Original Study

Clinical outcomes of percutaneous vertebroplasty for selective single segment dorsolumbar vertebral compression fractures

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ABSTRACT

Overview of literature: Elderly patients sustaining a trivial fall may develop vertebral compression fractures if they are predisposed to any factor that leads to decreased bone mineral density. Such patients suffer with severe pain and disability during the early healing stages. Percutaneous Vertebroplasty is mainly done to provide immediate pain relief and also believed to offer stability to the compressed vertebra by preventing further collapse.

Methods: Selected patients [$n=20$; Age = 57.9 ± 7.9 years] with osteoporotic vertebral compression fracture of a single dorsolumbar vertebra were treated with percutaneous vertebroplasty after 2–3 weeks of conservative trail. Their Pain score was noted using numeric rating scale (NRS) before and after the procedure. Functional outcomes were analysed using Roland Morris Disability Questionnaire (RMDQ) score.

Results: NRS pain score before procedure was 8.3 ± 0.6 . RMDQ score before procedure was 21.6 ± 0.5 . Third post procedural day NRS pain score was 4.7 ± 1.2 ($p < 0.0001$), denoting significant decrease in pain. Functional outcome analysis using RMDQ score showed an average of 87 ± 6.1 percent improvement ($p < 0.0001$), by 6 weeks following procedure. Considering pre-injury status all patients were in their best possible functional state by 6 weeks.

Conclusions: Percutaneous Vertebroplasty serves its purpose adequately and economically. Under controlled circumstances, it offers immediate pain relief and stability, leading to early recovery in selective patients. Yet, underlying poor bone mineral density status needs to be treated.

Study design: Observational Case Series (Level 4).

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1. Introduction

Axial loading due to a fall from height, particularly in a patient with poor bone mineral density, has high potential to produce vertebral compression fractures, even if the impact was trivial.¹ These fractures can cause severe pain, especially on loading, and does not allow patients to carry on with daily activities. This leads to decreased mobility and restricted activity resulting in more bone density loss predisposing to further kyphosis.^{1,2} Percutaneous vertebroplasty involves injecting radiopaque bone cement into the fractured vertebra by inserting a needle from the posterior

aspect that passes through the pedicle into the vertebral body.² The thermal reaction produced by the cement on setting, blocks the nerve endings that supply the fractured vertebra and thus provides immediate pain relief.³ The cement by itself offers stability by preventing further compression of the fractured vertebra on loading. We intend to analyse the clinical outcomes following percutaneous vertebroplasty for selective single segment dorsolumbar vertebral compression fractures in old age.

2. Patients and methods

Forty-two elderly patients (35 females and 7 males), having sustained an axial loading trivial fall, who presented with severe pain in the back leading to restricted activity were shortlisted over a period of time. Standard anteroposterior and lateral view radiographs that were initially taken showed one or more dorsolumbar vertebral compression fracture. Those patients with multiple level compression fractures, burst fractures with

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displaced bone fragments, fractures with involvement of posterior elements and those with neurologic complications were excluded. Only 26 patients with single level dorsolumbar vertebral compression fracture showing wedge or biconcave deformity with intense pain adjacent to the fracture level were selected for a trial of conservative management. All patients had less than 50% decrease in anterior vertebral height and less than 25° kyphotic angle of the affected vertebra. Pain was graded using numeric rating scale,⁴ and all patients had a pain score of more than 7.

These patients were subject to conservative management in the form of bed rest and analgesics for 2–3 weeks. A thoraco-lumbar brace was provided to all patients to be worn during sitting and standing. Those who tolerated conservative management well with gradual decrease in the pain score to ≤ 5 were excluded. Remaining patients showing no symptomatic improvement for more than 2 weeks with pain score of more than 7 were selected for the procedure. A sample containing 20 female patients with a mean age of 57.9 years having compression fracture of a single vertebra centred in the thoracolumbar junction between D11–L2 was obtained. Their functional status was noted using Roland Morris Disability Questionnaire (RMDQ) score before the procedure and all were found to have a score of more than 21.5 Bone mineral density of all the patients was 2.5 standard deviations less than that of the young adult mean which significantly denotes osteoporosis.

Percutaneous Vertebroplasty was planned in the third week after a failed conservative trial for 2 weeks. Appropriate informed consent was obtained from the patient prior to the procedure. We preferred general anaesthesia for most of our cases except for a couple of patients in whom we performed the procedure under local anaesthesia. Patients were made to lie down prone on the radiolucent operating table and C-arm was positioned appropriately. Fractured vertebra was identified in both anteroposterior and lateral view images. C- Arm was positioned for an anteroposterior view to visualize the pedicles of the affected vertebra. With AP view as initial reference, a disposable 11-gauge Jamshidi type trephine vertebroplasty needle was inserted percutaneously from the back and directed to a point on the lateral border of the pedicle which corresponds to the centre of the pedicle in lateral view (Fig. 1). Once position and direction was confirmed, the needle was hammered and advanced.

Care was taken that as long as the needle crosses the pedicle in a lateral view, it should not have crossed the medial border of the pedicle in an anteroposterior view (Fig. 2). Once the needle was placed in the desired point inside the vertebral body, similar procedure was done to place another needle through the opposite pedicle (Fig. 2). Hence 2 needles were placed in each vertebra, one through each pedicle. After confirmation of needle position, Kyphon[®] high viscosity radiopaque vertebroplasty cement [Medtronic, Minneapolis, MN, USA], which takes a longer time to set, was injected through one of the needles when another needle remains closed with a stylet. The cement was injected alternatively in both the needles to achieve symmetrical spread (Fig. 3). We were comfortable using 3 ml syringes to inject cement into the needle. Once adequate even spread was noted, needles were removed. At least 4–6 ml of cement was injected into the affected vertebra in all our cases.

A couple of our patients had cement leakage into the disc space when final pressure was given to inject the cement. Once cement leakage was considered dawning, no further pressure was given to inject more cement. We did not encounter instances of cement leakage into the spinal canal. Those patients in whom the same procedure was done under local anaesthesia also tolerated the procedure well. Analgesics and antibiotics were given only on the day of procedure. Post procedural X-ray was done on the next day of procedure (Fig. 4). All patients were allowed to weight bear from the next day of the procedure and everyone tolerated well. We advised our patients not to carry on with strenuous activities until 4 weeks after the procedure, this was done to provide adequate healing conditions for the surrounding structures. Pre and post procedural pain was analysed using numeric rating scale. Functional assessment was done before the procedure using Roland Morris Disability Questionnaire during the conservative trial and after the procedure at 6th week follow up. Percentage of improvement in function when compared to pre-procedural status is calculated. Ultimate time taken to return to normal activity is noted.

Results were tabulated and statistical analysis were carried out using Graph Pad Prism 5 [GraphPad Software Inc., San Diego CA]. Analysis were done using Student's T test for all continuous variables. Probability values of less than 0.05 were considered statistically significant. This study was reviewed by the appropriate ethical committee and was performed in accordance with the

Fig. 1. Placement of needle over the bone before hammering into the pedicle as seen in both AP and lateral views.

Fig. 2. Confirming the placement of needles through the pedicle into the vertebral body in both AP and lateral views.

Fig. 3. AP and lateral C-Arm images during alternatively injecting the cement through each needle.

ethical standards laid down in the most recent version of the 1964 Declaration of Helsinki.

3. Results

Among the 42 patients who sustained dorsolumbar vertebral compression fractures, 26 patients who fulfilled our selection criteria were selected for a conservative trial and the remaining required surgical stabilization. Conservative modalities helped 6 patients to have gradual decrease in pain during the first 2 weeks as noted by the decrease in their NRS pain score and were excluded. Remaining 20 patients with single level vertebral compression fracture were selected for percutaneous vertebroplasty. All patients were female between age group of 46–73 years [Mean = 57.9 ± 7.9 years]. Among them 12 had fracture of D12 (60%), 5 had fracture of L1 (25%), 2 had fracture of L2 (10%) and one had fracture of D11 (5%). 14 patients had a wedge deformity and 6 patients had a biconcave deformity without any canal compromise. The fractured vertebra in our patients had an anterior vertebral height decrease

of less than 50% (Ranging between 20 and 48%) and kyphotic angle of less than 25° (Ranging between 8° – 22°).

Mean pre-procedural NRS pain score was 8.3 ± 0.6 . Mean pre-procedural RMDQ score was 21.6 ± 0.5 , showing significant functional compromise. Following procedure, 17 patients (85%) recorded significant decrease in pain which was noted on the third post procedural day using NRS pain score. Their pain score was found to be less than 6. Remaining 3 patients (15%) who had pain score of 7, were reassured and advised bed rest. Overall mean NRS pain score on 3rd day was 4.7 ± 1.2 which denoted significant pain relief ($p < 0.0001$). Seventeen patients were discharged on the 3rd day and were asked to wear their thoracolumbar brace during sitting, standing and walking for another 4 weeks. Those 3 patients whose pain score was 7, also had significant decrease in pain by 5th day with NRS score less than 5, and were discharged. All patients were asked to continue use of thoraco-lumbar brace and review after 4 weeks of procedure.

Mean numeric rating scale pain score by 4 weeks was 1.8 ± 0.5 . Patients only had minimal correction of anterior vertebral height and kyphotic angle but significant symptomatic improvement was

Fig. 4. Post Procedural AP and Lateral X-ray films.

noted as seen with reducing pain score. We did not do a functional assessment at this point as we advised patients not to carry on with activities causing pain for the first four weeks. All patients were advised to carry on with regular household activities as tolerated from 4 weeks and were asked to discontinue use of thoracolumbar brace. They were evaluated for possible causes of osteoporosis and appropriate pharmacological and non-pharmacological management together with exercise and rehabilitation were provided. Such supportive management varied according to individual requirements and are not discussed in this article. Functional assessment using RMDQ score was done by 6 weeks. Mean RMDQ score at 6 weeks was 2.8 ± 1.3 which denotes 87 ± 6.1 percent improvement when compared to pre-procedural status. This difference was statistically significant ($p < 0.0001$) Table 1. All patients were followed up every month thereafter, until 6 months.

A 100 percent satisfactory reply to all the questions in RMDQ scoring is not expected in those patients who had predisposing degenerative spine conditions. Their RMDQ score varied between 3 and 5, during the entire follow up, depending on other factors. Two patients who previously sustained a D12 fracture reviewed at 5 months with adjacent level fractures. They were severely osteoporotic and required other modalities of treatment which are out of the scope of this article and not discussed here. Remaining patients were followed up over phone and they did not report any disabilities and were in their best functional status. Final follow up was done at 6 months. Except in those patients who had sustained adjacent level fractures RMDQ assessment revealed full function. All patients were able to bend forward to touch below their knees without any pain. Some patients reported they were

able to do physically demanding activities and even lifting moderate weight.

4. Discussion

Vertebral compression fractures can occur due to trivial trauma when there is decreased bone mineral density due to osteoporosis, infection or neoplasm, especially in elderly women.^{1,6} These fractures cause severe disability and reduce the quality of life.⁷ As a result of the disability there is subsequent loss of bone mineral density leading to further kyphosis.⁸ Hence, bringing the patient back to functional status at the earliest is very important to prevent further osteoporosis. To achieve that, pain needs to be managed at the earliest. Vertebroplasty is one of the minimally invasive procedures to achieve such pain relief and stability where less viscous bone cement is injected into the vertebral body.^{1–3}

The effect of cement setting that produces an exothermic reaction and thus blocking the intraosseous nerve endings supplying the affected vertebra is stressed by many authors.³ Mechanical stability is also said to be regained by restoring vertebral stiffness and load sharing.⁹ The procedure is only indicated after a failed conservative trial.¹⁰ We considered conservative trial for 2–3 weeks, during which few of our patients improved and in the remaining patients percutaneous vertebroplasty was done. However, the optimal time to perform vertebroplasty can be debated. HH Lee et al., did a study on the timing of vertebroplasty, and concluded that “subacute period (>1 month and <3 months) is the most ideal time for vertebroplasty and if the procedure was performed during the acute stage (<1 month), the chance for leakage is more”; but they did not have any

Table 1
Results.

Parameters	Pre-Procedural	Post-Procedural	Statistical analysis
NRS Pain Score	8.3 ± 0.6 (7–9)	4.7 ± 1.2 (3–7) – 3rd day 1.8 ± 0.5 (1–3) – 4 weeks	$p < 0.0001$ $p < 0.0001$
RMDQ score	21.6 ± 0.5 (21,22)	2.8 ± 1.3 (0–5) – 6 weeks	$p < 0.0001$
Percentage of improvement in RMDQ score at 6 weeks	87 ± 6.1 (76.2–100)		

Values are presented as “mean $\pm$ standard deviation (range)”.

A probability value (p) < 0.05 was considered statistically significant.

NRS – Numeric Rating Scale; RMDQ – Roland Morris Disability Questionnaire.

symptomatic complications and obtained superior results when the procedure was performed in both acute and subacute stages, when compared to performing at the chronic stage (>3 months).¹¹

We performed vertebroplasty in the acute stage, i.e., 2–3 weeks from trauma or start of back pain. This is the painful period that the patient needs to go through during the early healing stages. Giving pain relief at this stage will be a major relief for the patient. However, we restrained from doing the procedure any time before 2 weeks, giving time for the acute phase of trauma to settle. Besides that, we were extra cautious about cement leakage and were ready to abort the procedure if cement leakage was dawning during the procedure. Percutaneous vertebroplasty is performed with the main intention of giving immediate pain relief and not to restore vertebral height or correct the kyphotic angle. It is for this reason, anterior vertebral height and kyphotic angle were not discussed as a part of our outcome analysis. In most of our patients, both these parameters were almost similar compared to pre-procedural status. Other procedures like kyphoplasty and stentoplasty have similar indications, but perform better in restoring vertebral height and correcting kyphosis.^{12–14}

Kyphoplasty requires use of a balloon tamp that expands the compressed vertebra and restores height. Cement is injected into the expanded space after the balloon is withdrawn which maintains height.^{12,15} We preferred using kyphoplasty only for those fractures with more than 50% reduction in vertebral height and such were not included in this study. Most of our patients were from a poor economic background and vertebroplasty over kyphoplasty proved to be a cost-effective means of management. The cement used is less viscous polymethylmethacrylate which takes more time to set providing adequate time to inject. The viscosity at which the cement is injected is very important to prevent cement leakage.¹⁶ Chances of leakage is more when cement is injected very early at liquid state.

We used simple syringe systems that gives a force feedback during injection where pressure needs to be completely given by the surgeon. Force amplification devices are also available allowing higher forces to be applied without any burden.¹⁶ We preferred using the double pedicle approach for symmetrical distribution of cement. Literature also states that vertebroplasty can be successfully done using unipedicular approach.¹⁷ Complications of this procedure include neurological injury due to cement leakage into the spinal canal, extravasation of cement into circulation and rarely infection.¹⁸ We had 2 patients in whom there was cement leakage into the disc space which did not cause any symptoms.

Adjacent level fractures are reported after percutaneous vertebroplasty of one level in osteoporotic patients.¹⁹ Hence treating the underlying osteoporosis plays an important role in prognosis of these patients. Immediate and sustained pain relief obtained by this procedure at a reasonable cost is the major advantage of this procedure.²⁰ Other merits include early mobilization, tolerable rehabilitation and prevention of disability induced osteoporosis leading to kyphosis. The cost effectiveness and outcomes as described in various articles in the literature made us choose this procedure for our patients with poor economic background.²¹ With our experience, we feel that this procedure serves its purpose very well; yet, our study has few methodological shortcomings, including a small sample size and lack of a control group. This is a level 4 observational study and further prospective randomised studies are required to assess the exact role of this procedure in treating various types of vertebral compression fractures.

5. Conclusion

Percutaneous Vertebroplasty serves its purpose adequately and economically. It offers immediate pain relief, stability and early

recovery in selective patients. Cement viscosity at the time of injection and the pressure at which the cement is injected needs to be controlled. Complications can be avoided by careful selection of patients and having control over the procedure.

Conflict of interest

The authors have none to declare.

Source of support

Nil.

Contributions

Both authors contributed equally.

References

- Alexandru D, So W. Evaluation and Management of Vertebral Compression Fractures. *Perm J*. 2012;16(4):46–51.
- Afzal S, Dhar S, Vasavada NB, Akbar S. Percutaneous vertebroplasty for osteoporotic fractures. *Pain Physician*. 2007;10:559–563.
- Denaro V, Longo UG, Maffulli N, Denaro L. Vertebroplasty and kyphoplasty. *Clin Cases Miner Bone Metab*. 2009;6(2):125–130.
- Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: visual analog scale for pain (VAS pain), numeric rating scale for pain (NRS pain), McGill pain questionnaire (MPQ), short-Form McGill pain questionnaire (SF-MPQ), chronic pain grade scale (CPGS), short form-36 bodily pain scale (SF-36 BPS), and measure of intermittent and constant osteoarthritis pain (ICOAP). *Arthritis Care Res*. 2011;63:240–252.
- Roland M, Fairbank J. The Roland–Morris disability questionnaire and the Oswestry disability questionnaire. *Spine*. 2000;25:3115–3124.
- Cicala D, Briganti F, Casale L, et al. A traumatic vertebral compression fractures: differential diagnosis between benign osteoporotic and malignant fractures by MRI. *Musculoskelet Surg*. 2013;97:S169–79.
- Suzuki N, Ogikubo O, Hansson T. Previous vertebral compression fractures add to the deterioration of the disability and quality of life after an acute compression fracture. *Eur Spine J*. 2010;19:567–574.
- Katzman WB, Wanek L, Shepherd JA, Sellmeyer DE. Age-Related hyperkyphosis: its causes, consequences, and management. *J Orthop Sports Phys Ther*. 2010;40(6):352–360.
- Luo J, Adams MA, Dolan P. Vertebroplasty and kyphoplasty can restore normal spine mechanics following osteoporotic vertebral fracture. *J Osteoporos*. 2010;72925710.4061/2010/729257.
- McGraw JK, Cardella J, Barr JD, Mathis JM, Sanchez O, Schwartzberg MS. Society of Interventional Radiology quality improvement guidelines for percutaneous vertebroplasty. *J Vasc Interv Radiol*. 2003;14:S311–15.
- Lee HH, Chao KH, Wang SJ, Wu SS. The timing of vertebroplasty in the treatment of painful osteoporotic vertebral compression fractures. *J Med Sci*. 2004;24(3):129–134.
- Saxena BP, Shah BV, Joshi SP. Outcome of percutaneous balloon kyphoplasty in vertebral compression fractures. *Indian J Orthop*. 2015;49:458–464.
- Martín-López JE, Pavón-Gómez MJ, Romero-Tabares A, Molina-López T. Stentoplasty effectiveness and safety for the treatment of osteoporotic vertebral fractures: a systematic review. *Orthop Traumatol Surg Res*. 2015;101(5):627–632.
- Buranakarl T, Jaisanuk K, Varatorn R, Suchato C, Srisuphap S. Stentoplasty (Cemented kyphoplasty with stent) under biplane digital subtraction angiography (Biplane DSA). *Bangkok Med J*. 2011;2:48–52.
- Dohm M, Black CM, Dacre A, Tillman JB, Fueredi G. KAVIAR investigators: a randomized trial comparing balloon kyphoplasty and vertebroplasty for vertebral compression fractures due to osteoporosis. *Am J Neuroradiol*. 2014;35(12):2227–2236.
- Boger A, Wheeler KD, Schenk B, Heini PF. Clinical investigations of polymethylmethacrylate cement viscosity during vertebroplasty and related in vitro measurements. *Eur Spine J*. 2009;18:1272–1278.
- Chen LH, Lai PL, Chen WJ. Unipedicle percutaneous vertebroplasty for spinal intraosseous vacuum cleft. *Clin Orthop Relat Res*. 2005;435:148–153.
- Chen LH, Lai PL, Chen WJ. Current status of vertebroplasty for osteoporotic compression fracture. *Chang Gung Med J*. 2011;34:352–359.
- Lin WC, Cheng TT, Lee YC, et al. New vertebral osteoporotic compression fractures after percutaneous vertebroplasty: retrospective analysis of risk factors. *J Vasc Interv Radiol*. 2008;19:225–232.
- Klazen CA, Lohle PN, de Vries J, et al. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial. *Lancet*. 2010;376:1085–1092.
- Zhang GQ, Gao YZ, Chen SL, Ding S, Gao K, Wang HQ. Comparison of percutaneous vertebroplasty and percutaneous kyphoplasty for the management of Kümmell's disease. *Indian J Orthop*. 2015;49:577–582.