

# Percutaneous Vertebroplasty for Osteoporotic Vertebral Compression Fracture

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## ABSTRACT

**Objective:** To assess the safety and efficacy of percutaneous vertebroplasty in the treatment of single level Osteoporotic Vertebral Compression Fractures (OVCF).

**Study Design:** This was a case series study.

**Place and Duration of Study:** Department of Neurosurgery Unit I, Lahore General Hospital, Lahore from January 2012 to January 2014.

**Methodology:** All 57 patients received PVP in the current study. Feasibility of a unilateral approach was judged before surgery using the 64 – slice helical computed tomography (CT) multiplanar reconstruction technique, a 3D accurate puncture plan was then determined. The skin bone distance, puncture angle and needle insertion depth were recorded during surgery. 2D CT rechecking was performed for any complication at day 1 after operation. Preoperative and postoperative numerical data were compared patients fulfilling the inclusion criteria were given time in the out – patient department for vertebroplasty. Patients who had a neoplastic etiology (metastasis or myeloma), infection, neural compression, traumatic fracture, neurological deficit, spinal stenosis, severe degenerative diseases of the spine or previous surgery at the involved vertebral body were excluded from our study. Prior to vertebroplasty the patient's level of pain was recorded by using the visual analogue scale method: a scale of 0 – 10, with 10 indicating the most pain. After vertebroplasty, patients were asked whether their pain was completely relieved, partially relieved, unchanged, or worse. The post vertebroplasty visual analogue scale score were recorded on the day of vertebroplasty immediately after the end of the procedure and at 24 hours and then at the follow up visits at 2 weeks, 1 month, 3 months, 6 months, and 1 year intervals.

**Results:** In this study there were 20 (35.1%) male and 37 (64.9%) female patients. The mean age of patients was  $59.12 \pm 12.40$  years with minimum and maximum age 39-88 years respectively. On pre procedure assessment, fractures of L1, L2 and L3 were seen in 10 (17.5%), 6 (10.5%) and 5 (8.8%) respectively while T11 and T12 were seen in 6 (10.5%) and 16 (28.15%) respectively. Mean pre and postoperative pain on VAS was  $7.91 \pm 1.17$  and  $1.17 \pm 1.45$ . After surgery mean difference in pain score was  $6.73 \pm 1.90$  with fulfillment of normality assumptions (Kolmogorov-Smirnov  $Z = 1.18$ ,  $p$ -value = 0.123). On applying paired sample  $t$ -test significant improvement in pain was found after surgery,  $t=26.71$ ,  $p$ -value < 0.001. Mean cement volume and vertebral collapse was  $6.42 \pm 1.60$  and  $29.29 \pm 4.19$  respectively.

**Conclusion:** Vertebroplasty is safe and effective procedure for osteoporotic vertebral collapse and its a day care procedure and can be performed safely under local anaesthesia.

**Key words:** Osteoporosis, Spine fractures, vertebroplasty, pain relief.

**Abbreviations:** OVCFs: Osteoporosis Vertebral Compression Fractures. MR: Magnetic Resonance. PMM: Polymethyl Methacrylate.

## INTRODUCTION

Osteoporosis is characterized by low bone density that leads to fragile bones and higher fracture risk.<sup>1</sup> One of the major complications of osteoporosis is vertebral compression fractures (OVCFs). Due to the increasing age of the population, there has been a constant rise in OVCFs during the last decade.<sup>2</sup> Minor trauma and even ground level fall at home can cause osteoporotic vertebral collapse in such population. This vertebral collapse can cause a variety of symptoms ranging from pain to neural deficit and kyphosis. Different treatment options are available for such osteoporotic collapsed vertebrae. Recently percutaneous vertebroplasty and kyphoplasty is being used to treat such lesions. Vertebroplasty – a popular, minimally invasive treatment that uses injections of bone cement to seal up spinal vertebral fractures – is safe, effective, and provides more pain relief than conservative treatment. Percutaneous vertebroplasty is an imaging – guided procedure in which polymethyl methacrylate (PMM) is injected into an osteoporotic collapsed vertebra. It was first described in 1987 for the treatment of aggressive vertebral hemangioma.<sup>3,4</sup> The two recent applications of placebo controlled vertebroplasty randomized trails has incited great debate over the merits of vertebroplasty.<sup>5,6</sup> Percutaneous vertebroplasty is indicated for painful osteoporotic or neoplastic vertebral compression fractures refractory to medical therapy.<sup>7,8</sup> When injected cement hardens it can give strength to the vertebrae and stabilizes the spine and can relieve pain. Some people believe that when cement start settling there is an exothermic reaction that destroys the nerve endings and relieves pain. Loss of vertebral height to less than one third of adjacent level height is called as vertebrae plana. In vertebrae plana percutaneous vertebroplasty is technically difficult to perform. Some reports suggest<sup>6,10,11</sup> that this procedure should not be performed for vertebra plana. The purpose of our study was to determine the efficacy of percutaneous vertebroplasty in treating severe vertebral body compression fractures in patients with osteoporosis vertebral collapse.

Indications for vertebroplasty are focal intractable backache with no radiations of pain and no neural deficit and no compression of neural tissues on MRI and intact posterior cortex of that vertebrae on 3D CT spine. Retropulsed bone did not prohibit the procedure if it is not causing compression over thecal sac and root compression. Exclusion criteria were unstable osteoporotic collapse with compression over neural tissue and fractured posterior cortex and patients on anti-

coagulants or having bleeding disorders. Relative contraindications includes the patient's inability to lie prone due to some respiratory or cardiac compromise and patient who does not give informed consent. The complete neurologic examination was done before starting the procedure by two neurosurgeons and informed consent was obtained from all the patients after explaining the pros and cons of the procedure and alternative treatment options. The extent of vertebral body collapse was measured on lateral radiographs of that spinal level or midsagittal magnetic resonance (MR) images and compared with nearby normal vertebral height.

We performed the percutaneous vertebroplasty in a sterile way under fluoroscopic guidance by using a C-arm. The patient's vitals and pulse oximetry were monitored continuously. By using the vertebroplasty gun, the PMM mixture was injected with lateral fluoroscopic guidance until the PMM reached the posterior quarter of the vertebral body or until it started to pass into the disc space and paravertebral tissues. If leakage outside the vertebra occurred, the injection was stopped and the needle was repositioned and vertebra reinjected. 3D CT scan and MRI Image were analysed preoperatively as well as peroperatively and assessed properly whether they correlate with clinical signs and symptoms by all our team. Imaging features seen on MRI and 3D CT scan were percentage of vertebral collapse and its pattern, level of involved vertebra.

The total volume of PMM injected during the procedure was noted along with any leakage observed on fluoroscopic images. When the procedure was over, all the patients were reassessed clinically for outcome and any possible complications. The volume was prospectively recorded on data sheets. Patients were evaluated for severity of pain before vertebroplasty and follow up was done at regular intervals for 1 years in all patients included in the study. The patient's level of pain before and after the procedure was recorded by using the visual analogue scale method: a scale of 0 – 10, with 10 indicating the most pain. All patients were asked whether their pain was completely relieved, partially relieved, unchanged, or worse just after the procedure on the operation table and patient assessed for any new deficit. The post vertebroplasty follow up was done immediately after the end of the procedure and at 24 hours, 2 weeks, 1 month, 3 months, 6 months, 1 year. The patient level of pain before the procedure and after the procedure was entered on the data sheet.

**METHODOLOGY**

This study was conducted from January 2012 to January 2014. This study was approved by the ethical committee of the hospital. Informed consent was obtained from all patients. Complete history and clinical examination was done in all patients. In 57 consecutive patients percutaneous vertebroplasties were performed in our institution during 24 months. Of these, 57 patients (37 women, 20 men; age range, 44 – 91 years; mean age, 73.6 years) underwent 57 vertebroplasties to treat severe osteoporotic compression fractures. The duration of fractures was variable, ranging from 1 to 4 weeks. Those patients who had not responded to conservative treatment, which included all types of pain medications, nerve blocks, physiotherapy, and osteoporosis medications were included in the study. All patients were discharged on the day of surgery and postoperative pain control was measured using visual analogue score.

Vertebroplasty was performed at only one level in all patients. Patients who had vertebral compression fracture due to a neoplastic etiology (i.e. metastasis or myeloma), vertebral, paravertebral or disc space infection, nervous tissue compression with neurological deficit, traumatic fracture when posterior cortex is not intact, severe spinal stenosis and previous surgery at the involved vertebral body were excluded from our study.

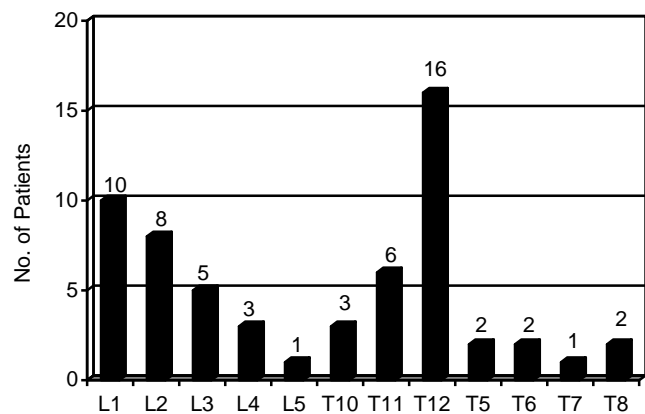
All data was entered and analysed using SPSS version 18. Mean ± S.D was used for quantitative data such as (age, pain on VAS and Cement Volume, Vertebral Collapse). Frequency and percentage was used for categorical data such as gender and vertebral levels. Pain was compared before and after surgery, normality (of difference in pain before and after) was checked using Kolmogorov – Smirnov test, whose value was Z = 1.18, p-value = 0.123, so assumption of normality was met then we applied paired sample t-test. We considered p-value ≤ 0.05 as significant.

**RESULTS**

In this study there were 20 (35.1%) male and 37 (64.9%) female patients. The mean age of patients was 59.12 ± 12.40 years with minimum and maximum age 39 – 88 years respectively. On pre-assessment L<sub>1</sub>, L<sub>2</sub>, L<sub>3</sub> was seen in 10 (17.5%), 6 (10.5%) and 5 (8.8%) respectively while T<sub>11</sub> and T<sub>12</sub> was seen in 6 (10.5%) and 16 (28.15%) respectively. Mean pre and postoperative pain on VAS was 7.91 ± 1.17 and 1.17 ± 1.45. After surgery mean difference in pain score was

**Table 1:** Descriptive Statistics of age and Pain characteristics.

	Pain Score		
	Pre-Operative	Post-Operative	Mean Difference
Mean	7.91	1.17	6.73
Std. Deviation	1.17	1.45	1.90
Range	5.00	6.00	10
Minimum	5.00	.00	0
Maximum	10.00	6.00	10
p-value (Paired Sample test)	t=26.71 , p-value < 0.001		



**Fig. 1:** Vertebral Level.

**Table 2:** Descriptive Statistics of Cement Volume and Vertebral Collapse.

	Cement Volume	Vertebral Collapse
Mean	6.42	29.29
Std. Deviation	1.60	4.19
Range	7.00	20.00
Minimum	3.00	15.00
Maximum	10.00	35.00

6.73 ± 1.90 with fulfillment of normality assumptions (Kolmogorov – Smirnov Z = 1.18, p-value = 0.123).

On applying paired sample t-test found significant improvement in Pain after surgery,  $t = 26.71$ ,  $p\text{-value} < 0.001$ . Mean cement volume and vertebral collapse was  $6.42 \pm 1.60$  and  $29.29 \pm 4.19$  respectively.

## DISCUSSION

Percutaneous vertebroplasty is a commonly performed procedure in patients with vertebral osteoporotic compression fracture who present with severe mechanical back pain with restricted mobility and require long term analgesics. Surgery is sometimes performed to stabilize a single level osteoporotic collapse when bone are not too much osteoporotic and patient's cardiopulmonary reserve is enough that he or she can tolerate the general anaesthesia, positioning for 2 – 3 hrs and surgical procedure. An added advantage of percutaneous vertebroplasty is that it can be performed in multiple vertebrae.<sup>9,10</sup> In patients with acute osteoporotic compression fractures in whom pain persists despite correct medical treatment, percutaneous vertebroplasty can be helpful.<sup>7</sup>

In the article by Weill et al,<sup>11</sup> in which 37 patients with metastases underwent 52 vertebroplasties, the authors state that lesions were treatable unless the vertebrae had collapsed to less than one – third of the original height. In their opinion, vertebroplasty was technically difficult if less than one – third of the height was preserved. Cotten et al<sup>10</sup> also agreed that the reduction to one – third of vertebral body height constituted severe vertebral compression and was considered a relative contraindication to the procedure. There is much discussion and controversy whether the vertebroplasty should be performed on severely collapsed vertebrae or not and whether it is safe or not in vertebrae plana. In our study, we have shown that it was safe and easy to perform percutaneous vertebroplasty in patients with severe osteoporotic vertebral compression. We did not find any difference in the difficulty level of vertebroplasty procedure in severely collapsed vertebrae compared to moderately collapsed vertebrae, although we were probably more cautious when we performed the procedure in these patients under careful and repeated flouro image guidance and with a keen eye over the patients neurological status.

The principal radiographic complication of PMM leakage is epidural and foraminal extravasation.<sup>10</sup> Cement leakage into the disc during vertebroplasty, although of no definite clinical consequence, has a theoretical increase in the risk of subsequent fractures of adjacent vertebral bodies,<sup>12</sup> therefore, it is advised to

place the needle laterally and far from the center of the vertebra in a centrally located fracture,<sup>12,13</sup> and to adjust the cement consistency so that the cement is more viscous, making it less prone to leak.<sup>14</sup> Any resultant spinal cord or nerve root damage may require emergency surgical decompression. Neurologic complications, however, are uncommon.<sup>10</sup> Perivertebral venous, paravertebral soft – tissue, and intradiscal leakages are of no clinical importance in the short- and midterm.<sup>10</sup> In the series by Weill et al,<sup>11</sup> slight PMM leaks toward the disc, epidural fat, perivertebral soft tissue, epidural veins, and perivertebral veins were observed in 20 (38%) of 52 vertebroplasties; leaks were symptomatic in only five vertebroplasties. These authors suggest that slight PMM leaks, when not symptomatic, should not be considered as complications. In our experience PMM leakage into the disc is not uncommon and it is almost always asymptomatic. But one should be very careful that large amount of cement will not leak into the foramina or spinal canal. Leakage rate of our study was comparable with the result of other studies and is directly related with the severity of vertebral compression fracture. We also noticed that it was safe that smaller mean amount of PMM should be injected into the severely compressed vertebra to get the less incidence of cement leak. Extra care should be taken when performing vertebroplasty in patients with severely collapsed vertebral bodies. In our practice, the injection of further cement was stopped once leakage into the disc was observed under fluoroscope. There were no differences in leakage rates whether the procedure was performed from single pedicle or from both sides. The average amount of PMM injected per vertebral body in our series (6.42 ml) was in fact comparable with that used in other series<sup>15,16</sup> which ranged from 5.5 to 7.1 ml for thoracic and lumbar vertebrae.

In our study we also noted that in severely compressed vertebrae that were compressed more centrally than peripherally within a vertebral body, the needle tip should be placed laterally by keeping the needle tip farther away from the central part of the vertebral body to decrease the leakage of PMM into the disc space. It is very important for the operating neurosurgeon to be aware of the normal anatomy of vertebrae and he should also be able to locate exactly where the pedicle is located and whether the pedicles are intact or fractured. He should be able to interpret the anteroposterior and lateral views of the spine on flouro image and should be expert enough to look at MRI to decide that there is no neural tissue compression. He should also be able to directly monitor the position of trocar

on flouroimage in both AP and LAT views. He should be able to decide on flouro that whether there is complete vertebral collapse, H – shaped collapse or there is gibbus vertebral compression and then decide the trajectory of the canula with trochar. He also has to decide whether to fill vertebrae from single pedicle or from both pedicles.

Pain relief is expected after a mean 24 hours after the procedure.<sup>10</sup> Marked or complete pain relief was demonstrated in more than 70% of patients with vertebral metastases or myeloma<sup>11</sup> and in 90% of patients with osteoporotic compression fractures<sup>16</sup> and hemangioma.<sup>4</sup> In the study of Deramond et al<sup>11</sup> with 80 patients with osteoporotic fractures, more than 90% of the patients had rapid and complete pain relief within 24 hours. Cyteval et al<sup>15</sup> reported complete pain relief within 24 hours in 75% of 23 patients with osteoporotic fractures. Barr et al<sup>16</sup> examined 38 patients with osteoporotic fractures and found complete pain relief in 63% of patients, moderate pain relief in 32%, and no pain relief in 5%. As for safety assessment, we analyzed the most common complications. Occurrence of cement leakage is up to 8% in PVP patients.<sup>17</sup> However, cement leakage does not usually cause any clinical symptoms. Although all of the included studies reported the incidence of cement leakage, no cases of spinal stenosis and pulmonary embolism due to cement leakage were reported. Further evidence was provided that little cement leakage is found by the standard radiographic imaging, whereas high rates are observed with computed tomography.<sup>17</sup> Some authors do not consider asymptomatic leaks to be a complication. Others have suggested that there are long term sequelae from asymptomatic cement leaks.<sup>18</sup> Unlike our Study, all previous studies in the literature had their own limitations, such as being retrospective, having small groups of patients, lack of patient participation in the entire follow-up period, other confounding medical treatments that might have affected their outcomes and pain relief, and persistence of other causes that produce pain.<sup>19,20</sup>

Our results are similar in that the majority of patients had pain relief after the procedure. However, the percentage of patients with complete pain relief was also good as in previous series. Although follow-up was longer in our patients, which ranged from 3 to 24 months, with a mean follow-up of 11 months and 3 days. Another reason for good pain relief and no neural deficit was this that cement was injected in inverse proportion to severity of vertebral osteoporotic collapse. Our study patients experienced improved mobility

within 24 hours, and the majority could bear weight soon after the procedure. The amount and type of pain medication was reduced to minimum just after the procedure and stopped after 24 hrs and none of our patient was dependent on narcotic analgesics. In some of our patients, especially those who were bedridden for a long period, pain relief sometimes occurred gradually over a few days. Some patients have follow up pain due to adjacent segment degeneration and they were able to differentiate follow up pain from pain of severely compressed fractured vertebrae.

## CONCLUSION

Percutaneous vertebroplasty is a useful, safe easy and comfortable technique for management of painful osteoporotic vertebral compression fractures and tolerated well in old age. It provides pain relief and vertebral stabilization in the majority of patients. We believe that percutaneous vertebroplasty of severe osteoporotic vertebral body compression fractures is safe and effective and should not be withheld in this group of patients.

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