
UAB Department of Neurosurgery
Neurosurgical Society of Alabama
July 9, 2017

Disclosures

• The University of Alabama at Birmingham received compensation from Medtronic for study-specific data collection.

• Funding Source: Medtronic Spine sponsored the EVOLVE trial and contributed to study design, data monitoring, statistical analysis, and reporting of results and provided funding for independent core laboratory services.

VCF Significance:

Severe physical and functional limitations, decreased appetite, incontinence, pulmonary restriction, disability, decreased social and physical quality of life, increased morbidity and mortality.
Vertebroplasty: What we know

CONCLUSIONS

Improvements in pain and pain-related disability associated with osteoporotic compression fractures in patients treated with vertebroplasty were similar to the improvements in a control group. (ClinicalTrials.gov number, NCT00068222)

Problems with NEJM Study:

- Fracture age < 1 year
- 56% had pain for > 3 months
- Minimal pain score: 3/10
- Average pain score: 6.9/10
- Patients allowed to crossover
- At 3 months: 51% of sham vs 13% of vertebroplasty crossed over
- Only followed for 3 months
Problems with BMJ Study:

• Looked at Fracture age <6 weeks OR Pain scores >8/10 (not both)
• Statistical power
• Vertebroplasty group 30% more likely to achieve at least 30% improvement in pain scores (P=0.07)

Problems with BMJ Study:

• Assessed at 1/2 weeks and 1 month

<table>
<thead>
<tr>
<th>Change in Pain between 1/2 weeks and 1 month</th>
<th>Vertebroplasty</th>
<th>Sham</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL Patients</td>
<td>-0.6</td>
<td>0.3</td>
</tr>
<tr>
<td>Pain ≤ 6 weeks</td>
<td>-0.7</td>
<td>0.1</td>
</tr>
<tr>
<td>Pain ≥ 6 weeks</td>
<td>-0.6</td>
<td>0.3</td>
</tr>
<tr>
<td>Pain ≤ 8</td>
<td>-0.9</td>
<td>0.2</td>
</tr>
<tr>
<td>Pain ≥ 8</td>
<td>-0.4</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Cochrane Review
**Kyphoplasty: What we know**

**Conclusion.** Compared with NSM, BKP improves patient quality of life and pain averaged during 24 months and results in better improvement of index vertebral body kyphotic angulation. Perioperative complications may be reduced with more care in patient positioning.

**Key words:** balloon kyphoplasty, vertebral fracture, osteoporosis, kyphosis correction.

**Level of Evidence:** 2

Spine 2013;38:971-983

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**EVOLVE Trial – Largest Prospective Outcomes Analysis to Date**

- 350 patients, Mean age of 78, 77% female, all Medicare eligible
- 24 centers
- 12 month follow up
- 1-3 Acute/Subacute Fractures between T5-L5
  - less than 4 months, confirmed with imaging
  - Due to Osteoporosis or Cancer
- Pain scores >7 (0-10)
- ODI > 30 (0-100)

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**Exclusion Criteria**

- Configuration contraindicating BKP (e.g., split fractures, burst fractures, pedicle fracture)
- VCFs due to high-energy trauma
- Asymptomatic VCFs
- VCF causing canal compromise or cord compression requiring decompression
- Patients with comorbidities that would contraindicate surgery
Primary Endpoints:
- SF-36v2 Physical Component Survey
- EuroQol-5-Domain (EQ-5D) questionnaire
- Back pain numerical rating scale (NRS)
- Oswestry Disability Index (ODI)

Secondary Endpoints
- Ambulatory status
- Procedure information
- Medication usage
- Limited activity days
- Bedrest Days
- Kyphotic angulation correction
- Cement leakage
- Vertebral height restoration
- New vertebral fractures
- Adverse events

Results: Procedure
- 350 subjects - kyphoplasty at a total of 499 levels.
- Bilateral kyphoplasty in 54.9% of subjects
- Mean procedure duration of 24.4 minutes
- Mean fluoroscopy duration of 5 minutes
- Baseline - 7/350 due to cancer, 343/350 due to osteoporosis
- Malignancy in 9 of 197 biopsies (4.6%)
- Mean length of stay of 9.2 hours
Results – 1° Endpoints

2° Endpoints

Kyphotic Angulation and Vertebral Height Improvement
2° Endpoints

- 71.5% of subjects taking opioids at baseline
- 55.3% at 12 months
- Subsequent fracture rate was 35% at 3 months and 46% at 12 months
- 18% of Patients on Bisphosphonates
- Cement Extravasation: 21.4%
  - Majority of leaks into adjacent discs or paraspinal tissue (80.4%)
  - 12 leaks into epidural space
  - 1 leak into foraminal space
  - No leak extended >15mm into canal or foramina
  - All leaks were asymptomatic

Adverse Events

- Procedure-related AE rate – 1.46%
- Symptomatic complications – 1.17%
- In all cases the symptoms from the adverse events resolved with appropriate treatment.

Conclusions

- All 4 primary endpoints demonstrated statistical improvement and these were maintained or improved throughout the 12 months
- Secondary endpoints including opioid usage, activity, angulation correction and height restoration showed statistical improvement
  - Reduction in opioid use by 16.2%
- Kyphoplasty is safe and has an excellent risk:benefit profile for this patient population
Thank you