Low Back Interventions and Opioid Treatment Guidelines: Comparison Between ACOEM and APS

GIN 2010

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Background

• Similar Evidence-based Methodology
• Similar Target Audience and Scope
• Independent Research and Panel Process
• Similar Systematic Review Efforts
• Overlapping Evidence/Recommendation Areas
  – Opioid Use
  – Low Back Interventions
• Parallel Efforts Allows Validation Analysis
Methodology

**APS**
- Multidisciplinary Panel
- Transparent COI
- RCT focused SR
- **Strength of Recommendation**
- **Strength of Evidence**
- Evidence Publication
- **Society Approval**
- Peer Rec Reviewed Publication

**ACOEM**
- Multidisciplinary Panel
- Transparent COI
- RCT focused SR
- **Strength Evidence Weighted Recommendation**
- Rec External Peer Review
- **Society Review**
- Electronic Publication
APS Recommendation Criteria

• Strength of Recommendation
  – A: Panel Strongly Recommends clinicians considering offering
  – B: Panel Recommends clinicians considering offering
  – C: Panel makes No recommendation
  – D: Panel recommends against offering
  – I: Panel found insufficient evidence to recommend for or against

• Strength of Evidence
  – Good: Min 2 consistent, high quality trial
  – Fair: Limited evidence to determine health effects
  – Poor: Insufficient evidence
ACOEM Recommendation Criteria

- Recommendations
  - Recommended
  - No Recommendation
  - Not Recommended

- Strength of Evidence
  - A: Strong Evidence-base: Two or more high-quality studies
  - B: Moderate Evidence-base: At least one high-quality study or multiple moderate-quality studies
  - C: Limited Evidence-base: At least one study of moderate quality.
  - I: Insufficient Evidence: Evidence of insufficient quality or irreconcilable
Evidence and Recommendation
Opioids

**APS**
- 334 References for 37 Evidence Areas (Oct 2008)
- 57 “primary studies”, 14 SR
- 25 Recommendations

**ACOEM**
- 86 Refs (May 2008)
- 46 High and Moderate Quality RCTs, 14 SRs
- 6 Recommendations
- Guidance Appendix
Opioid Recommendation Detail

APS

- 25 Opioid Recommendations
  - Pt Selection and Risk Stratification
  - Informed Consent and Management Plans
  - Initial and Titration Dosing
  - Methadone*
  - Monitoring
  - High risk pts
  - Dosing, discontinuation
  - Adverse Effects*
  - Psychotherapeutic Cointerventions*
  - Driving and Work Safety
  - Medical Home/Consultation*
  - Breakthrough Pain
  - Pregnancy
  - Opioid Policies

* Supported by Moderate Quality Evidence
Opioid Recommendation Detail
ACOEM

• 6 Opioid Recommendations
  – Routine Use (Not –C)
  – Selected Patients (Rec-I)
  – Trigger Points/Myofascial (Not-I)
  – Prior Screening (Rec-I)
  – Contract (Rec-I)
  – Urine Screening Opioid Pts (Rec-C)

• Supplemental Guidance
  – Approach to Pt Considering
  – Initiation Criteria
  – Initial Evaluation and Tx
  – Follow-up
  – Approach to Pt Using
  – Work Restrictions
  – Managing Risk of Abuse
Opioid Comparison

• Although quantity of RCTs, APS and ACOEM resulted primarily in low quality/insufficient evidence recommendations:
  – APS 4/25 moderate quality
  – ACOEM 2/6 moderate quality
Opioid Comparison (cont)

• APS Moderate Evidence Recommendations
  – Cautious Use of Methadone (ACOEM n/a)
  – Anticipate Adverse Effects (ACOEM n/a)
  – Routine use Psychotherapeutic Cointerventions (ACOEM Agree)
  – Specialty Consultation (ACOEM n/a)

• ACOEM Moderate Evidence Recommendations
  – Routine Use Not Recommended (APS appropriate pt selection)
  – Recommended Routine Urine Screening (APS low quality)
Evidence and Recommendation
Low Back Pain

APS
• 1082 References for 53 Evidence Areas (July 2008)
• 161 RCTs
• 29 Low Back Interventions Recommendations

ACOEM
• 906 References for 106 Areas (Sept 2007)
• 95 High and Moderate Quality RCTs
• 205 Low Back Disorder Recommendations
Low Back Comparison of Common Interventional Findings

• Many APS and ACOEM recommendations resulted from an insufficient evidence base:
  
  – APS 16/26 Insufficient or no evidence
  – ACOEM 12/26 Insufficient evidence
## Low Back Comparison (cont)

### ACOEM

<table>
<thead>
<tr>
<th>APS</th>
<th>Rec B</th>
<th>Rec C</th>
<th>Rec I</th>
<th>No</th>
<th>Not I</th>
<th>Not C</th>
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<td>1</td>
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<td>1(^3)</td>
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1. Fusion Surgery  
2. Coblation Nucleoplasty  
3. PIRFIT
In patients with nonradicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence).

<table>
<thead>
<tr>
<th>Fusion Surgery</th>
<th>APS</th>
<th>ACOEM</th>
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<tr>
<td></td>
<td>In patients with nonradicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence).</td>
<td>Lumbar fusion is recommended as an effective treatment for isthmic spondylolisthesis. (Limited Evidence (C)) Lumbar fusion is recommended as an effective treatment for degenerative spondylolisthesis. (Limited Evidence (C)) Spinal fusion is an option at the time of discectomy if a patient is having the third lumbar discectomy on the same disc. (Insufficient Evidence (I))</td>
</tr>
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</table>
Low Back Comparison (cont)

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<tr>
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<tr>
<td><strong>Coblation Nucleoplasty</strong></td>
<td><em>In patients with persistent and disabling radiculopathy due to herniated lumbar disc or persistent and disabling leg pain due to spinal stenosis</em>.....insufficient evidence exists to evaluate alternative surgical methods including laser- or endoscopic-assisted techniques, various percutaneous techniques, Coblation nucleoplasty</td>
</tr>
<tr>
<td></td>
<td>Not Recommended for Acute, Sub-Acute and Chronic Radicular Pain Syndromes (including Sciatica) <em>(Moderate Evidence (B))</em> Percutaneous discectomy (nucleoplasty), laser discectomy, and disc coblation therapy are not recommended as treatment for any back or radicular pain syndrome</td>
</tr>
</tbody>
</table>

ACOEM: The current literature does not permit a conclusion that open discectomy, microdiscectomy, or endoscopic discectomy should be the preferred procedure. And, **there is no quality evidence** that automated percutaneous discectomy, laser discectomy, or coblation therapy is an effective treatment for any back or radicular pain problem.
Low Back Comparison (cont)

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<tbody>
<tr>
<td>PIRFIT</td>
<td><em>There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injection, epidural steroid injection, intradiscal electrothermal therapy (IDET), therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, or intrathecal therapy with opioids or other medications for nonradicular low back pain.</em></td>
<td>Percutaneous intradiscal radiofrequency thermocoagulation is not recommended for treatment of acute, subacute, or chronic LBP particularly including discogenic LBP. (Strong Evidence (A)). There is no evidence of efficacy in two quality studies.</td>
</tr>
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**Low Back Comparison (cont)**

**APS:** Efficacy of PIRFT versus sham therapy for presumed discogenic low back pain.

For chronic, presumed **discogenic** low back pain (based on a positive response to analgesic discography), one small (n=28), higher-quality randomized trial found no significant differences between PIRFT and sham PIRFT for improvement in VAS pain scores, global effect, ODI, or proportion of treatment success, defined as the number of patients with a 2-point reduction on a 10 point VAS pain scale and >50% pain reduction on global perceived effect (1/13 in active treatment group and 2/15 in sham group). Table 91. A second trial compared two different durations of radiofrequency thermocoagulation. It found no differences and minimal improvement with either intensity of PIRFT.

**ACOEM:** A high-quality RCT (score = 10.0/11) of 28 patients with chronic LBP (at least 1 year duration) underwent PIRFT vs. placebo treatment for chronic discogenic LBP. Patients were required to have at least 50% pain relief on analgesic discography to be eligible for inclusion (45.7% were positive). Baseline differences may have favored the sham treatment (median pain durations 60 vs. 38 months). Regardless, at 8 weeks there were 2 successes in the sham group and 1 in the PIRFT group. PIRFT was noted not to be effective in reducing chronic discogenic LBP. A moderate-quality RCT (score = 5.5/11).....
Conclusions

• Evidence findings consistent
• Recommendations more variable
  – Areas of insufficient evidence
  – Therapeutic groupings
  – Indication nuances
  – Professionally directed recommendations
• Gap between Practice and Quality Evidence
• Bridging Gap May Require Integration of Outcomes-based Shared Experience
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Thank You!