. Painful vertebral body collapse from malignant disease is also amenable to vertebroplasty.

Conclusion

Percutaneous vertebroplasty is a new interventional radiology procedure which is rapidly becoming established in the management of painful osteoporotic compression fractures. It is a safe procedure, and the risks and complications are minimised by adequate visualisation of cement during administration. As far as we know, this is the first report from within the Asian and Oceanic region on this procedure, and our results and complication rates are comparable to the European and American studies.

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