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

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This information is current as of November 29, 2009

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Publisher Information

The Journal of Bone and Joint Surgery
20 Pickering Street, Needham, MA 02492-3157
www.jbjs.org
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 ≥21 years of age (mean age, 73 y; 77% women) had 1 to 3 vertebral fractures from T5 through L5, with ≥1 fracture showing edema on magnetic resonance imaging and ≥1 showing a 15% loss of height, and a back pain score ≥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, osteolytic 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.

Source of funding: Medtronic Spine.

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References

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.1,2 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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Disclosure: The author did not receive any outside funding or grants in support of his research for or preparation of this work. The author, or a member of his immediate family, received, in any one year, payments or other benefits of less than $10,000 or a commitment or agreement to provide such benefits from a commercial entity (DePuy Spine).