Clinical Article

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Chronic Painful Osteoporotic Vertebral Compression Fractures of Thoracolumbar Spine: Percutaneous Vertebroplasty versus Conservative Management among Egyptian Patients

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Abstract

Background Data: Vertebral augmentation procedures are widely used today in treating acute and subacute osteoporotic vertebral compression fractures (OVCFs). However, percutaneous vertebroplasty for patients with chronic painful OVCFs has been less well studied.

Study Design: A prospective cohort study.

Purpose: to compare the efficacy and safety of percutaneous vertebroplasty with conservative treatment for management of chronic painful OVCFs in the thoracolumbar spine among Egyptian patients.

Patients and Methods: Ninety-eight patients presented with acute OVCFs during the period from October 2009 to December 2013. They were treated conservatively and followed for at least 3 months. Thereafter, 38 patients were excluded from this study as significant pain improvement was noticed in 32 patients and 6 didn't fulfill the inclusion criteria of this study. The remaining 60 patients (38 females and 22 males, mean age: 65.42±8.63) with chronic painful OVCFs were included in this prospective cohort study. Twenty-eight patients were treated with percutaneous vertebroplasty (Vertebroplasty group). Thirty two patients refused surgical treatment and constituted the control group (Conservative group). All patients were evaluated with X-rays and CT scan, where Cobb angle and the anteroposterior height comparison (APHC) were measured. Overall pain and quality of life were assessed with the Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI) respectively.

Results: All patients were followed for at least 12 months. Statistical analysis of the demographic data of the two groups could not reveal any significant differences. At

latest follow up, there was significant improvement in Cobb angle and APHC in Vertebroplasty group when compared with Conservative group (P=0.001). Three patients in the Conservative group (9.37%) went into nonunion, while all patients in the Vertebroplasty group showed radiological evidence of good stability at latest follow up. A significant improvement of VAS Scores (P=0.001) and ODI (P=0.001) was observed in the Vertebroplasty group when compared to the Conservative group at the latest follow up.
Conclusion: Percutaneous vertebroplasty is safe and effective in treatment of chronic painful osteoporotic vertebral compression fractures with significantly better radiological and clinical outcomes when compared with conservative management. (2015ESJ086)
Keywords: Chronic painful osteoporotic vertebral compression fracture, vertebroplasty, conservative treatment, nonunion.

Introduction

Osteoporotic vertebral compression fractures (OVCFs) are commonly seen complication of primary or secondary osteoporosis. Although pain is usually the most pronounced initial problem, OVCFs can also lead to spinal deformity that may be associated with impaired mobility and physical function,[25] decreased pulmonary function,[12] and gastrointestinal problems.[21] These conditions may have a significant impact on quality of life[26] and may even contribute to a reduced life expectancy.[16]

Today, vertebral augmentation procedures (vertebroplasty and kyphoplasty) are commonly used in the treatment of OVCFs.[29,19,11] Augmentation of the vertebral body using polymethylmethacrylate (PMMA), vertebroplasty, has gained wide clinical acceptance as an effective treatment option for patients with intractable pain related to OVCFs especially in acute and subacute fractures. However, percutaneous vertebroplasty for patients with chronic painful OVCFs has been less well studied.[4]

Thus, the aim of this study was to compare the efficacy and safety of percutaneous vertebroplasty with conservative treatment for managing chronic painful OVCFs in the thoracolumbar spine among Egyptian patients.

Patients and Methods

Out of 98 patients presenting during the period from October 2009 to December 2013 with acute OVCFs at the Emergency Unit of Assiut University Hospital, who were treated conservatively and prospectively followed for at least 3 months, 32 patients showed significant pain improvement and functional recovery. The remaining 66 who were still complaining of severe back pain were then recruited for this prospective cohort study.

The inclusion criteria for this study were as follow: Chronic painful OVCFs matched with radiological finding (at least 3 months duration from the fracture), the age at least 50 years old, the fracture level from T5 down to L5, the presence of osteoporosis as defined by decreased bone mineral density (T-score -2.5 or lower), which was measured with Dual-Energy X-ray Absorptiometry (DXA) according to the world Health Organization (WHO)[18] the Visual Analogue Scale (VAS) at least 5, and absence of neurological deficits. We excluded all patients with: Acute and subacute OVCFs (less than 3 months duration of the fracture), the age less than 50 years old, the level of the fracture beyond T5 and L5, pathological fractures (due to metastases, myeloma, infection and etc), DXA T-score more than -2.5, VAS less than 5, and presence of neurological deficits. Six patients didn't fulfill the inclusion criteria of this study and were excluded. Of the remaining 60 patients, 28 consented to undergo percutaneous vertebroplasty (Vertebroplasty group) while the remaining 32 refused this surgical treatment and constituted the control group (Conservative group). There were 38 females and 22 males with a mean age of 65.42±8.63 years.

At presentation, all patients received back brace, analgesics, anti-osteoporosis therapy. Plain X-rays (anteroposterior and lateral views) were done for all patients. CT scan was done for all patients of Vertebroplasty group and 23 in Conservative group.

The fractured vertebral body (VB) was assessed by the Cobb angle, and anteroposterior height comparison (APHC). The Cobb angle was assessed in a lateral radiograph. A line was drawn along the superior end plate of the vertebra above the affected level and a second line was drawn along the inferior end plate of vertebra below. The angle between

these two lines (or lines drawn perpendicular to them) was measured as the Cobb angle.[3] APHC was expressed as the percentage of VB height at the anterior region compared with that at the posterior region.[24] Bony healing and stability of the fractures were determined by stability in flexion-extension lateral radiographs, presence of bridging callus and unchanged Cobb angle and APHC.

Overall pain and quality of life were assessed with the Visual Analogue Scale (VAS)[28] and Oswestry Disability Index (ODI)[9] respectively. Table 1 summarizes the demographic data of both groups.

Statistical Analysis:

The follow up results of either group were analyzed using Wilcoxon Signed Ranks test. Both groups were compared using Mann-Whitney test. The accepted level of statistical significance was $P<0.05$.

Results

All patients were followed for at least 12 months. The mean follow up duration was 16.43±2.55 months. Statistical analysis of the demographic data could not reveal any significant differences between the Vertebroplasty and Conservative groups (Table 1).The mean duration of fracture of all patients was 6.23±2.55 months without significant differences between the two groups (Table 1). In Vertebroplasty group, the 28 patients underwent vertebroplasty on 37 vertebrae (one level in 20 patients, two levels in 7, and three levels in one). In the Conservative group, the 32 patients were followed conservatively on 44 vertebrae (one level in 22 patients, two levels in 8 and, 3 levels in 2).

The average bone mineral density T score for the thoracolumbar spine in Vertebroplasty and Conservative groups were -3.46±0.65 and -3.58±0.70 respectively with no significant statistical difference between the two groups (Table 1). In Vertebroplasty group, the average amount of bone cement injected was 3.58±0.74 ml (Range, 2 to 5).

Table 2 compares the various treatment outcomes between the Vertebroplasty and the Conservative groups. The mean Cobb angle in the Vertebroplasty group improved significantly from 28.5±12.0° before treatment to 23.6±13.3° at 2 months (P=0.001), and was maintained at 23.2±12.6° and 24.7±10.4° at 6 months and latest follow up respectively. The mean Cobb angle in the Conservative group worsened significantly from 30.4±14.8°at time of presentation to 34.0±66.4°after 2 months of conservative treatment (P=0.001), and further worsened over time to39.7±22.3° and 39.2±58.6° at 6 months and latest follow up respectively (Figure 1).

The mean APHC in the Vertebroplasty group improved significantly from 64.4±18.6% at time of presentation to 73.3±13.1% at 2 months post-vertebroplasty (P=0.001), and was maintained at 73.2±13.2% and 71.2±16.4% at 6 months and latest follow up respectively. The mean APHC in the Conservative group worsened significantly from 66.8±12.6% at time of presentation to 58.8±16.3% after 2 months of conservative treatment (P=0.001) and further deteriorated to 51.6±24.5% and 50.2±16.7% at 6 months and latest follow up respectively (Figure 2).

Although there was no significant difference before treatment between the Vertebroplasty group and the Conservative group as regards the mean Cobb angle and the mean APHC (Table 1), the Vertebroplasty group Showed significantly better restoration of the mean Cobb angle (P=0.001) and better restoration of the mean APHC (P=0.001) when compared with the Conservative group at 2 months post treatment, 6 months and at latest follow up (Table 2). Three patients in the Conservative group (9.37%) showed established non-union at the latest follow up (Figure 3) while 29 patients (90.63%) showed good union and stability. All patients (100%) in the Vertebroplasty group showed good stability at the latest follow up (Figure 4).

There was no significant difference between the two groups in the mean VAS before treatment as it was 7.82±1.09 in the Vertebroplasty group and 7.56±0.84 in Conservative group (Table 1). Although the mean VAS improved with treatment in both groups (Figure 5), patients in the Vertebroplasty group showed significant improvement in their VAS when compared with the Conservative group (P=0.001) at 2 months, 6 months and latest follow up (Table 2).

Quality of life measured with ODI improved significantly from 81.79±8.41% to 35.50±6.88% in Vertebroplasty group. In Conservative group, ODI improved from 82.56±7.26% preoperatively to 46.75±8.28% at latest follow up. Statistical analysis showed better quality of life in Vertebroplasty group compared with Conservative group (P=0.001) (Figure 6).

Complications:

In Vertebroplasty group, we divided the complications into intraoperative and postoperative ones. The intraoperative complications included: Cement extravasation into the disc and paravertebral tissue occurred in 5 of 37 vertebrae (13.51%). None of the extravasated cement events was associated with neurological symptoms, cement embolism, or infection. At different follow up months, new osteoporotic vertebral fractures occurred in 3 patients (10.71%). They were adjacent to the formerly cemented ones in 2 patients and one in non-adjacent level.

In Conservative group, 5 patients (15.62%) presented with new osteoporotic vertebral fractures at different follow up months. They were adjacent to the primary levels in 3 patients and 2 in the non-adjacent levels. Three patients (9.37%) showed nonunion. However, they refused to do any surgical procedures.

Table 1. Demographic Data of Patients

Parameters		Vertebroplasty Group	Conservative Group	P value
Number		28	32	
Age (years)		66.86±6.35	67.66±10.83	0.454
Gender	Male Female	9(32.1%) 19(67.9%)	13(40.6%) 19(59.4%)	0.496
Fractured level	Thoracic(above T12) Thoracolumbar(T12-L1) Lumbar(below L1) Total	6 21 10 37	11 16 17 44	0.276 0.047 0.176 0.078
Fracture duration (months)		6.85±3.25	6.08±2.46	0.437
DXA (T-score)		-3.46±0.65	-3.58±0.70	0.585
Radiological	Cobb angle APHC	28.5±12.0° 64.4±18.6%	30.4±14.8° 66.8±12.6%	0.278 0.467
VAS (at presentation)		7.82±1.09	7.56±0.84	0.284
ODI (at presentation)		81.79±8.41	82.56±7.26	0.852

Table 2. Treatment Outcomes in Vertebroplasty and Conservative Groups

Parameters		Vertebroplasty Group	Conservative Group	P value
Follow up duration (months)		16.96±4.84	16.03±3.49	0.562
Cobb Angle	at presentation 2-month follow-up 6-month follow-up Latest follow-up	28.5±12.0° 23.6±13.3° 23.2±12.6° 24.7±10.4°	30.4±14.8° 34.0±66.4° 39.7±22.3° 39.2±58.6°	0.278 0.001* 0.001* 0.001*
APHC	At presentation 2-month follow-up 6-month follow-up Latest follow-up	64.4±18.6% 73.3±13.1% 73.2±13.2% 71.2±16.4%	66.8±12.6% 58.8±16.3% 51.6±24.5% 50.2±16.7%	0.467 0.001* 0.001* 0.001*
VAS	At presentation 2-month follow-up 6-month follow-up Latest follow-up	7.82±1.09 2.86±0.85 2.46±0.64 2.29±0.53	7.56±0.84 5.28±1.73 4.69±1.28 4.69±1.28	0.284 0.001* 0.001* 0.001*
ODI	At presentation Latest follow-up	81.79± 8.41% 35.50±6.88%	82.56±7.26% 46.75±8.28%	0.852 0.001*

* Statistical significant difference (P value < 0.05)

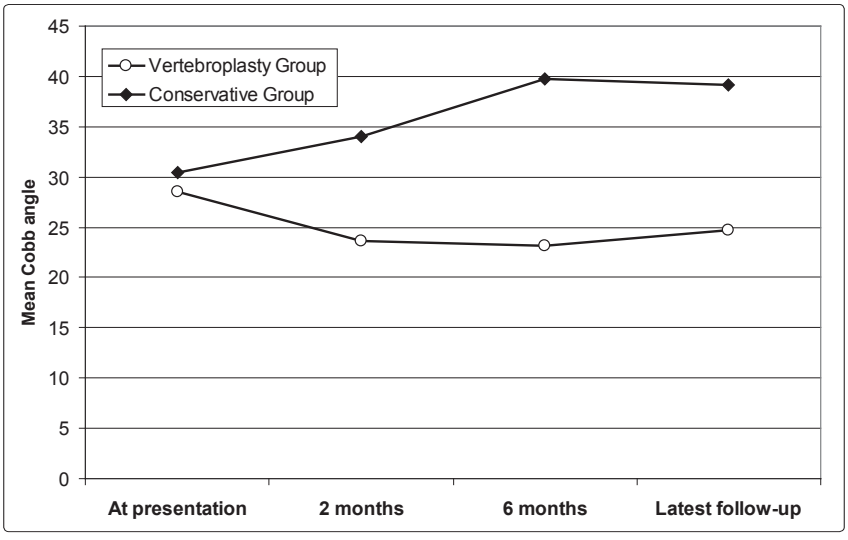

Figure 1. Cobb angle changes with treatment.

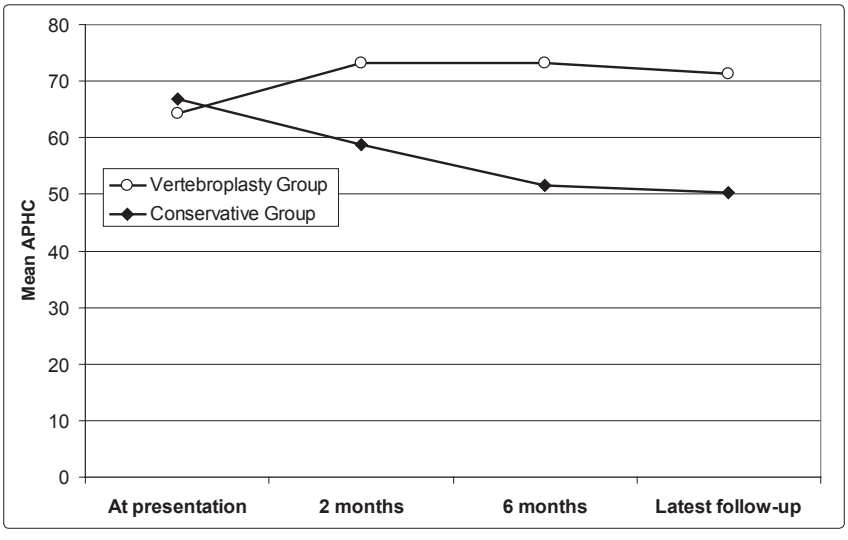

Figure 2. Anteroposterior height comparison (APHC) changes with treatment.

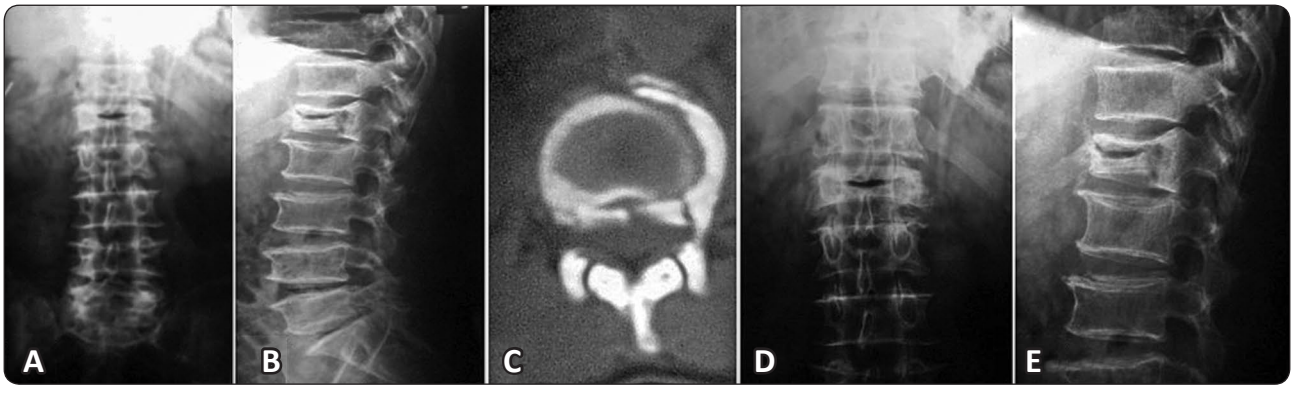

Figure 3. Female patient 76 years old with L1 chronic OVCF. VAS and ODI were 7 and 78% respectively. Anteroposterior (A) and lateral (B) radiographs at time of presentation show Cobb angle and APHC 17° and 68% respectively. Axial CT (C). Latest follow up anteroposterior (D) and lateral (E) radiographs show non-union and no change in Cobb angle and APHC. VAS and ODI were 6 and 68% respectively.

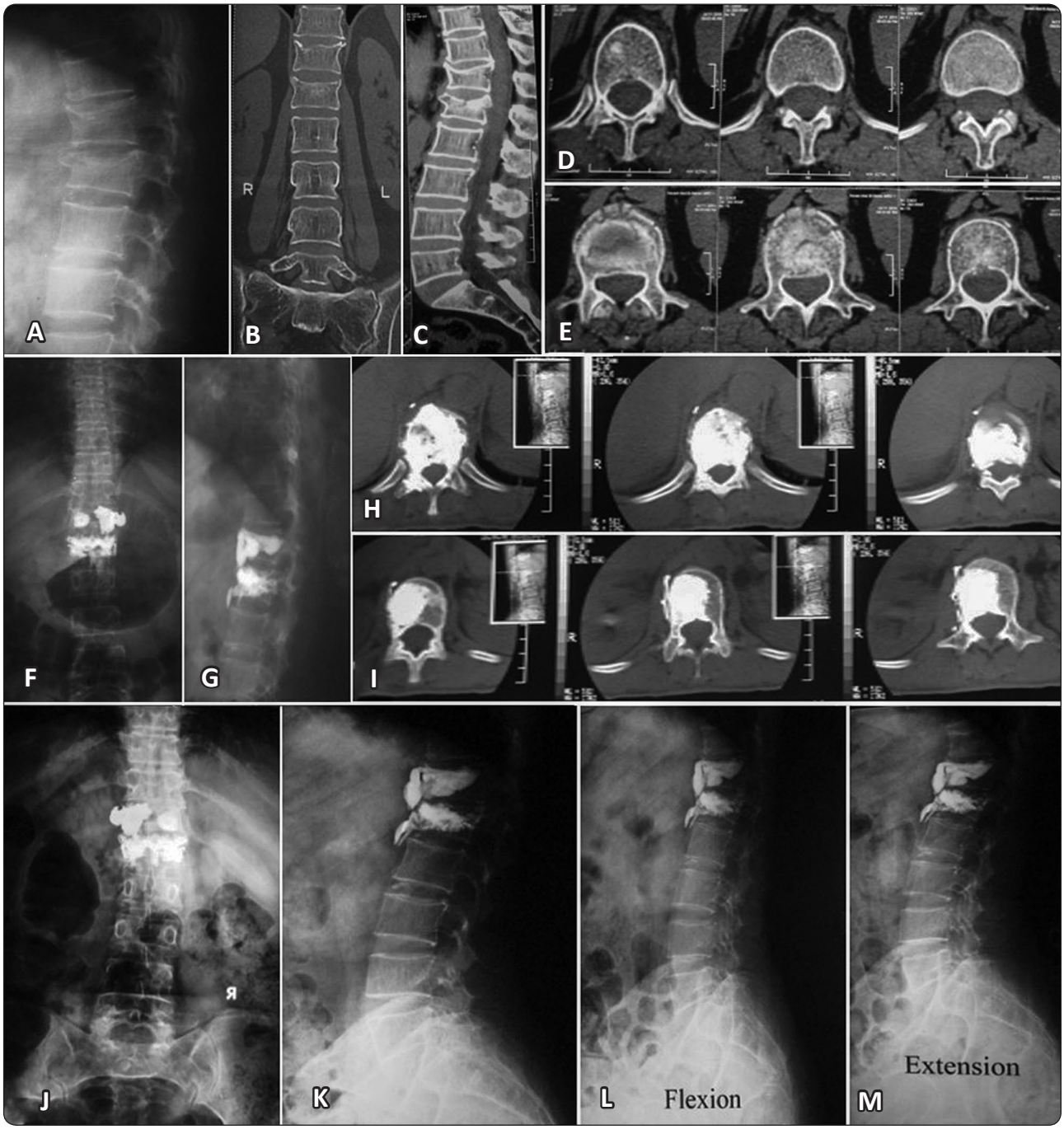

Figure 4. Female patient 66 years old, with chronic OVCFD12 and L1. VAS and ODI were 8 and 88% respectively. Preoperative lateralradiograph (A) and Preoperative anteroposterior (B), sagittal (C) and axial CT (D and E). Cobb angle of D12 and L1 were 16° and 26° respectively. APHC were 80% and 64% respectively. Postoperative anteroposterior (F) and lateral (G) radiographs. Cobb angle of D12 and L1 were 10° and 12° respectively. D12 and L1 APHC were 86% and 84% respectively. Postoperative axial CT of D12 (H) and L1 (I) show good cementation. Latest follow up anteroposterior (J), lateral (K), flexion (L) and extension (M) radiographs show good stability and no change in Cobb angle and APHC of both vertebrae. VAS and ODI were 2 and 36% respectively.

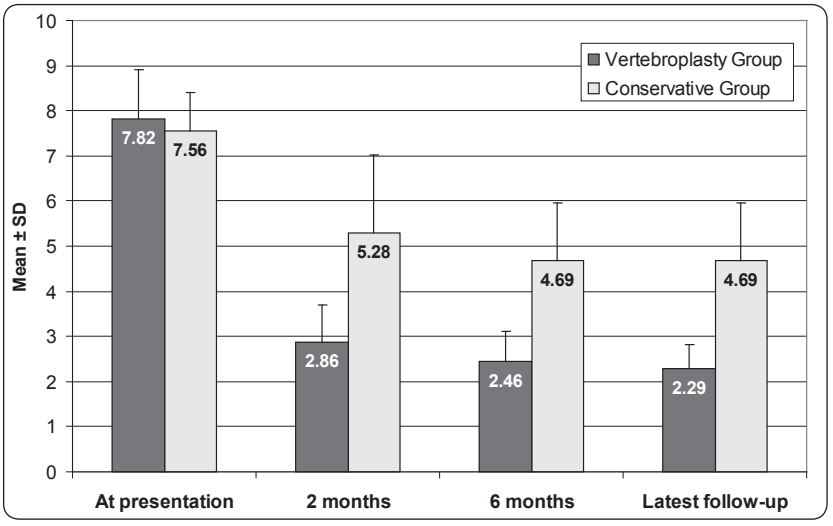

Figure 5. VAS changes with treatment.

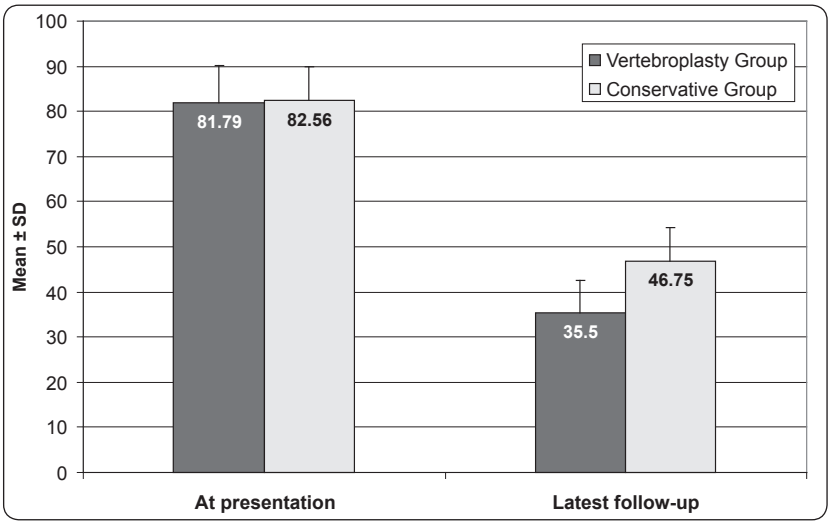

Figure 6. ODI changes with treatment.

Discussion

Osteoporotic vertebral compression fractures are common in the elderly and have serious potential consequences. The problem affects almost 30 percent of the Egyptian population.[27] Recent studies pointed out that almost 54% of post-menopausal women in the country have a primary form of the disease called osteopenia, while 28.4% had full blown osteoporosis.[27,15] Cooper et al,[8] reported that these fractures lead to increased debility and have been shown to increase mortality rate in women up to 15% compared to those without these fractures. Old and Calvert,[22] reported that women are particularly vulnerable due to postmenopausal osteoporosis-of which about 25% suffer from compression fractures. This number increases up to 40% at 80 years old.[18,20] In this study, women represented 59.4% in Conservative group and 67.9% in Vertebroplasty group.

For patients with acute or subacute pain, conservative treatment offers satisfactory clinical results (pain relief and mobility improvement) in many patients within two or three months. However, for patients with chronic painful OVCFs, satisfactory clinical results could not be obtained with conservative management particularly in patients with spinal deformity as conservative management does not allow restoration of the damaged vertebra and does not prevent kyphosis.[9,10] Vertebroplasty and kyphoplasty aim at stabilization and/or correction of acute osteoporotic vertebral fractures resulting in pain relief and restoration or conservation of spinal

curvature. The question here is: Can vertebroplasty change the natural history (pain and deformity) of chronic painful OVCFs and avoid the patients to undergo major reconstructive procedures?. In the present study, we aimed to evaluate the efficacy and safety of percutaneous vertebroplasty compared with conservative treatment for patients with chronic painful OVCFs.

Two multicenter randomized double-blind, placebo-controlled vertebroplastystudies[5,17] demonstrated similar improvement in pain and pain-related disability associated with acute and subacute OVCFs after a six-month follow up in both Vertebroplasty and Conservative groups. However, later reports challenged their conclusions[1,31] for not defining the type of pain they assessed, for not assessing the onset of improvement, and for neglecting the other benefits of vertebroplasty such as preventing worsening of kyphosis. Our current prospective controlled study differs from the placebo-controlled ones[5,17] in three main aspects. First, no patient with acute or subacute fracture was included but rather patients with chronic OVCFs with persistent pain and disability. Second, it included radiological parameters in the assessment such as the Cobb angle, the APHC, and the stability with healing rate. Lastly, the minimum follow up duration in this study was 12 months, significantly longer than previous reports and highlights the long-lasting effect of treatment.

In the current study, the mean VAS of back pain improved in the Vertebroplasty group as well as the Conservative group, but it was significantly better in Vertebroplasty group at all follow up times. Similarly, the quality of life assessed by ODI improved in both groups but it was significantly better in Vertebroplaty group at latest follow up. Other reports[6,13] have also concluded the superiority of vertebroplasty in relieving pain and disability due to chronic painful OVCFs and improving functional outcomes when compared to continuous conservative treatment.

Restoration of vertebral height and kyphotic angle are recommended in OVCFs that result in improving back pain and quality of life and may reduce the incidence of falling down and developing new OVCFs.[7] In the current study, the mean Cobb angle improved significantly from 28.5±12.0° to 24.7±10.4°in the Vertebroplasty group and rather deteriorated in the Conservative group from 30.4±14.8° to 39.2±58.6° at latest follow up. Likewise, the mean APHC significantly improved from 64.4±18.6% to 71.2±16.4% in the Vertebroplasty group and deteriorated from 66.8±12.6%to 50.2±16.7% at latest follow up in the Conservative groups. Other similar studies confirm these results.[7,14] Despite the longstanding duration from the initial injury (6.85±3.25 months), this correction of kyphosis and restoration of the anterior vertebral height could be obtained by placing bolsters under the chest and pelvis to hyperextend the spine to help in restoring the vertebral body height. This was based on the recommendation of Hyeun et al,[14] who also reported on 16 patients with chronic OVCFs of more than one year duration since injury treated by percutaneous vertebroplasty and found that the kyphotic angle and fraction of the involved vertebral height improved significantly from 21.2±4.9°and 0.30±0.12 preoperatively to 10.4±3.8° and 0.60±0.10 postoperatively respectively.

According to Bosczyk[2] a fill volume of 13-16% of the vertebral body volume that is equal to 4 milliliter of PMMA is necessary for relevant biomechanical effect on the restoration of vertebral strength. In this study, the average volume injected in each collapsed vertebra was 3.58±0.74 ml which is comparable with that of Bosczyk.[2] In the current study, Cement leakage into the disc and paravertebral tissue occurred in 5 of 37 vertebrae (13.51%). None of the extravasated cement events was associated with neurological symptoms, cement embolism, or infection.

Omidi-Kashaniet al,[23] reported 5 and 8 new vertebral fractures occurring in 28 and 29 patients in Vertebroplasty and Kyphoplasty respectively. In the current study, a new vertebral fracture developed in 3 patients (2 in adjacent level and one in non-adjacent level) in Vertebroplasty group, and in 5 patients (3 in adjacent level and 2 in non-adjacent level) in Conservative group. This was attributed by Wilcox[30] to the biomechanical changes of the augmented vertebra relative to others. To the best of our knowledge, no study in the English literature has been able to conclusively prove that cement augmentation compared to non-surgical treatment is associated with an increased risk of a new vertebral fracture in the future. Many of these osteoporotic patients, even without any vertebral augmentation procedure, will fracture more in the coming months or years.

Conclusion

Percutaneous Vertebroplasty is safe and effective in treatment of chronic osteoporotic vertebral compression fractures with significantly better radiological (Cobb angle and APHC) and clinical (back pain and quality of life) outcomes compared with conservative management.

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الملخص العربي

كسور الهشاشة المزمنة بالفقرات الصدرية القطنية: مقارنة بين العلاج الجراحي بالحقن الإسمنتي للفقرة المكسورة والعلاج التحفظي في المرضى المصريين

المقدمة: العلاج الجراحي بالحقن الإسمنتي للفقرات الصدرية القطنية للعمود الفقري أصبح شائعا عالمياً في حالات الكسور الحادة لكن هذه الدراسة محدودة في حالات الكسور المزمنة.

الغرض: مقارنة بين العلاج الجراحي بالحقن الإسمنتي والعلاج التحفظي للفقرة المكسورة في كسور الهشاشة المزمنة للفقرات الصدرية القطنية للعمود الفقري في المرضى المصريين.

تصميم الدراسة: دراسة مستقبلية

المرضى وطرق العلاج: شملت هذه الدراسة ٦٠ مريضاٌ يعانون من كسور هشاشة مزمنة بالفقرات الصدرية القطنية (٣٨ سيدة و ٢٢ رجل) متوسط أعمارهم حوالى ٦٥ سنة. تمت متابعة هؤلاء المرضى من خلال العيادات الخارجية لقسم جراحات العظام والعمود الفقري بمستشفيات أسيوط الجامعية في الفترة من أكتوبر ٢٠٠٩ حتى ديسمبر ٢٠١٣. كانت الصفة المشتركة لجميع المرضى هي وجود هشاشة شديدة مصاحبة لكسور قديمة بالفقرات الصدرية القطنية أدى إلى آلام شديدة بالظهر. وقد تم تقسيم هؤلاء المرضى إلى قسمين :

١- القسم الأول تم علاجه جراحياً بالحقن الإسمنتي للفقرة المكسورة ويبلغ عددهم ٢٨ مريضاٌ.

٢- القسم الثاني تم علاجه تحفظياً حيث رفض هؤلاء المرضى إجراء الجراحات بالعمود الفقري ويبلغ عددهم حوالى ٣٢ مريضاٌ.

تمت متابعة هؤلاء المرضى لفترة لا تقل عن ١٢ شهراٌ من خلال متابعة وملاحظة ما يلي :

(١) درجة الألم ومقدار تحسنه

(٢) درجة التئام الكسر ومقدار التحسن في اعوجاج العمود الفقري من خلال الأشعات العادية والمقطعية.

(٣) درجة التحسن الوظيفي العامة للمريض من خلال قدرته على ممارسة الحياة الطبيعية والعملية.

النتائج: بالمقارنة بين المجموعتين تبين ما يلي :

(١) درجة التحسن في الألم أفضل كثيراً في مجموعة الحقن الإسمنتي.

(٢) درجة التئام الكسر ومقدار التحسن في اعوجاج العمود الفقري أفضل نسبياً في مجموعة الحقن الإسمنتي.

(٣)) درجة التحسن الوظيفي أفضل كثيراً في مجموعة الحقن الإسمنتي.

المضاعفات: في مجموعة الحقن الإسمنتي : حدوث تسرب بسيط للأسمنت الطبي خارج الفقرة المكسورة بدون حدوث أي مضاعفات على الحبل الشوكي والضفيرة العصبية. في مجموعة العلاج التحفظي: عدم التئام الكسر في ثلاث حالات (٩,٣٧٪).

الاستنتاج: تبين من هذه الدراسة أن العلاج الجراحي بالحقن الإسمنتي للفقرات الصدرية القطنية للكسور المزمنة للعمود الفقري في مرضى هشاشة العظام ذو فاعلية كبيرة وآمنة مع تحسن أفضل في درجة الألم والتئام الكسر والحالة الوظيفية العامة للمريض مقارنة بالعلاج التحفظي.