Vertebroplasty and Kyphoplasty: Who, What, and When

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No Disclosures

Outline

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

What Would You Do?

68 WF with OP on bisphosphonate with 4 wks of severe midline back pain. In ER new T8 fx on X-ray, tx vicodin q 4hr. Activity limited to sitting/standing. Options?

1) Medical management, intensify narcotics, PT
2) Medical management, add calcitonin, PT
3) Referral for facet injection, PT
4) Referral for kyphoplasty
5) Referral for vertebroplasty

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

¹. National Osteoporosis Foundation
². Cooper C et al. J Bone Min Res. 1992
Consequences: Future Fracture Risk

- VCF increases risk of subsequent vertebral fracture:
  - 5-fold after first VCF
  - 12-fold after 2 or more VCFs
- Vertebral fracture is a strong indication for preventive therapy (i.e. anti-resorptive or anabolic)


Pain and Decreased Quality of Life

- Pain typically lasts 2-12 weeks
- Physical and functional performance lower in patients with vertebral fracture 1,2
  - Restricted ADL
  - Sleep disturbances
- Psychosocial consequences 3
  - Anxiety, depression, low self-esteem, and alteration in social role
- Long-term outcomes poorly studied


Mortality

- Study of Osteoporotic Fractures: Women ≥65 years (n=9,407) with or without vertebral fracture
- Prospective follow-up, cause-specific mortality
- Conclusions
  - Women with prevalent vertebral fracture had a 23% higher age-adjusted mortality rate
  - VCF patients are two to three times more likely to die of pulmonary causes
  - Most common cause of death was pulmonary disease, i.e., COPD and pneumonia


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
Radiologic Assessment

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

Vertebral Fractures: Three Types

- Wedge fractures are most common

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What Your Patients See and Hear:

- Kyphoplasty vs. Vertebroplasty
  - Vertebroplasty uses cement only (no balloon), no attempt to increase vertebral height
  - Both 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
  - Seldom 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 observed 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
- Mudano et al (2009)
  - Retrospective cohort from large health plan
  - 45 patients underwent vertebroplasty or kyphoplasty and 164 underwent conservative treatment
  - Adjustment for age, gender, history of osteoporosis and comorbidities
  - Risk of recurrent vertebral fracture higher among surgically treated after 90 d (OR=6.8) and 1 yr (OR=2.9)
  - Too small to analyze adjacent fractures


Mortality Benefit?

- Medicare claims data 2005-08
  - Compared to non-surgical treatment, risk of mortality reduced 24% with vertebroplasty and 44% with kyphoplasty
  - Adjusted for age, health status, comorbidity
- Medical claims data 2008-11
  - Traditional adjusted analysis: vertebral augmentation reduced mortality 17%
  - With propensity scores: no difference

Edidin et al, JBMR 2011
McCullough et al, Jama Internal Med 2013

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 just reported)

Wardlaw et al, Lancet 2009
Boonen et al, JBMR 2011
FREE Demographics

- **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

FREE Results: Back Pain
(0 to 10 Visual Analogue Scale)

FREE Results: Days of Limited Activity in the Previous 2 Weeks

FREE Results: Physical Component Summary (SF36)

At 12 months, 60 fewer days of limited activity in kyphoplasty group.

At 12 months, no difference in physical function.
FREE Results: Narcotic Use

![Graph showing narcotic use percentages over time.](image)

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)

FREE 24 Month Results
- Persistent benefit at 24 mo
  - VAS back pain score: 2.6 vs. 3.8 (p=0.01)
- No benefit at 24 mo
  - Activity limitation, physical function, narcotic use
- Two serious kyphoplasty events: spondylitis and anterior cement migration
- New vertebral fractures: 48% vs. 41% (p=0.68)

Boonen et al, JBMR, 2011

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
Kalines et al, NEJM 2009
Vertebroplasty vs. Sham: Back Pain

Vertebroplasty vs. Sham: QOL

Vertebroplasty Vs. Sham: Pain

Vertebroplasty Vs. Sham: SF-36

Buchbinder et al, NEJM 2009

Buchbinder et al, NEJM 2009

Kallmes et al, NEJM 2009

Kallmes et al, NEJM 2009
Vertebroplasty vs. Usual Care Trial: VERTOS II

- Randomized open label European trial
- Eligible if new VF (<6 wks, confirmed by MR) and VAS score > 5
- 934 screened to randomize 202
  - 229 improved before randomization
- VAS lower in vertebroplasty arm at 1 mo (-5.2 vs. -2.7) and 1 yr. (-5.7 vs. -3.7)
- Less narcotic use in surgical arm

Klazen et al, Lancet, 9746:1085, 2010

Discordant Trials?

- Duration of symptoms?
  - Sham RCTs: results similar if duration <6wks
- Sham vs. usual non-surgical care?
  - Prolonged placebo effect plausible. Likely?
- Benefit from anesthetic/steroid injection?
  - Case series found pain reduction in 34%
- Kyphoplasty vs. vertebroplasty?
  - Trials ongoing

Staples et al, BMJ, 2011
Wilson et al, Eur Radiol, 2011

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 and 24 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
Questions and Comments Welcome!