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## **Balloon Kyphoplasty Was Effective and Safe for Vertebral Compression Fractures Compared with Nonsurgical Care**

David Cohen

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## EVIDENCE-BASED ORTHOPAEDICS

## Balloon Kyphoplasty Was Effective and Safe for Vertebral Compression Fractures Compared with Nonsurgical Care

Wardlaw D, Cummings SR, Van Meirhaeghe J, Bastian L, Tillman JB, Ranstam J, Eastell R, Shabe P, Talmadge K, Boonen S. Efficacy and Safety of Balloon Kyphoplasty Compared with Non-Surgical Care for Vertebral Compression Fracture (FREE): A Randomised Controlled Trial. *Lancet*. 2009 Mar 21;373:1016-24.

**Question:** In patients with acute vertebral compression fractures, is balloon kyphoplasty more effective than nonsurgical care?

**Design:** Randomized (allocation concealed)\*, unblinded, controlled trial with up to 12 months of follow-up (Fracture Reduction Evaluation [FREE] trial).

**Setting:** 21 sites in 8 countries (Austria, Belgium, France, Germany, Italy, The Netherlands, Sweden, and the United Kingdom).

**Patients:** 300 patients who were  $\geq 21$  years of age (mean age, 73 y; 77% women) had 1 to 3 vertebral fractures from T5 through L5, with  $\geq 1$  fracture showing edema on magnetic resonance imaging and  $\geq 1$  showing a 15% loss of height, and a back pain score  $\geq 4$  on a scale of 0 to 10. Patients with up to 3 contiguous or noncontiguous fractures at any level were included if the additional fractures also had

magnetic resonance imaging signal changes, progressive height loss, or pseudarthrosis. Exclusion criteria were chronic fracture, pedicle fracture, previous vertebroplasty, neurological deficit, radicular pain, spinal cord compression, canal narrowing, use of anticoagulants, contraindications to kyphoplasty or magnetic resonance imaging, dementia, inability to walk before the fracture, or fractures resulting from primary bone tumors, osteoblastic metastases, or high-energy trauma. Follow-up was 89% at 1 month, 84% at 3 months, 82% at 6 months, and  $< 80\%$  at 12 months.

**Intervention:** Patients were allocated to kyphoplasty (n = 149) or nonsurgical care (n = 151). Kyphoplasty was done with use of introducer instruments, inflatable bone tamps, and polymethylmethacrylate bone cement and delivery devices (Medtronic Spine, Sunnyvale, California); a percutaneous, bilateral, transpedicular, or extrapedicular approach was used,

and almost all patients had general anesthesia. All patients received analgesics, bed rest, back braces, physiotherapy, rehabilitation programs, and walking aids as considered necessary by the treating physicians.

**Main outcome measures:** Change from baseline to 1 month in Short Form (SF)-36 physical component summary scale score (range, 0 to 100). Secondary outcomes included SF-36 scores at 3, 6, and 12 months and adverse events.

**Main results:** Kyphoplasty led to greater improvement in mean SF-36 physical component summary scores than did nonsurgical care (Table). This difference remained at 3 and 6 months (Table). The frequency of adverse events did not differ between groups. The kyphoplasty group had 2 serious adverse events (hematoma and urinary tract infection).

**Conclusion:** In patients with acute vertebral compression fractures, balloon kyphoplasty was effective and safe compared with nonsurgical care.

\*Information provided by author.

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Balloon kyphoplasty vs nonsurgical care for vertebral compression fractures*		
Outcomes	Difference in change from baseline (95% confidence interval)	
SF-36 PCS score at 1 month	5.2 (2.9 to 7.4)	
SF-36 PCS score at 3 months	4.0 (1.6 to 6.3)	
SF-36 PCS score at 6 months	3.2 (0.9 to 5.6)	

\*SF-36 PCS = Short Form-36 physical component summary (range, 0 to 100). Differences favor kyphoplasty.

## Commentary

Over the past decade, vertebral augmentation procedures (vertebroplasty and kyphoplasty) to treat painful compression fractures have become commonplace despite very limited evidence in the literature. Multiple case-series and small clinical trials have demonstrated that augmentation procedures are safe but have variable effectiveness<sup>1,2</sup>. When looking at different ages of fractures (acute, subacute, and chronic), previous studies have found differing treatment effects. The well-designed, randomized, clinical trial by Wardlaw and colleagues comparing kyphoplasty with nonsurgical care clearly shows the safety and utility of kyphoplasty to treat painful subacute compression fractures.

This study, however, does not address which method of vertebral augmentation (vertebroplasty versus kyphoplasty) is superior. Because there is a substantial cost differential between the 2 methods of augmentation, knowing which one works better is important. Fortunately, there are at least 3 randomized clinical trials (OSTEO+6, KAVIAR, and CEEP) at various stages of completion that may shortly provide the answer. Until these results are known, this study

shows that vertebral augmentation (via kyphoplasty) is better than traditional nonsurgical care.

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## References

- Diamond TH, Champion B, Clark WA. Management of acute osteoporotic vertebral fractures: a nonrandomized trial comparing percutaneous vertebroplasty with conservative therapy. *Am J Med*. 2003;114:257-65.
- Voormolen MHJ, Mali WP, Lohle PN, Fransen H, Lampmann LE, van der Graaf Y, Juttman JR, Janssens X, Verhaar HJ. Percutaneous vertebroplasty compared with optimal pain medication treatment: short-term clinical outcome of patients with subacute or chronic painful osteoporotic vertebral compression fractures. The VERTOS Study. *AJNR Am J Neuroradiol*. 2007;28:561-2.

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