

## Vertebroplasty and Kyphoplasty

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P and G

## Outline

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

## Epidemiology

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- **700,000 vertebral compression fractures (VCFs) occur each year in the U.S.**
  - More than hip and wrist fractures combined.<sup>2</sup>
- **>150,000/year hospitalized for VCFs.<sup>2</sup>**
- **Osteoporosis-related disability: more days in bed than stroke, heart attack or breast cancer.<sup>1</sup>**
- **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

## Identifying Vertebral Fractures

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- **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 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

## Radiologic Assessment

First week post fracture



8 weeks post fracture



Courtesy of B. Boszczyk & R. Bierschnieder, BG Unfallklinik

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## What Your Patients See and Hear:



## The Procedure

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- 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

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

## Summary of Non-randomized Studies

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- 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
- Komp et al (2004)
  - 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.

Komp, et al. (2004) J Miner Stoffwechs 11(Suppl 1):13-16

## What About Randomized Trials?

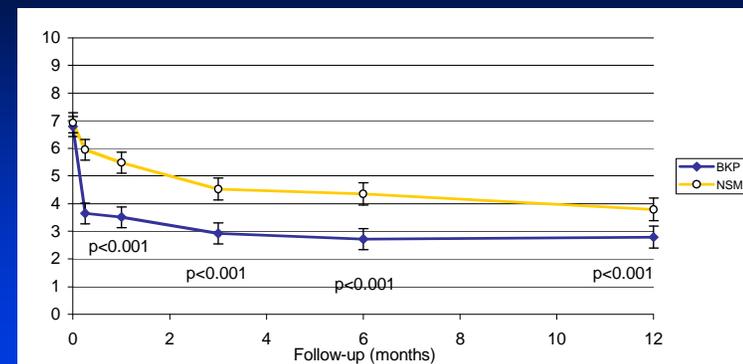
- Early NIH trial with sham-therapy abandoned
- First successful multi-centered randomized trial funded by Kyphon (FREE)
  - Up to 3 acute VF (< 3 months old)
  - Confirmed by x-ray and MR
  - Randomized to balloon kyphoplasty (n=149) vs. usual non-surgical care (n=151)
  - Outcomes: pain, QOL, function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

Wardlaw et al, Lancet 2009

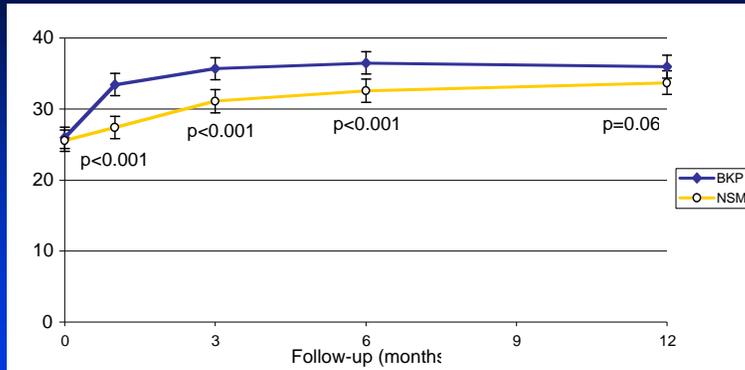
## FREE Results

- 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

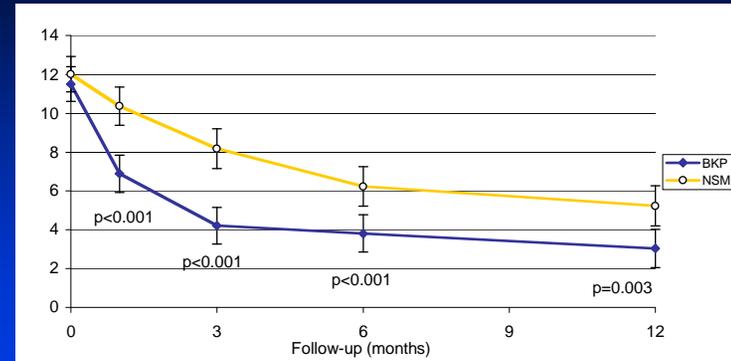
## Back Pain (0 to 10 Visual Analogue Scale)



## Physical Component Summary (SF36)

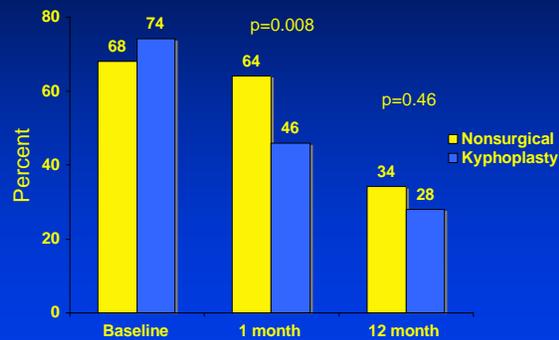


## Days of Limited Activity in the Previous 2 Weeks



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

## Using Narcotic Analgesics



## FREE Complications

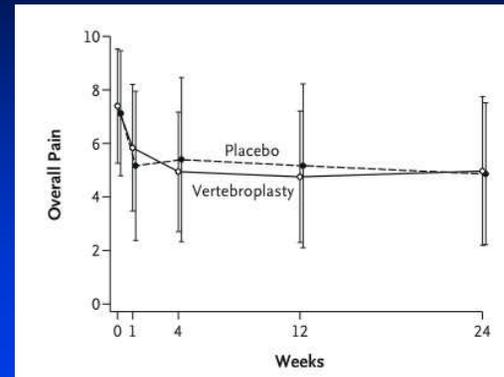
- Similar number of CV events, infections and deaths
- Cement extravasation in 27% (asymptomatic)
- Subsequent VF: 33% with kyphoplasty and 25% with non-surgical therapy ( $p = 0.22$ )

## 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

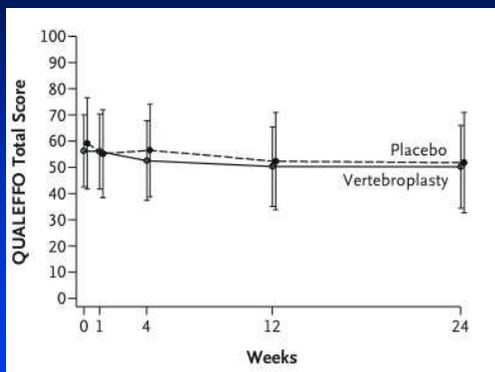
Buchbinder et al, NEJM 2009  
Kallmes et al, NEJM 2009

## Vertebroplasty vs. Sham: Back Pain



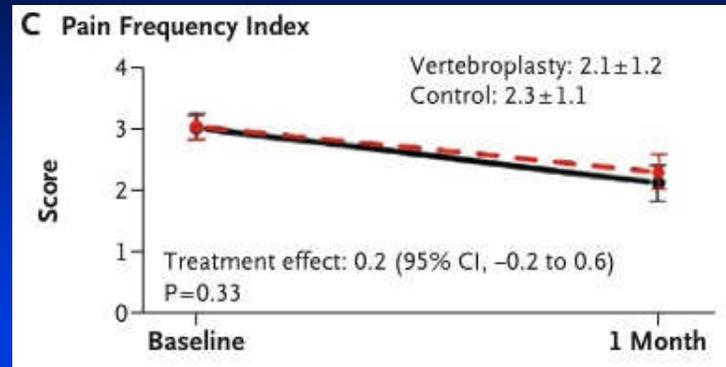
Buchbinder et al, NEJM 2009

## Vertebroplasty vs. Sham: QOL



Buchbinder et al, NEJM 2009

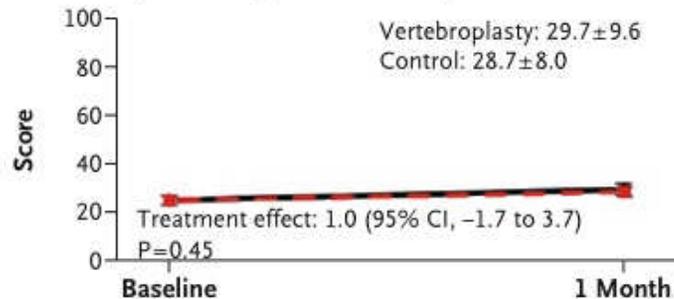
## Vertebroplasty Vs. Sham: Pain



Kallmes et al, NEJM 2009

## Vertebroplasty Vs. Sham: SF-36

### A SF-36 Physical Component Summary



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