State of the Evidence: Non-operative and Operative Treatment of Low Back Pain

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Honoraria for authoring topics on LBP for UpToDate
Professorship endowed by Kaiser Permanente
Federal grants
No commercial ties

3 Treatment Controversies

- Trends and evidence in
  - Prescribing opioids
  - Spinal Fusion Surgery
  - Spinal injections
- Is overall disability from LBP getting better?

Back Pain and Opioids

- 2% of US population uses opioid medications “regularly”
- Of these, 59% report back pain
- Back pain most common reason for long-term opioid Rx at Group Health
- Back pain is condition with the highest proportion of prescription opioid users

Case Report: Gen. David Fridovich

- 2006: 54 y.o. General doing leg presses at Marine gym in Hawaii, after visit to Iraq. Felt a twinge.
- Continued weight training, handball, racquetball several days, then awoke barely able to stand; pain radiating from low back down left leg
- ER: X-ray: “Grade 1-2 slip”. Motrin, morphine initially, then Roxicet & OxyContin
- “If drugs for pain relief, more drugs = more relief”
- Reported “fogginess”, anxiety, depression: decreased dose, but continued Roxicet & Oxycontin. Became “isolated, combative”

2008 – Spine fusion; increased dose of opioids postoperatively
- Few weeks later, told he had a long-standing opioid dependency.
- Underwent 4-week detox program, begun on Buprenorphine
- Named deputy commander of special forces in May, 2010
- Detox cleared his head, eased temperament, brightened outlook on life. “I should probably take an ad out... apologizing for everything I've said or done, because I'm a different person”

Some Key Features of the case

- Tough guy; not a whiner, not homeless, not a drug abuser, not lazy
- Opioids started early; necessary?
- Hard to stop
- Continued even after surgery
- Change in mood (?)
- Felt better when finally tapered, started Buprenorphine

Efficacy? Systematic Reviews on Opioids for Chronic LBP (RCTs)

- Poor quality studies; none >16 weeks
- Non-significant reduction in pain compared to non-opioids or placebo
- Diagnosed substance use disorder: current- up to 24%
  lifetime- up to 54%
- Cochrane: benefit for chronic LBP questionable

Cautious opioid prescribing for chronic low back pain

- Useful for severe acute pain; time-limited use or nighttime use with NSAIDs during day
- Generally switch after 2 weeks; announce at start
- Avoid >100mg/day morphine equivalents
- Avoid co-prescribing benzos and opioids
- Long-term use: screen very carefully for hx of substance abuse or depression; informed consent
- ACP/APS Guide: option for severe disabling LBP; carefully weigh benefits, risks; consider alternatives if no response to short course

Opioids and Surgery

- Pre-op opioid use assoc. with continued post-op use, worse functional outcomes (cervical arthrodesis)
- Lumbar fusions: Analgesic-related deaths most common cause of mortality in followup (to 6 years); higher with Degen. Disc Disease
- Disc arthroplasty trials: most still receiving opioids 2 years post-op, in both arms
- Erectile dysfunction: due to surgery or opioids?
Number of Operations
Population Growth: 24%
Growth age 65+: 30%

Diagnosis % all fusions
1. Lumbar degen. disc dis., spondylosis 18.9%
2. Cervical disc herniation 16.7%
3. Cervical spondylosis or degen. disc dis. 14.2%
4. Lumbar spondylolisthesis 9.7%
5. Lumbar stenosis 9.0%
6. Lumbar disc herniation 8.6%
7. Cervical stenosis 3.2%
8. Idiopathic scoliosis 2.3%


Success Rate of Lumbar Fusion for low back pain with DDD
- Prodisc Trial: 45% success rate in fusion arm
- Also: 59% still on opioids at 2 yrs. F/U
- Charite Trial: very similar results

Question: Is this a reasonable definition of success in fusion for discogenic pain?
- Improvement in self-reported function (15% improvement on Oswestry)
- Any quality of life improvement (SF-36)
- No new neurologic deficits
- No revision surgery (2-yr F/U)
- Radiographic success (solid fusion, no device migration, no radiolucency)
- What’s the success rate of lumbar fusion by these criteria?
**4 RCT results: Improvement in Oswestry Disability, Discogenic Pain**

<table>
<thead>
<tr>
<th>Surgery Group (n=201)</th>
<th>Brox (n=35)</th>
<th>Fairbank (n=176)</th>
<th>Brox (after discectomy) (n=29)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Improv.</td>
<td>11.6</td>
<td>15.6</td>
<td>12.5</td>
</tr>
<tr>
<td>Non-Op Group (n=63)</td>
<td></td>
<td></td>
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<tr>
<td>Mean Improv.</td>
<td>2.8</td>
<td>13.3</td>
<td>8.7</td>
</tr>
<tr>
<td>Difference, Surgery-Rehab</td>
<td>8.8</td>
<td>2.3</td>
<td>3.8</td>
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<tr>
<td></td>
<td></td>
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<td>(-3.9)</td>
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</table>

Mirza SK, Deyo RA. Spine 2007; 32: 816

Structured exercise & Cognitive-behavioral therapy

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**Fritzell RCT for Chronic LBP: Does Instrumentation improve Outcomes?**

- **N=211 fusion operations**

<table>
<thead>
<tr>
<th></th>
<th>Postero-lateral N=71</th>
<th>Pedicle screw N=68</th>
<th>360° Fusion N=72</th>
</tr>
</thead>
<tbody>
<tr>
<td>All reops</td>
<td>6%</td>
<td>22%</td>
<td>17%</td>
</tr>
<tr>
<td>Hardware removed</td>
<td>--</td>
<td>17%</td>
<td>10%</td>
</tr>
<tr>
<td>Major Complications</td>
<td>6%</td>
<td>18%</td>
<td>30%</td>
</tr>
<tr>
<td>Pain, disability</td>
<td>No significant diffs.</td>
<td></td>
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Spine 2001; 27: 1131

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**Fusion Outcomes: Ohio Workers’ Comp**

- 750 patients with lumbar fusion, 1999-2001

<table>
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<tr>
<th>outcomes</th>
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<tbody>
<tr>
<td>Lumbar reoperations</td>
</tr>
<tr>
<td>Return to work</td>
</tr>
<tr>
<td>Still using opioids</td>
</tr>
<tr>
<td>Avg. Total days work loss</td>
</tr>
</tbody>
</table>

Nguyen TH et al. Spine 2011; 36: 320

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**Conclusions: Spinal Fusion**

- Fusion rates highly variable; rising fast
- High rates of reoperation and complications
- LBP with degenerative disc(s): top indication for fusions: efficacy unclear
- Implants increase complications, reops; do not improve clinical outcomes
- Fusions are not reducing revision rates
**ProDisc Trial Results vs. 360° Fusion: FDA Summary**

- Success by FDA criteria: 53% with ProDisc vs. 41% with 360° fusion
- Mean ODI diff. after 6 mos: 5 pts
- Adverse events: 84% ProDisc, 88% fusion
- No sig. difference in pain score, opioids
- Disc had small advantage in employment (92% vs. 85%)
- FDA: disc is non-inferior

**Could Epidural Injections lead to less surgery? Geographic Variations**

**Epidural Steroid injections: Geographical variations**

- Connecticut: 12 injections/1000 Medicare Enrollees
- Alabama: 40 injections/1000 Medicare Enrollees

**More injections ≠ Less surgery: Medicare claims, 2001, 50 states**

\[ r = 0.59, p < 0.001 \]
**Injections for LBP, Medicare, 1994-2001**
- ↑ in Medicare population: 12%
- ↑ in epidurals: 266%; facet injections 231%
- ↑ in reimbursement per injection: 100%
- Total ↑ cost: 637%, due to rate and charges (adjusted for inflation)

**Efficacy of Epidural Steroid & Facet Injections?**
- Sciatica, mixed study results: ½ say modest benefit, ½ suggest none
- Axial back pain: no evidence of benefit; yet 58% of injections not for radiculopathy
- No reduction in surgery rate in 2 RCT’s;
- Facet injections: RCT’s consistently neg.
- Overall: modest sx relief from epidurals for sciatica, no change in natural history

**Injection Guidelines**
- AAN: No effect on functional impairment, need for surgery, or pain relief beyond 3mos; routine use for these reasons not recomm.
- Avoid for back pain alone; avoid facet inj.
- Insufficient evidence for spinal stenosis, cervical radiculopathy

**Does More Treatment Result in Better Outcomes?**
Reasonable Expectation: flurry of imaging, treatment, and new technology should lead over time to:
- Better patient functioning
- Lower rates of repeat surgery
- Decreased work disability due to musculoskeletal pain
Do more fusions & new technology help? 4-year reop rates following lumbar surgery

Cumulative Re-operations (%)

Approx. 25,000 procedures each time interval

Adjusted for Age, Gender, Primary dx, Insurance, Comorbidity

% of Social Security Disability Beneficiaries by Diagnostic Group

Musculoskeletal

Circulatory

Respiratory
### Current Evidence about Back Pain Treatment

- Opioids: uncertain efficacy for long-term use; substantial complications. Caution!
- Fusion surgery increasing rapidly; most common indication is the most controversial
- Injections: rapid growth; outpacing evidence
- More intensive Rx: not improving outcomes; more complications
- Exercise and Cognitive-behavioral Rx may be mainstays for chronic LBP

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### The argument for Evidence-based practice for Spine Disorders & Devices

Supposing is good, but finding out is better.

-Mark Twain