

Clinical Article

The Role of Bone Cement Augmentation in the Treatment of Chronic Symptomatic Osteoporotic Compression Fracture

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Objective : Bone cement augmentation procedures such as percutaneous vertebroplasty and balloon kyphoplasty have been shown to be effective treatment for acute or subacute osteoporotic vertebral compression fractures. The purpose of this study was to determine the efficacy of bone cement augmentation procedures for long standing osteoporotic vertebral compression fracture with late vertebral collapse and persistent back pain.

Methods : Among 278 single level osteoporotic vertebral compression fractures that were treated by vertebral augmentation procedures at our institute, 18 consecutive patients were included in this study. Study inclusion was limited to initially, minimal compression fractures, but showing a poor prognosis due to late vertebral collapse, intravertebral vacuum clefts and continuous back pain despite conservative treatment for more than one year. The subjects included three men and 15 women. The mean age was 70.7 with a range from 64 to 85 years of age. After postural reduction for two days, bone cement augmentation procedures following intraoperative pressure reduction were performed. Imaging and clinical findings, including the level of the vertebra involved, vertebral height restoration, injected cement volume, local kyphosis, clinical outcome and complications were analyzed.

Results : The mean follow-up period after bone cement augmentation procedures was 14.3 months (range 12-27 months). The mean injected cement volume was 4.1 mL (range 2.4-5.9 mL). The unipedicular approach was possible in 15 patients. The mean pain score (visual analogue scale) prior to surgery was 7.1, which decreased to 3.1 at 7 days after the procedure. The pain relief was maintained at the final follow up. The kyphotic angle improved significantly from $21.2 \pm 4.9^\circ$ before surgery to $10.4 \pm 3.8^\circ$ after surgery. The fraction of vertebral height increased from 30% to 60% after bone cement augmentation, and the restored vertebral height was maintained at the final follow up. There were no serious complications related to cement leakage.

Conclusion : In the management of even long-standing osteoporotic vertebral compression fracture for over one year, bone cement augmentation procedures following postural reduction were considered safe and effective treatment in cases of non-healing evidence.

KEY WORDS : Long standing · Compression fracture · Osteoporosis · Bone cement.

INTRODUCTION

Acute osteoporotic vertebral compression fractures may produce intolerable pain. However, in a number of cases, the pain subsides over a period of weeks or months. Most patients achieve bone union without surgery. Thus, initially, most

patients with painful osteoporotic vertebral compression fractures are treated conservatively with bed rest, analgesic medications, bracing and anti-osteoporotic drugs^{13,14,18}. However, the non-operative measures for some symptomatic vertebral compression fractures may not be successful and the patient continues to have intolerable pain, kyphotic deformity, loss of function, or a combination of these problems. Some patients develop chronic pain and a spinal deformity. Vertebral augmentation procedures such as the percutaneous vertebroplasty or balloon kyphoplasty are minimally invasive procedures used to prevent further vertebral collapse and result in rapid pain relief in patients with osteoporotic vertebral com-

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pression fractures. However, these procedures have been shown to be effective in acute or subacute fractures, especially one to four months old and treatment after 6 months was thought to be not successful in relieving pain^{10,21}). The treatment of long standing fractures, present for more than 1 year remains controversial. The purpose of this study was to evaluate the effect of bone cement augmentation for long standing osteoporotic vertebral compression fractures which showed late vertebral collapse and continuous back pain, present for more than 1 year.

MATERIALS AND METHODS

This study included 18 patients (15 females, 3 males) with osteoporotic vertebral compression fractures due to severe osteoporosis. Of the 278 single level osteoporotic vertebral compression fractures that were treated at our institute, 18 patients were included in this study. Study inclusion was limited to first, initially with minimal compression fractures; collapsed vertebra and vacuum clefts were present at more than one year follow up, second, in patients with incapacitating continuous back pain despite a variety of conservative treatments. A minimal compression fracture was defined as vertebrae that had collapsed to not more than 80% of their original heights. A collapse was defined by vertebrae that had collapsed to more than 50% of their original heights. Vacuum clefts were defined as areas in the collapsed vertebral body that were gas-like with radiolucency observed in the extension stress view or abnormal signal intensity on MR imaging suggesting avascular necrosis¹¹). MR imaging features of intravertebral clefts, which are varied in appearance, depending on whether they are filled with gas or fluid at the time of imaging. Avascular necrosis usually has a low signal on T1-weighted images and high signal on T2-weighted images. After postural reduction for two days, bone cement augmentation procedures following postural reduction were performed in all patients. The mean age of the patients was 70.7 years with range from 64 to 85. The mean follow-up period after bone cement augmentation procedures was 14.8 months and ranged from 12 to 27 months. Two patients had received steroid therapy due to asthma and nephritis. All patients with T-scores lower than -3.0 by BMD were considered to have severe osteoporosis; the mean T-score of the

patients included in this study was -3.82. Lateral radiographs were taken and analyzed at four different points in time; 1) at first admission after injury, 2) preoperative lateral (after conservative treatment including bed rest, medications, and bracing), 3) postoperative lateral (including postural reduction for two days before procedures and intraoperative pressure reduction), and 4) at final follow-up.

The vertebral height of the fractured vertebra was defined as the distance between identical points on the superior and inferior endplates at the anterior (Haf, line ac) portion. The vertebral height of the normal vertebra was defined as the distance between identical points on the superior and inferior endplates at the anterior portion at adjacent below vertebral body (Han, line eg). The relative anterior height (Ha = Haf / Han) was then calculated. The kyphotic angle was measured as the angle in degrees defined by the intersection of the superior and inferior endplates of the fractured body (line ab & cd) (Fig. 1).

The patients were evaluated according to a modified version of MacNab's criteria (Table 1) and using the visual analogue scale (VAS) for characterizing the clinical outcome after spinal surgery. Statistical analysis, including mean values (MV) and standard deviations (SD), was performed using SAS

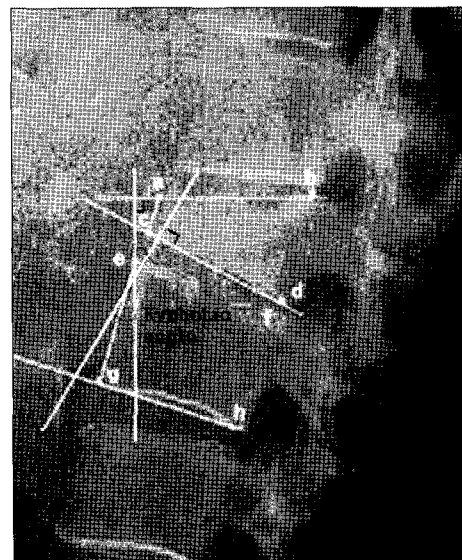


Fig. 1. Measurement of kyphotic angle, normal anterior (Han, line ac) vertebral height and fracture anterior (Haf, line eg) vertebral height. The relative anterior heights were reported as fractions of the referenced height (Ha = Haf / Han).

Table 1. Modified MacNab's criteria for characterizing the outcome after spinal surgery

Outcome	Description of Criteria
Excellent	No pain; no restriction of mobility; return to normal work & level of activity
Good	Occasional nonradicular pain; relief of presenting symptoms; return to modified work
Fair	Some improved functional capacity still handicapped and unemployed
Poor	Continued objective symptoms of root involvement; additional operative intervention needed at the index level regardless of the length of postoperative follow-up

6.12 (SAS Institute, Inc., Cary, NC, USA). Comparisons between different points in time were performed using the paired Student's t-test. Differences were considered statistically significant at $p < 0.05$.

RESULTS

All fractures occurred in the thoracolumbar junction. The

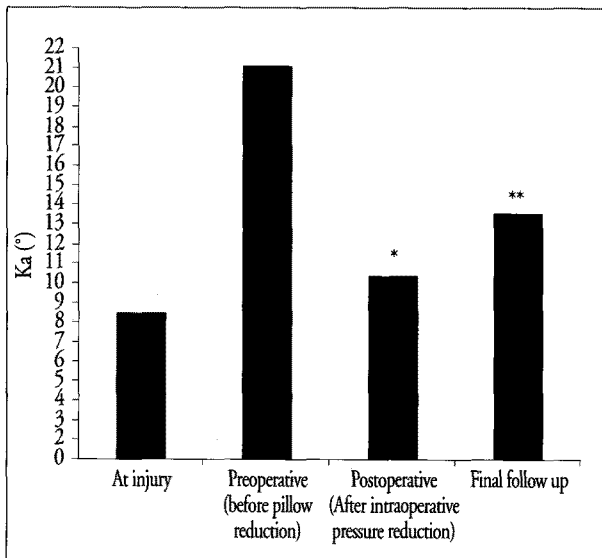


Fig. 2. Changes of kyphotic angle after bone cement augmentation procedures. Values are given as mean \pm SD; comparisons by means of paired t-test. * $p < 0.01$ for preoperative versus postoperative, ** $p < 0.05$ for preoperative versus final follow up.

levels were T11 (n = 1), T12 (n = 7), L1 (n = 7) and L2 (n = 3). Percutaneous vertebroplasty was performed in 16 patients, and balloon kyphoplasty was performed in 2 patients (Table 2). The mean length of time from initial injury to the bone cement augmentation procedure was 15 months. The mean injected cement volume was 4.1 mL (range 2.4-5.9 mL). Unipedicular percutaneous vertebroplasty was performed in 15 patients and bipedicular cement injection was performed in three patients. The kyphotic angle improved significantly from $21.2 \pm 4.9^\circ$ before surgery to $10.4 \pm 3.8^\circ$ after surgery. The improved alignments were maintained on a true lateral X-ray at the final follow-up evaluation. At the final follow up visit, the mean correction loss for the kyphotic deformity was a 3.2° from the angle after procedure (Fig. 2). The fraction of involved vertebral height also increased significantly from 0.30 ± 0.12 to 0.60 ± 0.10 ($p < 0.05$). The mean pain score (visual analogue scale) prior to vertebroplasty was 7.1, which decreased to 3.1 at 7 days after procedure. Pain relief was maintained and no patient complained of aggravated pain at the final follow up visit. No patient experienced neurological deterioration as a result of the procedure. All patients subjectively reported relief of their pain, and none of them complained of severe worsening of pain during the follow-up (Fig. 3). Sixteen patients were graded as having an excellent or good result according to modified MacNab's criteria (Excellent : 12, Good : 4, Fair : 2). Asymptomatic cement leakage into the paravertebral area or adjacent upper disc occurred in two patients. However, there were no major

Table 2. Demographic and clinical characteristics of the patients

No	Age	Sex	Fx Level	Sx Period	BMD (T-score)	Operation		Inj cement Volume (cc)	F/U period (months)	MacNab's criteria (postoperative)	Complications	
						Procedure	App				Adjacent Fx	Cement leakage
1	72	F	L1	23	-4.18	VP	Bi.	5.9	25	E	T12	-
2	70	F	L2	20	-3.73	VP	Uni.	3.2	13	E	-	-
3	64	M	T12	12	-3.50	VP	Uni.	5.1	14	G	-	-
4	67	M	L1	12	-4.03	VP	Uni.	5.3	18	E	L2	-
5	85	F	T12	21	-4.12	VP	Uni.	5.8	17	E	T11	-
6	72	F	L1	13	-3.79	VP	Uni.	4.2	12	E	-	-
7	66	F	L1	27	-3.63	VP	Uni.	3.6	12	E	-	-
8	71	F	L1	13	-3.81	VP	Uni.	4.1	16	E	-	-
9	75	F	L2	12	-3.65	VP	Uni.	4.7	15	F	-	PV
10	73	F	T12	12	-3.23	VP	Uni.	3.0	13	G	-	ID
11	65	F	L1	13	-3.62	VP	Uni.	3.5	12	E	-	-
12	67	F	T12	12	-3.85	VP	Uni.	4.0	12	G	-	-
13	66	F	T12	13	-4.17	VP	Uni.	2.8	12	F	T10	-
14	70	F	T12	16	-4.05	KP	Bi.	3.6	15	E	-	-
15	71	F	L1	13	-3.65	KP	Bi.	4.7	13	G	-	-
16	72	F	T12	14	-3.46	VP	Uni.	3.6	12	E	-	-
17	72	F	L2	13	-4.28	VP	Uni.	3.0	13	E	-	-
18	75	F	T11	12	-3.95	VP	Uni.	2.4	13	E	-	-

No : number, Fx : fracture, Sx : symptom, BMD : bone mineral densitometry, OP : operative, Redu : reduction, F/U : follow-up, Inj : injection, VP : vertebroplasty, KP: kyphoplasty, App : approach, Uni : unipedicular, Bi : bipedicular, PV : paravertebral, ID : intradiscal

complications such as spinal cord compression, pulmonary embolism, or serious infection. During the follow up, another fracture occurred on the adjacent level in 4 patients; these fractures were also successfully treated by bone cement augmentation with vertebroplasty or kyphoplasty (Fig. 4).

DISCUSSION

Osteoporotic compression vertebral fractures are common and a leading cause of disability and morbidity in the elderly⁹. The pain associated with acute osteoporotic vertebral compression fractures may be initially intolerable. In a number of cases, the pain subsides over a period of several weeks or months¹⁷. However, some patients develop secondary vertebral collapse or intravertebral vacuum clefts, which can trigger continuous back pain and kyphotic deformity and it is possible that the pain can become chronic after conservative treatments without surgical management²⁰.

Bone cement augmentation procedures such as percutaneous vertebroplasty and balloon kyphoplasty have been widely used to treat painful osteoporotic compression fractures. However, these procedures have been shown to be effective for acute and subacute fractures, especially for those fractures that are less than four months old^{10,19}. One study reported good result treating a post traumatic osteoporotic vertebral compression fracture that was 5-years-old, and another study reported successful management of chronic symptomatic compression fractures with percutaneous vertebroplasty^{4,8}. They insisted that chronic symptomatic osteoporotic compression fracture, even showing isointense on T1-weighted images, could be caused by compressive force acting on the nociceptor endings in the bone marrow. Enhancing the rigidity and strength by bone cement reduces bone deformation and painful micromotion at the fracture site. Moreover, pain relief can be thought to be induced by the destruction of sensitive nerve endings in the matrix by

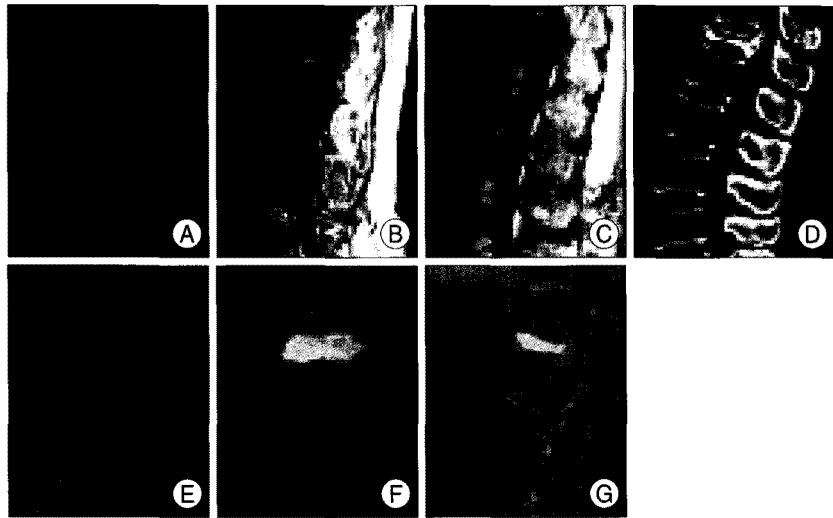


Fig. 3. Osteoporotic compression fracture at T12 level in a 64-year-old man. A : Simple lateral radiograph at initial injury shows minimal compression fracture at T12. B : T12 body had collapsed 3 months after injury. C, D and E : T12 body had more collapsed 12 months after injury and vacuum cleft was observed in extension stress view. F and G : Simple radiographs obtained after percutaneous vertebroplasty show complete filling of T12 body without any leakage.

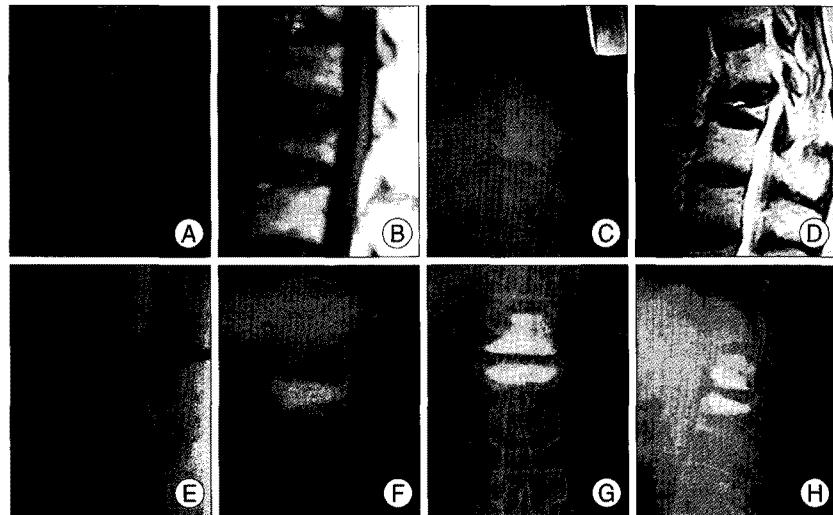


Fig. 4. Osteoporotic compression fracture at L1 level in a 72-year-old woman. A and B : Simple lateral radiograph and magnetic resonance image show minimal compression fracture at L1. C and D : L1 vertebral body had seriously collapsed 23 months after injury and intravertebral fluid was observed in the T2-weighted magnetic resonance image. E : Vertebroplasty needle insertion is shown after intraoperative pressure reduction. F : Postoperative simple radiograph after percutaneous vertebroplasty shows effective filling of L1 body without any leakage. G and H : Another fracture that occurred on the adjacent upper level at 7 months after percutaneous vertebroplasty, and this was also effectively treated by percutaneous vertebroplasty.

the bone cement, which is directly toxic due to enhanced production of free radicals and heating during polymerization. Despite these reports, outcomes in patients with chronic fractures treated by bone cement augmentation have still remained unclear.

The causes of chronic pain after osteoporotic vertebral compression fracture are caused by : 1) incomplete vertebral healing with progressive osseous collapse, 2) altered spine kinematics as a consequence of spinal deformity, or 3) the

development of a pseudarthrosis at the involved vertebra⁶. These problems can also lead to an impaired quality of life and depression. Kümmell first described delayed post-traumatic vertebral collapse in 1895. There are many possible explanations for these events, such as poor nutrition, vascular disruption with microhemorrhage and thrombosis, and biomechanical failure^{3,7,12,15,16}. However, understanding of the exact causes of this entity remains unclear. Some investigators agree that the intraosseous vacuum phenomenon results from a vascular insult causing secondary bone necrosis². Others suggest that the cleft in the affected vertebral body of the osteoporotic spine is a false joint lined by fibrocartilaginous tissue and significant movement consistent with a pseudarthrosis. The radiographic signs of this disease have been described as the presence of a band-like radiolucency in a collapsed vertebral body, referred to as an intraosseous vacuum cleft. The cleft is hypointensive on the T1-weighted MRI scans. On T2-weighted images, the cleft may be either hypointensive or hyperintensive, depending on whether it is occupied by gas or fluid. In a study of vertebral collapse, the vacuum phenomenon was seen in 15% of patients by plain radiography and in 21% when all imaging modalities were considered¹³. Magnetic resonance imaging helped to show the cleft when the findings of the radiographs were ambiguous or unclear. Kim et al.¹¹ suggested that flexion-extension radiographs obtained in patients with osteoporotic compression fractures increases the detection of the intravertebral vacuum phenomenon.

There has been an attempt to classify the several seemingly minor differences in shape of the vertebrae in the early radiographs, to better predict the prognosis of vertebral compression fractures in the elderly, and to clarify the relationship between the initial radiographs and the clinical results. Ito et al.⁷ reported the pathogenesis of progression to delayed vertebral collapse, and the initial radiograph of their case indicated a bow-shaped type. Moreover, an intravertebral cleft and instability of the affected vertebra were risk factors for late collapse resulting in neurological deficits. They concluded that the correct initial diagnosis and immobilization were important factors in preventing delayed collapse with neurological deficits. Sugita et al.²² classified the early features into five types based on lateral radiographs: the swelled-front-type, bow-shaped-type, and projecting-type fractures had a poor prognosis with late collapse and commonly showed a vacuum cleft. On the other hand, the concave and dented-type of fractures had a good prognosis and achieved almost complete fusion without surgical treatment. However, in this series, we did not analyze the relationship between the fractures type and frequency of late collapse due to the non specific diagnosis of the initial fracture types. A substantial

correction of kyphosis and the restoration of anterior vertebral height could be obtained by extended posture despite the long standing length of time from the initial injury. In addition to using the technique of postural reduction, we found that placing bolsters under the chest and pelvis, to hyperextend the spine while patients were in a prone position, helped restore the vertebral body height and enlarge the vacuum cleft. This study shows that bone cement can fill easily the entire vacuum cleft usually via the unipedicular approach in most patients. Due to the pre-existent cleft, the majority of the procedures could be performed successfully via the unipedicular approach. The usefulness of postural reduction for a thoracolumbar spinal fracture and conservative treatment of compression fractures with postural reduction have been advocated by many authors⁵. Bedbrook¹ noted that 90% of the fractures of the thoracic and lumbar spine could be treated using this closed method. Although intravertebral clefts are thought to represent trabecular defects caused by bone destruction associated with fractures, within the post-traumatic period, there is the risk of progression, destruction of new trabeculae, and circulatory disturbances. These conditions can result in disturbances and delays in the normal healing process of the fracture resulting in nonunion. Therefore, postural reduction in the supine hyperextended position and intraoperative pressure reduction can re-expand the collapsed vertebral body in patients with an intravertebral cleft. The results of this study suggest that patient selection for vertebral augmentation procedures should not be based on the stage of the compression fracture but rather on evidence of non-healing on the dynamic stress radiographs or MR images as well as the degree of persistent pain.

CONCLUSION

Kyphotic deformity and chronic pain caused by long-standing osteoporotic vertebral compression fractures may occur and limit the patient's activities of daily living as well as quality of life. Patients with long-standing but non-healing osteoporotic compression fractures can be successfully managed with bone cement augmentation procedures following postural reduction and intraoperative pressure reduction.

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