
Design: Randomized clinical trial

Population/sample size/setting:
- 100 patients (77 women, 23 men, mean age 73) treated for osteoporotic vertebral compression fractures at a university hospital in Taiwan
- Eligibility criteria were acute fracture demonstrated on MRI or CT concordant with pain at site for fracture at T12-L1 (indications listed in Ledlie 2003)
- Exclusion criteria were pregnancy, bleeding disorders, high-velocity fractures, burst fracture, pain unrelated to vertebral body collapse, pedicle or facet fracture, tumor, osteomyelitis, and device or cement allergy

Main outcome measures
- Randomized by block randomization to either vertebroplasty (n=50) or kyphoplasty (n=50)
- Both procedures involved general anesthesia with IV Propofol under a mobile C-arm x-ray
- Kyphoplasty procedure required more operating time (mean of 46.2 vs 44 minutes) and a greater amount of PMMA cement (5.56 vs 4.91 ml)
- Two patients in kyphoplasty group had adjacent segment fractures, one at T11 and one at L2 in the first 50 days after the procedure
- Both groups had similar decreases in pain VAS between baseline and final follow-up
  - In the kyphoplasty group, the baseline mean VAS was 8.0; the 6 month score was 2.6
  - In the vertebroplasty group, the baseline VAS was 7.9; the 6 month mean score was 2.6
- The kyphoplasty group had a greater increase in vertebral body height and a greater reduction in kyphotic wedge angle than the vertebroplasty group

Authors’ conclusions:
- There is little difference in clinical outcome between vertebroplasty and kyphoplasty
- With the higher cost of the kyphoplasty balloon, vertebroplasty is recommended over kyphoplasty in the treatment of osteoporotic vertebral fractures
- The superior vertebral height restoration with kyphoplasty may lead to increased risks of adjacent vertebral body fracture

Comments:
- The occurrence of two adjacent level fractures in the kyphoplasty group versus none in the vertebroplasty group is too small a number to justify a comparison of fracture risk
- Other comparisons of vertebroplasty and kyphoplasty have not discovered significant differences in fracture risk between the two procedures (Han 2011).
  - Functional outcomes were not reported, only pain and radiographic outcomes.
  - The eligibility criteria had to be inferred from another study (Ledlie 2003), and some criteria (neurological impairment and vertebra plana) do not appear to have been selection criteria for that study.
  - There is insufficient information to prefer vertebroplasty over kyphoplasty; the study is not strong enough to support one procedure over another and is best seen as inconclusive.

Assessment: Inadequate for evidence of the comparative effectiveness of one vertebral augmentation procedure over another.

References:
