Vertebroplasty and Kyphoplasty

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Outline

• Vertebral fracture epidemiology, consequences and diagnosis
• Kyphoplasty and vertebroplasty: what are they and how are they done?
• Outcomes
  – Efficacy
  – Safety

Epidemiology

• 700,000 vertebral compression fractures (VCFs) occur each year in the U.S.
  – More than hip and wrist fractures combined.²
• >150,000/year hospitalized for VCFs.²
• Osteoporosis-related disability: more days in bed than stroke, heart attack or breast cancer.¹
• Risk factors for VCF: age, BMD, BMI, falling, smoking, low calcium intake

Identifying Vertebral Fractures

• Approximately two thirds of all vertebral fractures go undiagnosed, in part due to difficulty determining cause of symptoms.
• Vertebral fractures may be asymptomatic.
• Pain ranges from mild to severe and may be chronic, but typically resolves over 2-12 weeks

1. National Osteoporosis Foundation
2. Cooper C et al. J Bone Min Res. 1992
Radiologic Assessment

- Lateral spine X-ray examination is the standard test to identify vertebral compression fractures.
- Differentiation between back pain from vertebral compression fracture and disk disease or osteoarthritis often difficult
  - Correlate radiographic findings with exam
- STIR sequence MRI can be useful to determine cause and/or acuity of plain radiograph abnormality.
- Increasing IVA use will identify more unexpected vertebral fractures

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What Your Patients See and Hear:
The Procedure

• Vertebroplasty uses cement only (no balloon), no attempt to increase vertebral height
• Minimally invasive
  – Bilateral, 1cm incisions
• Typically one hour per treated fracture
• General or local anesthesia
  – Most are performed under general anesthesia
  – Can be performed under local anesthesia, often supplemented with conscious sedation.
• May require an overnight hospital stay

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Kyphoplasty and Vertebroplasty Literature

• Uncontrolled studies or historical controls
• Case-series
• Registries (Kyphon)
• Randomized controlled trials

Summary of Non-randomized Studies

• Beneficial effects on
  – Vertebral body height and angular deformity
  – Pain
  – Quality of life
  – Ambulatory status
  – Physical function
• Asymptomatic cement extravasation common
• Safe and well tolerated, but...
Risk of Subsequent Fracture

- Concern that rigid cement alters biomechanics
- Case reports of new adjacent fractures after procedure
  - Prospective, non-randomized study
  - 21 patients underwent balloon kyphoplasty and 19 underwent conservative treatment.
  - Patient populations were similar in age, gender, fracture history
  - After 6 months, 7 out of 19 evaluable balloon kyphoplasty patients had new fractures (37%), whereas 11 out of 17 conservatively-treated patients (67%) had new fractures.
  - Too small to analyze adjacent fractures.


What About Randomized Trials?

- Early NIH trial with sham-therapy abandoned
- First successful multi-centered randomized trial funded by Kyphon (FREE)
  - Up to 3 acute VF (< 3 months old)
  - Confirmed by x-ray and MR
  - Randomized to balloon kyphoplasty (n=149) vs. usual non-surgical care (n=151)
  - Outcomes: pain, QOL, function and new VF after 3 and 12 months (24 mo pending)

Wardlaw et al, Lancet 2009

FREE Results

- Subjects
  - 72 years old, 77% female
  - 96% primary osteoporosis
- Previous exposures
  - 17% steroids
  - 33% bisphosphonates
- Duration of symptoms
  - 6 weeks on average
- Fracture location
  - 22% T5-T9
  - 62% T10-L2
  - 16% L3-L5

Back Pain
(0 to 10 Visual Analogue Scale)
Physical Component Summary (SF36)

Days of Limited Activity in the Previous 2 Weeks

Using Narcotic Analgesics

FREE Complications

- Similar number of CV events, infections and deaths
- Cement extravasation in 27% (asymptomatic)
- Subsequent VF: 33% with kyphoplasty and 25% with non-surgical therapy (p=0.22)
Recent Vertebroplasty Vs. Sham Procedure Trials

- Two similar trials (N=131 and N=71)
  - Up to 2 or 3 acute VF (< 12 months old)
  - Confirmed by x-ray and/or MR
  - Randomized to vertebroplasty vs. sham procedure
  - Outcomes: pain, QOL, physical function, medication use after 3 or 6 months

Buchbinder et al, NEJM 2009
Kallmes et al, NEJM 2009
Vertebroplasty Vs. Sham: SF-36

A SF-36 Physical Component Summary

Vertebroplasty: 29.7±9.6
Control: 28.7±8.0

Treatment effect: 1.0 (95% CI, -1.7 to 3.7)
P=0.45

Baseline 1 Month

Kallmes et al, NEJM 2009

Discordant Trials?

• Duration of symptoms?
• Sham vs. non-surgical care?
• Kyphoplasty vs. vertebroplasty?

Summary

• Vertebral fractures associated with significant disability and high risk of subsequent fractures
  – Should be aggressively treated with effective anti-resorptive (or anabolic) therapy
• Kyphoplasty and vertebroplasty associated with reduced pain and disability in non-randomized studies
  – Serious complications rare, but do occur
• Single unblinded kyphoplasty trial found reductions in pain and disability, less apparent after 12 mo.
• Two smaller but blinded sham-controlled vertebroplasty trials found no benefit.

Conclusions

• Effect on subsequent fracture rates unknown, preliminary data reassuring
• Kyphoplasty, but not vertebroplasty, may be useful to reduce pain and disability
  – Consider after failure of 6-12 weeks non-surgical therapy
  – Need additional trials before widespread use
• Unanswered issues: optimal patient selection, prevention of kyphosis, long-term outcomes