CLINICAL ARTICLE

Modified unilateral transpedicular percutaneous vertebroplasty for treatment of osteoporotic vertebral compression fractures

Xiao-ming Yang MD¹, Tian-liang Wu MD², Hong-guang Xu MD¹, Hong Wang MD¹,
Ping Liu MD¹, Ling-ting Wang MD¹, Xue-wu Chen MD¹

¹Department of Orthopaedics, Yijishan Hospital, and ²Wuhu Second People's Hospital, Wuhu, China

Objective: To comparatively assess the clinical outcome of modified unilateral percutaneous vertebroplasty for the treatment of osteoporotic vertebral compression fractures.

Methods: The clinical outcome and incidence of cement extrusion in a consecutive group of 70 patients at our institution between December 2005 and December 2008 was retrospectively reviewed. Thirty-five patients were randomly distributed to modified percutaneous vertebroplasty (Group A) and 35 to traditional percutaneous vertebroplasty (Group B). A visual analog scale (VAS) was used on the first post-operative day and 1 year later to assess the severity of pain before and after vertebroplasty. The incidence of cement extrusion on CT scan was also compared between the two groups.

Results: The treatment was successful in all seventy patients. The incidence of cement extrusion was 14.29% (5/35 patients) in group A, and 37.12% (13/35 patients) in group B, this difference being statistically significant ($P < 0.05$). No patients had serious complications. Complete pain relief was achieved in 50 patients, and significant relief in the other 20 (20/70 patients). There was no statistically significant difference between Groups A and B.

Conclusion: Modified percutaneous vertebroplasty enhances the accuracy of cement injection into the center of the vertebral body, increasing the safety of the procedure with no increase in cost. It is a safer and more easily performed technique for treating patients with osteoporotic vertebral compression fractures than traditional percutaneous vertebroplasty.

Key words: Fractures, compression; Osteoporosis; Polymethyl methacrylate; Treatment outcome.

Introduction

Patients with osteoporotic vertebral compression fractures are associated with relatively severe morbidity and mortality. A large prospective study noted a 23% increase in mortality in women over 65 years old with vertebral compression fractures compared with age-matched control subjects¹. The mortality rate increases with the number of fractured vertebrae. Osteoporotic compression fractures can cause chronic pain, sleep loss, reduced mobility, depression, and restricted independence. The most painful osteoporotic compression fractures are conventionally treated by bed rest, narcotic analgesia,

orthosis, and physical therapy. However, bed rest accelerates bone loss and causes muscle wasting, which also causes increasing pain. Medications taken for symptomatic relief can cause additional drug-related side effects, such as gastrointestinal tract disturbance.

Galibert *et al.* proposed percutaneous acrylic vertebroplasty for the treatment of aggressive vertebral hemangiomas². At present this technique is used extensively for osteoporotic and malignant vertebral fractures for which conventional therapies are not effective or well tolerated. The complication of polymethyl methacrylate (PMMA) cement leakage from the compressed vertebral body is of most concern. Traditional bilateral puncture has the disadvantages of being more time-consuming and expensive and having a higher incidence of PMMA leakage. Compared to bilateral puncture, unilateral transpedicular puncture may well avert the above shortcomings. The advantages of a unilateral approach over the bilateral transpedicular approach are that fewer needles and

Address for correspondence Hong-guang Xu, MD, Department of Orthopedics, Yijishan Hospital, Wannan Medical College, 92 Zheshan West Road, Wuhu, China 241001 Tel: 0086-553-5739037; Fax: 0086-553-5739037; Email: sunny2008ming@sina.com

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punctures are required, thereby permitting reductions in both cost and the occurrence of complications such as hemorrhage at the puncture site, hematoma, and pain. Additionally, operative time and radiation exposure are reduced. As a result, the unilateral approach is better for both patient and operator.

In this study, we used a modified unilateral transpedicular percutaneous vertebroplasty (PVP) to treat osteoporotic vertebral compression fractures and compared the clinical outcome and incidence of cement extrusion to that obtained with the bilateral transpedicular approach.

Materials and methods

Patients' data

A consecutive group of 70 patients with a total of 90 vertebral compression fractures attending our institution between December 2005 and December 2008 were retrospectively reviewed. Thirty-five patients (50 vertebrae) underwent modified PVP (Group A) and 35 patients (40 vertebrae) traditional PVP (Group B). All patients were randomly assigned to group A or B. The two groups were comparable in age, sex, involved segments and degree of pain. There were 30 men and 40 women, with a mean age of 72.8 years (range, 60–85 years).

The inclusion criteria included: (i) painful vertebral body fractures; (ii) diagnosis of acute or subacute vertebral body fractures on the basis of MRI; and (iii) less than 50% height loss. Contraindications included: (i) presence of pain with radicular symptoms that did not

correspond to the area of the fracture; (ii) active localized or systemic infection; (iii) known allergy to PMMA; (iv) uncorrected coagulopathy; (v) painless compression fracture; (vi) complete vertebral collapse; (vii) epidural tumor; (viii) significant extrusion causing spinal stenosis; and (ix) patient unable or unwilling to give informed consent^{3,4}.

The clinical outcome and incidence of cement leakage were compared between the two groups. A visual analog scale (VAS) was used to assess the severity of pain before and after vertebroplasty (on the first post-operative day and 1 year later). The affected levels were T₁₁ (n = 30), T₁₂ (n = 25), L₁ (n = 15), L₂ (n = 10), L₃ (n = 5) and L₄ (n = 5). All patients had painful osteoporotic vertebral fractures that had been refractory to medical therapy for at least 2 months. Accurate medical histories were taken from all patients enrolled in this study and they all underwent clinical examination to confirm and evaluate the role of osteoporotic vertebral compression fracture in their disability.

All subjects underwent instrumental investigation, including traditional radiographic examination in two orthogonal projections and/or MRI (Fig. 1). Multislice CT scans (64 plus CT, Philips Brilliance, Best, the Netherlands) were performed for all evaluations. Generally, imaging was performed in the prone position as in PVP, and multiplanar reconstructions of the original horizontal, sagittal, and coronary images were acquired. In order to improve puncture accuracy, we adopted a simple puncture simulation method based on the preoperative CTs for determining the puncture angle on CT as described by

Figure 1 (a) Anteroposterior and (b) lateral radiographs of a 60-year woman with T₁₂ osteoporotic vertebral compression fractures and (c) T1 and (d) T2 images on MRI of the same patient.

Figure 2 (a) Anteroposterior and (b) lateral fluoroscopic images showing the surgical techniques.

Kobayashi *et al.*⁵. In addition, all enrolled patients continued their drug therapy for osteoporosis.

Operative procedure

All procedures were performed using a C-arm angiographic unit and with the patient in the prone position. Patient blood pressure, heart rate, and oxygen saturation were monitored during the whole procedure. All PVPs were performed under local anesthesia by injecting 2 mL of 2% lidocaine hydrochloride both at skin level and deep enough to include the periosteum of the pedicle. The pathway was transpedicular for all vertebrae. All the procedures were performed by the same surgeon. In Group A, modified PVP was performed using a unilateral approach only, and the cement injections were performed manually (all being done by the third author). Care was taken to ensure that the cement injector crossed the midline of the vertebrae. In the control group (B), PVP was carried out by the traditional PVP procedure. The soft ice cream-like mixture of PMMA was injected using a bone cement injector for the vertebroplasties in group B. The bone cement was injected under lateral fluoroscopy while confirming that there was no leakage into the vertebral canal or blood vessels (Fig. 2). Injection was terminated when the injected cement reached the region around the posterior vertebral border, at which point the puncture needle was removed. On the basis of our previous clinical experience and the data in the literature on the filling volume and clinical outcome ratio, from 1 to 3.5 mL (mean, 2.5 ± 1.1 mL) of cement was injected into the anterior two-thirds of each treated vertebra.

Evaluation methods

To evaluate the effects of treatment, subjective assessment of pain was performed by obtaining VAS scores before and after surgery. Clinical and radiographic mea-

sures were observed and collected (Fig. 3). After surgery, assessment was done at regular intervals: one day postoperatively, then at 2 weeks, 1 year, and annually thereafter. Anteroposterior and lateral radiographs were taken at each follow-up visit. Special attention was paid to distribution of bone cement in the vertebral body, restoration of body height, and development of adjacent vertebral fractures. Cement leaks were classified as follows: (i) cement leak into an adjacent intervertebral disc; (ii) cement leak into a para- or pre-vertebral vein; and (iii) cement leak into an epidural vein.

Statistical analysis

The incidence of cement leakage and the clinical outcomes in each group were recorded and analyzed using the χ^2 test and analysis of variance using the statistical software package SPSS 13.0. $P < 0.05$ was considered statistically significant.

Results

The results of the two groups are shown in Tables 1 and 2. The VAS score before surgery was not significantly different in the two groups ($P > 0.05$). There was a statistically significant difference ($P < 0.05$) between the two groups in the incidence of postoperative cement leakage. The average hospital stay were 4.1 days (range, 3–7 days), and the average surgery time was 18 minutes (range, 12–30 minutes). Blood loss was not recorded because the quantity was minimal. The average amount of bone cement injected was 2.5 mL (range, 1–3.5 mL). No major perioperative complications, such as spinal cord compression, pulmonary embolism or infection, occurred. Cement leakage into an adjacent intervertebral disc occurred in 10 patients, into a para- or pre-vertebral vein in 13 and into an epidural vein in 5; all leakages were

Figure 3 (a) Anteroposterior and (b) lateral radiographs of a T₈ compression fracture after vertebroplasty. (c) Sagittal, (d) coronal and (e) cross-sectional CT reconstruction was performed postoperatively.

asymptomatic. Seventeen patients had developed fractures in the adjacent proximal vertebral body by 1 year after operation. Ten of these patients were treated conservatively, whereas the others underwent repeated vertebroplasty for the adjacent fracture.

Table 1 Cement leakage in Groups A and B

Cement leakage	Yes	No	χ^2	<i>P</i>
Group A	5	30	4.79	0.03
Group B	13	22		

Table 2 Comparison of changes in VAS in the two groups before, and one day and one year after, PVP ($\bar{X} \pm S$)

Time	Group B (n = 35)	Group A (n = 35)	<i>t</i>	<i>P</i>
Before PVP	8.2 ± 1.3	8.0 ± 1.1	0.69	0.49
1 day after PVP	2.1 ± 1.4	2.2 ± 1.2	0.32	0.75
1 Year after PVP	2.2 ± 1.3	2.3 ± 1.4	0.31	0.76

Discussion

Vertebroplasty and kyphoplasty have become common surgical techniques for the treatment of vertebral compression fractures. Vertebroplasty involves the percutaneous injection of bone cement into the cancellous bone of a vertebral body with the goals of pain alleviation and prevention of further loss of vertebral body height. Kyphoplasty utilizes an inflatable balloon to create a cavity for the cement and has the additional goals of restoring height and reducing kyphosis. Vertebroplasty and kyphoplasty are effective treatment options for the reduction of pain associated with vertebral body compression fractures. Eck *et al.* performed a comprehensive review of 1036 abstracts of published reports of vertebroplasty and kyphoplasty⁶. Both vertebroplasty and kyphoplasty provide significant improvement in VAS pain scores. Vertebroplasty produced a significantly greater improvement in pain scores. Thus PVP is a safe and reliable procedure for the treatment of vertebral compression fractures caused by osteoporosis and metastatic disease⁷.

In recent years, a unilateral approach has been used more and more in PVP. A unilateral approach offers the

advantages of reducing the risks and operation time. It has been reported that there is no significant difference between PVP by the unilateral and bilateral transpedicular approaches in the effects of treatment⁸. This is consistent with our results. In our study, all patients (both groups) experienced good back pain relief after surgery and there were no significant differences between the two groups in VAS scores. However, there have only been a few studies comparing unilateral and bilateral approaches in regard to cement leakage.

Complications of vertebroplasty are relatively infrequent. However, Hulme *et al.* reported that cement extravasation rate in PVT has been documented to occur in up to 88% of patients⁹. Most cement leakages are asymptomatic⁷. They may be divided into two categories according to whether or not they are related to PMMA cement leakage from the compressed vertebral body. PMMA leakage, a very frequent occurrence in vertebroplasty, is also the main source of complications¹⁰. Pulmonary embolism with PMMA may occur when there is a failure to recognize venous migration of cement early in the procedure. Cortical destruction, presence of an epidural soft-tissue mass, highly vascularized lesions, and severe vertebral collapse are factors which increase the rate of complications, which is therefore much higher in metastatic than in osteoporotic vertebral collapse. Prevention of PMMA leakage-related complications is multifactorial, issues including preparation for the procedure, needle approach and placement, and cement application¹¹.

In our study, use of a screwing cement injection syringe in Group B resulted in a higher incidence of cement extrusion than in Group A. The reason for this difference may be that the direction in which the PMMA goes cannot be controlled when using these syringes. However, this is not so with modified PVP. It has been reported that the injection pressure during vertebroplasties exceeds 1500 kPa, which approaches the limit of what can be applied manually. Thus the injection procedure can be better controlled when performed manually, because the occurrence of cement extrusion due to excessive pressure is then minimized. Furthermore, good cement diffusion was proved by postoperative CT scans. It is important that the cement injector crosses the midlines of the vertebrae. It has also been suggested that too much pressure during PMMA cement injection has disadvantages. The greater the pressure of injection, the higher is the incidence of cement leakage. Anselmetti *et al.* confirmed that use of new high-viscosity cement can effectively reduce the risk of cement leakage during PVP¹². However, a special delivery system is required, which increases the cost. Baroud *et al.* designed a new

cannula with a larger internal diameter in the proximal section¹³. It significantly decreased the delivery pressure and made high-viscosity cement injection possible¹⁴. The rigidity of the augmented vertebrae was much increased because high-viscosity cement injection changes the biomechanics of load transfer to the adjacent vertebrae. Although very little is known of the effect of vertebroplasty on the overall alignment and function of the spine, particularly the adjacent vertebrae, the current practice of maximum filling with cement to restore the rigidity and strength of a vertebral body may provoke fractures in adjacent, non-augmented vertebrae¹⁵. Furthermore, some reports have suggested that multilevel treatment using low-volume PMMA might be effective in preventing new fractures in high-risk patients^{16,17}. The clinical result is not closely dependent on the amount of cement injected. In addition, a small amount of cement is sufficient to restore biomechanical strength and rigidity.

Conclusion

Vertebroplasty is generally a safe and effective procedure to control pain associated with fractures of the spinal column. Significant complications can occur and are likely underreported. Modified unilateral transpedicular PVP technique using manual injection minimizes the risk of PMMA migration, compared to traditional PVP. The learning curve should be moderately quick and safe if physicians familiarize themselves with these principles.

Disclosure

No benefits in any form have been, or will be, received from a commercial party related directly or indirectly to the subject of this article.

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