

Conservative Treatment versus Percutaneous Vertebroplasty for Osteoporotic Stable Dorsolumbar Vertebral Fracture

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ABSTRACT

Introduction: Osteoporosis is rapidly becoming a significant healthcare burden in a population aged over 69 years. Dorsolumbar osteoporotic compression fractures are common between these patients. Percutaneous vertebroplasty (PVP) is considered a minimally invasive method to relieve the pain secondary to vertebral fracture.

Aim of study: This study aimed to compare the role of conservative treatment to percutaneous vertebroplasty that is used to treat stable dorsolumbar vertebral fractures in osteoporotic patients.

Patients and methods: This prospective cohort study was carried out in the Department of Neurosurgery, School of Medicine, Zagazig University Hospitals at Gamal Abdelnaser Insurance Hospital in Alexandria. The study included thirty-six patients with osteoporosis. 18 people have received treatment for their spinal compression fractures by conservative management and eighteen patients have been treated by percutaneous vertebroplasty.

Results: The most common level of fracture was thoraco-lumbar junction (61% in both groups). Single fractures were more common than double fractures in both groups. Patients in PVP had significantly improved clinical outcomes of VAS of the back and leg and ODI scores at 6 months follow-up compared to those at the conservative group. There was marked improvement in ODI and VAS score immediate post-operative and six-month follow-up in PVP group with a high statistically significant difference. **Conclusion:** Percutaneous compared to conservative treatment, vertebroplasty can offer better clinical and radiological results for individuals with osteoporotic vertebral fractures.

Keywords: Osteoporosis, Percutaneous vertebroplasty.

INTRODUCTION

Osteoporosis is described as skeletal fragility caused by low bone mass, degradation of the bone's microarchitecture, or both in the absence of a mineralization deficiency⁽¹⁾. Before to menopause, it is uncommon in females, with post-menopausal women having the highest prevalence. Osteoporotic vertebral compression fractures (OVCFs) are considered serious 200 million people worldwide suffer from this health issue^(2, 3). Furthermore, the majority of osteoporotic fractures are happening in roughly 20% of individuals older than 70 years^(3,4).

One vertebral fracture quadruples the likelihood of a subsequent fracture, while a second fracture increases the risk of subsequent fractures by 12 times^(5, 6). Fifty percent of post-menopausal women have a fracture caused by osteoporosis at some point in their lives. Men's risk of osteoporotic fractures is lower but still significant and peaks 10 years later than that of women^(7, 8). Osteoporotic vertebral compression is happening in 20% of adults over the age of 70 and 16% of postmenopausal women experience fractures. The purpose of this study was to compare the role of conservative treatment to percutaneous vertebroplasty in management of osteoporotic stable dorsolumbar vertebral fractures.

PATIENTS AND METHODS

The study was carried out at Department of Neurosurgery, Faculty of Medicine, Zagazig University Hospitals and

Neurosurgery Department at Gamal Abdelnaser Insurance Hospital in Alexandria. The study included thirty-six patients who were divided into two groups: Group A included 18 cases for medical treatment and group B contained 18 cases for percutaneous vertebroplasty.

Inclusion criteria:

Stable vertebral fracture. Patients fulfill the criteria for osteoporosis in at least one segment of dorsal and lumbar spine (by dexa scan).

Exclusion criteria:

Unstable vertebral fracture. Neurologic deficits (motor, sensory or sphincteric). Vertebral fracture due to any cause other than osteoporosis. Acute traumatic fracture of non-osteoporotic vertebrae. Bad general condition.

Each patient had a complete clinical examination and history taking. Each subject had a laboratory investigation (e.g. CBC, PT, PTT, INR, LFT, KFT and viral markers). The patient shouldn't be using coumadin, and the results of the coagulation test should be normal.

Preoperative preparation:

Radiological assessment X-ray with AP and lateral views: for detection of level of vertebral fractures and assessment of vertebral height and osteoporosis. CT scan

for dorso-lumbar spine with sagittal reconstruction & 3DCT for better visualization of bony compartment of spine, detection of type, shape and site of wedging fractures and detection of different columns of fractured spine.

MRI for dorso-lumbar spine for detection of soft tissue injuries and spinal cord compromise. DEXA scan for measurement of bone mineral density (BMD). Vertebroplasty (VP) trans-pedicular injection of polymethyl-methacrylate (PMMA) cement into compressed bone for patients with osteoporotic vertebral fracture.

Operative procedure:

Trans-pedicular injection of PMMA cement into compressed bone for patients with osteoporotic vertebral fractures. Hypotensive all of our patients received general anaesthesia to help with intraoperative hemostasis and lessen blood loss.

It is necessary to thoroughly infiltrate the epidermis, subcutaneous tissues along the anticipated needle track, and the periosteum of the bone at the entry site. Using fluoroscopy or C-arm, the needle is introduced into the appropriate mediolateral and cranial-caudal angulation of the pedicle to enter the vertebral body and insert its tip around halfway through the vertebral body. The insertion site on the skin is 3 to 7 cm from the midline with angle range from 30 to 45 degree mediolaterally in lumbar region, while decrease in thoracic region from 10 to 20 degree. Only after every needle has been inserted is cement made.

PMMA is mixed homogeneously to minimize the number of pores and is left for 5 to 10 minutes till achieving suitable viscosity for injection. Afterwards, it is administered using tiny syringes (usually 1cc) or injection-specific tools.

The injection should be stopped if there is any cement leakage outside the vertebral body. After the injection devices are no longer able to deliver cement, cement can still be added. The trocar is helpful in inserting more thick cement into the spine from the cannula. After the cement has become too hard to inject, the cannula can be safely removed without reintroducing the trocar. PMMA injection volume and pain alleviation are unrelated.

Postoperative care and Follow-up:

2 weeks after surgery; a routine visit for all cases

3 months after surgery for assessment visual analogue scale and Oswestry Disability Index

6 months after surgery: follow up was done for patients in the form of clinical and radiological assessment

Outcome measures:

Data on pain, assessed by means of the visual analogue scale, and function, assessed using Oswestry Disability Index, were collected at baseline (Time zero), the three-, six-, and twelve-month marks. After six weeks, just the level of discomfort in the conservative therapy group's patients was assessed. Patients were included in the trial only if their pain intensity remained at or above 50 mm on the VAS, those who had a drop in pain intensity were not.

Ethics approval:

The protocol for this study was approved by both the Institutional Review Board [IRB] and The Local Ethics Committee at Zagazig University's Faculty of Medicine. Consents were taken from all cases included in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical Analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Number and percentage were used to describe qualitative data. The normality of the distribution was examined using the Kolmogorov-Smirnov test. The range (minimum and maximum), mean, standard deviation, median, and interquartile range were used to characterize quantitative data (IQR). At the 5% level, significance of the results was determined.

RESULTS

Table (1) showed that females were more predominant than males. Also, it appeared that the mean age was 66 years for conservative group and 61 years for the operative group.

Table (1): Comparison between the two studied groups according to demographic data

Demographic data	Group A (n = 18)		Group B (n = 18)		Test of sig.	p
	No.	%	No.	%		
Sex						
Males	7	38.9	5	27.8	c ² = 0.500	0.480
Females	11	61.1	13	72.2		
Residence						
Urban	10	55.6	9	50.0	c ² = 0.111	0.738
Rural	8	44.4	9	50.0		
Age (years)						
Mean ± SD.	66.72 ± 4.66		61.67 ± 8.03		t=2.310*	0.029*
Smoking						
No	9	50.0	11	61.1	c ² = 0.450	0.502
Yes	9	50.0	7	38.9		

χ²: Chi square test , t: Student t-test p: p value for comparing between group A and B *: Statistically significant at p ≤ 0.05 Group A: Medical treatment (Conservative), Group B: Percutaneous vertebroplasty SD: Standard deviation. IQR: Inter Quartile Range

Table (2) showed that there was about 61% reduction of VAS of the back and leg after 6 months of percutaneous vertebroplasty.

Table (2): Comparison between the two studied groups according to ODI, VAS back

ODI	Group A (n = 18)	Group B (n = 18)	t	p
Pre				
Mean ± SD.	50.28 ± 4.69	66.39 ± 3.76	11.375*	<0.001*
Post 6 months				
Mean ± SD.	38.06 ± 5.72	5.56 ± 1.12	23.183*	<0.001*
Reduction				
Mean ± SD.	23.37 ± 4.99	91.65 ± 2.20	19.123*	<0.001*
% of reduction				
Mean ± SD.	23.37 ± 4.99	91.65 ± 2.20	19.123*	<0.001*
VAS back				
Pre				
Mean ± SD.	5.17 ± 1.04	6.11 ± 0.90	98.50*	0.044*
Post 6 months				
Mean ± SD.	4.67 ± 0.84	2.28 ± 0.53	98.50*	0.044*
Reduction				
Mean ± SD.	0.50 ± .07	3.83 ± 0.7	14.0*	<0.001*
% of reduction				
Mean ± SD.	16.67 ± 51.45	213.89 ± 151.60	10.0*	<0.001*

t: Student t-test p: p value for comparing between group A and B*: Statistically significant at p ≤ 0.05 Group A: Medical treatment (Conservative), Group B: Percutaneous Vertebroplasty SD: Standard deviation . IQR: Inter Quartile Range

Table (3) showed that percutaneous vertebroplasty was more effective than conservative treatment as regards VAS of the back and leg.

Table (3): Comparison between the two studied groups according to VAS leg and duration of back pain in weeks percutaneous

VAS leg	Group A (n = 18)	Group B (n = 18)	U	p
Pre				
Mean ± SD.	1.50 ± 0.31	3.11 ± 0.66	31.50*	<0.001*
Post 6 months				
Mean ± SD.	0.89 ± 0.15	0.83 ± 0.11	155.0	0.839
Reduction				
Mean ± SD.	0.61 ± 0.61	2.28 ± 0.46	25.50*	<0.001*
% of reduction				
Mean ± SD.	38.89 ± 7.42	73.61 ± 13.68	73.0*	0.004*
Duration of back pain (weeks)				
Mean ± SD.	3.56 ± 1.04	5.33 ± 2.25	94.50*	0.031*

U: Mann Whitney test p: p value for comparing between group A and B *: Statistically significant at $p \leq 0.05$
 Group A: Medical treatment (Conservative), Group B: Percutaneous Vertebroplasty SD: Standard deviation IQR: Inter Quartile Range

Single osteoporotic vertebral compression fractures were the most common compression fractures. Most of osteoporotic compression fractures were located in the dorsolumbar region. This was explained by that this is a transition zone in the vertebral column, so it is more susceptible for traumatic insults. Also, the degree of loss of vertebral height was more marked in patients indicated for vertebroplasty than for those indicated for medical treatment (Table 4).

Table (4): Comparison between the two studied groups according to number of fractured vertebrae, level of fracture, degree of loss of vertebral body height and T- score

Number of fractured vertebrae	Group A (n = 18)		Group B (n = 18)		c ²	MCp
	No.	%	No.	%		
Single	15	83.3	15	83.3	1.203	1.000
Double	3	16.7	2	11.1		
Quadrable	0	0.0	1	5.5		
Level of fracture						
Lumbar	7	38.9	7	38.9	0.000	1.000
Dorsolumbar junction	11	61.1	11	61.1		
Degree of loss of vertebral body height						
Preoperative						
Mean ± SD.	20.39 ± 3.67		62.89 ± 2.85		0.000*	<0.001*
6 months						
Mean ± SD.	25.56 ± 6.16		57.50 ± 6.70		0.000*	<0.001*
p₁	<0.001*		1.000			
T- score						
Mean ± SD.	-3.22 ± 0.16		-3.22 ± 0.12		151.0	0.743

χ²: Chi square test , MC: Monte Carlo test p: p value for comparing between group A and B
 Group A: Medical treatment (Conservative), Group B: Percutaneous vertebroplasty

Table (5) showed that the percentage of cement leak was about 11% in cases treated with percutaneous vertebroplasty. Also, the probability of incidence of neurological deficit was more common in cases treated conservatively than in cases treated via percutaneous vertebroplasty.

Table (5): Distribution of postoperative cement leak for percutaneous vertebroplasty and distribution of neurological deficit for conservative group (n= 18)

Postoperative cement leak for percutaneous vertebroplasty group	No.	%
No	16	88.9
Yes	2	11.1
Neurological deficit for conservative group	No.	%
No	10	55.6
Yes	8	44.4

DISCUSSION

In our study on 36 patients, regarding sex distribution, females were more predominant than males in both operative group (72%) and conservative group (61%). The mean age was 66 years for conservative group and 61 years for the operative group. In **Du et al.** ⁽⁹⁾ prospective cohort study that included 470 patients, with an average age of 71.0 years, of whom 352 were women (74.9%). 277 cases were included in the conservative group, with an average age of 71.5 years, of whom 205 (74.0%) were women; 193 were included in the percutaneous vertebroplasty, with an average age of 69.7 years, of whom 147 (76.2%) were women. Regarding sex, age, and other fundamental traits, the conservative group and the surgical group did not differ significantly from one another.

In our study the most common level of fracture was thoraco-lumbar junction (61.1 % each group). Solitary fractures predominated more often than double fractures in both groups. In **Yang et al.** ⁽³⁾ the fracture level was more common in thoraco-lumbar junction in both groups (82% in both groups). Single fractures were more common than double fractures in both treatment groups (83.9% in PVP group and 86.2% in conservative group). In all previous studies the most common level of fracture was the thoraco-lumbar junction because it is between the thoracic spine's (kyphosis) and the lumbar spine (lordosis), but the little change in percentage can be attributed to different sample sizes in different studies.

In our study the mean baseline visual analogue score (VAS) of the back at clinical evaluation was 6.1 in PVP group and 5.1 in conservative group and the mean Oswestry disability index (ODI) was 66% in operative group and 50% in conservative group. The mean duration of back pain was 3.5 weeks in conservative group and 6 weeks in PVP group. All patients included in our study were neurologically intact. In **Yang et al.** ⁽³⁾, the mean initial VAS score was 7.5 in PVP group and 7.5 in conservative group with no statistically significant difference. Mean ODI was 80% in PVP group and 81% in

conservative group with statistically insignificant difference.

In our results, preliminary radiological evaluation, T-score was lower than (-2.5 SD) and the mean in both groups was -3.2. The degree of vertebral body height loss showed a statistically significant difference between operative group and conservative group (the mean was 62 % in PVP group vs. 20.50 % in conservative group). These results agree with **Klazen et al.** ⁽¹⁰⁾ who stated that T-score was -3.0 in both conservative and PVP groups, and the degree of vertebral body height loss was more severe in PVP than conservative groups. Also, **Du et al.** ⁽⁹⁾ found that T-score was -3.0 in PVP group and -2.8 in conservative group.

All patients included in our study showed no spinal cord compression. In PVP group there was marked improvement in VAS score and ODI comparing baseline, immediate post-operative and six month follow-up with a very high statistically significant difference (p<0.001). Percentages of reduction in VAS and ODI in 6 months post-vertebroplasty were 61% and 92.5% respectively, compared to 21% and 16% reduction in VAS and ODI in 6 months post-conservative treatment respectively. Also in a study by **Patil et al.** ⁽¹¹⁾, overall, the clinical result had significantly improved [baseline mean VAS = 7.5 and mean ODI = 64.6 % to a mean VAS = 3 and mean ODI = 30.8 % at last follow-up (p= 0.001)].

Six months post-conservative treatment, we assumed that the degree of vertebral loss of height was 25% compared to 20% at the onset of symptoms, while in the PVP group the degree of vertebral loss of height was almost the same as that of the onset of symptoms. These variations in values explain the role of vertebroplasty in preserving the vertebral height via augmenting the body with the cement material.

In our study we assumed that 2 out of 18 cases have suffered intraoperative cement leak (11%), one at the canal and the other at the disc space with no significant neurological compromise. In **Mirovsky et al.** ⁽¹²⁾ individuals in all were monitored for at least two years after experiencing one cemented osteoporotic vertebral fracture between the T5 and L5 vertebrae. Cement leaking into the disc area, which was discovered in 27 patients, had no detrimental effects on how happy the patients were with the treatment. Leakage occurred in 7 of these individuals through an intravertebral vacuum cleft and in 8 of these patients by a perforation of the endplate brought on by the needle tip. Cement was discovered to cross the vertebral body's height and leak into the oblique disc in just 2 individuals.

In our study, we assumed that about 45% of patients treated conservatively had suffered from neurological deficit during the course of follow-up to six months post-conservative.

CONCLUSION

Females are more prone to osteoporotic spinal compression fractures than males especially females at postmenopausal period. Thoraco-lumbar junction (T11-L2) is the most common site of osteoporotic vertebral compression fractures. For individuals with osteoporotic vertebral fractures, percutaneous vertebroplasty can offer better clinical and radiological outcomes than conservative therapy. Vertebroplasty is generally regarded as a safe treatment, however rare but serious complications might happen. The most common type of leak is cemental.

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