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Increased sagittal vertical axis is associated with less effective control of acute pain following vertebroplasty

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Objectives

Although vertebroplasty is very effective for relieving acute pain from an osteoporotic vertebral compression fracture, not all patients who undergo vertebroplasty receive the same degree of benefit from the procedure. In order to identify the ideal candidate for vertebroplasty, pre-operative prognostic demographic or clinico-radiological factors need to be identified. The objective of this study was to identify the pre-operative prognostic factors related to the effect of vertebroplasty on acute pain control using a cohort of surgically and non-surgically managed patients.

Patients and Methods

Patients with single-level acute osteoporotic vertebral compression fracture at thoracolumbar junction (T10 to L2) were followed. If the patients were not satisfied with acute pain reduction after a three-week conservative treatment, vertebroplasty was recommended. Pain assessment was carried out at the time of diagnosis, as well as three, four, six, and 12 weeks after the diagnosis. The effect of vertebroplasty, compared with conservative treatment, on back pain (visual analogue score, VAS) was analysed with the use of analysis-of-covariance models that adjusted for pre-operative VAS scores.

Results

A total of 342 patients finished the 12-week follow-up, and 120 patients underwent vertebroplasty (35.1%). The effect of vertebroplasty over conservative treatment was significant regardless of age, body mass index, medical comorbidity, previous fracture, pain duration, bone mineral density, degree of vertebral body compression, and canal encroachment. However, the effect of vertebroplasty was not significant at all time points in patients with increased sagittal vertical axis.

Conclusions

For single-level acute osteoporotic vertebral compression fractures, the effect of vertebroplasty was less favourable in patients with increased sagittal vertical axis (> 5 cm) possible due to aggravation of kyphotic stress from walking imbalance.

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Article focus

 To identify the pre-operative prognostic factors linked to the effect of vertebroplasty on acute pain control in comparison with conservative treatment.

Key messages

For patients with single-level acute osteoporotic vertebral compression fracture, vertebroplasty was more effective for acute pain control than conservative treatment regardless of age, body mass index, medical comorbidity, presence of previous fracture, pain duration, bone mineral density, degree of vertebral body compression, canal encroachment, and kyphotic Cobb angle.

However, the effect of vertebroplasty was less favourable in patients with increased sagittal vertical axis (> 5 cm). Aggravation of kyphotic stress by walking imbalance might be suggested as one of the causes.

Strengths and limitations

- Previous studies to identify pre-operative prognostic factors of vertebroplasty are only focused on the postoperative pain improvement within the vertebroplasty group without comparison with a conservative group.
- A large number of patients (342 patients) were enrolled even after strict inclusion and exclusion criteria in our study.

Introduction

Conservative treatment for osteoporotic vertebral compression fractures (OVCFs) have shown a good clinical outcome^{1,2} despite post-traumatic kyphotic change.³ However, some patients whose pain is persistent even after sufficient conservative treatment eventually undergo vertebral augmentation procedures. Vertebroplasty is known to be effective for acute pain control of OVCFs refractory to conservative treatment.⁴ Furthermore, vertebroplasty has shown an association with vertebral height restoration^{5,6} and longer patient survival than conservative treatment.⁷ Recently published articles emphasised the potential benefit of early vertebroplasty.^{8,9}

Although vertebroplasty is very effective for relieving acute pain from OVCFs, not all of the patients who underwent vertebroplasty received the same degree of benefit from the procedure. In order to identify the ideal candidates for vertebroplasty, pre-operative demographic or clinicoradiological factors that correlate with clinical outcome need to be identified. In addition, these correlations should be assessed in comparison with conservative treatment. Despite the importance of finding such pre-operative prognostic factors, few studies have addressed this point.

Our aim was to perform a prospective comparative cohort study to identify the pre-operative prognostic factors related to the effect of vertebroplasty on acute pain control.

Patients and Methods

Patient enrolment. Between September 2012 and March 2015, consecutive patients aged over 70 years with a single-level acute stable OVCF at the thoracolumbar junction (T10 to L2) were prospectively recruited by a trained clinical research coordinator in the clinic. Acute OVCF was confirmed by MRI of the thoracic or lumbar spine which routinely includes a T2-weighted sagittal plane of the whole spine with fat suppression (1.5T Intera MRI scanner; Philips Medical Systems, Andover, Massachusetts). Osteoporosis was diagnosed by a T-score of ≤ 2.5 on dual-energy X-ray absorptiometry (DXA; QDR - 4500A, Hologic; Waltham, Massachusetts).

To overcome any potential for confounding of the non-randomised study design, we excluded patients with known general contraindications for vertebroplasty. The known contraindications were as follows:^{4,10} severe

cardiopulmonary disease; uncorrectable coagulopathy; severe OVCF compressed over 75%; unstable fracture with the involvement of the posterior elements; spinal cord or nerve root compression causing radicular pain; and active sign of infection. The patients with previous vertebroplasty, pathologic fracture, workers' compensation, or any diagnosed psychological problem, including depression, were also excluded.

12-week post-traumatic management protocol including vertebroplasty. At the time of diagnosis, a rigid thoracolumbosacral orthosis (TLSO) was applied, and a non-steroidal anti-inflammatory drug or opioid was administered. Tolerable weight-bearing was started immediately after bracing. The treatment was performed at an outpatient clinic, and only patients who could not walk due to severe back pain, were admitted to the hospital.

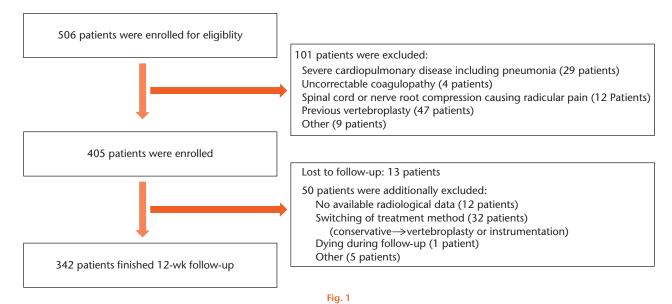
The patients were routinely followed at three weeks after the diagnosis at the outpatient clinic. The location and severity of back pain on the fracture site was reevaluated. If the location of the back pain was confirmed as that of the fracture site and patients were not satisfied with pain improvement after three weeks of conservative treatment, vertebroplasty was suggested only as a possible treatment option for reducing acute pain. The risks and benefits were described to the patient who then decided whether or not to go ahead with vertebroplasty.

Percutaneous vertebroplasty was performed with the patient under local anaesthesia using the unilateral or bilateral transpedicular approach with a ten-gauge needle. Approximately 4 cc of polymethylmethacrylate was injected under fluoroscopic guidance.

Bisphosphonates (risedronate 35 mg) were recommended at the routine follow-up visit of six weeks after diagnosis. Bisphosphonate therapy was delayed in seven patients who were scheduled for invasive dental procedures. Teriparatide (20 ug, daily subcutaneous injection) was used in five patients. TLSO was maintained for 12 weeks.

A total of 342 patients finished the routine 12-week management course for a stable OVCF (Fig. 1). Written informed consent was obtained before enrolment, and the following assessments were conducted by a trained clinical research coordinator, who followed detailed testing protocols. Data collection and 12-week management course were routine procedures for all patients who visit our clinic and included patients were not subjected to extra procedures or questions.

Assessment by interview. Sociodemographic characteristics were assessed in a patient interview. Characteristics included age, gender, and level of education. Height and weight for body mass index (BMI) were measured. A medical history was obtained from every patient based on the Charlson comorbidity index.¹¹ Previous vertebral fracture was evaluated based on the patient's history and MRI findings. According to the previous article,¹² the



Flow chart showing patient enrolment and follow-up.

cause of fracture was classified as follows: falling down; lifting heavy objects; and no specific trauma. The duration since time of pain onset was recorded.

Assessment of bone mineral density. Bone mineral density (BMD) was measured by DXA (QDR-4500A; Hologic), and the values of total lumbar and total hip were used for analysis.

Assessment of the radiological data. According to the previous reports, several validated radiological assessments were undertaken using the radiographs taken three weeks after the diagnosis. From the standing anteroposterior radiographs of the thoracolumbar spine, the severity of the body compression was assessed by anterior vertebral body compression percentage. 13-16 As a local sagittal alignment, the Cobb angle, formed by a line drawn parallel to the superior endplate of one vertebra above the fracture and a line drawn parallel to the inferior endplate of the vertebra one level below the fracture, was measured.13 Spinal canal encroachment was measured on MRI in relation to the cross-sectional spinal canal area at the level of injury relative to the cross section adjacent to the injured level. 13,17 From the standing whole spine radiograph, sagittal vertical axis (SVA) was measured.

Assessment of back pain. The location of the pain was recorded using a validated McGill Pain Map, ^{18,19} a homunculus showing the front and back of the human figure. Back pain intensity was measured with a VAS, ranging from 0 to 10, where 0 is no pain, and assessed as location-specific ratings (for upper and/or lower back). Pain assessment was carried out at diagnosis and at three, four, six, and 12 weeks after the diagnosis.

Data collection from chart review on complications from OVCF. According to Lee et al,²⁰ data on complications from OVCFs were collected and classified into three types: procedure-related; medical; and adjacent vertebral

fracture. Cement leakage was identified and also classified into three types: leaks via basivertebral vein; leaks via segmental vein; and leaks through a cortical defect.²¹

Statistical analysis. Comparison of each independent variable between the two groups (vertebroplasty *versus* conservative treatment) was done by independent *t*-test for continuous variables and Pearson chi-squared test or Fisher's exact test for categorical variable (Table I).

The effect of vertebroplasty on acute back pain (VAS) was calculated with the use of analysis-of-covariance (ANCOVA) models including adjustment for possible confounders (Tables II and III). Each treatment group (vertebroplasty group and conservative group) was divided into subgroups according to the independent variables (Table I), and ANCOVA analyses were also performed to compare the effect of treatment between each subgroup. Through subgroup analysis by the ANCOVA model, pre-operative prognostic factors associated with a less favourable outcome after vertebroplasty were identified among the independent variables, and multivariate logistic regression analysis was performed to confirm the relationship between pre-operative prognostic factors and a less favourable outcome of vertebroplasty. A less favorable outcome of OVCF is closely related to adjacent vertebral fracture. Adjacent vertebral fracture can occur regardless of treatment method, and act as a confounder for the association between pre-operative prognostic factors of vertebroplasty and a less favourable outcome. Therefore, multivariate logistic regression analysis was also performed to identify association between preoperative prognostic factors and adjacent vertebral fracture which could act as a confounder. All statistical analyses were performed using the SPSS 17.0.0 statistics package (SPSS, IBM, Chicago, Illinois). A value of p < 0.05 was accepted as significant.

Table I. Baseline characteristics of the patients who finished 12-week follow-up

Independent variables	Category	Conservative treatment group	Vertebroplasty group	p-value
Patients (n)		222	120	
Age (yrs)		74.9 (SD 2.8)	75.1 (sp 3.9)	0.587*
Male:female		32:190	13:107	0.350^{\dagger}
Body mass index		24.3 (SD 3.3)	24.7 (SD 3.3)	0.295*
Medical comorbidity (n)		1.2 (SD 0.8)	1.5 (SD 0.8)	0.006*
Education	Less than high school	173	100	0.346^{\dagger}
	High school	37	13	
	College or college graduate	12	7	
History of previous fracture (n, %)		75 (33.8)	45 (3 <i>7.5</i>)	0.492^{\dagger}
Cause of the fracture	Falling down	125	73	0.648^{\dagger}
	Lifting heavy object	13	5	
	No trauma	84	42	
Pain duration before the diagnosis	< 2 wks	154	88	0.072†
-	2 wks to 4 wks	40	26	
	> 4 wks	28	6	
Presence of degenerative disease	Lumbar spinal stenosis (n, %)	59 (26.6)	25 (20.8)	0.239 [†]
-	Osteoarthritis of lower extremity (n, %)	58 (26.1)	41 (34.2)	0.118 [†]
Bone mineral density	Spine	-3.1 (SD 0.7)	-3.1 (SD 0.6)	0.817*
•	Femur	-3.0 (SD 0.8)	-3.1 (SD 0.5)	0.352*
Anterior vertebral body compression (%)		37.8 (SD 16.0)	40.3 (SD 14.8)	0.150*
Canal encroachment	< 20%	182	93	0.319 [†]
	> 20%	40	27	
Cobb's angle		16.9 (SD 6.7)	18.1 (sd 6.1)	0.105*
Sagittal vertical axis		47.8 (SD 22.2)	48.5 (SD 21.8)	0.782*
Pain visual analogue score	At diagnosis	6.6 (SD 1.5)	6.8 (SD 1.4)	0.161*

^{*} independent t-test

Table II. Comparison of the effect between the groups: overall treatment

		Conservative treatment	Vertebroplasty	Effect of treatment (95% CI)	p-value
No. of patients		222	120		
Pain VAS	3 wks	4.5 (SD 1.3)	5.4 (SD 1.2)		< 0.001*
	Vertebroplasty undertaken:				
	At 4 wks	3.5 (SD 1.0)	2.6 (SD 1.2)	-1.112 (-1.361 to -0.863)	< 0.001 [†]
	At 6 wks	2.9 (SD 1.0)	2.5 (SD 1.1)	-0.550 (-0.783 to -0.317)	< 0.001 [†]
	At 12 wks	2.0 (SD 1.0)	2.1 (SD 0.9)	-0.029 (-0.251 to 0.192)	0.794 [†]

^{*} independent t-test

Results

Baseline characteristics of the patients. Among 342 patients who finished the routine 12-week management course for a stable OVCF, 120 patients underwent vertebroplasty (35.1%) (Table I). There were no significant differences in the baseline characteristics of the patients between the two groups except for the number of medical comorbidities (p = 0.006) (Table I), which were higher in the vertebroplasty group. The intensity of pain at the time of diagnosis was not significantly different between the two groups (p = 0.161) (Table I).

Effect of vertebroplasty: overall treatment. Vertebroplasty was performed at a day between three and four weeks after the diagnosis, and there was a significant difference in the pain VAS score at three weeks after diagnosis (aka pre-operatively for the vertebroplasty group) between the two groups (Table II). The effect of vertebroplasty

on acute back pain was analysed with ANCOVA models, including adjustment for the pain VAS score of three weeks after diagnosis. After vertebroplasty the effect of vertebroplasty was significant, measured at four and six weeks after diagnosis (one or three weeks after vertebroplasty) (Table II). However, the effect of vertebroplasty was not significant at 12 weeks after diagnosis (nine weeks after vertebroplasty) (p = 0.794) (Table II).

Effect of vertebroplasty: subgroup analysis. We performed subgroup analyses to identify pre-operative prognostic factors associated with a less favourable outcome after vertebroplasty in comparison with conservative treatment. At four or six weeks after the diagnosis (at one or three weeks after vertebroplasty), the effect of vertebroplasty still remained significant regardless of advanced age (> 75 years), high BMI (> 25 kg/m²), medical comorbidity, previous fracture, longer pain duration

[†] chi-squared test

sp, standard deviation

[†] analysis-of-covariance including adjustment for the pain VAS score of three weeks after diagnosis (which means pre-operative value for the vertebroplasty group)

VAS, visual analogue score; CI, confidence interval; SD, standard deviation

Table III. Multivariate logistic regression analysis on the relationship between increased sagittal vertical axis (> 5 cm) and a less favourable outcome of vertebroplasty

Dependent variable		Univariate			Multivariate	
	Odds ratio	95% CI	p-value	Odds ratio	95% CI	p-value*
Less favourable outcome at 4 wks after diagnosis (1 wk after vertebroplasty)	3.087	(1.984 to 4.802)	< 0.001	3.518	(2.023 to 6.115)	< 0.001*
Less favourable outcome at 6 wks after diagnosis (3 wks after vertebroplasty)	1.877	(1.209 to 2.912)	0.005	1.807	(1.035 to 3.154)	0.037
Less favourable outcome at 12 wks after diagnosis (9 wks after vertebroplasty)	2.110	(1.192 to 3.735)	0.010	2.314	(1.171 to 4.571)	0.016

^{*} adjusted for medical comorbidity and pain visual analogue score 3 weeks after diagnosis CI, confidence interval

Table IV. Comparison of complications according to the treatment group

		Conservative treatment	Vertebroplasty	p-value
Patients (n)		222	120	
Procedure related (n, %)	All	0 (0)	30 (25)	< 0.001*
	Cement leakage	0	29	
	Cement embolism	0	0	
	Neurological deficit	0	0	
	Fracture (rib, transverse process, pedicle)	0	1	
	Discitis	0	0	
Medical (n, %)	All	12 (5.4)	6 (5.0)	0.873 [†]
	Non-cement embolism	2	0	
	Pneumonia	5	4	
	Stroke	2	1	
	Cardiovascular	3	1	
Adjacent vertebral fracture (n, %)		13 (5.8)	13 (10.8)	0.097 [†]

^{*} Fisher's exact test

before diagnosis (more than two weeks), decreased bone mineral density (T-score < -3.0), increased anterior vertebral body compression ratio (> 40%) and increased canal encroachment (> 20%) (Supplementery table). The effect of vertebroplasty in all of these subgroups was not significant at 12 weeks after the diagnosis (Supplementery table). However, the effect of vertebroplasty was not significant in patients with increased SVA (> 5 cm) at all time points (Supplementery table) (p = 0.563 at four weeks, p = 0.329 at six weeks, and p = 0.505 at 12 weeks).

Multivariate logistic regression analysis on the relationship between increased SVA (> 5 cm) and a less favourable outcome of vertebroplasty. Multivariate logistic regression analysis was performed to confirm the relationship between increased SVA (> 5 cm) and a less favourable outcome of vertebroplasty. According to Ostelo et al,²² the minimal important change (MIC) for pain alleviation is considered to be two points in VAS score (0 to 10), therefore a less favourable outcome after vertebroplasty was defined as an improvement in pain at less than two points using the VAS. Vertebroplasty was performed between three and four weeks after the diagnosis, and there was a significant difference in pain VAS at three weeks after the diagnosis (pre-operative value for the vertebroplasty group) between the two groups (Table II).

Therefore, multivariate adjustments were done for medical comorbidity and pain VAS score at three weeks after diagnosis according to the results of our analysis (Tables I and II). Even after multivariate adjustment, increased SVA was closely related to a less favourable outcomes after vertebroplasty (Table III).

Analysis of complications according to the treatment method. Complications of vertebroplasty were classified into three types:²⁰ procedure-related; medical; and adjacent vertebral fracture (Table IV).

The most common procedure-related complication was cement leakage. There were 29 cases (24.2%) of cement leakage in the vertebroplasty group, 11 leaks via the basivertebral vein, seven leaks via the segmental vein and 11 leaks through a cortical defect. However, there were no fatal procedure-related complications such as cement embolism or neurological deficit (Table IV). There were no differences in medical complications between the two groups (p = 0.873) (Table IV).

Adjacent vertebral fracture can occur regardless of treatment method. Adjacent fracture occurred in 5.8% (13 of 222 patients) of the conservative treatment group and in 10.8% (13 of 120 patients) of the vertebroplasty group. There was no statistical difference in occurrence of adjacent fracture between the two groups (p = 0.097).

[†] chi-squared test

Table V. Risk of adjacent fracture in patients with increased sagittal vertical axis (> 5 cm)

	Occurrence of adjacent		Univariate			Multivariate	
	fracture	Odds ratio	95% CI	p-value	Odds ratio	95% CI	p-value
Vertebroplasty group (n, %) Conservative treatment group	13 (10.8) 13 (5.8)	1.836 0.971	(0.476, 7.078) (0.316, 2.9087)	0.378 0.959	2.069 0.873	(0.508 to 8.423) (0.390 to 1.954)	0.310* 0.873 [†]

^{*} adjusted for body mass index, cement leakage, bone mineral density of femur

Logistic regression analyses were carried out to identify the association, if any, between increased SVA and risk of adjacent fracture which could act as a confounder for the association between increased SVA and a less favourable outcome after vertebroplasty. After multiple logistic regression analysis, increased SVA (> 5 cm) was not associated with increased risk of adjacent fracture in either the vertebroplasty group or the conservative treatment group (Table V).

Discussion

For the treatment of OVCFs, vertebroplasty is an effective procedure with short- and long-term radiological and clinical benefits.^{23,24} It is also a safe procedure with rare complications.²⁵ According to Hierholzer et al,²⁶ most patients who undergo osteoplasty experience immediate and dramatic pain relief following the procedure. However, in our clinical practice, back pain recurred in a considerable number of patients within several days or weeks despite the "immediate and dramatic pain relief after the procedure".26 Previous articles describing such an unfavourable outcome of vertebroplasty have had methodological limitations. Some studies have concluded that the outcome was mainly due to procedurerelated complications such as cement leakage or adjacent vertebral fracture, without considering pre-operative factors.^{27,28} Other studies that identified pre-operative prognostic factors only focused on the post-operative pain improvement within the vertebroplasty group without comparison with the conservative group.²⁹⁻³¹ Conservative treatment including a rigid brace and painkillers is still the treatment of choice in OVCFs. Therefore, pre-operative prognostic factors should be compared with those of conservatively treated patients.

To identify pre-operative prognostic factors associated with a successful outcome after vertebroplasty in comparison with conservative treatment, we tried to include all possible factors available associated with the treatment outcome of OVCF in the analysis (Tables I and III), and we demonstrated that vertebroplasty was more effective in acute pain control for OVCFs than conservative treatment, regardless of age, BMI, medical comorbidity, presence of previous fracture, pain duration, bone mineral density, degree of vertebral body compression, canal encroachment, and kyphotic Cobb angle

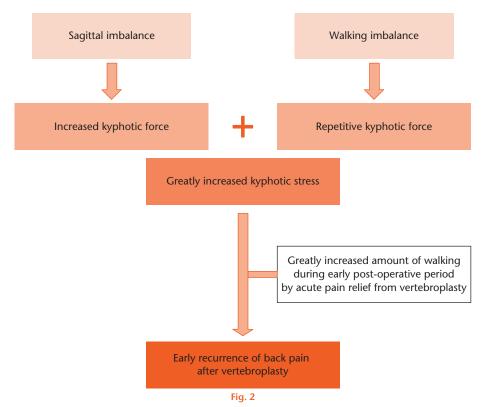
(Supplementary table). These results are in line with previous articles which showed excellent pain relief within the vertebroplasty group.²⁹⁻³¹

Additionally, our study demonstrated that the effect of vertebroplasty was less favourable in patients with increased SVA (> 5 cm) (Table III). However, this study is not a randomised study but an observational study. Although increased SVA showed a correlation with a less favourable outcome of vertebroplasty even in multivariate adjustment (Table III), this non-randomised study is never free from bias from its methodological limitations. The mean improvement in the pain VAS in patients with increased SVA is still more pronounced in the vertebroplasty group than in the conservative group (1.4 points versus 1.0 point at four weeks, and 2.1 versus 1.5 at six weeks) (Supplementary table).

Although inferring causes of less favourable early outcome after vertebroplasty in patients with increased SVA is beyond the range of our study, we suggest the following hypothesis as a possible explanation for such a result. First, patients with increased SVA are exposed to more kyphotic force both at the fracture site and at the osteoporotic adjacent segment. Second, increased SVA is closely related with walking imbalance,32 and kyphotic stress is further increased with walking. From this point of view, a less favourable early outcome of vertebroplasty especially in patients with increased SVA might be explained as follows: patients with increased SVA already have increased kyphotic force at the fracture site due to positive sagittal imbalance. Walking imbalance of the patient with increased SVA causes such increased kyphotic force to be transferred more repetitively. Acute pain relief from vertebroplasty during the early postoperative period allows the amount of walking to be greatly increased but eventually such an increase in walking and kyphotic stress causes back pain to recur in the early post-operative period after vertebroplasty (Fig. 2). As we have shown in Figure 2, we think that "immediate and dramatic pain relief after the procedure"26 is still observed in patients with increased SVA. However, the duration of such pain relief in patients with increased SVA might not be as long as that of patients with normal SVA. Vertebroplasty is a safe procedure with few complications²⁰ (Table IV), and acute pain relief from the procedure is very helpful in order for the patient with respect to

[†] adjusted for body mass index, bone mineral density of femur

CI, confidence interval



Flow chart showing the hypothesis for less favourable early outcome after vertebroplasty in patients with increased SVA.

early ambulation, regardless of the period of pain relief. Therefore, the actual benefit of vertebroplasty in patients with increased SVA should not be underestimated from the results of our study.

The main limitation of the present study is that it is a non-randomised observational study. Observational studies are never free from inherent potentials for confounding biases. However, a large number of patients were required for subgroup analyses in order to identify significant risk factors, which would be challenging for a randomised trial. In our study, we were able to enrol a sufficient number of patients (342 patients) even after strict inclusion and exclusion criteria. Inevitably, there were significant differences in pre-operative pain VAS (score at three weeks after the diagnosis) between the conservative group and the vertebroplasty group. However, to overcome bias from such differences in the initial pain score, the effect of vertebroplasty was analysed with the use of ANCOVA models including adjustment for the pain VAS three weeks after diagnosis. Secondly, we did not compare health-related quality of life using the Short Form-36 or any other test. However, the patients with an OVCF already had several chronic diseases such as lumbar spinal stenosis, osteoarthritis, and other medical comorbidities. We feel that healthrelated quality of life measures are greatly influenced by such chronic diseases and the actual effect of vertebroplasty may not be reflected on quality of life due to

those influences. Thirdly, we did not perform any certified assessment for psychologic status of the patients which could influence as a potential bias of outcome assessment.

In conclusion, for the patients with single-level acute osteoporotic vertebral compression fracture, vertebro-plasty was more effective for acute pain control than conservative treatment regardless of age, BMI, medical comorbidity, presence of previous fracture, pain duration, bone mineral density, degree of vertebral body compression, canal encroachment, and kyphotic Cobb angle. However, the effect of vertebroplasty was less favourable in patients with increased SVA (> 5 cm), possibly due to aggravation of kyphotic stress from a walking imbalance.

Supplementary material

A table showing a comparison of the effect of treatment between the groups: subgroup analysis is available alongside this article online at www.bjr. boneandjoint.org.uk

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Author Contribution

- Y-C. Kim: First author, Data aquisition, Writing paper, Revision.
- D. H. Bok: Co-author, Data collection, Writing paper
- H-G. Chang: Co-author, Data acquisition.
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- J. K. Oh: Co-author, Data acquisition.
- . Kim: Co-author, Statistical analysis, English writing.
- T-H. Kim: Corresponding author, Study design and planning, Data acquisition, Statistical analysis, Writing paper.

ICMIE conflict of interest

- None declared
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