# Updates in Management of Vertebral Compression Fractures by Percutaneous Vertebroplasty and Kyphoplasty

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**Abstract: Background:** Percutaneous vertebroplasty and kyphoplasty are an emerging interventional technique in which surgical Polymethylmethacrylate (PMMA) is injected via a large bore needle into a vertebral body under imaging guidance. This techniques provides increased strength and pain relief for patients with vertebral compression fractures. **Objective:** To evaluate the technique & the early results of percutaneous vertebroplasty or kyphoplasty in the management of vertebral osteoporotic and traumatic vertebral compression fractures. **Materials and methods:** The technique was used between January 2015 till March 2017 in 20 patients (14 females and 6 males) patients with 24 painful vertebral fractures. The etiology was osteoporotic vertebral collapse in 16 cases, 4 cases with traumatic vertebral collapse. Age ranges from 36 to 83 years (average 59.5 years). The vertebrae augmented with PMMA were between D6 and L3. 8 (33.3%) were dorsal and 16 were lumbar (66.6%). On a 10-point scale, in osteoporotic patients, the mean visual analogue scale preoperative was 8, decreasing to 1.51. In traumatic group of patients experienced symptomatic complications (none major or life threatening). **Conclusion:** Percutaneous vertebroplasty or kyphoplasty are effective methods in the management of vertebral osteoporotic and traumatic vertebral osteoporotic and traumatic vertebral osteoporotic and traumatic vertebral osteoporotic and traumatic vertebral osteoporotic patients, the mean visual analogue scale preoperative was 8, decreasing to 2.7 after the procedure. Two patients experienced symptomatic complications (none major or life threatening). **Conclusion:** Percutaneous vertebroplasty or kyphoplasty are effective methods in the management of vertebral osteoporotic and traumatic vertebral compression fractures.

[Mohamed H. Abou Shahba; Mostafa A. Rabie; Mohamed S. Ali and Mahmoud E. Eladl. Updates in Management of Vertebral Compression Fractures by Percutaneous Vertebroplasty and Kyphoplasty. *Researcher* 2017;9(6):94-102]. ISSN 1553-9865 (print); ISSN 2163-8950 (online). <u>http://www.sciencepub.net/researcher</u>. 14. doi:<u>10.7537/marsrsj090617.14</u>.

Keywords: Vertebroplasty, Kyphoplasty, vertebral compression fractures

## 1. Introduction

Vertebral compression fractures (VCF) are an important source of acute back pain, chronic back pain and spinal deformity. Most frequently, those fractures are caused by osteoporosis. (Resnick DK, Garfin SR. et al, 2005).

Vertebral compression fractures (VCFs) occur more frequently on women and increase by increasing age. VCFs most commonly occur T8-L4, anterior or lateral flexion causes failure of Anterior column only. (Old et al, 2004).

The complaints from VCF, mainly driven by pain, can often be managed by conservative (i.e. noninvasive) treatment such as bed rest, pain medication, osteoporosis medication and physical therapy, walking aids or external bracing. Further this will be called 'optimal pain management' (OPM) or non-surgical management. An additional specific radiotherapy or chemotherapy can be indicated. (Wilson et al, 2011).

Open surgical decompression and fusion may be considered in a minority of patients (<2%) who present with VCF-associated neurological deficit. (Chandra et al, 2013).

## Objective

To evaluate the technique & the early results of patients who underwent percutaneous polymethylmethacrylate (PMMA) vertebroplasty or kyphoplasty in the management of one or more vertebral osteoporotic and traumatic vertebral compression fractures.

## 2. Materials and methods

The work in this thesis is a prospective study that was done in Al-Azhar university hospital, New Damietta, Egypt starting January 2015 till March 2017. All patients were subjected on admission to:

**A.** Clinical assessment: by 1. History for Evaluation of Pain by Visual Analogue scale and Basic Activities of Daily Livings (ADLs), then 2. Clinical Examination via General examination, Local examination and Neurological examination (motor, sensory & reflexes).

**B. Radiological assessment:** by ◆ Standard antero-posterior and lateral plain radiographs. ◆ Computerized Tomography (CT) scan. ◆ Magnetic resonance imaging (MRI).

**C. Laboratory investigations:** • Complete blood picture. • Bleeding and coagulation time. • Prothrombin time and activity.

# II. Methods of treatment:

Patient selection criteria:-

Patients with vertebral lesions resulting from osteoporotic compression fracture and traumatic

compression fracture were selected for this study if the following criteria have been met:

• Pain is severe and debilitating, and cannot be relieved by medical therapy.

# Patient exclusion criteria:-

• Osteoporotic vertebral fracture that is completely healed or is clearly responding to conservative management.

• Presence of untreated coagulopathy.

• Presence of discitis/osteomyelitis or sepsis (active infection).

• Significant compromise of the spinal canal by retro pulsed bone fragment or tumors invading the epidural space.

• All patients suffering from Neurological manifestations.

• Unstable fracture involving the posterior elements.

• Absence of a defined level of collapse.

• All patients were followed-up for an average period of 6months month (range 3-10 months) postoperatively. Follow-up was done according to a predetermined time schedule, which was followed as long as no complications occurred that necessitated shorter follow up intervals.

# C) Post operative Care:

Immediate postoperative care:

• spinal support brace postoperatively for 1 to 3 days with early ambulation the 2nd day of the procedure.

• Discharge at the second day of the procedure from the hospital.

Before discharge:

• Check X-ray was done before discharge.

• Neurological examination and VAS were recorded.

**Post operative assessment:** Both Neurological examination and VAS were recorded.

## Technique:

The patient is placed prone on the fluoroscopy table with the arms above the shoulders. Adequate padding is placed under pressure points. The patient's vital signs, such as blood pressure, heart rate, and pulse oximetry, are monitored continuously. The entire procedure should be performed under strict aseptic conditions. A prophylactic broad-spectrum antibiotic is usually administered intravenously at the start of the procedure. We use a combination of local anesthetic with intravenous conscious sedation or full general anesthetic.

The transpedicular approach is used either unipedicular or bipedicular and either with direct injection of the Polymethylmethacrylate (PMMA) into the fractured vertebrae (vertebroplasty) or indirect into balloon (kyphoplasty), The needle traverses only skin, soft tissues, and bone to enter the vertebral body.

#### 3. Results

# 1. Aetiological distribution:

Table 1: Aetiological distribution

Etiology	no of cases	%
Osteoporotic	16	80
Traumatic	4	20

#### 2. Age distribution:

Age ranges from 36 to 83 years (average 59.5 years). Out of the osteoporotic group, one had steroid induced vertebral collapse. His age was relatively younger (41 years) than the other patients with osteoporotic collapse.

3. Gender distribution:

Gender	no of cases	%
Male	6	30
Female	14	70

# 4. Number of vertebral levels affected in each patient:

Table 3: Number of vertebral levels affected in each patient

no of vertebral levels affected	no of cases	%
Single level	16	80
Double level	4	20

#### 5. Spinal region distribution:

Table 4: Augmented vertebrae distribution

Spinal region	no of cases	%
Lumbar	16	66.6
Dorsal	8	33.3

#### 6. Pre-operative relative vertebral height:

It ranged from 35% to 80% and the mean was 68.5%.

7. Pre-operative wedge angle:

It ranged from  $0^{\circ}$  to  $30.86^{\circ}$  and the mean was  $10.418^{\circ}$ .

#### 8. Associated medical conditions:

Table 5: Associated medical conditions

Medical disease	Number of cases	Percentage
Bronchial asthma	1	5%
Cardiac	2	10%
Hypertensive	4	20%
Diabetic & Hypertensive	2	10%
Hyperthyroidism	1	5%
Hepatic	1	5%
Free	9	45%

#### 9. Duration before intervention:

It ranged from 2 weeks to 32 weeks with a mean of 8.5 weeks.

## 10. Operative Time:

The mean operative duration in this study was 57.5 minutes, with a minimum of 25 minutes and a maximum of 90 minutes.

• The average time for a single level was 28 min.

• The average time for a double level was 38 min.

Negligible blood loss.

No significant difference between the duration of vertebroplasty and kyphoplasty.

#### 11. Portal:

Table 6: Portal of the procedure

Portal	no of vertebrae	%
Unilateral	22	92
Bilateral	2	8

12. Amount Of Cement injected:	

Table 7: Amount of cement injected

level	Amount	average
Dorsal	2-5 ml	3.5 ml
Dorsolumbar	2.5-8.5 ml	5.5 ml
lumbar	2.5-9 ml	5.6 ml

#### 13. Post-operative data analysis Assessment using the Visual Analogue Scales VAS of osteoporotic patients:

Table 8: VAS of	osteoporotic	patients
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	VAS	Immediate	1m	3m	6m
Mean	7.66	1.51	1.24	1	1.16
14 Complications					

14. Complications:

A) Operative complications:

#### Cement leakage

Table 9: Leakage analysis in vertebroplasty patients

Leakage	no of cases (10 total)	%
Non	6	60
occurrence	4	40

Table 10: Leakage analysis in kyphoplasty patients. Cement may leak into a large variety of anatomical compartments, four sites were reported in our study including:-

Leakage	no of cases (10 total)	%
Non	9	90
occurrence	1	10

Intervertebral disc.

•Venous cement leakage: -Paravertebral veins. -Epidural veins.

• Paravertebral soft tissue.

Table 11: Sites of leakage in osteoporotic patients

Type of Leakage	no of cases (16 total)	%
Diskal	6	33.7
Venous paravertebral	4	25
Soft tissue paravertebral	3	18.7
Needle track	2	12.5
Venous epidural	1	6.1

In trauma patients (4 cases ) leakage occurred in 2 cases which were treated by percutaneous vertebroplasty probably due to less anatomical barriers, however our traumatic group of patients were small number only 4 cases (20 % of patients included in our study).

B) Postoperative complications:

#### **Early complications:**

• Two patients developed post operative nerve root symptoms (L3, L4

radiculopathy) caused by cement leakage. In one case the symptoms disappeared overnight after treatment with intravenous steroids. The second case resolved after 2 months.

• One patient complained postoperatively intercostals neuralgia treated by local steroid injection.

#### Late complications: ( adjacent level fractures)

Four patients developed adjacent level fractures 1 M, 6 M, 8 M, and 9 M post operative. The patients are complaining of back pain with no radicular symptoms.

All of them were treated by PV. Clinical outcome was assessed by evaluating severity of pain, using a visual analog scale (average VAS 7.6) and ability to perform ADL (average 1) before and after the procedure (average VAS 1.5 & ADL 5).

#### Patient satisfaction:

(1) Very satisfied: - 10 patients (50 %).

(2) Satisfied: - 6 patients (30 %).

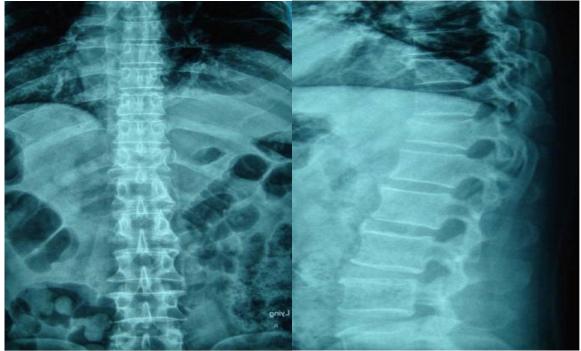
- (3) Acceptable: 3 patients (15%).
- (4) **Dissatisfied**: one (5 %).

#### Case study

- Male patient, 77 years old, has fallen down on the bathroom floor 10 days ago.

- Osteoporotic fracture T 11, Preop VAS: 9 & ADL: 1.

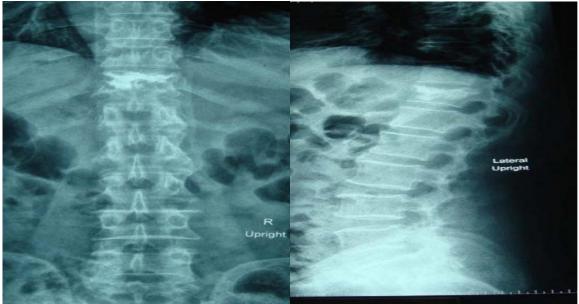
<sup>•</sup> Needle track.



Plain x-ray Lower dorsal and lumbo-sacral showing vertebral compression fracture at D11



MRI Lower dorsal and lumbo-sacral showing Bone marrow edema at D11



Post-operative plain x-ray showing cement injection

- 4cc cement was injected.
- Postop VAS: 1 & ADL 5.

- No leakage.

- No clinical complications.

## 4. Discussion

#### **Epidemiologic data:**

The study included 20 patient (14 females and 6 males) diagnosed as osteoporotic vertebral collapse in 16 cases and 4 cases with traumatic vertebral collapse, with age ranges from 36 to 83 years (average 59.5 years). Out of the osteoporotic group, one had steroid induced vertebral collapse. His age was relatively younger (41 years) than the other patients with osteoporotic collapse. Our osteoporotic patients relatively have younger age (mean age 59 years) than other studies as reported by **Anand et al** (mean age 73.8), **Juerg et al** (mean age 70.4) and **Eric et al** (mean age 72). This is may be influenced by many hormonal, hereditary, medical, and lifestyle factors.

Also the females (16 cases) are more affected than males (4 cases) forming a ratio of 4:1. This is a matching gender distribution to other studies as **Anand et al 2006**, **Juerg et al 2003** and **Eric et a 2002**.

#### Intervention timing:

Although the subjective failure of conservative therapy generally is used as an indication for the procedure, the time from fracture to the procedure ranges from 2 weeks to at least several months. The duration of conservative therapy varies among studies (Timothy et al, 2001).

We performed percutaneous vertebroplasty in 4 patients with 4 acute osteoporotic vertebral collapses within 9 days of onset of severe incapacitating pain. procedure was fast and produced no The complications. All patients showed immediate objective improvement (graded by visual analog scale, mean preop 8, mean postop 1.5), ability to perform different component of ADLs were improved from 1 to 5 (average) and no vertebral collapse of an adjacent vertebra was seen at the 6-month follow-up. Treatment of acute osteoporotic vertebral fractures with percutaneous vertebroplasty or kyphoplasty appears to be safe and results in substantial immediate pain reduction and improved functional status (graded by visual analog scale, mean preop 8, mean postop 1.5) & improvement in ability to perform ADLs, avoiding complications of prolonged immobilization, the potential adverse effect of strong analgesics such as opiates to which elderly people are particularly suspected. Also NSAIDs have significant toxicity. Our results suggest that percutaneous vertebroplasty or kyphoplasty in osteoporotic VCF is highly efficacious for pain relief and improvement of patient mobility across a wide range of fracture ages, as measured with the duration of symptoms referable to a VCF (range

from 9 days to 90 days). In our study, fracture age was determined by patient verbal history. Although many patients could precisely recall the day the fracture occurred, all our osteoporotic patients with evidence of marrow edema on MRI had elimination or improvement of pain (average preop VAS 7.66, postop 1.5).

Treatment of long-standing fractures remains controversial but pain relief has been reported by **Daniel et al 2003** and **Timothy et al 2001**, after 24 months. Symptom relief after vertebroplasty or kyphoplasty was not dependent on fracture age but complete relief of pain is more likely when less mature fractures are treated as reported by **Daniel et al, 2003**.

## Level of the collapse:

The thoraco-lumbar area is the more susceptible to osteoporotic and traumatic compression fractures. This is based on biomechanical factors as described by **Keller et al, 2003. Raj et al 2003** and **Peh et al 2002** as well as others showed that osteoporotic vertebral fractures commonly occur in the thoracolumbar region, but they may be present anywhere in the spine. Osteoporotic fractures in the upper thoracic spine may be indicative of an underlying malignant tumor, and a thorough search for a possible primary lesion should always be carried out. We always perform percutaneous vertebral biopsy prior to the procedure for osteoporotic fractures above T9 and the result of the biopsy was negative for tumor.

In our study, from 20 osteoporotic vertebral collapse, 5 at L1 (25%) 4 at L2 (20%), 3 at T12 (15%), 2 at T11 (10%), 1 at L4 (5%), 2 at T9 (10%), 1 at L3 (5%) and 2 at T10(10%). The thoracolumbar area is the most affected. This is similar to what is reported by **Peh et al 2002**, and **Raj et al 2003**.

## **Image Evaluation**

In our study MRI was used to identify compression fractures that might be amenable to vertebroplasty or kyphoplasty treatment, given the efficacy of this procedure.

All our osteoporotic patients must have positive STIR (marrow edema) to be scheduled for the procedure. We report good pain relief in our patients as measured by VAS (average preop 7.66, postop 1.5).

Many authors as **Anand et al 2006**, **Daniel et al 2005** and **David et al** consider that MR imaging or scintigraphy are essential for detecting all vertebral collapses and for allowing treatment of multiple recent lesions in the same procedure.

In our practice, all patients were able to undergo MR imaging. The edema in a fractured vertebra is mandatory to select this level for percutaneous vertebroplasty or kyphoplasty. All patients routinely undergo AP and lateral radiography immediately following cement injection. With conventional radiography alone, exact determination of cement location within the vertebra is difficult. CT allows accurate evaluation of cement leakage.

The standard A-P & lateral views radiographs obtained following vertebroplasty or kyphoplasty were reviewed. The following types of PMMA leakage were determined for all the procedures: intradiskal, venous epidural, venous paravertebral, soft tissue leakage, and leakage along needle track. There was a choice of leakage present or not. However, the AP view allows accurate determination of the width of cement in both halves of the vertebra. Thus, we focused on the AP follow-up radiographs to quantify the extent of cement deposition. We viewed the AP radiographs to determine whether cement was present in both vertebral halves.

With unipedicular approaches, where cement was present in both halves of the vertebra, the cement was considered to have crossed the midline. Cement deposition was achieved in all vertebrae. With the unipedicular approach (22 vertebrae), cement crossed beyond the midline to the contralateral vertebral half in 15 (78.5 %). Better filling of both vertebral half was achieved with the bipedicular approach (The 2 vertebrae achieved in our study). But in our study, bipediculate approach was used in small subset (8 %) of treated vertebral levels. We didn't find difference in clinical outcome (measured by VAS & ADLs) between cases with cement crossing to contralateral half of the vertebral bodyand cases where cement is deposited in one half only of the vertebral body vertebrae). Also we didn't notice increased chance of collapse of the unfilled part of the vertebra.

# Technique:

The guidance method is a controversial point concerning the vertebroplasty or kyphoplasty procedures. One group of authors as **Barr et al 2000** has emphasized the use of CT to facilitate accurate needle placement particularly in the thoracic spine. The potential disadvantage of CT guidance alone is the lack of real-time visualization of cement leaks. According to **Barr et al**, this drawback may be avoided by smaller and more closely monitored injections.

Ideally, according to **Barr et al 2000 & Gangi et al 2003** the safest procedure would involve a combination of CT and fluoroscopic guidance. Only prospective randomized studies could compare guidance methods in terms of safety, duration of the procedure, and cost.

Another group as **David et al 2003, Jensen et al 1997** and others recommends the use of venograms to

prevent early cement leaks in the vena cava or in the perivertebral veins or both.

We and other groups of authors as **Cotton et al 1998**, recommend that fluoroscopic guidance with the transpedicular approach is safe, even without using venograms. The single-side technique has the advantage of being easy and fast. Needle progression and cement injection are best assessed with radiographic procedures that allow both anteroposterior and lateral fluoroscopic guidance without moving the patient. General anesthesia or IV sedation is needed because pain may intensify during cement injection.

# Portal

In our procedure experience, we have never used parapedicular route, all our injections are done using transpedicular route. Use of the transpedicular route avoids spinal segmental nerve injury and decreases the risk of leakage of methyl methacrylate into the paravertebral tissue.

Use of a unilateral approach allows filling of both vertebral halves from a single puncture site with no statistically significant difference in clinical outcome from that of bipediculate vertebroplasty this is as reported by **Ann et al, 2002**.

In our study: unilateral injections were performed in 92 % of vertebral bodies (22 verebrae), and bilateral injections were performed in 8 % (4vertebrae). However, because mostly in our study we used single approach, it is difficult to compare single and double approaches (only 6 vetebral bodies). The double approach should be better for filling of the vertebrae, but single approach allow placement of the needle tip within the contralateral vertebral half and facilitated filling of both vertebral halves with a single injection.

More important than the radiographic outcome was the clinical outcome, in which we found no statistically significant difference between, filling across the midline and partial vertebral filling in term of pain relive as measured with VAS.

Advantages of our unipediculate approach include the following. First, it would appear that less time would be needed for the unipediculate (one needle insertion) versus the bipediculate (two needle insertions) approach. Second, the unipediculate approach is less complex than the bipediculate approach; only one injection is needed instead of two, and the second injection in the bipediculate approach is frequently hampered by indwelling bariumopacification. Third, the risk of complications, such as pedicle fracture, dural injury, and nerve injury, is reduced if fewer needles are introduced. The choice of needle route depends on the experience of the practitioner.

## Amount of cement:

In our patients, the average amount of cement injected in patients with osteoporosis and trauma was 5 mL. Our results support the question that the amount of PMMA filling is not an important outcome factor because good pain relief were obtained with 2-3 mL of cement as measured with VAS.

There are many interesting points about the appropriate endpoint of the procedure.

What are the goals of percutaneous vertebroplasty or kyphoplasty? Most practitioners would agree that the primary goal of vertebroplasty is to reduce or alleviate the acute symptoms associated with painful osteoporotic vertebral compression fractures.

How much cement is enough to alleviate the pain associated with acute and subacute compression fractures?

In vitro studies have suggested that injection of as little as 2 mL ofcement results in the restoration of vertebral body strength as shown by **Belkoff et al 2000**.

## PMMA leakages

PMMA leakage is a very frequent occurrence in vertebroplasty and is also the main source of complications.

In osteoporotic group of patient, leakage occurred in 43 %, the most frequent type of leakage was diskal leakage followed by venous leakage. We observed a moderate incidence of leakage in our osteoporotic patients compared to other studies. It has been reported to occur in 30% Jensen et al 1997, 59.5% Gaughen et al and 65% Cortet et al 1999 of patients with osteoporotic VC. Fortunately, it is well tolerated in the large majority of patients. In our series no clinical symptoms were related to leakages. In the series of Heini et al, no clinical symptoms were related to leakages. Many authors as Juerg et al 2003, Heini et al 2000, and others documented that small to moderate amounts of PMMA may escape from the vertebral body with no significant effect on therapeutic success. Not all PMMA leakages are clinically relevant. The leakage rate must be compared only in studies that use fluoroscopy to perform the procedure and to visualize eventual leaks.

In our study the various types of PMMA leakages did not impair outcome. In addition, we used conventional radiography for follow-up in our study; CT is more sensitive in the detection of leakages than is conventional radiography.

## Conclusion

Vertebroplasty and kyphoplasty for the treatment of osteoporotic and traumatic vertebral collapse is a minimally invasive procedure that provides immediate pain relief and enables the patient to become quickly mobile.

Vertebroplasty and kyphoplasty appear to be safe and results in substantial immediate pain reduction and improved functional status (avoiding complications of prolonged immobilization, the potential adverse effect of strong analgesics such as opiates to which elderly people are particularly suspected. Also NSAIDS have significant toxicity).

Most practitioners would agree that the primary goal of vertebroplasty or kyphoplasty is to reduce or alleviate the acute symptoms associated with painful osteoporotic and traumatic vertebral compression fractures.

Many studies have failed to show any positive correlation between cement volume and pain relief (Sinha et al, 2002).

Potential leakage of PMMA during injection is a concern of everyone performing vertebroplasty or kyphoplasty; however, small amounts of leakage recognized early that do not pass into the spinal canal or impinge on exiting nerves are well tolerated.

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6/18/2017