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Analysis of percutaneous vertebroplasty—a prospective study



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Abstract

Background: The objective of this study was to document the efficacy of vertebroplasty procedure for pain relief and also to measure pain-related disability and quality of life after the procedure, as well as to access whether the amount of cement injected affects the outcome.

Results: Fifty patients with severe pain not responding to conservative management of vertebral collapse were included in this study. Clinical severity of pain was documented in a 10-point ordinal scale. Mean preoperative pain score was 7.3 ± 1.2 , and activity score was 1.6 ± 1.1 . The analgesic score was 1.0 ± 0.2 . Eight and 14 patients had clinical improvement in symptoms immediate and at 1 week, respectively, after the procedure. At 3-month follow-up, 16 patients (32%) became asymptomatic, 30 patients (60%) showed significant improvement, while 4 of them (8%) had no improvement in symptoms. This suggests that there is a significant relief in clinical symptoms at 3-month follow-up.

Conclusion: Vertebroplasty is a safe, cost-effective, sustainable minimal invasive procedure for the treatment of pain associated with vertebral fractures/collapse associated with different vertebral pathologies with high success rate. Accurate and correct selection of patients is mandatory for the success of the procedure.

Keywords: Vertebroplasty, Osteoporotic collapse, Vertebral hemangioma, Bone cement

Background

Osteoporosis and osteoporotic compression fracture are increasingly prevalent with aging population. Pain is the most common symptom for which medical assistance is sought in this set of population. Osteoporotic and nonosteoporotic vertebral deformities are equally responsible for musculoskeletal pain and other morbidities in an older age group. Clinical and subclinical vertebral fractures may cause persistent often excruciating pain, which impairs mobility and reduces the patient's quality of life [1]. The updated American College of Radiology (ACR) Criteria for vertebral compression fractures management emphasize on conservative approach; however, anti-osteoporotic medications, calcium, and vitamin D should be started immediately [2]. Pain relief is of utmost concern in these sets of patients which may require a short course of anti-inflammatory for 1-2 months. If unresponsive patients or a longer duration of pain killer requirement is there, then vertebroplasty or kyphoplasty

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should be strongly considered. Percutaneous vertebroplasty was initially described by French radiologists for the treatment of painful vertebral hemangioma, metastatic lesions, and myeloma [2]. With time, it has evolved fluently and is now also being used in patients with osteoporotic compression fractures. The primary goal of treatment by vertebroplasty is to alleviate pain, and the other goal is vertebral body stabilization.

We conducted a study in our department where 50 prospective patients of vertebroplasty were studied to assess procedural efficacy in pain relief immediate and long-term sustainability and also to assess any correlation between the amount of bone cement injected and pain relief.

Methods

The study was done in Department of Radiodiagnosis, Sanjay Gandhi PostGraduate Institute of Medical Sciences, from 1 January 2014 to 31 October 2015. Fifty prospective patients were selected for study, and these patients were followed up until December 2017. Patient selection:



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Inclusion criteria:

- 1. Patients having osteoporotic vertebral compression fractures in the cervical, thoracic, and lumbar spine causing moderate to severe pain and unresponsive to conservative therapy
- 2. Patients with painful metastasis and multiple myelomas with or without adjuvant radiation or surgical therapy
- 3. Patients with painful vertebral hemangiomas

Clinical assessment

A general physical, neurological, and systemic examination was performed before taking up patients for percutaneous vertebroplasty. Tenderness at the site of pain was evaluated. The clinical severity of pain was documented in a 10-point ordinal scale (VAS; visual analog scale) pre- and post-procedure and also on follow-up visits. Patients were asked to rate their pain according to the severity.

Pain severity score

The VAS pain scoring system was used for evaluation of severity of pain.

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0 = No pain
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10 = Most severe pain
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0 - 1	10	VAS	Nun	neri	сРа	in	Dist	ress	s So	ale		
No				M	lodera	Unbearable						
pain	1		pain					pain				
0	1	2	3	4	5	6	7	8	9	10		

Activity score and intake of analgesics were documented in a 5-point score, respectively, before and after the procedure as well as on the follow-up.

Activity score

- 0 Independent without assistance
- 1 Walk with assistance
- 2 Bound to wheel chair
- 3 Sitting in bed
- 4 Lying in bed

Medication score

- 0 None
- 1 NSAIDs
- 2 Non-narcotic opioids
- 3 Narcotic drugs
- 4 IV narcotic drugs

The score ranged from a minimum of zero to a maximum of 18. The patients were examined, and all the systemic and neurological findings were noted.

Pre-procedure investigations which were included in the study

Laboratory investigations which were done for patients:

- 1. Complete blood count
- 2. Coagulation profile.

Imaging

All imaging including anterior and lateral radiographs of the spine and if patient had CT or MRI were also reviewed.

Procedure

We performed all procedures in an angiographic unit with a C-arm digital subtraction angiography (DSA) fluoroscopy system used in 50 patients. Patients were asked to stop there pain killers at a minimum of 3 days before the procedure, and injectable antibiotic inj ceftriaxone 2 gm was given just before procedure.

Patients were kept in a prone position, and all procedures were performed under strict sterile conditions. All procedures were done under local anesthesia via transpedicular approach using a 13 gauge needle. Gentle tapping guided the needle through the pedicle into the anterior third of the involved vertebral body. Frontal and lateral images were recorded with the needle in correct position.

Preparation of the cement mixture

We prepared a mixture of polymethyl methacrylate (PMMA) mixed with barium in toothpaste-like consistency. The prepared PMMA was slowly injected into the vertebral body, and satisfactory infiltration of the vertebral body was confirmed radiographically. The amount of cement injected was variable depending on the vertebral level that had to be treated and the size of the lesion: larger for dorsal and lumbar bodies and smaller for cervical bodies. The cement introduction was always performed under fluoroscopic guidance with a slow and careful injection of high viscosity material. The filling of the vertebra was aimed to obtain as complete and homogenous as possible without causing intraspinal leakage of bone cement. In case the unipedicular approach did not give the desired or aimed result, the other pedicle was also used (bipedicular approach). Injection was stopped when substantial resistance was met or when the cement reached the posterior quarter of the vertebral body; injection was also stopped if cement leaked into extra osseous structures or veins. The needle was then removed, and all patients were observed in the

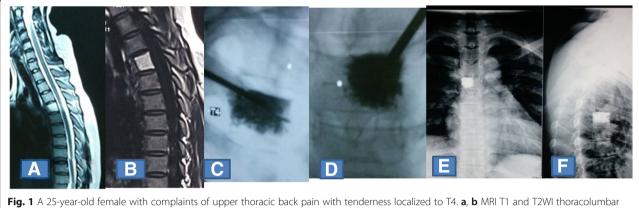


Fig. 1 A 25-year-old female with complaints of upper thoracic back pain with tenderness localized to 14. **a**, **b** Mkl 11 and 12Wl thoracolumbar spine shows a hyperintense lesion on both T1 and T2 s/o vertebral hemangioma in D4 vertebral body. **c**, **d** DSA image AP and lateral view showing unipedicular injection of cement. **e**, **f** Post-vertebroplasty X-ray image of thoracic spine shows adequate filling of bone cement in the body of D4 vertebra with no extension in to IV disc space. On follow-up, patient had significant relief in pain with decrease in morbidity and no tenderness at D4 level

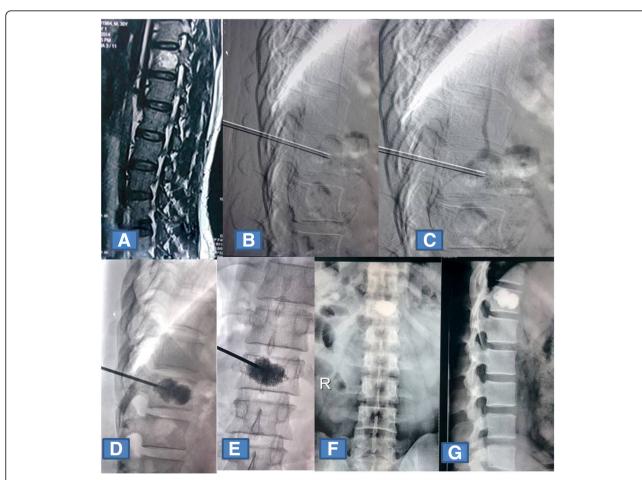


Fig. 2 A-30-year-old male patient presented with back pain since last 1 year seldom radiating to left lower leg. **a** MRI T2WI shows a vertebral hemangioma in D12 vertebral body. **b** DSA image lateral view showing transpedicular approach of needle placement at junction of anterior one third and posterior two third. **c** DSA image lateral view showing paravertebral venous plexus when contrast was injected so a thicker bone cement paste was used to prevent venous extension of cement. **d**, **e** DSA images showing adequate filling of vertebral body by cement. **f**, **g** Post-vertebroplasty X-ray image shows good filling of bone cement in the body of D12 vertebra. On follow-up, at 1 week, there was significant pain relief

supine position for 2 h after the procedure. All participants in the vertebroplasty group received oral antibiotic for 3 days and analgesics if needed.

- Periprocedural complications were evaluated and were documented
- Postprocedural clinical evaluation was done to look for hemodynamic parameters and neurological status of the patient after the procedure
- Postprocedural imaging done by either frontal and lateral radiography or CT of the spine, and follow-up was done after 7 days and 3 months for assessing the severity of pain. Telephonic follow-up was done of all patients till December 2017 for analyzing pain.

Vertebroplasty procedure started with treatment for vertebral hemangiomas, and now is one of the main stay treatments for pain relief due to compressive pathologies to provide biomechanical strength.

The exact mechanism of pain relief following vertebroplasty is not known. Many theories have been proposed for mechanism of pain relief. The commonly considered theories include:

• Mechanical theory

Vertebroplasty leads to mechanical stabilization. The cement stabilizes fractures including microfractures within the cancellous bone of vertebral body and thus reduces the irritation of free nerve endings thereby reducing pain. This restores the strength and stiffness of the diseased vertebrae thus causing relief in pain [4]. • Thermal theory

The heat generated by PMMA cement leads to damage to the free nerve endings of vertebral nerves and thus reduces pain. Percutaneous vertebroplasty reduces pain by thermal neurolysis. As the bone cement begins to harden within the body, there occurs an exothermic process capable of producing temperatures as high as 70 °C, which in turn damage nerve endings sufficiently to negate pain [5].

• Decompression theory

The intraosseous pressure increases significantly following compression fracture in the vertebral body. This is decompressed after vertebroplasty, thus providing pain relief.

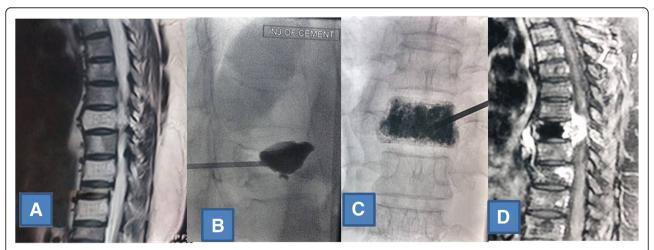
So, in brief, vertebroplasty offers analgesic effect, biomechanical strength, and antitumoral effect. The analgesic effect is due to in situ immobilization of fractures, destruction of nerve endings, cytotoxic effect, and exothermic reaction. The antitumoral effect is due to local toxicity of methyl-meth-acrylate [6, 7].

Observation and results

In our study, percutaneous vertebroplasty was done in 50 patients, out of which 37 (74%) were female and 13 (26%) were male.

The mean age was 52.65 \pm 13.1 (range 20–69 years).

Out of the 50 patient's in our study, 11 patients (22%) had vertebral hemangioma, 36 (72%) had osteoporotic/ traumatic collapse and 3 (6%) of them had vertebral collapse due to malignant etiology (multiple myeloma). Figures 1, 2, and 3 show symptomatic vertebral hemangioma where vertebroplasty is done.



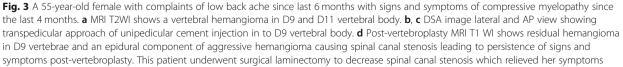
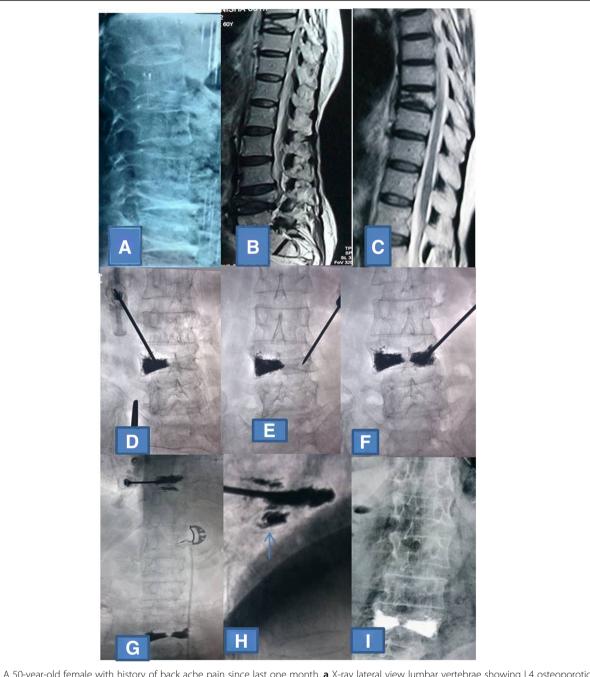


Fig. 4 A 50-year-old female with history of back ache pain since last one month. a X-ray lateral view lumbar vertebrae showing L4 osteoporotic collapse. b, c MRI T1 AND T2WI shows osteoporotic collapse of D9 and L4 vertebral body, with adjacent bone marrow edema. d-f DSA images showing bipedicular approach of cement injection in L4 vertebrae. g, h DSA images showing unipedicular cement injection in D9 vertebral body, magnified image of D9 vertebra showing extension of cement in adjacent intervertebral disc space(arrow). i Post-vertebroplasty X-ray image shows adequate filling of bone cement in the body of L4 vertebra. There was extension of cement mixture in to D9–D10 IV disc space. However, patient had no clinical symptoms of sensori-motor radiculopathy. Patient had significant relief in pain on 3-month follow-up

Figures 4, 5, and 6 show osteoporotic collapse, and Fig. 7 show post-traumatic collapse where vertebroplasty was done.

The diseased vertebrae were distributed between D4 and L5 vertebrae, in which the most common vertebrae was D12 in 11 patients (22%) followed by L1 in 10 patients (20%).

The most common symptom in study subjects was low back ache in 50 patients (100%) followed by tenderness in 20 patients (40%).





had significant relief in pain and is now able to walk without support

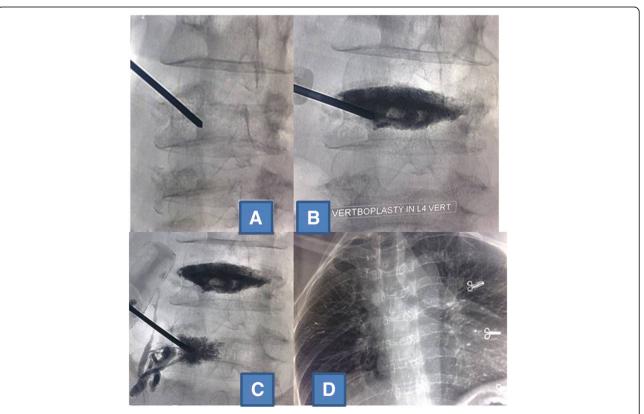
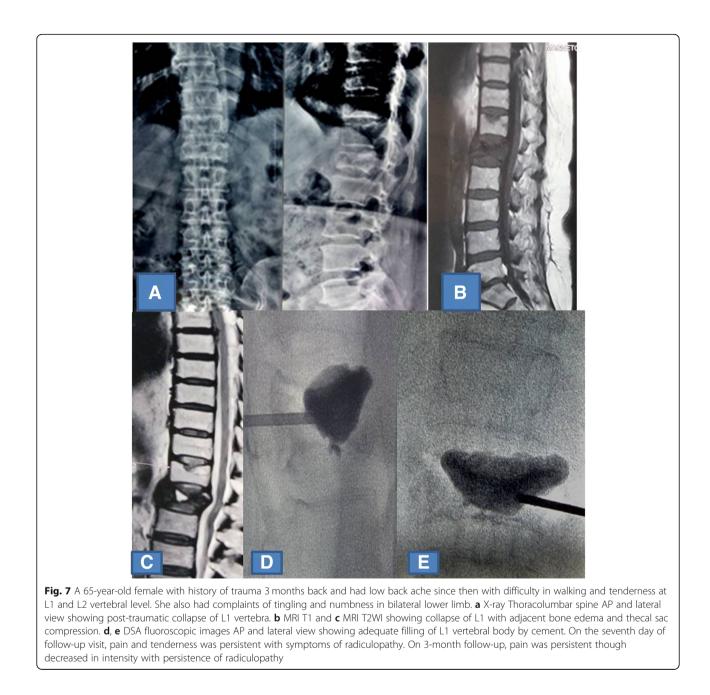


Fig. 6 A 59-year-old female with complaints of low back ache since the last 4 months. Her X-ray lumbar spine was done which shows osteoporotic collapse of L4 and L5 vertebrae. a DSA image showing transpedicular placement of needle in body of L4 vertebrae in AP view.
b DSA image showing adequate filling of cement in L4 vertebral body in AP view. c DSA image C showing needle in L5 vertebral body with paravertebral venous extension of cement. d Thoracic fluoroscopy image showing linear streaks of barium in bilateral lung fields suggestive of pulmonary embolism of cement mixture. The patient had no clinical deterioration postprocedure. But the patient had intraprocedural complication of paravertebral venous extension of cement mixture extending into pulmonary embolism. So, she was closely followed up after the procedure had no clinical signs and symptoms of respiratory distress

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The frequency of patient presenting with back pain of 1–6-month duration was maximum (20 patients, 40%) followed by 12–24 months (24%), 6–12 months (20%), and > 24 months (16%).

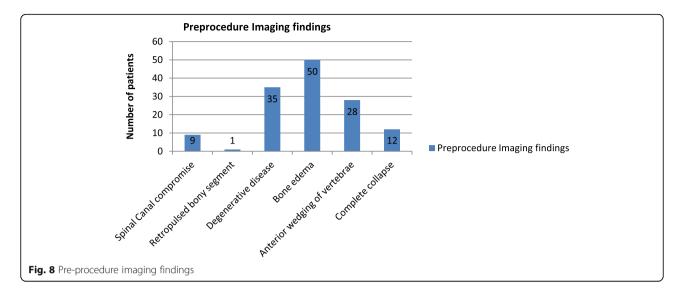
Pre-procedure imaging findings showed bone edema to be the most prevalent followed by degenerative changes and anterior wedging of vertebral body (Fig. 8).

Mean preoperative pain score was 7.3 \pm 1.2, and activity score was 1.6 \pm 1.1. The medication (analgesic) score was 1.0 \pm 0.2 (Table 1).

The most common route of vertebroplasty was right transpedicular (52%) followed by left

transpedicular (36%) and bipedicular (12%). Figure 4 showed bipedicular approach where injection was done one by one from each side as no appropriate distribution of cement was there when injected from one side.

The amount of cement injected through bipedicular route was more as compared to that of unipedicular route. There was no significant difference (p = 0.4 which is insignificant; for significance, p should be less than 0.05) between the amount of pain relief and the amount of cement injected irrespective of the unipedicular or bipedicular approach (Table 2).



Complications

Intraprocedure pain

In 10 (20%) procedures, patients complained of intraprocedural pain despite routine pre-medications. Injectable analgesia was given but two patients had persistent pain even after analgesia.

Two patients had extension of cement in paravertebral veins, and one had extension of cement in to pulmonary artery (Fig. 6 shows paravertebral extension as well as pulmonary embolism in one patient). However, both the patients were asymptomatic but required vital monitoring for few hours. To rest, all patients were sent home 2 h after the procedure. One of the patients had epidural extension of cement with increased severity of pain post-procedure which was relieved by analgesics (Table 3).

Ten patients (20%) had local site swelling and tenderness post-procedure for which analgesics and antibiotics were given for 7 days. At the seventh followup day, pain and tenderness have significantly reduced in all. Two patients had complaints of paraesthesia and tingling numbness in lower limbs which got relieved by conservative means at 1 week follow-up.

Paired sample *t* testing of preoperative versus postoperative pain score, activity score, and medication score were done at the seventh day and 3-month follow-up. It was found to be insignificant (p < 0.05 is taken as significant) at the seventh day. However, at 3 months, and it was found to be significant. This suggests that there is

Table 1 Pain score, activity score and medication score

Pre-vertebroplasty								
Index	Mean	Standard deviation						
Pain	7.30	1.2						
Activity score	1.6	1.1						
Medication score	1	0.2						

significant relief in clinical symptoms that might take some time and is static thereafter (Tables 4 and 5).

It was found that patients with pain duration < 12 month has significant reduction in pain score and activity score (p < 0.05) while patients with duration of pain > 12 month had insignificant results suggesting that there was no significant reduction in the severity of pain score and activity score in patients with chronic/long duration pain (Table 6).

On applying paired *t* test, there was a significant (p < 0.05) reduction in pain score and activity score on comparing the pre-vertebroplasty and post-vertebroplasty score irrespective of the type of vertebral pathology (Table 7).

We also compared patients in whom there was radiculopathy, and it was found that pain relief in them is not significant (Table 8).

On following these patients for two more years (till December 2017), there has been no change in pain relief or severity, which was there after 3 months of the procedure which concludes that pain that responds to vertebroplasty does so within 3 months and no further effect of pain relief is there, but no further increase in pain was noted even in patients where the results were static.

Discussion

Percutaneous vertebroplasty was first introduced in1987 by Galimbert and Deramond, a French neurosurgeon and radiologist, respectively, as an "alternative" treatment for vertebral hemangiomas [3]. The technique consists of an injection of an acrylic material, poly methylmethacrylate (PMMA), in the pathological vertebral body. When the great potential of this procedure became evident, its indications were extended to vertebral collapses of osteoporotic or different etiologies and to primary and repetitive vertebral neoplasm. Today, it

Approach	No. of procedures	Size of needle used	Mean amount of cement injected(in ml)	Standard deviation	Amount of pain relief unipedicular versus bipedicular and amount of cement injected (<i>p</i> value)
Unipedicular	44	13 G	5.3	1.5	P = 0.4 (Insignificant)
Bipedicular	6	13G	7.3	1.7	

 Table 2 Vertebral approach, size of needle used and amount of cement injected

has become an essential technical tool with the interventional neuroradiologist for the treatment of vertebral painful syndromes.

In our study, 26% were male and 74% were female patients with mean age 52.65 \pm 13.1 (range 20–69 years). All patients presented with moderate to severe backache. Local tenderness was the most common complaint and was noted in 20 (40%) patients. Difficulty in walking was present in 10 (20%) patients. Sensory deficit and bladder involvement was noted in 8 (16%) and 3 (6%) patients, respectively.

Out of the 50 patient's in our study, 11 patients (22%) had vertebral hemangioma, 36 (72%) had osteoporotic/ traumatic collapse, and 3 (6%) of them had vertebral collapse due to malignant etiology (multiple myeloma).

On pre-procedure imaging, the vertebral body was involved in all of the cases, and the most common vertebrae was D12 in 11 patients (22%) followed by L1 in 10 patients (20%).

Route of vertebroplasty and correlation between amount of relief in pain on the basis of amount of cement injected and unipedicular versus bipedicular approach

Percutaneous vertebroplasty is usually done via bipedicular approach for better lesion filling. But unipedicular approach has several advantages. It is less time consuming, associated with less complication. However, it is slightly more difficult to use the unipedicular approach than the bipedicular in the thoracic spine, given the relatively small size of pedicles in the thoracic region [8].

Kim et al. described a modified unipedicular approach in which more lateral angulation of the needle was suggested. They compared the technique with a bipedicular approach. Lesions filling across the midline were achieved in 96% of cases with mean filling of 77% in both vertebral halves. There was no statistically significant difference in clinical outcome from that of bipedicular route. The author considers this lateral approach to be considerably safe with little risk of neural injury [8].

Table 3 Technical	complications
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Technical Complications	Number of patients	Percentage						
Paravertebral venous filling	2	4%						
Disc space filling	9	18%						
Epidural extension	1	2%						
Pulmonary embolism	1	2 %						

We performed all the 50 procedures via transpedicular route and lateral approach. We did 6 (12%) procedures via bipedicular approach and 44 procedures (88%) via unipedicular approach. Bipedicular injection was used when satisfactory filling was not achieved after first injection. By our study, we found statistically significant difference in the amount of cement injected in unipedicular versus bipedicular procedures with more amount of cement injected in bipedicular approach.

The amount of pain relief from bipedicular approach as compared to unipedicular approach and also the amount of cement injected were found to be insignificant (p = 0.4) in relief of pain.

Complications

The major risk of vertebroplasty is related to the possibility of cement leak in the prevertebral and paravertebral venous plexus with risk of spinal cord compression or pulmonary embolism [9].The rate of thromboembolic complications has been reduced considerably by the increased operator skills and the use of denser cements, and it is now the complication rates are around 0.5–1% [10].

Many studies have found that cement leakage into the intervertebral disc space and paravertebral soft tissues were frequent and almost always asymptomatic [5, 11, 12].

We also had nine patients (18%) with extension of cement into the IV disc space but were asymptomatic with no long-term complications.

In one study, cement leakage into the disc was found in 5 (25%) of 20 patients, with none of them having any complications [13]. Similarly, in other series, slight PMMA leak into the disc space, epidural fat, and paravertebral veins were observed in 20 (38%) of 52 vertebroplasties; the leaks were symptomatic in only 5 vertebroplasties [14]. These authors suggest that slight PMMA leaks, when not symptomatic, should not be considered as complications; moreover, there is no direct

Table 4 Post procedural clinical pain relief

Clinical status	Immediate Patient (percentage)	7th day Patient (percentage)	3 months Patient (percentage)
Asymptomatic	0 (0%)	3 (6%)	16 (32%)
Improved	8 (16%)	14 (28%)	30 (60%)
Static	42 (84%)	33 (66%)	4 (8%)
Deteriorated	0 (0%)	0 (0%)	0 (0%)

Prevertebroplasty			Post vertebroplasty follow up after 7 days			Post vertebroplasty follow up after 3 months		
	Mean	Standard deviation (SD)	Mean	SD	P value	Mean	SD	P value
Pain score	7.3	1.2	5.7	1.1	0.06	2.4	1	0.004
Activity score	1.6	1.1	1.2	0.4	0.11	0.6	0.09	0.003
Medication score	1	0.2	0.7	0.1	0.15	0.3	0.06	0.004

Table 5 Pain score, activity score and medication score after 7 days and 3 months post procedure

relationship between the rate of PMMA leakage and the severity of vertebral body compression.

In one study, it was recommended that placement of the needle in the central part of the vertebra decreases the risk of cement leakage thus preventing complications [15].

In another study, different factors were evaluated which can keep the low rate of cement leakage like usage of PMMA, which polymerizes rapidly, and can reduce extravasation. Liquid consistency of PMMA increases extravasation. Insufficient polymerization has been implicated as a major risk factor for pulmonary embolization, which, in some series, had been fatal [16].

The second important factor is the volume of cement injection. Few authors have correlated complications with excessive PMMA injection, whereas others found no correlation [17].

In our study, we do not found any correlation between the volume of cement injected and the incidence of complications but certainly liquid consistency of cement led to more leakage than less liquid cement injection; moreover, when there is leakage it is better to wait for some time before injecting again which leads to solidification and less further leakage.

Kyung et al. however stated more incidence of epidural leak when a larger volume of cement is injected in osteoporotic fractures [18]. A transient decrease in blood pressure is generally observed during the injection which has been attributed to vasodilatation which is supposed to be the consequence of methylmethacrylate toxicity [19].

In our study, technical complications were seen in 26% of cases, in the form of an extravasation of cement into the paravertebral venous plexus in two patients (4%). Epidural leak and venous extension of contrast in to the IVC tributaries was seen in one patient each (2%) and intervertebral disc space filling was observed in nine patients (18%), while one patient had asymptomatic

extension of cement mixture into the pulmonary artery branches.

Clinical complications was seen in 24% cases (2 major and 10 minor complications) out of which 2 patients (4%) had major complications like paraaesthesias, tingling and numbness in the bilateral lower limb which were relieved in a 7-day follow-up without any intervention. Ten patients (20%) had minor complications like local site swelling and tenderness for which analgesics and antibiotics were prescribed for 7 days after which the swelling and tenderness subsided.

Pain relief and activity score after vertebroplasty in various pathologies

As described in various case series and studies, pain relief is expected after a mean of 24 h after the procedure. Marked or complete pain relief was demonstrated in 90% of patients with osteoporotic compression fracture and hemangiomas and 70% of patients of vertebral metastasis and myeloma [13, 14]; however, we found no correlation between the type of vertebral pathology and the amount of relief of pain or activity (p value was insignificant > 0.05)

Pain relief and activity score after vertebroplasty immediately, at the 7-day follow-up and at 3-month follow-up

In the series of 24 patients, Boschi et al. found marked pain relief in 8 patients within 24 h. In 10 patients, the pain disappeared 5–6 days after operation and in 6 patients after 2 weeks (thoracic spine localization). Following the postoperative period of the next 4–9 years, they did not record the pain recurrence. The average extent of pain severity decreased from 8.40 preoperatively to 0.85 1 month postoperatively (p < 0.001) [20].

Table 6 Correlation between duration of pain and amount of pain relief post procedure

Pre-vertebroplasty				Post vertebr	Post vertebroplasty 7th day Post-vertebroplasty follow up			after 3 month		
Duration of pain (in months)	Mean Pain score	Mean activity score	SD	Mean pain score	Mean activity score	P value	Mean Pain score	Mean activity score	SD	P value
1-6 (20 patients)	8.1	1.2	1.8	4.82	1.1	0.041	2.5	0.8	1.3	0.002
6-12 (10 patients)	7.2	1.1	1.7	4.9	1.1	0.09	2.2	0.9	1	0.004
12-24 (12 patients)	7.7	1.02	1.3	5.65	1.04	0.14	4.1	1.2	11	0.43
>24 (8 patients)	8	1.2	1.6	6.2	1.05	0.18	6.6	1.8	1	0.64

Pre-vertebroplasty		Post-vertebroplasty follow up after 3 month			
Pathology (no of patients in bracket)	Mean Pain score	Mean activity score	Mean Pain score	Mean activity score	P value
Hemangioma (11)	8.0	1.6	4.1	0.4	0.002
Osteoporotic (36)	6.9	1.5	3.6	0.2	0.005
Metastatic/Neoplastic (3)	6	1	3	0.5	0.002

 Table 7 Vertebral pathology and amount of Pain relief

Cyteval et al. [13] found in their study that there was immediate (within 24 h) pain relief in 75% of patients treated for painful osteoporotic collapse.

In our study, we compared pre- and post-procedure scores with paired t test. Eight patients (16%) had clinical improvement in symptoms on the day of the procedure. In the rest of the patients, there was no significant improvement.

On the seventh day of follow-up, three patients (6%) had complete relief in pain and 14 patients (28%) had mild relief in pain while 33 patients (66%) had no improvement in amount of pain and activity as calculated by the scales. On statistical calculation, mean preoperative pain score was 7.3 \pm 1.2 (SD), and their mean postoperative pain scores on the seventh day of follow-up was 5.7 \pm 1.1(SD) with a p value of 0.06 which was statistically insignificant (p < 0.05 is considered as significant) suggesting that there was no significant relief in pain post-procedure on the seventh day of follow-up which was contrary to the above mentioned study which describes significant pain relief in maximum patients after 5–6 days. The p value of mean activity score and medication score were 0.11 and 0.15, respectively, which was insignificant suggesting no significant relief in activity and patient continued to take analgesics for pain relief (Table 9).

On the 3-month follow-up, 46 patients (92%) had clinical relief in pain and activity while 4 (8%) of them had no relief in symptoms. On statistical calculation, mean preoperative pain score was 7.3 \pm 1.2 (SD), and their mean postoperative pain scores on the 3-month follow-up was 2.4 \pm 1 (SD). The *p* value of pain score, activity score, and medication score came out to be 0.004, 0.003, and 0.004, respectively, which were statistically significant (*p* < 0.05 considered to be significant) suggesting that there is significant relief in clinical symptoms at 3-month follow-up.

There were no delayed complications of any sort seen in any of the patients in our study.

Correlation of significance between effectiveness of vertebroplasty in patients based on duration of pain

In our study, we studied correlation between the duration of pain patient had before the procedure and the amount of pain relief post-vertebroplasty. On seventh day and 3-month follow-up, we found that patients who had duration of pain less than 12 months had more relief in pain and significant increase in activity (signifying decreased morbidity) post-vertebroplasty (*p* value was < 0.05, significant) as compared to patient who presented with long duration pain > 12 months (*p* > 0.05, insignificant).

So, with the above findings, we came to a conclusion that with chronicity of pain, the effectiveness of vertebroplasty in reduction of pain and thus improving the quality of life decreases. Though no large studies have been done related to the effectiveness of vertebroplasty based on duration of pain to support our findings. We also observed that patients with complaints of associated radicular pain had insignificant relief in pain post-vertebroplasty (p value for mean pain score 0.5, insignificant) as compared to patients with no radiculopathy (p < 0.001).

Conclusion

Based on our study, we conclude that vertebroplasty represents a safe, cost-effective, and a very beneficial therapeutical option available for the neuroradiologist and interventional radiologist for the treatment of pain associated with vertebral fractures/collapse associated with different vertebral pathologies with high success rate. With our study, we also came to a conclusion that the accurate and correct selection of the patients is mandatory. We concluded that there was no correlation with the amount of cement injected

Table 8 Comparison between patients with or without associated radiculopathy

Pre vertebroplasty			Post-vertebroplasty follow up after 3 months				
Radiculopathy	Mean Pain score	Mean activity score	Mean Pain score	Mean activity score	P value		
Present (6 patients)	7.6	1.8	6.1	1.3	0.5		
Absent (44patients)	7.8	1.5	2.2	0.9	0.001		

Author	Followup (months)	Mean pain score pre vertebroplasty	Mean pain score post vertebroplasty	Patients with pain relief % within 24 hour	Patients with pain relief % long term
Kyung 2002 [19]	3	-	-	60	87
Grados F 2000 [21]	48	8	3.4	-	96
Cyteval C 1999 [14]	6	7.5-9.5	-	75	100
McGraw 2002 [22]	6-44	8.9	2.02	97	93
Peh WC 2002 [23]	3-24	8.3	-	-	47 (complete) 50 (partial)
Our study	3-36	7.3	2.4	16 (partial) 84(static)	32 (asymptomatic) 60 (improved) 8 (static)

Table 9 depicting Effect of percutaneous vertebroplasty on pain relief in various studies compared to our study

and pain relief. We did not find any significant difference in the amount of pain relief in bipedicular approach as compared to that in unipedicular approach, and also, we found that pain with less duration are effectively alleviated than more chronic pain. In experts, hand vertebroplasty is associated with minimal complications and is very safe procedure.

Abbreviations

ACR: American College of Radiology; CT: Computed tomography; DSA: Digital subtraction angiography; MRI: Magnetic resonance imaging; PMMA: Polymethyl methacrylate; SD: Standard deviation; VAS: Visual analog scale

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Authors' contributions

VS and RVP are responsible for the concepts and definition of the intellectual content. VS, AT, and RVP did the design and are the guarantor. AT and SNP did the literature search. VS, AT, RVP, and ZN did the data acquisition. VS, RVP, ZN, and SNP did the data analysis. SNP provided the statistical analysis. VS, AT, and ZN prepared the manuscript. VS and ZN edited the manuscript. VS and SNP reviewed the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

This was a prospective study, and patients were followed up in an outpatient department and on telephonic conversation.

Ethics approval and consent to participate

This project was approved by the institutional ethical committee, and all patients gave written consent to participate in this study.

Consent for publication

The data acquired from the patients were taken during the study.

Competing interests

The authors declare that they have no competing interest.

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