

Efficacy of Percutaneous Kyphoplasty in Treating Osteoporotic Multithoracolumbar Vertebral Compression Fractures

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abstract

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Percutaneous kyphoplasty is a minimally invasive technique that has become an effective and routine alternative for managing osteoporotic vertebral compression fractures. This article reports the clinical outcome of a series of 54 cases of osteoporotic thoracolumbar vertebrae compression fractures treated by percutaneous kyphoplasty. Fifty-four patients with confirmed osteoporosis and at least 1 level of thoracolumbar vertebrae compression fracture were retrospectively selected. Pre- and postoperative and last follow-up clinical evaluation and radiological data were analyzed, including change of visual analog scale (VAS), reduced use of painkillers, locomotor activity, Cobb's angle, and average vertebral body height.

Mean follow-up was 20.4 months (range, 6-36 months). In all cases, percutaneous kyphoplasty treatment was successful, significantly increasing vertebral body height, diminishing kyphosis in the fractured vertebrae, and decreasing painkiller use. In all patients, percutaneous kyphoplasty partially or completely relieved back pain. No new deformity was found within the follow-up period, nor were any other complications. The cement leakage rate was 3.86% (8 of 207 vertebrae) with percutaneous kyphoplasty, but no neurological or other complaints were received.

Percutaneous kyphoplasty is a simple and safe procedure in managing osteoporotic vertebrae compression fractures. It relieves pain quickly, restores vertebral height, prevents further fracture, and improves patient quality of life.

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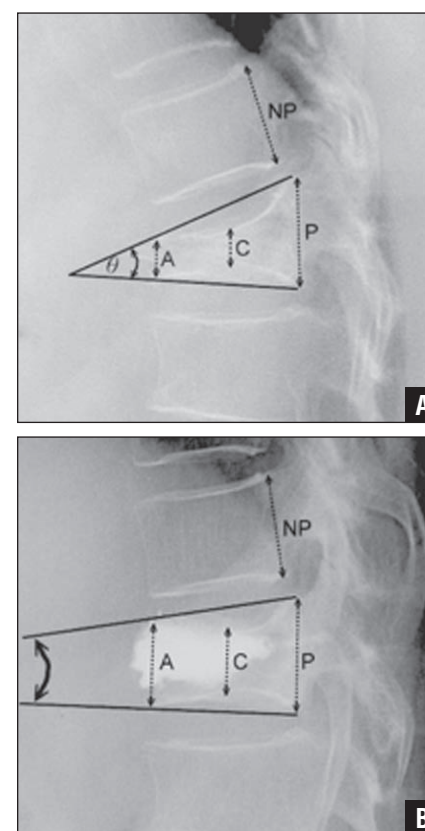


Figure: Measuring vertebral body height at the anterior (A), central (C), and posterior (P) aspects pre- (A) and postoperatively (B). Abbreviation: NP,

The prevalence of osteoporosis has increased over the past decade as society has aged. Vertebral fractures are the most common fractures associated with osteoporosis and have a substantial negative impact on the quality of patients' lives.¹ It is important to treat osteoporotic vertebrae fractures promptly to reduce pain in elderly patients.

The effectiveness of traditional, conservative treatments, such as bed rest, pain control, and back braces, is uncertain. Long-term bed rest could lead to further bone loss, muscular atrophy, and unhealed fractures. Traditional surgery for treatment of spinal fracture constitutes a major operation with potential large volumes of blood loss, and it is difficult to properly secure the implants in severely osteoporotic bones.² Percutaneous kyphoplasty is a new technique with many advantages: it is minimally invasive and does not require implants or open surgery, and patients can recover quickly. Percutaneous kyphoplasty is an invaluable alternative to treat elderly patients' osteoporotic vertebral compression fractures. However, concern exists as to the safety of using the percutaneous kyphoplasty technique as a routine management of osteoporotic vertebral fractures.

This article describes our results treating 54 cases of vertebral compressive fracture using percutaneous kyphoplasty between 2003 and 2006.

MATERIALS AND METHODS

We retrospectively studied 54 patients (6 men and 48 women; mean age at surgery, 71.6 years) with symptomatic acute amyelic osteoporotic fractures (total, 207 osteoporotic vertebral compression fractures). The 207 vertebrae involved T4-L5 (one T4, four T5, three T6, fifteen T7, seven T8, fourteen T9, six T10, nineteen T11, thirty-six T12, thirty-eight L1, twenty-one L2, sixteen L3, eighteen L4, and nine L5). All patients had low back pain and could not sit continuously for >1 hour. The pain aggravated after activity and was not relieved by bed rest. Physical examinations

showed that the corresponding spinal processes had tenderness and percussion pain. The degree of vertebral compression was in the range of 25% to 75%. Symptoms lasted from 2 months to 48 months (average, 29 months). All patients had poor responses to pain relief or anti-osteoporosis drug treatment.

The diagnosis of osteoporotic vertebral compression fracture was confirmed by: (1) general health examination; (2) bone mineral density examination using bone densitometry (Lunar DPX-L; GE Healthcare, Waukesha, Wisconsin) (mean BMD of the femoral neck, 0.605 g/cm²); (3) routine anteroposterior (AP) and lateral radiograph examinations of the spine (Genant semi-quantitative method, II and III degree); and (4) computed tomography (CT) and magnetic resonance imaging (MRI; T1-weighted demonstrated hypointense and T2-weighted hypointense). There was no sign of spinal cord or nerve root damage in any case.

SURGICAL TECHNIQUE

Anteroposterior and lateral radiographs and CT of the spine were obtained to confirm the integration of the posterior border of the vertebral body, and cases with burst fractures were excluded. Laboratory examination and general physical checkup were also taken to confirm the imaging findings.

For the percutaneous kyphoplasty procedure, we used the balloon kyphoplasty set (Kyphon, Inc, Sunnyvale, California), comprising an introducing cannula, operative cannula, Kirschner guidewires, manual drill, inflatable balloon, dedicated pressure transducer-equipped syringe, working cannula, and reconstituted acrylic polymethylmethacrylate, which was used to fill the vertebral cavity following balloon expansion.

All patients underwent surgery under general anesthesia in the prone position with the belly suspended in midair. The minimally invasive kyphoplasty apparatus and special balloon device were used via either a transpedicular or bipedicular ap-

proach. Under C-arm imaging guidance, the surgeon probed a guide pin into the lateral upper edge of the pedicle of the vertebral arch. The percutaneous puncture needle was centered at 10 o'clock over the left pedicle and 2 o'clock over the right pedicle on the AP view under fluoroscopic guidance. A cannula with touch needle was then inserted to the anterior 2 to 3 mm of the vertebral body posterior edge of the cortical plate, and the guide pin and touch needle were extracted.

The drill was inserted along the cannula, and a channel was drilled into the fractured vertebral body, then a balloon was inserted through the drill tunnel and inflated slowly. The ideal position for the balloon was considered to be occupying three-fourths of the vertebral bodies showing at the lateral view. The inflatable balloon was used to reduce the fracture, elevate the endplates, and create a void in the vertebral body. The inflated balloon was filled with liquid contrast medium to monitor the balloon position and size continuously during fracture reduction. The pressure used for inflating the balloon was controlled at <250 to 300 psi. When a cavity had been created in the vertebral body and the compressed fracture was reduced, the balloon was deflated and removed through the tunnel. Two point zero to 7.5 cm³ (mean, 5.7 cm) bone cement was then injected slowly into the cavity within the vertebral body, and the surgery was completed by dressing the wound. In some patients, percutaneous kyphoplasty was repeated in a similar fashion in several adjacent vertebrae with fractures or with early signs of compression.

For osteoporosis management, our standard regime included initial use of calcitonin for pain relief (20 IU/week for 1-2 months) and calcium carbonate (600 mg/day) or calcitriol (0.5 µg/day) for calcium and vitamin D supplementation. One to 2 months after kyphoplasty, patients switched to bisphosphonates such as alendronate (70 mg/week) for 18 months.

Clinical Evaluations

Evaluations were performed 3 times: one day preoperatively, 3 days postoperatively, and 6 to 36 months postoperatively (average postoperative follow-up, 20.4 months). Visual analogue scale (VAS), painkiller score (0, no medicine; 1, use of nonsteroidal anti-inflammatory drugs; 2, use of painkiller not used for anesthesia; 3, use of painkiller used for anesthesia; 4, use of intravenous or intramuscularly injected painkiller), and locomotor activity score (1, no difficulty; 2, difficulty walking; 3, use of wheelchair or can only sit; 4, lying in bed only)³ were monitored. Anteroposterior and lateral radiographs of the spine were taken pre- and postoperatively and during follow-up. The Cobb angle and vertebral heights of the anterior, middle, and posterior border were measured on the lateral projection (Figure), and the changes were compared over time.

SPSS11.0 software (SPSS, Inc, Chicago, Illinois) was used to analyze the data. Statistical analyses were performed using paired samples *t* test, and *P* < .05 was considered significance.

RESULTS

All patients completed the percutaneous kyphoplasty surgery as planned. Mean surgery time per vertebra was 25 minutes. There was no evidence of side effects or complications due to the anesthesia protocol, except for discomfort reported by some patients about the surgical position. No nerve or spinal cord injury or disruption of the balloon occurred in any case. The mean amount of bone cement filled in each vertebra was 5.7 mL (range, 2.0-7.5 mL). Mean blood loss during surgery was 35 mL (range, 20-50 mL) (Table 1).

Among the 54 patients (207 vertebrae) undergoing the percutaneous kyphoplasty technique, 8 vertebrae had bone cement leakage, including 3 cases leaking into the tunnels of the vertebral arches, 2 leaking into the next intervertebral spaces, 2 leaking to the side of vertebra, and 1 leaking into the vertebral canal. The rate of bone cement

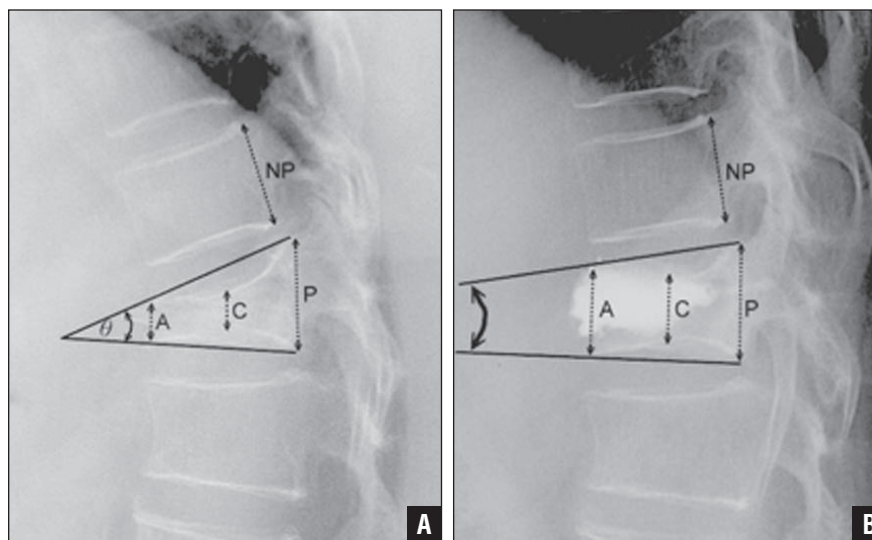


Figure: Measuring vertebral body height at the anterior (A), central (C), and posterior (P) aspects pre- (A) and postoperatively (B). Abbreviation: NP,

leakage was 3.86%. However, no patients with bone cement leakage had symptoms of nerve damage postoperatively.

After lying in bed for 6 to 12 hours, patients could sit freely, and 24 hours postoperatively, they were allowed to walk freely. No nerve injury, spinal cord compression, or lung embolism was seen in any patient.

Postoperative Changes

Significant improvements in VAS values, painkiller scores, and locomotor activity scores were found in the postoperative data compared to the preoperative data. The difference between the VAS values for pain detected before and after percutaneous kyphoplasty was statistically significant, whereas no difference in VAS value was found between the time immediately postoperatively and at follow-up (Table 2).

There were significant differences between the pre- and postoperative period in the anterior and middle heights of the vertebral bodies, and no significant difference was found in the posterior heights of the vertebral bodies at all time points. There was a significant increase in the anterior heights (0.24±0.32 cm) and the middle heights of the vertebral bodies (0.35±0.33 cm) postoperatively. Mean

	Mean±SD
Age, y	71.6±7.5
No. women (%)	48 (88.9)
Degree of compression, %	64.6±5.9
Duration of symptoms, mo	29±3.0
BMD of lumbar vertebrae, T-score	-3.1±1.0
BMD of hip, T-score	-2.8±1.0
Balloon pressure, psi	271.2±18.3
Surgery time, min	25±1.9
Cement used per vertebral body, cm ³	5.7±0.4
Leakage rate, %	3.86
Blood loss, mL	35±2.8

Abbreviation: BMD, bone mineral density.

Cobb angle decreased by 2.57°±6.59° (*P* < .05) postoperatively, and mean kyphotic angle decreased by 10.2% postoperatively (Table 3).

DISCUSSION

Percutaneous kyphoplasty is a convenient, efficient, reliable, economic, and minimally invasive technique developed by

Table 2

Scores Before and After Percutaneous Kyphoplasty ^a			
	Mean±SD		
	Visual Analog Scale	Painkiller Score	Locomotor Activity Score
Preoperatively	8.20±1.14	1.59±0.91	2.91±0.75
Immediately postoperatively	2.60±1.10 ^b	0.18±0.39 ^b	1.27±0.46 ^b
Postoperative follow-up	2.70±1.24 ^c	0.21±0.32 ^c	1.30±0.34 ^c

^an=54.
^bP<.01 compared with preoperatively.
^cP<.01 compared with immediately postoperatively.

Table 3

Vertebral Height and Cobb Angle Changes ^a				
	Mean±SD			
	Anterior Body, cm	Middle Body, cm	Posterior Body, cm	Cobb Angle, deg
Preoperatively	1.98±0.61	1.92±0.61	2.62±0.56	24.32±12.37
Immediately postoperatively	2.23±0.60 ^b	2.27±0.54 ^b	2.72±0.53 ^b	21.85±11.02 ^b
Postoperative follow-up	2.23±0.53 ^c	2.26±0.60 ^c	2.70±0.54	22.77±12.01 ^c

^an=207.
^bP<.01 compared with preoperatively.
^cP<.01 compared with immediately postoperatively.

Reiley in the early 1990s.⁴ It inserts a guide pin into the vertebral body, sends an inflatable bone tamp/balloon to create a void and reduce the elevation of the compression vertebra, and then fills bone cement in the vertebral void created by the bone tamp. Percutaneous kyphoplasty can relieve pain quickly and correct kyphosis by enhancing the rigidity and intensity of vertebrae.

Vertebral compression fractures are common fractures that occur whenever loads on the vertebral bodies overstep stability and stiffness. It has been reported that percutaneous kyphoplasty can significantly relieve pain in 90% to 100% of patients with osteoporotic vertebral compression fractures within 1 week postoperatively, and in most cases patients can stand and walk within 24 to 48 hours postoperatively.⁴⁻⁶ In our study, VAS values decreased from 8.2 to 2.6 following percutaneous kyphoplasty, suggesting that pain relief was

quick and significant. The relapse of pain was rare in the 6-month follow-up period. The mean painkiller score decreased from 1.59 to 0.18, and the mean locomotor activity score decreased from 2.91 to 1.27, indicating that the quality of patients' lives improved remarkably. Reports indicate that 92% of vertebral compression fracture patients had pain relief and function improvement immediately postoperatively.^{4,7} Although the mechanism of pain relief following percutaneous kyphoplasty is still unclear, most reports speculate that it may be due to: (1) the heat generated during the cement consolidation destroying the nerve endings in the surrounding tissues⁸; or (2) the injected bone cements improving the strength of the vertebral bodies and the stability of the spine, hence reducing the irritation to vertebral nerves.^{9,10}

Patients with multithoracolumbar vertebral compression fractures often have

severe kyphosis, so that multilevel percutaneous kyphoplasty surgery could significantly improve their clinical symptoms. It has been reported that 1 percutaneous kyphoplasty session can reinforce 6 levels of vertebrae.¹¹ Percutaneous kyphoplasty was developed on the basis of percutaneous vertebroplasty. Percutaneous vertebroplasty injects bone cement into compression vertebrae in hypoviscosity by percutaneous puncture and fixes it in the compression position, which can relieve pain rather than correct the deformity of spine.¹² Percutaneous kyphoplasty has more advantages than percutaneous vertebroplasty because it can restore the anterior and middle heights of the vertebral bodies, correct the kyphosis, and restore the spinal line of force with bone tamp bracing.


Garfin et al⁶ reported that approximately 67% of compression vertebral fractures could be recovered totally or partially in 340 cases (603 vertebrae) with percutaneous kyphoplasty. Rhyne et al⁷ reported that corrected kyphosis averaged 14% after percutaneous kyphoplasty; the anterior and middle vertebral height increased by 4.6 and 3.9 mm, respectively. Our study showed an immediate and marked clinical improvement in patients after percutaneous kyphoplasty, with a significant increase in vertebral body height and normalization of vertebral body shape. In addition to excellent pain relief, our study confirms that percutaneous kyphoplasty can also restore the heights of compressed vertebrae, correct the kyphosis, reduce complications, and improve the quality of patients' lives.

If the vertebral compression fractures in our patients involved >1 vertebra, we used the same balloon kit for multilevel vertebral correction, and on average 1 balloon kit could be used for 4 vertebral corrections. Since all patients sustained osteoporotic compression fractures, the main purpose of kyphoplasty was to stabilize the fracture and reduce the pain (allow early weight-bearing movements). Kyphoplasty can also restore the vertebral

body height and reinforce the adjacent vertebral bodies to prevent similar fractures. The decision on how to select the adjacent levels for preventative injection was based on the patient's clinical assessments (eg, the bone mineral density scores and radiographic appearances of the adjacent vertebral bodies). If a patient has a T-score < -2.5 standard deviation and signs of vertebral body compression fracture (early stage), then adjacent levels should be injected, and usually we will do at least 2 more levels (eg, below and above the fractured vertebra), although multilevels can be injected if necessary. We gave all patients anti-osteoporosis medication immediately following percutaneous kyphoplasty; this is essential to prevent or slow osteoporotic fracture.

Cement leakage is the most common complication of percutaneous kyphoplasty because of the high pressure needed for cement injection. Other factors causing leakage include an excessive amount of bone cement, longer bone cement consolidation time, and defects of the vertebral walls. Garfin et al⁶ reported the incidence of cement leakage rate to be 1% with percutaneous kyphoplasty, whereas in our study the cement leakage rate was 3.86%. No patients with cement leakage reported complications within the follow-up period, suggesting that cement leakage is not a major concern. The incident of cement leakage can be minimized by using the correct cement injection pressure and amount and not using percutaneous ky-

phoplasty when the posterior wall of the vertebra is incomplete. In our experience, the amount of cement injection should not exceed 4.5 mL in thoracic vertebrae and 6 mL in lumbar vertebrae. Under fluoroscopic monitoring, the surgeon should do his best to insert the puncture pin at lateral upper edge of the pedicle of the vertebral arch to avoid the spinal cord and vertebral plexus. The cement should be injected in the cement drying-off period; otherwise the liquid from the cement may leak into the vertebral canal. If the bone cement leaks into the vertebral canal, the surgeon must stop the operation, wait until the cement completely consolidates, and then continue the procedure.

We experienced no balloon breakage, vertebral fracture, or pedicle fracture. Because the average vertebral body and volume of Chinese women is smaller than that of their European and American counterparts, we did not need to use excessive force to expand the balloon. The average pressure we used was 140 to 200 psi. 

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