

# The variability of vertebral body volume and pain associated with osteoporotic vertebral fractures: conservative treatment versus percutaneous transpedicular vertebroplasty

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## Abstract

**Introduction** Osteoporotic vertebral fractures (OVF) can lead to late collapse which often causes kyphotic spinal deformity, persistent back pain, decreased lung capacity, increased fracture risk and increased mortality. The purpose of our study is to compare the efficacy and safety of vertebroplasty against conservative management of osteoporotic vertebral fractures without neurologic symptoms.

**Material and methods** A total of 66 patients with recent OVF on MRI examination were included in the study. All patients were admitted from September 2009 to September 2012. The cohort was divided into two groups. The first study group consisted of 33 prospectively followed consecutive patients who suffered 40 vertebral osteoporotic fractures treated by percutaneous vertebroplasty (group 1), and the control group consisted of 33 patients who suffered 41 vertebral osteoporotic fractures treated conservatively because they refused vertebroplasty (group 2). The data collection has been conducted in a prospective registration manner. The inclusion

criteria consisted of painful OVF matched with imagistic findings. We assessed the results of pain relief and minimal sagittal area of the vertebral body on the axial CT scan at presentation, after the intervention, at six and 12 months after initial presentation.

**Results** Vertebroplasty with poly(methyl methacrylate) (PMMA) was performed in 30 patients on 39 VBs, including four thoracic vertebrae, 27 vertebrae of the thoracolumbar junction and eight lumbar vertebrae. Group 2 included 30 patients with 39 OVFs (four thoracic vertebrae, 23 vertebrae of the thoracolumbar junction and 11 lumbar vertebrae). There was no significant difference in VAS scores before treatment ( $p = 0.229$ ). The mean VAS was 5.90 in Group 1 and 6.28 in Group 2 before the treatment. Mean VAS after vertebroplasty was 0.85 in Group 1. The mean VAS at six months was 0.92 in Group 1 and 3.00 in Group 2 ( $p < 0.05$ ). The mean VAS at 12 months was 0.92 in Group 1 and 2.36 in Group 2. The mean improvement rate in VAS scores was 84.40% and 62.42%, respectively ( $p < 0.05$ ). For Group 1, mean area of the VBs measured on sagittal CT images was 8.288 at the initial presentation, 8.554 postoperatively, 8.541 at five months and 8.508 at 12 months, respectively, and 8.388 at the initial presentation, 7.976 at six months and 7.585 at 12 months for Group 2 (Fig. 4).

**Discussions** Although conservative treatment is fundamental and achieves good symptom control, in patients who suffer osteoporotic compression fractures (OCF), the incidence of late collapse is high and the prognosis is poor. In order to relieve the pain and avoid VB collapse, vertebroplasty is the recommended treatment in OCFs. Considering the above findings, the dilemma is whether vertebroplasty can change the natural history (pain and deformity) of OCFs.

**Conclusion** In our study on OVF, vertebroplasty delivered superior clinical and radiological outcomes over the first year from intervention when compared to conservative treatment

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of patients with osteoporotic compression fractures without neurological deficit.

We believe that the possibility of evolution towards progressive kyphosis is sufficient to justify prophylactic and therapeutic intervention such as vertebroplasty, a minor gesture compared with extensive correction surgery and stabilization.

**Keywords** Vertebroplasty · Osteoporotic vertebral fractures · Vertebral body volume · Visual analogic scale · CT scan · Kyphotic deformity

## Introduction

The overall incidence of osteoporotic vertebral fracture (OVF), in the United States alone, is estimated to be 1.5 million per year [1]. A demographic model predicted that in the next four decades the number of osteoporosis related fractures will increase six-fold due to aging population [2]. Available data for the Romanian population is mostly confined to a single citation, which used admissions of one regional hospital hip fracture over five years between January 2008 and December 2012 [3]. The study emphasized that the patients with hip fragility fractures in that part of Europe are younger than the European averages, but with slightly better survival. The incidence of osteoporotic vertebral fractures (OVF) is increasing due to the higher life expectancy nowadays and can lead to vertebral collapse which determine loss of sagittal balance, persistent back pain, decreased lung capacity, increased fracture risk and increased mortality [4–6]. Since the first attempt of Lapras [7], vertebroplasty has gained wide clinical acceptance as an effective treatment option for patients with intractable pain related to OVF [7–9].

The purpose of our study was to compare the efficacy and safety of vertebroplasty against conservative management of osteoporotic vertebral fractures without neurologic symptoms.

## Materials and methods

A total of 66 patients with recent OVF on MRI examination were included in the study. The cohort was divided in two groups: the first study group consisted of 33 prospectively followed consecutive patients who suffered 40 OVF treated by percutaneous vertebroplasty (Group 1), and the control group consisted of 33 patients who suffered 41 OVF treated conservatively because they refused vertebroplasty (Group 2). The data collection has been conducted in a prospective registration manner. The two groups were made to have 1:1 matching, the matching criteria being age (based on decade), gender, the level of injury and type of fracture. There were four newly developed fractures at an adjacent level in three patients in the vertebroplasty group and five vertebral

fractures in three patients including three vertebral fractures at an adjacent level in the second group up to one year after injury (Fig. 1a and b). After these patients were excluded from the study, the statistical analysis included 30 patients with ages ranging from 60 to 76 years (mean age 67.03) with 39 OVF in Group 1 and 30 patients with ages ranging from 57 to 73 years (mean age 66.31 years) with 39 OVF in Group 2 (Fig. 2).

All patients were admitted from September 2009 to September 2012. The mechanism of these injuries were minor trauma, such as falling on buttocks, stooping or careless weight lifting with straight knees [10, 11].

The inclusion criteria consisted of painful OVF matched with imagistic findings. In the assessment of these patients, the level of OVFs was diagnosed by radiography, the approximate time from the injury to admission was determined correlating anamnestic data with magnetic resonance imaging (MRI) and the vertebral body volume was measured on computed tomography scan (CT) using a BrainLAB Software (iPlan RT image 4.0) program.

Exclusion criteria were compression fractures older than two months, a newly developed fracture during follow up (Fig. 1), pathologic fractures due to tumours that involves vertebral body, neurological deficit related to fracture, and no understanding of the pain scale due to cognitive dysfunction.

## Evaluation method

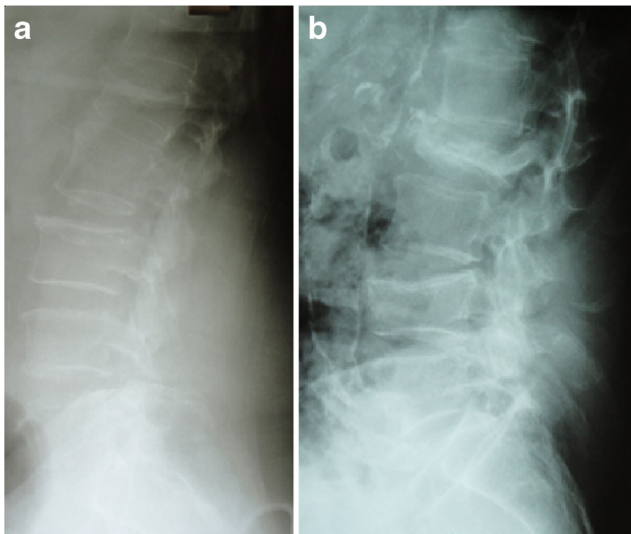
We assessed the results of pain relief and vertebral body volume on CT scan at presentation, after the intervention, at six and 12 months after initial presentation. We recorded data regarding the back pain evaluated using the modified visual analogic scale (VAS, cm) [12] and the duration of analgesic treatment requirements. Independent assessors blindly evaluated these outcomes. The evaluation of pain in patients who suffered newly developed fractures was discontinued. Clinical evaluation included intra- and post-operative complications of vertebroplasty.

## Statistical analysis

Groups were compared using unpaired Student *t* test and Mann Whitney *U* test. Analysis of covariance was applied to control for covariates. The accepted level of statistical significance was  $p < 0.05$ . No adjustment for multiple testing was used.

## Results

In Group 1, five patients were included with two-level fractures and two patients with three-level fractures, and in Group 2, there were three patients with two-level fractures and three



**Fig. 1** a L2 osteoporotic compression fracture in a 73-year-old patient. b Newly L4 developed fracture up to 1 year after initial admission for the L2 fracture

patients with three-level fractures. Imagistic evaluation was performed for all fractures.

Vertebroplasty with polymethyl methacrylate (PMMA) was performed in 30 patients on 39 vertebral bodies, including four thoracic vertebrae, 27 vertebrae of the thoracolumbar junction and eight lumbar vertebrae. In Group 2, there were 30 patients with 39 OVs (four thoracic vertebrae, 23 vertebrae of the thoracolumbar junction and 11 lumbar vertebrae).

No clinically relevant complications were observed both intra- or post-operative.

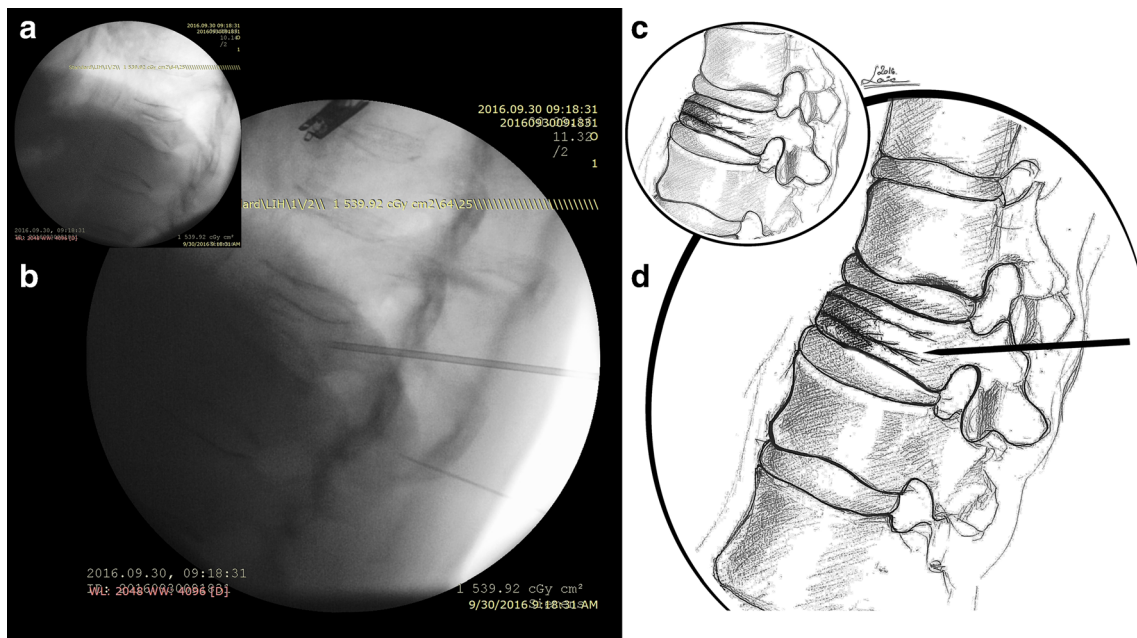
All patients in both groups were prescribed similar analgesia and physical exercises, in bed or at our rehabilitation centre under the surveillance of a specialized physical therapist.

The patients in a conservative treatment group were prescribed a short period of rest. This gives the fracture a chance to heal and aids in pain control. Most of them were fit with an orthosis.

Initial treatment in both groups aimed to decrease the inflammation and pain caused near the area of the compression fracture. Our physical therapist used electrical modalities such as ultrasound or interferential current to ease these symptoms and massage to the muscles or other hands-on techniques such as gentle traction to the joints for muscular relaxation.

We prescribed strengthening exercises which focus on the deep abdominal muscles for overall support of the spine, as well as exercises to strengthen the back muscles which resist the forward bending of the spine. For patients with osteoporosis, it is important to include weight bearing exercises such as walking or stair climbing. Exercises that improve the range of motion in the back, neck, shoulders and hips were prescribed. The extension motion of the upper back (thoracic spine) is of paramount importance.

Table 1 gives demographics and injury level characteristics of patients in both groups. Patients who underwent vertebroplasty had similar characteristics to those in the group treated conservatively.



**Fig. 2** Representative case in the vertebroplasty group. A 65-year-old woman underwent vertebroplasty 30 days after she sustained osteoporotic compression vertebral fracture of T11. a Intra-operative fluoroscopy image demonstrated compression fracture of T11 (b). Intra-operative

fluoroscopy image demonstrating correct 11-gauge needle position into the T11 vertebral body. c and d Representation of the fractured vertebra and vertebroplasty technique

**Table 1** Characteristics of patients with OVFs, stratified by treatment (vertebroplasty vs. conservative treatment)

Group 1	Group 2	Group 3	P-value
Case (man:woman)	30 (7/23)	30 (7/23)	NS
Mean age (years)	67.03	66.31	NS
Level (T/TL/L)	39 (4/27/8)	39 (4/23/11)	NS

T thoracic region, TL thoracolumbar region, L lumbar region, NS not significant

There was no significant difference in VAS scores before treatment ( $p = 0.229$ ). The mean VAS was 5.90 in Group 1 and 6.28 in Group 2 before the treatment. Mean VAS after vertebroplasty was 0.85 in Group 1. The mean VAS at six months was 0.92 in Group 1 and 3.00 in Group 2 ( $p < 0.05$ ). The mean VAS at 12 months was 0.92 in Group 1 and 2.36 in Group 2. The mean improvement rate in VAS scores was 84.40% and 62.42%, respectively ( $p < 0.05$ ) (Fig. 3).

Comparing with the results presented in literature [13], we notice a slight decreased VAS score in our study, both pre-operative and post-operative, with a similar mean age of patients with OVF and a similar improvement rate.

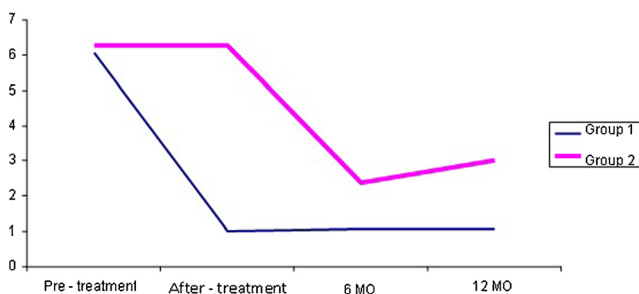
The mean duration of required analgesic medication was 4.18 days in Group 1 and 13.97 days in Group 2 ( $p = 0.001$ ).

In Group 1 independent ambulation started at mean 0.90 days after vertebroplasty, and in Group 2 after 24.92 days of treatment.

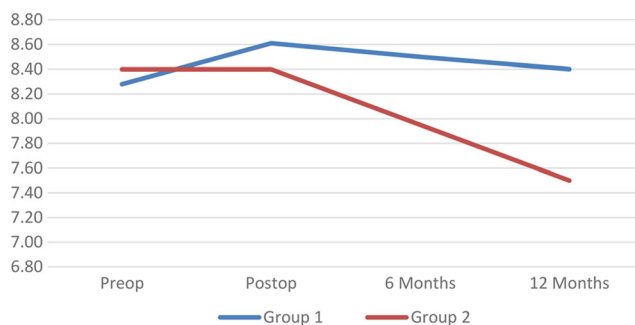
For Group 1, mean vertebral body volume measured on sagittal CT images was 21.18 cm<sup>3</sup> at the initial presentation, 21.28 cm<sup>3</sup> post-operatively, 21.27 cm<sup>3</sup> at six months and 21.26 cm<sup>3</sup> at 12 months, respectively 21.09 cm<sup>3</sup> at the initial presentation, 20.04 cm<sup>3</sup> at six months and 18.45 cm<sup>3</sup> at 12 months for Group 2 (Fig. 4).

**Discussion**

The conservative treatment nowadays has a much more scientific approach based on core stabilization or postural



**Fig. 3** Graphic plotting of the average VAS score for the two groups before treatment, after treatment, at six and 12 months. The improvement was significant in both groups at six and 12 months. The improvement in Group 1 was immediately after vertebroplasty and it was significantly greater than in Group 2



**Fig. 4** Evolution of vertebral body volume on the sagittal CT scan images. We can observe the preservation of the vertebral body volume after vertebroplasty and dramatic loss of vertebral body volume in Group 2

retraining guided by physiotherapists, so the times of “supervised neglect of masterly inactivity” are fading [13]. Usually, with conservative treatment such as medical, physical and orthotic therapy, the pain associated with acute osteoporotic vertebral fractures resolves over six to eight weeks [14].

Treatment by conservative means represents a basis and achieves very good pain control in patients suffering from acute osteoporotic vertebral fractures, but, there is a high incidence of late further collapse leading to a poor prognosis. Thus, for pain relieving and vertebral body collapse avoidance, transpedicular vertebroplasty is recommended as treatment in OVFs [9]. Considering these statements, the dilemma is whether vertebroplasty can influence the OVFs natural history (pain and deformity).

Two multi-centre, double-blinded, randomized, placebo-controlled studies concluded that there is an improvement in pain and pain-related disability in patients with OVF treated by vertebroplasty, similar to sham operation group [15, 16]. However, these two studies were based on a short-term clinical outcome of up to six months and did not include a radiological assessment.

Their conclusions caused disturbances in the scientific, specialists and social-media worlds, leading to headlines like “Spine Surgery Found No Better Than Placebo” in *Wall Street Journal* and “Unnecessary Procedures” on CBS News [17, 18].

The first of these, by Buchbinder et al., was a multicentre, randomized, double-blind, placebo-controlled trial with 78 patients enrolled [15]. The patients presented back pain with a duration not longer than 12 months and had one or two vertebral fractures graded as at least grade I according to the Genant assessment system [19]. The fracture must have had oedema (indication of acute injury), a visible fracture line, or both, quantified by MRI means. The study had the patients separated into two groups: one group of patients that underwent vertebroplasty according to standard protocol (38 patients) and those that underwent the sham procedure (40 patients). The fictive procedure entailed all steps similar to vertebroplasty, except the actual puncture with the 13-gauge needle into the vertebral body, and included PMMA



preparation inside the operating room in order to allow the smell to reach the patients. All the patients underwent standard post-operative care.

The study's primary outcome was a score for the overall pain on a 10-point scale and the secondary outcome was the measurement of quality of life based on various scales including the Quality of Life Questionnaire of the European Foundation of Osteoporosis (QUALEFFO), Quality of Life Questionnaire, European Quality of Life –5 Dimensions Scale and a vertebral fracture-specific along with an osteoporosis-specific questionnaire [20]. At three-months follow-up there was no significant difference between the two groups in terms of pain with a mean reduction of pain of  $2.6 \pm 2.9$  for vertebroplasty and  $1.9 \pm 3.0$  for placebo. At one week, the QUALEFFO score actually favoured the placebo group, but at three months' follow-up the difference was not significant. The authors thus concluded there was no actual improvement after vertebroplasty as compared to placebo in terms of pain relief and quality of life.

The Kallmes et al. study published in *The New England Journal of Medicine* was published in the same period as the paper of Buchbinders et al. entitled 'Investigational Vertebroplasty Safety and Efficiency Trial (INVEST), which was a multi-centre, randomized, controlled trial study and included 131 patients. The patients must have had one to three acute osteoporotic vertebral fractures between T4 and L5, associating pain with the onset of symptoms less than one year prior to evaluation. For the fractures in which the exact onset of pain could not be identified, there was an additional criterion required: the presence of marrow oedema on MRI. Other criteria were inadequate pain relief with standard medical care and a current pain rating of at least three out of ten on the numeric rating scale. After inclusion, the patients were randomly assigned to the vertebroplasty group or the control group. They all had an injection with a local anaesthetic above the targeted vertebra first, followed by an anaesthetic injection in the periosteum of the pedicle. The control procedure included verbal cues, pressure on the patients back, mimicking of PMMA mixing, but no actual needle insertion. Primary outcomes measured by the study were disability using the modified Roland-Morris Disability Questionnaire and pain using a 10-point pain rating scale. There was no significant difference between the groups at one month follow-up, although both groups registered an improvement in the primary measured parameters. The three months' follow-up showed a higher cross-over rate in the control group compared to the vertebroplasty group (51% vs 13%).

Aebi published an editorial in the *European Spine Journal* laying out some of the foundational criticisms associated with the paper by Buchbinder [21]. One highlighted issue was the fact that the authors did not specify or define the type of back pain, this was because pain associated with mechanical instability is very different from the one originating from

compressive forces. Another argued issue is that the authors failed to notice other benefits of vertebroplasty such as its role in stabilizing the segmental kyphosis, and thus, reducing its contribution to the worsening of the existent arthritis or pain originating from the facet joints (as described by Wilson) [22].

The present study emphasizes that the possibility for the kyphosis to progress is sufficient in order to justify the vertebroplasty as prophylactic and therapeutic intervention, knowing that this is a minor gesture as compared to extensive correction and stabilization surgery. Although, just like the balloon kyphoplasty, vertebroplasty did not improve the global sagittal spinal alignment, it did provide immediate pain relief [23]. Even with the association of posterior spinal fusion, a correction of more than  $16^\circ$  of sagittal malalignment cannot be achieved without the risk of subsequent fracture [24].

## Conclusion

This study showed that PMMA vertebroplasty in OVF had better radiological and clinical results at one-year follow-up compared to conservative treatment. There were no significant differences in VAS score before the treatment, however, at six months follow-up the patients in the vertebroplasty group had significantly lower scores. The use of analgesics was significantly lower in the vertebroplasty group. Progressive kyphotic deformity at the last follow up appointment may have a role in the prognosis of pain control.

Vertebroplasty can provide superior clinical and radiological outcomes, compared to conservative treatment, over the first year for patients with OVF without neurological deficit. We consider that the possibility of evolution towards progressive kyphosis is sufficient to justify prophylactic and therapeutic intervention such as vertebroplasty, a minor gesture compared with extensive correction surgery and stabilization.

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**Compliance with ethical standards** The authors declare that they have no competing interests.

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