RCT on vertebroplasty and its afterlife

Professor Rachelle Buchbinder
NHMRC Senior Principal Research Fellow
Monash University and Cabrini Institute
Vertebroplasty for acute osteoporotic vertebral fractures

- First introduced late 1980s
- Medicare coverage US 2001: local coverage determinations based on case studies only, no evidence review
- Doubled in use between 2001 and 2005

Gray et al Spine 2008. Nation-wide and State-specific primary vertebroplasty rates per 100,000 Part B fee-for-service
## Technology appraisals 2002–2005; conflicting conclusions

<table>
<thead>
<tr>
<th>Country</th>
<th>Body</th>
<th>Published</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>CCE</td>
<td>May 2002</td>
<td>“...there is insufficient evidence to be able to conclude that percutaneous vertebroplasty is a safe and effective procedure in the treatment of [OVCF].”</td>
</tr>
<tr>
<td>Canada</td>
<td>CCOHTA</td>
<td>May 2002</td>
<td>“Long-term safety and effectiveness remain unknown.”</td>
</tr>
<tr>
<td>England &amp; Wales</td>
<td>NICE</td>
<td>Sept 2003</td>
<td>“Current evidence on the safety and efficacy of percutaneous vertebroplasty appears adequate to support the use of the procedure...”</td>
</tr>
<tr>
<td>United States</td>
<td>ICSI</td>
<td>Dec 2003</td>
<td>“Vertebroplasty should be offered only to carefully selected patients whose pain is not controlled by conservative management...” (Grade III (uncertain) evidence).</td>
</tr>
<tr>
<td>Denmark</td>
<td>CEMTV</td>
<td>Feb 2004</td>
<td>“[Vertebroplasty] is an effective and safe procedure for treating pain caused by osteoporotic vertebral fractures.”</td>
</tr>
</tbody>
</table>

CCE, Center for Clinical Excellence on behalf of Southern Health in Australia; CCOTA, Canadian Coordinating Office for Health Technology Assessment; ICSI, Institute for Clinical Systems Improvement; CEMTV, Center for Evaluering og Medicinsk Teknologivurdering; BCBS, BlueCross BlueShield.

Pre- and post–vertebroplasty pain scores: 30 studies, 7 prospective

Pre: Mean 8.1 (6.4 to 9.7)
Post: Mean 2.6 (1.7 to 3.9)

Serious complications < 1% (23 studies)
Bone cement leakage 41.2%
(7 to 81%) (20 studies) but >98% asymptomatic

A treatment that enables the bed-bound to walk again - the ‘Lazarus effect’
A Randomized Trial of Vertebroplasty for Painful Osteoporotic Vertebral Fractures

Rachelle Buchbinder, Ph.D., Richard H. Osborne, Ph.D., Peter R. Ebeling, M.D., John D. Wark, Ph.D., Peter Mitchell, M.Med., Chris Wriedt, M.B., B.S., Stephen Graves, D. Phil., Margaret P. Staples, Ph.D., and Bridie Murphy, B.Sc.

A Randomized Trial of Vertebroplasty for Osteoporotic Spinal Fractures

Before publication of these 2 trials, vertebroplasty had been used for almost a decade, with little evidence to recommend it. As a society, we can surely do better for our patients.

Timothy S. Carey, MD, MPH
Cecil G. Sheps Center for Health Services Research
University of North Carolina at Chapel Hill
Chapel Hill, North Carolina, USA
Editorial

The vertebroplasty affair: the mysterious case of the disappearing effect size

Eugene J. Carragee, MD, Editor-in-Chief*

Department of Orthopedic Surgery, Stanford Medicine Outpatient Center, Stanford University School of Medicine, 450 Broadway, Mail Code 6342, Redwood City, CA 94063, USA
Received 14 January 2010; accepted 14 January 2010

Vertebroplasty is a “poster child for a systematic failure to perform the appropriate evaluation of invasive procedures before they are widely accepted.”
When experience clashes with evidence

Many treatments are introduced into medical practice prematurely, before they have been scientifically evaluated.

Two studies have turned vertebroplasty (VP) on its head.
COMMENTARY

Response to “Randomized Vertebroplasty Trials: Bad News or Sham News?”

Vertebroplasty: when randomized placebo-controlled trial results clash with common belief

Rachelle Buchbinder, MBBS(Hons), MSc, PhD, FRACP,⁎,⁎⁎, David F. Kallmes, MD⁎⁎

⁎Monash Department of Clinical Epidemiology, Cabrini Hospital, and Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria 3144, Australia
⁎⁎Department of Radiology, Mayo Clinic, Rochester, MN, 55905, USA

Received 22 December 2009; accepted 5 January 2010

Vertebroplasty appears no better than placebo for painful osteoporotic spinal fractures, and has potential to cause harm

Rachelle Buchbinder, Richard H Osborne and David Kallmes

Two randomised placebo-controlled trials show the importance of establishing the efficacy of procedures before adopting them into clinical practice
...Then strange things began to happen. Just before the editorial was published, I received an email critical of its content. Then, further emails arrived advising, among other things, that the editorial be retracted, suggesting that the reputations of the NEJM and the MJA had been diminished...

...More sinister, perhaps, is the fact that Professor Buchbinder was subjected to a far more vitriolic campaign, necessitating the threat of legal action.
Effectiveness of vertebroplasty using individual patient data from two randomised placebo controlled trials: meta-analysis

Margaret P Staples biostatistician¹, David F Kallmes professor², Bryan A Comstock operations director³, Jeffrey G Jarvik professor of radiology and neurological surgery and director⁴, Richard H Osborne professor of public health and director⁵, Patrick J Heagerty professor⁶, Rachelle Buchbinder director and professor¹
Australia: Policy response

Number of Medicare-funded vertebroplasties


‘Interim’ Item number  Year  Item number removed
Can Coverage Be Rescinded When Negative Trial Results Threaten A Popular Procedure? The Ongoing Saga Of Vertebroplasty

- Aetna, USA: 90 days notice of rescinding coverage, retracted
- Noridian Admin Services (11 Western states) intent to rescind, retracted
- Medicare USA: no national determination
- NICE UK: ..although trials ‘raised questions’, favoured clinical experience and open-label trials .... better reflect 'real life' (2013)
- BlueCross BlueShield, USA and Ontario Canada – rescinded coverage
- BlueCross BlueShield, Mississippi – investigational only
STANDARDS OF PRACTICE

Position Statement on Percutaneous Vertebral Augmentation: A Consensus Statement Developed by the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR).

• Clearly beneficial
• Complications very infrequent


THE TREATMENT OF SYMPTOMATIC

• Strong recommendation against use
• Future evidence unlikely to overturn conclusion

Adopted by the American Academy of Orthopaedic Surgeons
Board of Directors
September 24, 2010

J.D.B. owns shares in Spine Wave (Shelton, Connecticut). J.K.M. receives royalties from Cook (Bloomington, Indiana) and owns stock in Dfine (San Jose, California). A.L.B. is a paid consultant for DePuy (Raynham, Massachusetts). J.E.O. is a paid consultant and receives royalties from Globus Medical (Audubon, Pennsylvania) and Pioneer Surgical (Marquette, Michigan). T.C.R. is a paid consultant for Medtronic (Minneapolis, Minnesota) and Arbor Pharmaceuticals (Atlanta, Georgia). S.M.T. is a paid consultant for Benvenue Medical (Santa Clara, California). None of the other authors have identified a conflict of interest.
Medline publications including vertebroplasty in title/abstract

- Placebo-controlled trials published
- (PhD thesis)
- Another 2

Includes case reports of harms
20-30 reviews per annum
- almost all ‘positive’
Percutaneous vertebroplasty for osteoporotic vertebral compression fracture (Review)

Mean difference, 1-2 weeks
-0.25 (-0.82 to 0.33)

Mean difference, 1 month
-0.73 (-1.18 to -0.28)
Pain (0–10 scale), MID 1.5 points

Mean difference (95% CI)

1-2 wks: -0.25 (-0.82 to 0.33)

1 mo: -0.73 (-1.18 to -0.28)

3 mos: -0.48 (-1.01 to 0.05)

6 mos: -0.59 (-1.18 to 0.01)

1 yr: -0.43 (-1.02 to 0.18)

2 yrs: -1.10 (-2.68 to 0.48)
<table>
<thead>
<tr>
<th>Time Period</th>
<th>Mean Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 2 weeks</td>
<td>0.21 [-1.23 to 1.65]</td>
</tr>
<tr>
<td>1 month</td>
<td>-1.50 [-2.61 to -0.38]</td>
</tr>
<tr>
<td>3 months</td>
<td>-0.81 [-3.15 to 1.52]</td>
</tr>
<tr>
<td>6 months</td>
<td>-1.82 [-4.12 to 0.47]</td>
</tr>
<tr>
<td>1 year</td>
<td>0.12 [-1.56 to 1.80]</td>
</tr>
<tr>
<td>2 years</td>
<td>0.10 [-3.67 to 3.87]</td>
</tr>
</tbody>
</table>

RMDQ (0–23 scale), MID 2–3 points
The subgroup hypothesis: It is effective for acute fractures

“You called me just in time. Another day or two, and you would have been up and around.”
8.2 Pain at 1 month

8.2.1 'Acute' fractures

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Vertebroplasty Mean</th>
<th>Vertebroplasty SD</th>
<th>Vertebroplasty Total</th>
<th>Placebo (sham) Mean</th>
<th>Placebo (sham) SD</th>
<th>Placebo (sham) Total</th>
<th>Std. Mean Difference IV, Random, 95% CI</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buchbinder 2009 (1)</td>
<td>5.08</td>
<td>2.57</td>
<td>12</td>
<td>5.08</td>
<td>3.28</td>
<td>13</td>
<td>4.7% [0.00, -0.78, 0.78]</td>
<td></td>
</tr>
<tr>
<td>Clark 2016 (2)</td>
<td>-4.6</td>
<td>3</td>
<td>55</td>
<td>-3.2</td>
<td>2.7</td>
<td>57</td>
<td>20.6% [-0.49, -0.86, -0.11]</td>
<td></td>
</tr>
<tr>
<td>Firanescu 2018 (3)</td>
<td>3.36</td>
<td>2.63</td>
<td>90</td>
<td>3.77</td>
<td>2.91</td>
<td>86</td>
<td>33.2% [-0.15, -0.44, 0.15]</td>
<td></td>
</tr>
<tr>
<td>Kalmines 2009 (4)</td>
<td>4</td>
<td>3.04</td>
<td>9</td>
<td>3.9</td>
<td>3.7</td>
<td>10</td>
<td>3.6% [0.03, -0.07, 0.03]</td>
<td></td>
</tr>
<tr>
<td>VOFEP 2015 (5)</td>
<td>17.33</td>
<td>21.81</td>
<td>22</td>
<td>26.27</td>
<td>22.29</td>
<td>24</td>
<td>8.5% [-0.40, -0.96, 0.19]</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>188</strong></td>
<td></td>
<td></td>
<td><strong>190</strong></td>
<td></td>
<td></td>
<td><strong>70.7% [-0.26, -0.46, -0.05]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.00; Chi² = 2.99, df = 4 (P = 0.56); I² = 0%

Test for overall effect: Z = 2.49 (P = 0.01)

8.2.2 'Subacute' fractures

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Vertebroplasty Mean</th>
<th>Vertebroplasty SD</th>
<th>Vertebroplasty Total</th>
<th>Placebo (sham) Mean</th>
<th>Placebo (sham) SD</th>
<th>Placebo (sham) Total</th>
<th>Std. Mean Difference IV, Random, 95% CI</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buchbinder 2009 (6)</td>
<td>4.87</td>
<td>2.1</td>
<td>23</td>
<td>5.56</td>
<td>3</td>
<td>25</td>
<td>9.0% [-0.26, -0.83, 0.31]</td>
<td></td>
</tr>
<tr>
<td>Kalmines 2009 (7)</td>
<td>3.83</td>
<td>2.91</td>
<td>58</td>
<td>4.71</td>
<td>2.83</td>
<td>51</td>
<td>20.3% [-0.30, -0.68, 0.07]</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>81</strong></td>
<td></td>
<td></td>
<td><strong>76</strong></td>
<td></td>
<td></td>
<td><strong>29.3% [-0.29, -0.61, 0.02]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.00; Chi² = 0.02, df = 1 (P = 0.90); I² = 0%

Test for overall effect: Z = 1.81 (P = 0.07)

**Total (95% CI)**

<table>
<thead>
<tr>
<th></th>
<th>Vertebroplasty Mean</th>
<th>Vertebroplasty SD</th>
<th>Vertebroplasty Total</th>
<th>Placebo (sham) Mean</th>
<th>Placebo (sham) SD</th>
<th>Placebo (sham) Total</th>
<th>Std. Mean Difference IV, Random, 95% CI</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>269</strong></td>
<td><strong>266</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>100.0% [-0.27, -0.44, -0.10]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.00; Chi² = 3.04, df = 6 (P = 0.80); I² = 0%

Test for overall effect: Z = 3.07 (P = 0.002)

Test for subgroup differences: Chi² = 0.03, df = 1 (P = 0.86); I² = 0%

Footnotes:
(1) ≤ 6 weeks
(2) < 6 weeks
(3) ≤ 9 weeks
(4) ≤ 6 weeks
(5) ≤ 8 weeks
(6) > 6 weeks
(7) > 6 weeks

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias): Self-reported...
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias
### Figure 3: Prespecified subgroup outcomes

Risk difference (percentage points) of meeting the primary endpoint of a Numeric Rated Scale pain score less than 4 out of 10, at 14 days after the procedure. Positive numbers favour vertebroplasty and negative numbers favour placebo.

<table>
<thead>
<tr>
<th>Spinal region</th>
<th>Risk difference (%) [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracolumbar</td>
<td>48 (27 to 68)</td>
</tr>
<tr>
<td>Non-thoracolumbar</td>
<td>-15 (-40 to 9)</td>
</tr>
<tr>
<td><strong>Age of fracture</strong></td>
<td></td>
</tr>
<tr>
<td>≤3 weeks</td>
<td>31 (12 to 50)</td>
</tr>
<tr>
<td>&gt;3 weeks</td>
<td>-4 (-39 to 31)</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td>23 (6 to 39)</td>
</tr>
</tbody>
</table>

### Participants (symptoms 3 weeks or less)

<table>
<thead>
<tr>
<th></th>
<th>Placebo (n=20)</th>
<th>Vertebroplasty (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) age, years</td>
<td>79.7 (8.2)</td>
<td>80.4 (5.8)</td>
</tr>
<tr>
<td>Mean (SD) duration pain, weeks</td>
<td>2.1 (0.8)</td>
<td>2.0 (0.8)</td>
</tr>
<tr>
<td>Mean (SD) pain</td>
<td>7.5 (2.1)</td>
<td>8.8 (1.7)</td>
</tr>
<tr>
<td>Baseline pain score ≥8, N (%)</td>
<td>10 (50.0)</td>
<td>11 (84.6)</td>
</tr>
<tr>
<td>Mean (SD) RMDQ score</td>
<td>18.9 (2.5)</td>
<td>17.8 (2.1)</td>
</tr>
<tr>
<td>Mean (SD) EQ-5D score</td>
<td>0.4 (0.2)</td>
<td>0.4 (0.2)</td>
</tr>
</tbody>
</table>

Combined individual patient data, Kallmes 2009 and Buchbinder 2009
<table>
<thead>
<tr>
<th></th>
<th>Placebo Mean (SD)</th>
<th>Placebo N</th>
<th>Vertebroplasty Mean (SD)</th>
<th>Vertebroplasty N</th>
<th>Adjusted between group difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1-2 weeks</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>3.1 (4.1)</td>
<td>20</td>
<td>2.8 (2.9)</td>
<td>13</td>
<td>-0.8 (-2.7 to 1.1)</td>
</tr>
<tr>
<td>RMDQ</td>
<td>4.9 (5.9)</td>
<td>18</td>
<td>2.8 (5.6)</td>
<td>13</td>
<td>-1.2 (-4.8 to 2.4)</td>
</tr>
<tr>
<td><strong>1 month</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>3.2 (4.3)</td>
<td>20</td>
<td>4.2 (2.8)</td>
<td>13</td>
<td>0.3 (-1.7 to 2.3)</td>
</tr>
<tr>
<td>RMDQ</td>
<td>5.6 (6.1)</td>
<td>18</td>
<td>4.7 (6.2)</td>
<td>13</td>
<td>0.3 (-3.9 to 4.5)</td>
</tr>
</tbody>
</table>

Combined individual patient data, Kallmes 2009 and Buchbinder 2009
### Number improved by 30% or more: participants with symptoms 3 weeks or less

<table>
<thead>
<tr>
<th></th>
<th>Placebo N (%)</th>
<th>Vertebroplasty N (%)</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1-2 weeks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30%</td>
<td>9 (45)</td>
<td>5 (38.5)</td>
<td>1.1 (0.5 to 2.8)</td>
</tr>
<tr>
<td>≥30%</td>
<td>11 (55)</td>
<td>8 (61.5)</td>
<td></td>
</tr>
<tr>
<td><strong>1 month</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30%</td>
<td>8 (4)</td>
<td>4 (30.8)</td>
<td>1.1 (0.5 to 2.8)</td>
</tr>
<tr>
<td>≥30%</td>
<td>12 (60)</td>
<td>9 (69.2)</td>
<td></td>
</tr>
</tbody>
</table>

Combined individual patient data, Kallmes 2009 and Buchbinder 2009
Vertebroplasty is extremely safe.
<table>
<thead>
<tr>
<th>Spine Augmentations 2001–2008</th>
<th>Patient Demographics and Complications</th>
<th>Total No. of Discharges</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>All discharges</td>
<td></td>
<td>247,278</td>
<td>100.00</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>60,311</td>
<td>24.39</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>186,967</td>
<td>75.61</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>18–44</td>
<td>3,066</td>
<td>1.24</td>
</tr>
<tr>
<td></td>
<td>45–64</td>
<td>25,143</td>
<td>10.17</td>
</tr>
<tr>
<td></td>
<td>65–84</td>
<td>155,674</td>
<td>62.96</td>
</tr>
<tr>
<td></td>
<td>≥85</td>
<td>63,395</td>
<td>25.64</td>
</tr>
<tr>
<td>Complications</td>
<td>Pulmonary embolus</td>
<td>841</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td>Cardiovascular</td>
<td>1,162</td>
<td>0.47</td>
</tr>
<tr>
<td></td>
<td>Postoperative surgical</td>
<td>3,264</td>
<td>1.32</td>
</tr>
<tr>
<td></td>
<td>Postoperative neurologic</td>
<td>297</td>
<td>0.12</td>
</tr>
<tr>
<td>Mortality</td>
<td>Died</td>
<td>1,244</td>
<td>0.50</td>
</tr>
<tr>
<td>Avg. age (yr)</td>
<td></td>
<td>77.2</td>
<td></td>
</tr>
</tbody>
</table>

Percutaneous vertebroplasty for osteoporotic vertebral compression fracture (Review)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assumed risk</td>
<td>Corresponding risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo¹</td>
<td>73 per 1000</td>
<td>95 per 1000 (34 to 264)</td>
<td>RR 1.29 (0.46 to 3.62)</td>
<td>840 (6 studies)⁵</td>
</tr>
<tr>
<td>Incident symptomatic vertebral fractures Follow-up: 12 - 24 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other serious adverse events Follow-up: 12 - 24 months</td>
<td>56 per 1000</td>
<td>34 per 1000 (18 to 62)</td>
<td>RR 0.61 (0.33 to 1.10)</td>
<td>821 (5 studies)⁵</td>
</tr>
</tbody>
</table>

Reported serious adverse events: osteomyelitis, cord compression, thecal sac injury, and respiratory failure.

downgraded for imprecision & potential for bias
uncertainty about risk estimates of harms
Quality of internet information on vertebroplasty

- 100% offered a benefit vs 53% reported any risks
- None mentioned placebo-controlled trials or their results
- No mention of any controversy (but 27% referenced peer-reviewed literature)

Table 3. Benefits of vertebroplasty reported

<table>
<thead>
<tr>
<th>Authorship</th>
<th>Pain reduction (%)</th>
<th>Improved mobility (%)</th>
<th>Decreased analgesia (%)</th>
<th>Improved quality of life (%)</th>
<th>Height restoration (%)</th>
<th>Minimally invasive (%)</th>
<th>Early mobilization (%)</th>
<th>Any benefit</th>
<th>Mean total benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic</td>
<td>18 (100)</td>
<td>6 (33)</td>
<td>5 (28)</td>
<td>3 (17)</td>
<td>2 (11)</td>
<td>11 (61)</td>
<td>9 (50)</td>
<td>18 (100)</td>
<td>3</td>
</tr>
<tr>
<td>Private</td>
<td>63 (98)</td>
<td>23 (36)</td>
<td>14 (22)</td>
<td>7 (17)</td>
<td>5 (8)</td>
<td>53 (83)</td>
<td>36 (56)</td>
<td>64 (100)</td>
<td>3</td>
</tr>
<tr>
<td>Industry</td>
<td>8 (100)</td>
<td>6 (75)</td>
<td>3 (38)</td>
<td>4 (50)</td>
<td>0 (0)</td>
<td>8 (100)</td>
<td>4 (50)</td>
<td>8 (100)</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>15 (100)</td>
<td>6 (40)</td>
<td>2 (13)</td>
<td>1 (7)</td>
<td>2 (13)</td>
<td>8 (53)</td>
<td>8 (53)</td>
<td>15 (100)</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>104 (99)</td>
<td>41 (39)</td>
<td>24 (23)</td>
<td>15 (14)</td>
<td>9 (9)</td>
<td>80 (76)</td>
<td>57 (54)</td>
<td>105 (100)</td>
<td>3</td>
</tr>
</tbody>
</table>

Vertebroplasty

Authors: A/Prof Kenneth R Thomson*
Dr James Burnes *

What is a vertebroplasty?

Vertebroplasty is a medical term which refers to the injection of a plastic cement, called polymethylmethacrylate (PMMA), into a vertebral body or small bones that make up the spinal column.

What are the benefits of a vertebroplasty?

Vertebroplasty is successful in removing pain and restoring mobility in 60-90% of patients.

If, in the future you have more vertebral bone fractures, further vertebroplasty can be performed.
Patient Info

General IR

General Intervention includes a range of image-guided procedures that provide a minimally invasive way of treating different problems.

Procedures

Percutaneous Vertebroplasty:

Often just called vertebroplasty, this procedure involves injecting special 'cement' into vertebrae that have collapsed or fractured. Similar to stabilising a broken bone, vertebroplasty may reduce pain from an acute vertebral body fracture by fixing the fractured bone together. The cement is like that used for holding hip and knee replacements in place, and has been specially made to allow it to be seen clearly under X-ray imaging.

The procedure is performed under local anaesthetic with light sedation, and patients can often go home the same day. A special needle is introduced into the fractured or collapsed vertebral body using X-ray guidance and then cement is injected into the vertebral body, using X-ray's to make sure the cement does not go outside the bone.
State-of-the-art interventional treatments

- Precision X-ray guided Spinal Injections / Nerve Blocks
- Radiofrequency Denervation (Facet / Sacroiliac)
- Radiofrequency/Pulsed Radiofrequency Sympathectomy
- Sympathetic Plexes Blockade (Coeliac, Hypogastric)
- Peripheral/Regional Nerve Blocks
- Trigeminal Ganglion Block
- Spinal Cord and Peripheral Nerve Stimulation (Neuromodulation)
- Trigger Point Injections
- Peripheral Intra-Articular Injections (Hip, Shoulder, Knees, Sacroiliac, Facets)
- Botulinum Toxin A Injections
- Vertebroplasty for Spinal Pain
- Epidural Steroids – Cervical, Thoracic, Lumbar, and Sacral Epidurals and Transforaminal Injections
- IV Drug Infusions
- Anaesthetic Intervention
The Covert World of People Trying to Edit Wikipedia—for Pay

Can the site’s dwindling ranks of volunteer editors protect its articles from the influence of money?

On January 11, 2013, James Heilman, an emergency-room physician and one of Wikipedia’s most prolific medical editors, was standing watch over the online encyclopedia’s entry for a back procedure called a kyphoplasty. The page originally suggested that the procedure’s effectiveness was “controversial,” and an unidentified Wikipedia user had proposed changing the text to “well documented and studied”—a characterization that Heilman thought wasn’t supported by existing research. He rejected the change.

Soon, Heilman found himself rejecting other changes to the page for vertebroplasty and kyphoplasty. After the word “controversial,” a user who Heilman says was most likely Schelble, tried to add “among some but not among the actual physicians who perform these procedures.” The site’s Talk page for the procedures, where proposed edits are discussed,
October 2, 2018

Osteoporosis and vertebral compression fractures: Advocacy groups and medical device maker spin misleading message

health care marketing, osteoporosis
Medical devices, overdiagnosis, overtreatment

Michael Joyce is a writer-producer with HealthNewsReview.org and tweets as @mlmjoyce
In case you ever wondered, October 20th is World Osteoporosis Day.

In preparation, two advocacy groups — the National Osteoporosis Foundation and the National Bone Health Alliance — have joined forces with Medtronic, the world’s largest medical device maker, to “raise awareness” about what they consider to be an “under-diagnosed” problem: vertebral compression fractures (VCF) from osteoporosis.

- Both organisations have conflicted financial relationships with Medtronic
- Goes on to promote kyphoplasty “It will give people their lives back...and keep them off opioids..”
- Use of anecdote, either kyphoplasty or a life of opioids and excruciating pain
- Mentions doctor (who happens to have received $80,000 from Medtronic...)
Utilization of vertebroplasty and kyphoplasty procedures throughout the United States over a recent decade: an analysis of the Nationwide Inpatient Sample

Joseph L. Laratta¹, Jamal N. Shillingford¹, Joseph M. Lombardi¹, John D. Mueller¹, Hemant Reddy¹, Comron Saifi¹, Charla R. Fischer², Steven C. Ludwig³, Lawrence G. Lenke¹, Ronald A. Lehman¹

- Vertebroplasty decreased 53%, 2008 to 2014 (13,128 to 6,130)
- Kyphoplasty decreased 17% (23,320 to 19,420)
- 75% in areas ‘not low income’
- South Atlantic region do about quarter of both
Mean Total Cost by Year for Kyphoplasty and Vertebroplasty

- Vertebroplasty Mean Total Cost
- Kyphoplasty Mean Total Cost
Eradicating vertebroplasty or not?

• Rates *are* declining
• But being replaced by kyphoplasty (no placebo-controlled trials)
• Publication bias: 20-30 journals accepting biased reviews per year while negative trials not reported
• Funders elsewhere say too hard to withdraw coverage...
• Complaints targeting research/ers- - media, Cochrane
• Intimidation of Wikipedia custodian
• Doctors and public still largely unaware of the evidence?
Australia: Policy response

Number Medicare-funded vertebroplasties

New submission 2017
MSAC Nov 2018

Item number
Year
Item number removed
The story continues....

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