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Original Article

Pain relief and associated factors in patients undergoing vertebroplasty due to osteoporotic vertebral fracture

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Abstract: Background: Osteoporotic vertebral fracture (OVF) is a common spinal fracture in the elderly population treated with conservative or surgical techniques. Patients with such fractures may experience chronic pain due to nonunion and instability, deformity with kyphosis and neurologic symptoms due to neural compression. Surgical interventions have definite roles in treatments especially when conservative therapy fails. Cement augmentation in forms of vertebroplasty and kyphoplasty or even surgical fixation with or without column reconstruction are among our armamentarium to deal with problems arising during the treatment of these patients. Methods: We entered patients with OVF who did not respond to conservative treatments for more than 4 weeks and were candidates for vertebroplasty. Pain Visual Analog Scale (PVAS) was assessed for patients before the procedure, in the first month and 6 months after surgeries. We also analyzed factors including time passed from fractures, amounts of injected cement, age, sex, types of fractures, segmental kyphosis and sites of fractures. Data were collected and analyzed using SPSS software version 24. Results: A total number of 140 patients entered. The mean age of the patients was 64.90±7.97 years. Mean preoperative pain level was 8.35±0.97 points on VAS (0-10) score. The mean Post-operative VAS score after one month and after six months were 4.65±0.66 and 5.28±0.75 respectively. The mean consumed cement volume was 5.77±1.40 ml. Cement volume of more than 5 ml was injected for 53.6% of patients. 78.7% of fractures were located in T10-L2 levels (thoracolumbar fractures). 14.2% of fractures in L3-L5 (lumbar fractures) and 7.1% in T4-T9 (thoracic fractures). 53.6% of the patients had kyphosis levels below 20 degrees. Reduction of pain in patients younger than 60 years was more than patients older than 60 years but both groups indicated pain reduction ($P<0.001$). The end-plate fracture had a higher likelihood of pain relief compared with burst or retropulsed fractures (OR=1.161). Patients with thoracolumbar fractures had higher chances of pain reduction compared with other locations (OR=1.870). Kyphosis less than 20 degrees and also cement volume more than 5 ml had also significant effects on reducing the pain after surgeries (OR=2.054 and OR=2.412 respectively ($P<0.05$)). Conclusion: Vertebroplasty is an effective option in treating patients with OVF who have not respond to conservative treatment. Factors such as younger age, OVFs involving either end-plates, more than 5 ml of cement injection, segmental kyphosis below 20 degrees and thoracolumbar fractures are associated with better results for pain amelioration.

Keywords: Vertebroplasty, pain, osteoporosis, VAS

Introduction

Osteoporosis is known as one of the most important diseases of the elderly causing different bone fractures in patients [1-3]. Osteoporosis brings a heavy economic burden for societies [2]. With increased life expectancy and changes in lifestyle, the prevalence of osteoporosis has raised in the past decades. Epidemiologic studies in Iran have indicated that the prevalence of osteoporosis is 8.4% among males and 7.7% in females [4]. They also showed that almost 2 million people are exposed to bone fractures alone in Iran. Epidemiologic studies in the United States have indicated that the prevalence of osteoporosis is

10.3% and in 2005, 2 million fractures occurred because of osteoporosis. 27% of these fractures had occurred in the spine [5].

Spinal fractures account for a prevalent fracture in elderly population [6]. The main cause of this trend could be the rise in elderly population in countries and their tendency for increasing their physical activities [7]. The most common form of spinal fracture in patients is compression fracture which could be later associated with chronic pain due to osteoporotic vertebral fracture (OVF) nonunion, sagittal deformities, kyphosis deformities and also depression [8, 9]. Acute pain in OVF could be due to fracture itself but studies have indicated that chronic pain is because of pseudarthrosis [10].

Treatments of OVF are divided into medical and surgical treatments. Most common medical therapies are performed via analgesics, physical activity corrections, physiotherapy and using brace [11]. These therapies have also some complications such as gastric bleeding due to nonsteroidal anti-inflammatory drugs (NSAIDs) and lack of sufficient compliance for braces [12]. Surgical treatments include cement injections for vertebroplasty and kyphoplasty [13, 14]. Most common indications for surgical therapies are painful vertebral fracture unresponsive to medical treatments, hospitalization due to pain or other issues following the fracture and patients with progressive kyphotic deformities [14-16]. Studies have investigated different aspects of vertebroplasty for OVF by the use of cement. These studies have mostly explained that surgical treatments have results that are more beneficial for patients but on the other hand, very few studies have paid attention to pain in affected patients. In a meta-analysis by Li and others in 2015, 8 previous randomized clinical trials were assessed.

Pain relief and fracture assessments are two most important issues for patients with OVF. In this regard, studies should concentrate on factors, which could affect these factors. Here in the present study, we aimed to investigate the efficacy of vertebroplasty by cement injection in patients with OVF and pain in such patients. We also aimed to assess different factors that could affect pain in patients with OVF.

Methods and material

Study design

This study is a before-after clinical trial performed in 2019 in Isfahan, Iran. The Research Committee of Isfahan University of Medical Sciences and the Ethical Committee approved the current study. The current study was performed on patients with OVF who were referred to Al-Zahra hospital.

Inclusion and exclusion criteria

Our inclusion criteria were patients with single-level osteoporotic fractures, unresponsive to at least 2-4 weeks of conservative treatments and signing the informed consent to participate in the study. The exclusion criteria were acute fractures (less than 2 weeks), fractures in multiple levels of spine and fractures with other etiologies than osteoporosis such as tumors or metastasis. Patients with multiple level fractures were excluded due to their limited population.

Measuring tools

Patients were recruited based on our inclusion and exclusion criteria. Demographic data of all patients including age, sex, type of fractures and location of fractures were collected. Segmental kyphosis was measured using Cobb's method. The patient's written informed consent were obtained from all patients before interventions.

Pain in patients was assessed using Visual Analog Scale (VAS) at the beginning of the study [17]. Using VAS, the pain in patients is scored from 0 to 10 meaning no pain at all (0) and highest pain (10).

Surgical procedures

Surgical procedures were then performed for patients as follows: patients underwent regional anesthesia and conscious sedation. Sites of fractures were assessed in prone position using (C-Arm) fluoroscopy guidance. After P&D a Jamshidi needle was then inserted in the fractured vertebral body under sterile condition and (C-arm) fluoroscopy guidance. 2 ml of meglumine (Gd-DOTA) diluted with 3 ml of distilled water was then injected to ensure the cor-

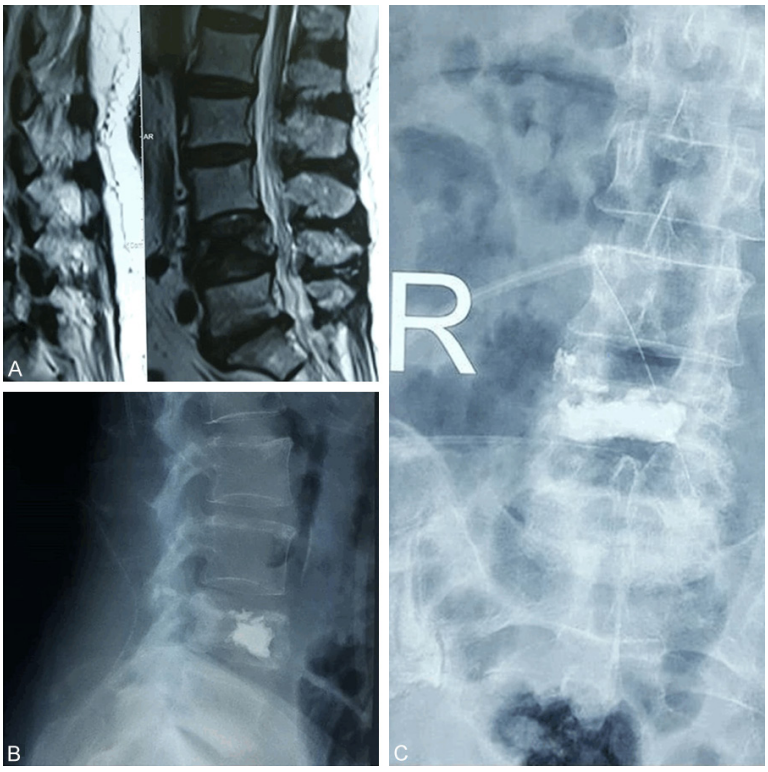

Figure 1. Vertebroplasty in patients. A: T2 weighted midsagittal MRI image of a subacute pincer-type fracture of L4 body. B: Plain lateral X-ray view after injecting cement. C: A-Px-ray view.

rect position of the needle and lack of leakage in epidural space or anterior of the fractured body. As a routine, samples were not sent for the laboratory. Afterward, low viscosity cement (Synimed France, synicem VTP) was injected very slowly into the vertebral body and after each ml injection, conditions of vertebrae were checked by (C-Arm) fluoroscopy (**Figure 1**). If any epidural extravasations occurred, the procedure was discontinued. Amounts of injected cement were also noted and needle was extracted after cement dried. We should also note that the current surgical method has some differences compared to previously performed techniques. Here we did not use common vertebroplasty kits or pressurizers for cement injection. Our method was based on injections with normal syringes and dye injection to ensure the correct location for cement injections. These techniques led to reduced surgery costs.

Follow-ups and data collection

Patients were suggested to wear a lumbar corset and discharged from hospital on oral analgesics and allowed to have physical activity as much as they could. Patients were visited during the first month and 6 months after the procedures and VAS scores were checked and recorded in each visit.

Patients were categorized into 7 subgroups based on time passed from fractures (more or less than 6 weeks), amounts of injected cement (more or less than 5 ml), age (more or less than 60 years), sex, types of fractures (endplate, burst or retropulsed), segmental kyphosis (more or less than 20 degrees) and sites of fractures (thoracic (T4-T10), thoracolumbar (T11-L2) and lumbar (L3-L5)).

Statistical analysis

Data were collected and analyzed using SPSS software version 24 (SPSS 24.0, SPSS JAPAN, Tokyo, Japan). The differences in the demographic data were analyzed using Chi-square test and independent T-test was used for analyzing frequency of different fracture characteristics. We also used repeated measure ANOVA, One way ANOVA and independent T-test to analyze mean VAS score based on different variables. Regression analysis was also performed to figure out possible risk predictors for pain reduction and differences of $P<0.05$ were decided significant.

Results

Demographic information and associated factors in patients

A total number of 148 patients entered into the study based on inclusion and exclusion criteria. Eight patients were excluded due to incomplete follow-ups. Our study population consisted of 42 males and 98 females. The primary analysis showed that the average follow up time was 221 days. The mean age of the patients was 64.90±7.97 years and the mean duration from fracture to operations was 3.01±1.45 months.

Table 1. Demographic information and associated factors in patients

Variables		N=140
Sex*	Male	42 (30%)
	Female	98 (70%)
Age (year) (mean ± SD)*		64.9±7.97
Time after fractures (month) (mean ± SD)*		3.01±1.45
Cement volume*	Less than 5 ml	65 (44.4%)
	More than 5 ml	75 (53.6)
Fracture location**	Thoracic (T4-T9)	10 (7.1%)
	Thoracolumbar (T10-L2)	110 (78.7%)
	Lumbar (L3-L5)	20 (14.2%)
Type of fracture**	end-plate	58 (41.4%)
	burst or retropulsed	82 (58.6%)
Segmental kyphosis**	Less than 20 degrees	86 (61.4%)
	More than 20 degrees	54 (38.6%)
VAS**	Before	8.63±0.97
	In the first month	4.65±0.66
	After 6 months	5.28±0.75

*Chi-square, **independent T-test.

Mean preoperative pain level was 8.35±0.98 points on VAS (0-10) score. Post-operative VAS scores were 4.65±0.66 and 5.28±0.75 respectively. Stratified by sex mean preoperative pain levels were 8.37 in females and 8.33 in male patients. Mean postoperative pain levels were 4.67 in women and 4.62 in men during the first months and 5.29 in women and 5.27 in men after 6 months.

The mean consumed cement volume was 5.77±1.40 ml. Cement volume more than 5 ml was injected for 53.6% of patients while on the other hand, 46.4% had an injection of cement volume less than 5 ml. 78.7% of fractures were located in T10-L2 levels (thoracolumbar fractures). 14.2% of fractures in L3-L5 (lumbar fractures) and 7.1% in T4-T9 (thoracic fractures). 53.6% of the patients had kyphosis levels below 20 degrees and 46.4% had more than 20 degrees kyphosis. Analysis of fracture types in patients showed that 58.6% of patients had burst or retropulsed fractures and 41.4% had end-plate fractures (**Table 1**).

Predictors of pain relief in patients within 6 months after surgeries

Age and sex: We indicated that the levels of pain reduced in both sexes within 6 months (P<0.001) but this reduction was not different between males and females (P>0.05). Patient's age was an influencing factor for pain relief. Patients below 60 were more likely to have less pain than patients over 60 but both groups had significant pain reduction (P< 0.001) (**Table 2**; **Figure 2**). We also observed no significant differences for the pain amounts among patients with less or more than 6 weeks after fractures.

Fracture type and location, segmental kyphosis and cement volume: The type of fractures was simplified as end-plate involving type or burst (retropulsed) type. End-plate fracture had a higher likelihood of pain relief compared with burst or retropulsed fractures. Patients with both fracture types achieved pain relief within 6 months after surgeries but this reduction was greater in patients with end-plate fractures (P<0.001). Location of fractures was also simplified as thoracic, thoracolumbar and lumbar fractures. Patients with thoracolumbar fractures had higher chances of pain reduction compared with other types (OR=1.870) (**Table 3**). Kyphosis less than 20 degrees and also cement volume more than 5 ml had also significant effects on reducing the pain after surgeries (OR=2.054 and OR=2.412 respectively (P<0.05)). We showed that the relationship between cement volume and pain reduction followed a dose-dependent pattern meaning that patients with more than 5 ml cement

Table 2. Mean VAS score based on different variables

Variable		VAS before	VAS within the first months after surgeries	VAS 6 months after surgeries	*P*-value
Sex	Male	8.26±0.97	4.12±1.20	4.13±1.31	<0.001*
	Female	8.46±0.96	4.16±1.12	4.31±1.29	<0.001*
	P-value	0.24	0.80	0.42	
Age	Less than 60	8.06±0.17	4.14±1.17	4.23±1.41	<0.001*
	More than 60	8.24±0.46	4.46±1.30	4.57±1.20	<0.001*
	P-value	0.24	0.03	0.02	
Type	end-plate	8.36±0.96	3.93±1.24	4.05±1.28	<0.001*
	burst or retropulsed	8.35±0.98	4.29±1.09	4.32±1.31	<0.001*
	P-value	0.96***	0.83	0.42	
Time passed from fracture	Less than 6 weeks	8.34±0.90	3.34±1.12	4.25±1.17	<0.001*
	More than 6 weeks	8.25±0.88	4.40±1.15	4.71±1.21	<0.001*
	P-value	0.82***	<0.001***	<0.001***	
Kyphosis	Less than 20 degrees	8.41±0.98	3.54±0.91	3.61±1.01	<0.001*
	More than 20 degrees	8.25±0.95	5.09±0.85	5.16±1.0	<0.001*
	P-value	0.34***	<0.001***	<0.001***	
Cement volume	Less than 5 ml	8.23±0.91	4.36±1.15	4.55±1.27	<0.001*
	More than 5 ml	8.46±1.01	3.94±1.14	3.91±1.26	<0.001*
	P-value	0.15***	0.03***	0.004***	
Location	Lumbar	8.68±0.99	4.01±1.36	4.43±1.26	<0.001**
	Thoracic	8.24±0.93	4.75±0.95	4.68±1.42	<0.001**
	Thoracolumbar	8.26±0.97	3.77±1.02	3.77±1.09	<0.001**
	P-value	0.09***	<0.001***	0.001***	

*Repeated measure ANOVA, **One way ANOVA, ***independent T-test.

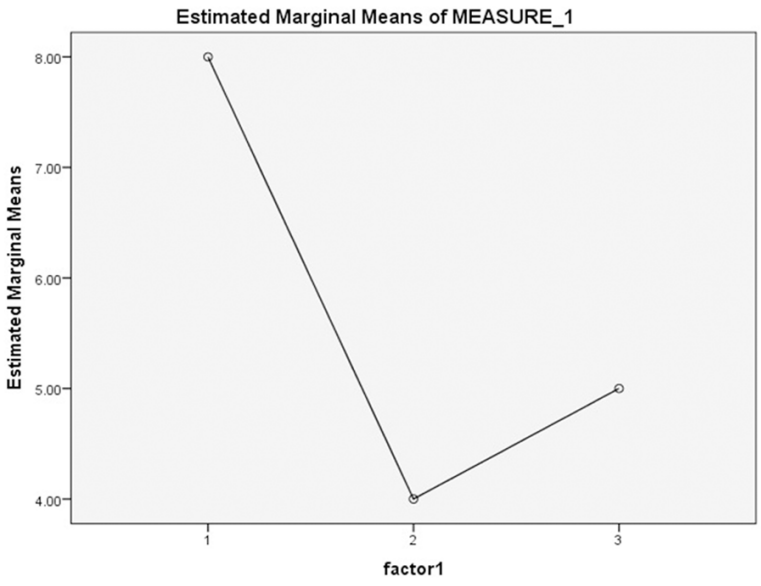

Figure 2. VAS score during the study.

injections had more pain reduction compared with other groups.

Discussion

Here we investigated 140 patients with OVF and assessed the beneficial factors in reducing pain the patients. We showed that vertebroplasty is an effective method for reducing pain in patients within 6 months follow up. Our results indicated that there were significant differences between groups based on fracture types. In patients with impression on endplates, better therapeutic results were observed while on the other hand, in patients with burst fractures and fractures with retropulsion the VAS scores were higher. Here in the present study, we indicated that in cases with severe fractures, pain reduction was observed in a short-term period

Table 3. Regression analysis of possible risk predictors for pain reduction

Predictor	*P*-value	Odds ratio (OR)	CI (95%)	
			Upper	Lower
Age of patients	0.021	1.840 (younger than 60 years vs. older)	1.798	1.017
Sex of patients	0.155	Not significant	-	-
Type of fracture	0.018	1.161 (end-plates vs. burst or retropulsed)	1.650	1.038
Fracture age	0.287	Not significant	-	-
location of fracture	0.002	1.870 (thoracolumbar vs. other)	1.751	1.157
Kyphosis	0.014	2.054 (less than 20 degrees vs. more than 20 degrees)	1.620	1.274
Cement volume	0.001	2.412 (more than 5 ml vs. less than 5 ml)	1.897	1.388

but a slight increase was observed in long-term follow-ups. We also showed that patients with sagittal kyphosis had lower VAS scores, which indicates less vertebral body involvements. Our data also showed that patients with thoracolumbar fractures seem to have more chance of pain relief (OR=1.87). Patients with thoracic fractures had higher VAS scores postoperatively while it might be considered that thoracic area has higher anatomical stability and therefore, lower pain in fractures. In 2018, the German society for orthopedic and trauma has classified osteoporotic fractures based on posterior wall injuries which is a practical classification. They showed that type 1, 2 and 3 OVF might indicate better responses to vertebroplasty compared to type 4 and 5 [18]. These data are in line with our findings. We showed that type two and three OVF had lower VAS score compared with burst or retropulsed fractures. This issue could imply that in cases with disrupted integrity of vertebral body other treatment options such as fixation with augmentations may play role if circumstances permit.

The mean VAS score increased slightly within 6 months after surgeries but the score was still lower than before surgeries. Furthermore, patients with segmental kyphosis below 20 degrees had lower VAS score. Better pain reduction in patients with kyphosis below 20 degrees might be due to lower involvement of vertebral body. Our data also showed that no significant differences were observed between male and female patients regarding VAS score. Different lines of evidence have assessed variable factors in patients undergoing vertebroplasty due to OVF or other causes. In a retrograde study that was performed by Diel and colleagues, 1408 vertebroplasties were evaluated in patients with traumatic, lytic and osteoporotic fractures. The pain of the patients, complications and predictors for better results were assessed. They reported that vertebroplasty is a safe and efficient surgical choice in patients with vertebral fractures which leads to pain amelioration. Furthermore, they declared that the male sex, lumbar or thoracolumbar fractures had higher risks for refracture [19]. These results are somehow in line with our study. Here we declared that vertebroplasty is a beneficial surgical technique in reducing pain in patients. We also showed that patients with thoracic fractures have higher pain scores compared with others. These differences could be due to the study populations as we evaluated patients with OVF but in the study by Diel and colleagues, they entered patients with traumatic, lytic and osteoporotic fractures.

Röder and others also performed a study on 276 patients with single-level vertebral fractures in 2013 and evaluated different factors affecting pain relief and progression in patients. They indicated that cement volume is a significant predictor for pain relief in vertebroplasty. They recommended that a cement volume >4.5 ml should be utilized to achieve maximum pain relief in patients with vertebral fractures. Higher pre-operative pain levels, thoracolumbar fractures and A.3.1 fracture were other predictors for lower progression for pain and functions in patients [20]. They also showed that lower cement volume (OR=0.36), thoracolumbar fractures (OR=3.04), higher preoperative pain (OR=1.08) and female sex (OR=2.09) were associated with higher pain in patients. These results are also in line with our findings indicating that the cement volume is an important predictor factor in reducing pain

(OR=2.412). Based on the results of Röder and colleagues, the amount of cement should be optimal because if lower amounts are administered, pain reduction would not be achieved and if higher amounts are injected, the probability of future complications such as adjacent vertebral body fracture will increase. In another study by Papanastassiou and colleagues in 2014 in USA, 27 prospective multiple-arm studies on patients with osteoporotic spinal fractures were analyzed. Different demographic and prognostic factors were compared and they concluded that early intervention is associated with better results while on the other hand, thoracic fractures indicated poor results for pain relief. They also suggested that early surgical procedures and less conservative treatments bring the best results for osteoporotic spinal fractures [21]. These results are also in line with our findings. We reported that patients with thoracic fractures have higher pain scores in 6 months follow up.

Yimin and others performed a review article about the beneficial effects of percutaneous vertebroplasty and percutaneous kyphoplasty in vertebral compression fractures. They showed that vertebroplasty is a useful and beneficial surgical method for patients especially when treated during the first 6 weeks after fracture. Lower age and absence of past medical diseases were other positive prognostic factors for patients [22]. These results are not in line with our study because we showed that no significant relation was found between time passed from fractures and age in patients with VAS scores. One of the limitations of our study was that we had limited study populations and limited study period. We also did not evaluate patients' co-morbidities that may have a significant role in pain relief so a more comprehensive study encompassing other pertaining risk factors is suggested. On the other hand, here we performed a prospective study, which is a strong point in our study.

Conclusion

Taken together, we believe that vertebroplasty can significantly reduce pain in patients with OVF. Furthermore, we showed that patients with more than 5 ml cement injection, age lower than 60 years, segmental kyphosis below 20 degrees and thoracolumbar fractures and less severe fractures involving either and plate had lower pain.

Disclosure of conflict of interest

None.

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