Update in Pain Medicine

2013 SGIM 36th Annual Meeting
Denver, CO

Friday, April 26, 2013
3:00pm-4:30pm
<table>
<thead>
<tr>
<th>Faculty</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Daniel Alford, MD MPH</td>
<td>Boston University</td>
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<tr>
<td>Matthew Bair, MD MS</td>
<td>Indianapolis VA</td>
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<tr>
<td>William Becker, MD</td>
<td>VA Connecticut</td>
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<tr>
<td>Joseph Frank, MD</td>
<td>Brigham &amp; Women’s Hosp.</td>
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<td>Erin Krebs, MD MPH</td>
<td>Minneapolis VA</td>
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<tr>
<td>Jane Liebschutz, MD MPH</td>
<td>Boston University</td>
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Aims

• Obtain familiarity with recent articles (& their key findings) in pain medicine

• Understand how new findings may be incorporated into clinical practice, education & research

• Gain insight into current controversies & gaps in evidence
Agenda

• Article Selection Process
• Update in Pain Medicine
  – What’s Known?
  – What’s Added?
  – What Should Change?
• Question & Answer, Evaluations
Article Selection

- Electronic databases (MEDLINE & PubMed)
- MeSH terms
  - Pain; Pain Management; Pain Measurement; Pain Clinics; Analgesia; Analgesics
  - Excluding Acute Pain; Pain, Postoperative; Cancer; Chest pain; Pediatrics
  - Limited to Humans; English language; Study type (trial, epidemiologic, review, meta-analysis, guideline)
- SGIM Pain Medicine IG members suggested relevant articles
Article Selection

• 2738 references obtained
• List cut to 47 based on overall impact
• Selection of final list based on:
  – GIM clinical implications
  – GIM research/policy implications
  – Quality of study methods
• We will highlight 11 articles today
  – Reference list & additional articles in handout on SGIM website
Article Categories

• Interventional Pain Medicine
• Opioid Dose & Overdose Death
• Central Sensitization
• Neuropathic Pain
• Yoga
• Cognitive Behavioral Therapy
• Systems Approaches to Pain
Interventional Pain Management

William C. Becker, MD
VA Connecticut Healthcare System
Yale University School of Medicine
Vignette

• Mr. P is a 54-year-old man with Type II diabetes who has had brief episodes of low back pain off and on since his 40’s but has noticed it becoming more consistent over the past 6 weeks as well as a new shooting pain down his left leg. His BMI is 31 and he has a (+) straight leg raise on the left. He notes that a friend got an injection and is back playing tennis.

• “Doc, what do you think about sending me to the pain specialist for an injection?”
Multiple Choice

A) Those injections cause paralysis and meningitis and frankly don’t work.

B) A large study combining the results of several smaller studies showed that they generally only give short term relief, if any

C) I’m all for it. I believe in going straight to the root of the problem.

D) Let’s give medications a try first, they usually take most of the pain away for good.
Rafael Zambelli Pinto, MSc; Chris G. Maher, PhD; Manuela L. Ferreira, PhD; Mark Hancock, PhD; Vinicius C. Oliveira, MSc; Andrew J. McLachlan, PhD; Bart Koes, PhD; and Paulo H. Ferreira, PhD

Epidural Corticosteroid Injections in the Management of Sciatica: A Systematic Review and Meta-analysis

What’s known?

- Sciatica is a common, readily identifiable condition with known pathophysiology.
- Pharmacotherapy is generally minimally effective or not effective.
- Epidural corticosteroid injection (ECI) has shown efficacy in small studies but a robust evidence base to guide clinical decisions is lacking.
Aims/Purpose

• Determine the efficacy of all 3 anatomical approaches to ECI (caudal, interlaminar, transforaminal) in the management of sciatica compared with placebo-control interventions via meta-analysis

• Investigate relationship between trial methods or characteristics and treatment effect size
Methods

• Literature search

• Study selection criteria:
  – RCT comparing ECI with inert placebo intervention among patients with sciatica
  – Duration of symptoms not restricted
  – Reported one of the following outcome measures: overall, leg or back pain intensity, disability status, percentage of improved patients
  – Studies of patients with spinal stenosis or prior surgery excluded
Methods

• Trial methodology rating using the Physiotherapy Evidence Database scale and data extraction performed by 2 independent reviewers

• Estimates of treatment effects extracted from each study in the following hierarchical order: mean difference adjusted for differences in baseline score and other covariates, change in score, and final values.
Methods

• Outcome data extracted and grouped into 4 time points of assessment: immediate term, short term, intermediate term and long term follow-up

• Scores for pain intensity and disability converted to scales from 0 (no pain or disability) to 100 (worst possible pain or disability)

• Pooled estimates calculated using a random-effects model
Results

Systematic Review

• 23 trials met the inclusion criteria:
  – Transforaminal (n=6); Caudal (n=4) and interlaminar approach (n=13)
  – Clinical definition of sciatica utilized (n=16); also required imaging (n=7)

• Overall methodological quality assessment was high; however 15/23 trials failed to adopt allocation concealment, perform intention-to-treat analysis, and blind the therapist responsible for injecting the corticosteroids or placebo.
## Results

### Meta-analysis

<table>
<thead>
<tr>
<th></th>
<th>Outcome</th>
<th>Trials</th>
<th>Patients</th>
<th>I-squared</th>
<th>Mean difference [95%CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SHORT TERM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leg Pain</td>
<td>14</td>
<td>1316</td>
<td>10</td>
<td>-6.2 [-9.4, -3.0]</td>
<td></td>
</tr>
<tr>
<td>Back Pain</td>
<td>6</td>
<td>723</td>
<td>0</td>
<td>0.5 [-3.9, 4.8]</td>
<td></td>
</tr>
<tr>
<td>Disability</td>
<td>10</td>
<td>1154</td>
<td>0</td>
<td>-3.1 [-5.0, -1.2]</td>
<td></td>
</tr>
<tr>
<td><strong>LONG TERM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leg Pain</td>
<td>7</td>
<td>714</td>
<td>15</td>
<td>-4.8 [-10.2, 0.7]</td>
<td></td>
</tr>
<tr>
<td>Back Pain</td>
<td>3</td>
<td>453</td>
<td>0</td>
<td>3.4 [-2.4, 9.2]</td>
<td></td>
</tr>
<tr>
<td>Disability</td>
<td>6</td>
<td>691</td>
<td>22</td>
<td>-2.7 [-6.8, 1.3]</td>
<td></td>
</tr>
</tbody>
</table>
What these studies add

Author Conclusions

- Overall quality of evidence high and data generally homogenous
- Short term efficacy demonstrated for leg pain and disability; clinical significance questionable, irrespective of anatomical approach
- No long term efficacy, irrespective of anatomical approach
- Safety aspects not reviewed
Safety Issues

- Bacterial (skin flora) and fungal meningitis (contaminated steroids)
  - Unknown incidence, described as extremely rare

- Spinal cord infarction
  - 8 cases reported in literature (Kennedy, DJ et al. *Pain Med*, 2009)

- Minor complications (transient headache, transient numbness, vascular entry of needle)
  - 2-6% depending on anatomic approach

- Concern voiced in the literature over increasing rates of non-indicated procedures (e.g. ESI for non-specific low back pain)
How should I change practice?

• ECI should not be first-line treatment in lumbar radiculopathy, regardless of anatomic approach.

• However, given limited effective options, a patient informed of potential risks and benefits may be offered referral.

• Non-specific low back pain is not an appropriate indication.
Multiple Choice

• “Doc, what do you think about sending me to the pain specialist for an injection?”

• B) A large study combining the results of several smaller studies showed that they generally only give short term relief, if any
  – Trial of conservative care: medication management and multimodal care (physical therapy, structured exercise, weight loss, health psychology) is recommended as first-line treatment.
  – If patient is informed of low likelihood of benefit and opts for referral, that’s their prerogative.
Opioid Dose & Risk of Overdose Death

Joseph W. Frank, MD

Division of General Medicine and Primary Care
Brigham and Women’s Hospital
Vignette

Mr. P was started on an opioid analgesic 4 months ago. His dose has since been increased. His current long-acting dose is not lasting long enough. He has needed more PRN medication.

Mr. P’s current regimen:
• Morphine SR 30mg Q12h
• Oxycodone 10mg Q4-6h PRN
• Morphine Equivalent Dose (MED) = 150mg

“We increased my dose before and it helped. Is that an option?”
A. We should increase the dose until we find the dose that works for you.
B. You’re at the maximum dose now so we should stick with the current dosing regimen.
C. Let’s reassess the risks of these medications & your goals before we make any changes.
D. I think we should begin to discontinue these medications & look for another option.
Articles

Dunn KM, Saunders KW, Rutter CM et al.  
**Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study.**  

Gomes T, Mamdani MM, Dhalla IA et al.  
**Opioid Dose and Drug-Related Mortality in Patients With Nonmalignant Pain.**  

Bohnert ASB, Valenstein M, Bair MJ et al.  
**Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths.**  
What’s known?

• Opioids widely prescribed for chronic non-cancer pain$^1$
  – Often at doses exceeding those recommended in clinical practice guidelines$^2,3$

• Rate of prescription opioid-related overdose death increased in past decade$^4$

• Relationship of overdose to opioid dose & patient characteristics not well understood

Aims/Purpose

• To characterize the association between opioid dose and overdose outcomes
  – Dunn: Any opioid-related overdose event
  – Gomes: Opioid-related death
  – Bohnert: Opioid-related death
## Methods

<table>
<thead>
<tr>
<th></th>
<th>Dunn</th>
<th>Gomes</th>
<th>Bohnert</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design</strong></td>
<td>Cohort study</td>
<td>Case-control study</td>
<td>Case-cohort study</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>HMO in WA state, 1997-2005</td>
<td>Ontario, Canada, 1997-2006</td>
<td>Veteran’s Health Administration, 2004-2008</td>
</tr>
<tr>
<td><strong>Inclusion criteria</strong></td>
<td>• Age ≥ 18</td>
<td>• Age 15-64</td>
<td>• VHA patient</td>
</tr>
<tr>
<td></td>
<td>• New opioid Rx</td>
<td>• Low SES</td>
<td>• Any opioid Rx</td>
</tr>
<tr>
<td></td>
<td>• 3+ Rx fills in 90d</td>
<td>• Any opioid Rx</td>
<td>• Any opioid Rx</td>
</tr>
<tr>
<td></td>
<td>• CNCP dx</td>
<td>• CNCP pain</td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td>Dunn</td>
<td>Gomes</td>
<td>Bohnert</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------------------------------</td>
<td>-------------------------------------------------------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>Exposure</td>
<td>Avg. daily dose during 90d exposure window</td>
<td>Daily dose on index date</td>
<td>Maximum prescribed daily dose</td>
</tr>
<tr>
<td>Outcome</td>
<td>All overdose events</td>
<td>Opioid-related death</td>
<td>Opioid-related death</td>
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</tbody>
</table>
# Results

<table>
<thead>
<tr>
<th></th>
<th>Dunn</th>
<th>Gomes</th>
<th>Bohnert</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age</strong></td>
<td>54.1 years</td>
<td>44.5 years</td>
<td>81% of cases age 40-59</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>59.6%</td>
<td>58.8%</td>
<td>6.7%</td>
</tr>
<tr>
<td><strong>Opioid overdose deaths</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number</strong></td>
<td>6 deaths, 45 nonfatal events</td>
<td>1463 deaths → 498 cases</td>
<td>1136 deaths → 750 cases</td>
</tr>
<tr>
<td><strong>Rate</strong></td>
<td>1.8% annual rate for 100+mg/d</td>
<td>0.8% 2-year mortality for 200-400mg/d</td>
<td>0.04% 5-year mortality overall</td>
</tr>
</tbody>
</table>
## Results

<table>
<thead>
<tr>
<th>Dose (mg/d)</th>
<th>Dunn</th>
<th>Gomes</th>
<th>Bohnert*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HR (95% CI)</td>
<td>OR (95% CI)</td>
<td>HR (95% CI)</td>
</tr>
<tr>
<td>1-&lt;20</td>
<td>1.00 (REF)</td>
<td>1.00 (REF)</td>
<td>1.00 (REF)</td>
</tr>
<tr>
<td>20-&lt;50</td>
<td>1.44 (0.57-3.62)</td>
<td>1.32 (0.94-1.84)</td>
<td>1.88 (1.33-2.67)</td>
</tr>
<tr>
<td>50-&lt;100</td>
<td>3.73 (1.47-9.50)</td>
<td>1.92 (1.30-2.85)</td>
<td>4.63 (3.18-6.74)</td>
</tr>
<tr>
<td>≥100 or 100-199</td>
<td>8.87 (3.99-19.72)</td>
<td>2.04 (1.28-3.24)</td>
<td>7.18 (4.85-10.65)</td>
</tr>
<tr>
<td>≥200</td>
<td>---</td>
<td>2.88 (1.79-4.63)</td>
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</table>

*For chronic pain subgroup*
## Results

<table>
<thead>
<tr>
<th></th>
<th>Dunn</th>
<th>Gomes</th>
<th>Bohnert</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Rx at overdose</td>
<td>12%</td>
<td>50%</td>
<td>63%</td>
</tr>
<tr>
<td>Sed/hyp Rx</td>
<td>75% of cohort</td>
<td>85% vs. 64% of controls</td>
<td>...</td>
</tr>
<tr>
<td>Dosing schedule</td>
<td>...</td>
<td>...</td>
<td>Standing + PRN ≠ Increased risk</td>
</tr>
</tbody>
</table>
What these studies add

Author Conclusions

• Increasing risk of overdose at high opioid doses in 3 distinct populations

• Unable to assess specific behaviors associated with overdose
  – Providers: Monitoring, education
  – Patients: “Doctor shopping”, recreational use

• Advise risk assessment, close supervision, especially at high doses
How should I change practice?

With increasing dose:

- ↑ Overdose risk / ?? ↑ Benefit

- Careful assessment of risks, benefits & goals of opioid therapy
- Risk mitigation through patient education, close supervision
Multiple Choice

“We increased my dose before and it helped. Is that an option?”

C. Let’s reassess the risks of these medications & your goals before we make any changes.

– Mr. P’s dose = ↑ risk in all 3 studies
– Increasing risk should be balanced with any benefit & accompanied by:
  • Patient education on overdose risk
  • Monitoring (pill counts, UDT)
Neuropathic Pain
Central Sensitization
Pharmacological Treatment of Neuropathic Pain

Daniel P. Alford, MD, MPH
Boston Medical Center
Boston University School of Medicine
Vignette

• Mr. P asks you why his pain has lasted so long when previous episodes of pain resolved entirely.

• He now complains of pain consistent with painful diabetic neuropathy “when the sheets touch my feet they hurt”.

• His current medications are not helping this new pain and he would like to know if there are any medications that can help.
Multiple Choice

A. Your new pain will likely resolve in a couple of weeks
B. Sorry...there are no good medications to treat your new pain
C. You likely have neuropathic pain and there are medications we can try
D. Let’s obtain an MRI of your feet to see if we are missing something
Woolf CJ.

Central Sensitization: Implications for the Diagnosis and Treatment of Pain

Pain 2011; 152: S2-S15
Aims/Purpose

• What Central Sensitization (CS) has taught us about the nature and mechanism of pain
• What are the implications of CS for pain diagnosis and therapy

Methods

• Narrative Review
What is Central Sensitization?

Normal Sensation

Nociceptor

Low-Threshold Mechanoreceptor

Pain

Touch

Nociceptor

Low-Threshold Mechanoreceptor

Pain

Touch

Woolf CJ. Pain 2011
What is Central Sensitization?

Woolf CJ. Pain 2011
What is Central Sensitization?

• Central Sensitization (CS) reflects a state if excitability of the central nociceptive circuits manifesting as pain hypersensitivity (allodynia [reduction in threshold], hyperalgesia [increased responsiveness]) in the absence of inflammation or an acute neural lesion.
What is Central Sensitization?

• “CNS can change, distort or amplify pain, increasing its degree, duration and spatial extent in a manner that no longer directly reflects the specific qualities of peripheral noxious stimuli, but rather the particular functional states of circuits in the CNS.”

• CS likely contributes to neuropathic pain, OA, RA, fibromyalgia, headache, CRPS, visceral pain hypersensitivity syndromes
Why is it important?

- CS explains why pain can occur without a peripheral noxious stimulus.
- Diagnosing CS will assist in choosing treatments that produce analgesia by normalizing hyperexcitable central neural activity such as antidepressants and anticonvulsants.
- The contribution of CS to many “unexplained” clinical pain conditions offers a therapeutic target.
Finnerup NB, Sindrup SH, Jensen TS. The Evidence for Pharmacological Treatment of Neuropathic Pain. Pain 2010; 150:573-581
What’s known?

• The estimated community prevalence of neuropathic pain in the US is 9.8%\textsuperscript{1}

• Pharmacological management remains one of the most important therapeutic option for chronic neuropathic pain yet results remain unsatisfactory\textsuperscript{2}

\textsuperscript{1}Yawn BP et al. Pain Med 2009, \textsuperscript{2}Finnerup NB et al. Pain 2005
Aims/Purpose

• Without head-to-head comparisons between different medications to treat NP, **numbers needed to treat (NNT)** and **numbers needed to harm (NNH)** are alternative methods for determining efficacy and safety across medications and conditions.

• Provide up-to-date calculations of **NNT** and **NNH** values in neuropathic pain.
Methods

• Systematic Review (new data added to previous published review in 2005*)


• Included: RPCDB with at least 10 patients with specified neuropathic pain conditions

• Excluded: not written in English, where pain was not primary outcome, enrich-enrollment, preemptive studies and the following conditions of mixed pain etiologies: radiculopathies, CRPS and cancer neuropathic pain

*Finnerup NB et al. Pain 2005
Methods

• **NNT**: number of patients needed to be treated for one patient to obtain 50% pain intensity reduction (alternatively 30% pain reduction or at least good pain relief)  
  **BETTER=LOW NUMBER**

• **NNH**: number of patients needed to be treated for one patient to drop out due to adverse effects  
  **BETTER=HIGH NUMBER**
Results

- 174 RDBPCT included
  - 69 painful poly-neuropathy (most often DM)
  - 23 studied PHN
  - 19 peripheral nerve injury
  - 16 HIV neuropathy
  - 15 central pain
  - 7 trigeminal neuralgia
  - 25 mixed neuropathic pain
- Tricyclic antidepressants
- Gabapentin/pregabalin
- Opioids/tramadol
- Lamotrigine

Painful polyneuropathy

Postherpetic neuralgia

Peripheral nerve injury

HIV neuropathy

Central pain

NNT
Finnerup NB et al. 2010
Pharmacological treatment still represents a main option for treating chronic neuropathic pain.

Our improved understanding of NP-generating mechanisms has not been matched by similar improvements in treatment efficacy.

The lowest NNT was for TCAs, followed by opioids and the anticonvulsants gabapentin and pregabalin.

Despite increases of 66% in new RPCDB trials in NP since 2005, there is no evidence for changes of a 2005 treatment algorithm.
How should I change practice?

Peripheral neuropathic pain

- yes: Postherpetic neuralgia and focal neuropathy
  - yes: Lidocaine patch*
  - no: TCA contraindication

- no: Gabapentin/pregabalin
  - yes: TCA contraindication
  - no: TCA (SNRI)

TCA (SNRI)

Tramadol, oxycodone

Finnerup NB et al. Pain 2005
C. You likely have neuropathic pain from your diabetes and there are medications we can try

- First line: TCAs
- Second line: Alpha-2-delta binding agents (i.e., pregabalin and gabapentin)
  - No evidence for superior efficacy though lower cost may favor gabapentin
Yoga for Chronic LBP

Erin E. Krebs, MD, MPH
Minneapolis VA Health Care System
University of Minnesota Medical School
Vignette

• Mr. P successfully reduced his opioid dose and has not had any worsening of his back pain. He hates taking medications every day and is tired of being unable to participate in his usual activities. He would like to be more physically active again.

• His daughter is into “hot yoga” and has been trying to get him to go. He says, “It sounds crazy to me. What do you think?”
Multiple Choice

A. I agree with you. That does sound crazy.

B. Yoga is very popular, but there is no strong evidence that it helps back pain.

C. Studies show that yoga can help back pain. You should go with your daughter.

D. Studies show that yoga can help back pain, but they tested a different form of yoga than your daughter’s.
Articles

A Randomized Trial Comparing Yoga, Stretching, and a Self-Care Book for Chronic Low Back Pain  
Arch Intern Med 201;171: 2019-26

Yoga for Chronic Low Back Pain: A Randomized Trial  
Annals Intern Med 2011;155:569-578
What’s known?

• Small trials of yoga for a variety of pain indications have suggested benefit.
• 3 published systematic reviews (2011-12)
  – Included 10-16 trials (4-6 for back pain)
  – Moderate effect size for back pain & disability
  – Trials small (n=12-101), heterogeneous, with methodological limitations

Aims/Purpose

• To determine whether a 12-week yoga program for adults with chronic low back pain (LBP) leads to greater improvements in function compared with...
  – Usual care + self-care book (both RCTs)
  – 12-week stretching class (Sherman)
Participants and Setting

- Participants recruited from generalist settings (Group Health members in WA; 39 UK general practices)
- Eligibility: Adults with chronic LBP
- Exclusions: Back pain red flags, “complex” back pain, mental health conditions, serious medical disease
Interventions

• **Yoga**: Twelve 75-minute weekly classes
  – Experienced yoga teachers with manual
  – Adapted poses, guided relaxation

• **Stretching**: Twelve 75-minute weekly classes (Sherman only)
  – Experienced PTs with manual

• **All**: Handouts, CD/DVD to support practice
Outcome measures

• Primary outcome: Roland Morris Disability Questionnaire at 3 months (both RCT)

• Follow-up duration
  – 6 months (Sherman)
  – 12 months (Tilbrook)
## Participant Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Sherman (n=228)</th>
<th>Tilbrook (n=313)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean)</td>
<td>48 years</td>
<td>46 years</td>
</tr>
<tr>
<td>Sex (female)</td>
<td>64%</td>
<td>70%</td>
</tr>
<tr>
<td>Race (white)</td>
<td>87%</td>
<td>...</td>
</tr>
<tr>
<td>Higher education</td>
<td>62%</td>
<td>39%</td>
</tr>
<tr>
<td>Not employed</td>
<td>13%</td>
<td>22%</td>
</tr>
<tr>
<td>LBP duration (mean)</td>
<td>10.8 years</td>
<td>10.1 years</td>
</tr>
<tr>
<td>Baseline RMDQ (mean)</td>
<td>9.1</td>
<td>7.8</td>
</tr>
<tr>
<td>Currently use pain meds</td>
<td>59%</td>
<td>56%</td>
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</table>
## Results

Sherman trial

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>3 months</th>
<th>6 months</th>
</tr>
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<tbody>
<tr>
<td><strong>Yoga</strong></td>
<td>9.8</td>
<td>4.3</td>
<td>4.1</td>
</tr>
<tr>
<td><strong>Usual care</strong></td>
<td>9.0</td>
<td>6.8</td>
<td>5.9</td>
</tr>
<tr>
<td><strong>Difference (Y vs. U)</strong></td>
<td></td>
<td>-2.5 (-3.7, -1.3)</td>
<td>-1.8 (-3.1, -0.5)</td>
</tr>
<tr>
<td><strong>Stretching</strong></td>
<td>8.6</td>
<td>4.6</td>
<td>4.5</td>
</tr>
<tr>
<td><strong>Difference (Y vs. S)</strong></td>
<td></td>
<td>-0.3 (-1.3, 0.7)</td>
<td>-0.4 (-1.5, 0.8)</td>
</tr>
</tbody>
</table>
## Results

### Tilbrook trial

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>3 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yoga</strong></td>
<td>7.8</td>
<td>-2.1</td>
<td>-2.0</td>
</tr>
<tr>
<td><strong>Usual care</strong></td>
<td>7.8</td>
<td>-0.0</td>
<td>-0.5</td>
</tr>
<tr>
<td><strong>Difference</strong></td>
<td></td>
<td><strong>-2.2 (-3.3, -1.0)</strong></td>
<td><strong>-1.6 (-2.7, -0.4)</strong></td>
</tr>
</tbody>
</table>
What these studies add

Author Conclusions

• Yoga leads to greater improvements in back pain-related function than usual care
  – Differences clinically important: 52% in yoga group had 50% improvement (compared with 23% in usual care group)

• Yoga & stretching exercise classes do not differ in their effects on back function
How should I change practice?

• Consider recommending yoga to improve physical functioning in patients with mild-moderate back pain-related disability
  – Advise patients to seek classes oriented towards people with physical limitations, and taught by therapeutically-oriented instructors
    • Look for: “gentle,” “restorative,” “chair,” “senior”
    • Avoid: “power,” “flow,” “hot”
Multiple Choice

“It sounds crazy to me. What do you think?”

D. Studies show that yoga can help back pain, but they tested a different form of yoga than your daughter’s.

– Hot yoga is too strenuous—you might get hurt. Check the senior center for a gentle yoga class or stretching exercise class.
– Yoga may improve your ability to move and be active more than it improves your pain.
Psychological Treatment: Cognitive Behavioral Therapy

Matthew J. Bair, MD, MS
Roudebush (Indianapolis) VA Medical Center
Indiana University School of Medicine
Mr. P feels that he is able to do more physically thanks to his yoga practice, but he is still bothered by pain. He is concerned that his back pain has been present for 12 months now and wondering if it is only going to get worse. He’s afraid he will “end up in wheelchair.”

Mr. P states and asks: “I’m willing to try anything...what are my other options?”
Multiple Choice

A. Sorry...we have run out of other treatment options

B. I’d like to refer you to physical therapy to see if you will need a wheelchair

C. CBT has shown promise in patients with LBP

D. Let’s obtain an MRI of your back every year to rule out worsening

Group cognitive behavioural treatment for low-back pain in primary care: A randomised controlled trial and cost-effectiveness analysis

Lancet 2010;375:916-23
What’s known?

• Effective treatments w/ sustained improvements in low back pain are elusive

• Paucity of definitely sized trials of psychological treatments w/ long-term f/u

• Few high-quality economic studies of CBT
Aims/Purpose

• To test the effectiveness and cost-effectiveness at 1-year:
  – A group cognitive behavioral intervention coupled with “best practice advice”
  – In persons with at least moderately “troublesome” sub-acute or chronic low back pain in primary care
Participants and Setting

- **Participants**: 56 general practices in 7 regions of England
- **Eligibility**: Adults with > “moderately troublesome” LBP of > 6 weeks duration
- **Exclusions**: “serious cause” of LBP, severe psychiatric disorders, previous CBT intervention for LBP
Interventions

- Two study arms
  - Advice plus 6 group-based sessions of CBT
    - Patient education about LBP, cognitive restructuring to improve coping skills
    - Goal setting, pacing skills, graded physical activity, effective communication
  - Advice alone (control arm)
    - 15 minute session emphasizing remaining active, avoiding bed rest, appropriate use of pain meds
Outcome measures

• **Primary outcomes:** Pain-related disability and pain severity
  – Change baseline to 12 months
  – Roland Morris Disability Questionnaire

• **Secondary outcomes:** SF-12 mental and physical, fear avoidance, self-efficacy

• Quality-adjusted life-years
## Participant Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Lamb (n=701)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean)</td>
<td>54 years</td>
</tr>
<tr>
<td>Sex (female)</td>
<td>60%</td>
</tr>
<tr>
<td>Race (white)</td>
<td>88%</td>
</tr>
<tr>
<td>Severity of back pain</td>
<td></td>
</tr>
<tr>
<td>Moderate troublesome</td>
<td>55%</td>
</tr>
<tr>
<td>Very/extremely</td>
<td>45%</td>
</tr>
<tr>
<td>troublesome</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>49%</td>
</tr>
<tr>
<td>LBP duration (mean)</td>
<td>13 years</td>
</tr>
<tr>
<td>Baseline RMDQ (mean, 0-24)</td>
<td>9.0</td>
</tr>
<tr>
<td>Pain severity (0-100)</td>
<td>59.0</td>
</tr>
</tbody>
</table>
Results

<table>
<thead>
<tr>
<th></th>
<th>Baseline RMDQ</th>
<th>12 months RMDQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advice + CBT</td>
<td>9.0</td>
<td>-2.4 (95% CI 1.89–2.84)</td>
</tr>
<tr>
<td>Advice alone</td>
<td>9.0</td>
<td>-1.1 (0.39–1.72)</td>
</tr>
<tr>
<td>Difference</td>
<td></td>
<td>-1.3 (-0.56–2.06)</td>
</tr>
</tbody>
</table>

- Follow-up of 85% at 12-month
- Modified Von Korff disability score
  - CBT arm decreased by 13.8% (11.4–16.3%) vs. 5.4% (2.0–8.9%) in control
- Von Korff pain score
  - CBT decreased by 13.4% (10.8–16.0%) vs. 6.4% (3.1–9.7%) in control
- Additional quality-adjusted life-year (QALY) gained from CBT; incremental cost per QALY was £1786
What these studies add

Author Conclusions

• Over 1 year, CBT had a sustained effect on troublesome sub-acute and CLBP

• The intervention was low cost from the perspective of the health care provider
How should I change practice?

- Get to know locally available psychological treatments for pain
- Explore patient willingness to try psychological treatments for their pain
- Advise patients of the evidence showing CBT’s effectiveness for LBP
- Refer patients “earlier” to providers/clinics that deliver CBT for pain
What are my other options?”

C. CBT has shown promise in patients with LBP

– If we strive to keep you active, the likelihood that you will end up in wheelchair is very small

– Thank you for being open to CBT. It can help you find better ways to manage your pain on your own and better ways to cope with pain

– We don’t need additional diagnostic studies unless you develop “red flag” symptoms
Systematic Approaches

Jane Liebschutz, MD MPH

Boston Medical Center
Boston University School of Medicine
Vignette

• On monthly review of your patient panel, you are struck by the large number of patients with low back pain in your clinic. You have earned a reputation as the "Back Pain Doc" among your peers.

• With the transition to Patient Centered Medical Home, the clinic leadership asks for suggestions to improve overall care for back pain in the clinic.
Multiple Choice

A. Only refer older patients for treatment because younger ones get better on their own

B. Perform intensive primary care clinician education, combined with patient symptom monitoring and feedback to clinicians.

C. Give all patients referrals to any of a number of evidence-based treatments based on their preference.

D. Refer patients based on a risk stratification assessment.
Hill J, Whitehurst D, Lewis M, et. al.

Comparison of stratified Primary Care Management for Low Back Pain with Current Best practice (STaRT Back): A randomised controlled trial

Lancet 2011; 378: 1560-1571
What’s known?

- Multiple evidence-based treatments for back pain available
- Not clear how to refer patients to appropriate therapies
- Not clear whether risk stratification will be cost-effective
Aims/Purpose

• To determine whether administering a risk-stratification tool by physical therapist improved clinical outcomes, disability and cost-effectiveness for patients seeking care for back pain at the primary care
Participants and Setting

- Participants recruited from generalist settings (14 UK general practices)
- Eligibility: Adults who consulted GP with back pain
- Exclusions: potentially serious disorders, serious illness or comorbidity (physical, mental), surgery, pregnancy
Interventions

• STaRT Back Screening Tool
• 1 for Yes, 0 for No
Thinking about the last 2 weeks....

1. My back pain has spread down my leg(s) at some time in the last 2 weeks

2. I have had pain in the shoulder or neck at some time in the last 2 weeks

3. I have only walked short distances because of my back pain

4. In the last 2 weeks, I have dressed more slowly than usual because of back pain

5. It’s not really safe for a person with a condition like mine to be physically active
6. Worrying thoughts have been going through my mind a lot of the time

7. I feel that my back pain is terrible and it’s never going to get any better

8. In general I have not enjoyed all the things I used to enjoy

9. Overall, how bothersome has your back pain been in the last 2 weeks?
   Not at all/Slightly/Moderately (0 Points)
   Very much/Extremely (1 point)

Low Risk: Score 0-3
High Risk: Score 4-5 on questions 5-9
Medium Risk: All others
**Interventions**

- Control
  - 30 minute assessment, initial treatment by PT
  - Discretion on referral for further PT
Interventions

- Intervention
  - 30 minute assessment, initial treatment by PT informed by STaRT Screener
  - 15 minute video, Back Book
  - Medium Risk- referral for standardized PT
  - High Risk- referral for psychologically informed PT
Outcome measures

• Primary outcome
  – Roland Morris Disability Questionnaire at 4 and 12 months

• Secondary outcome:
  – Referral for PT
  – Health care resource use and costs
  – Number of days out of work
### Results

#### Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intervention N=568</th>
<th>Control N=283</th>
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<tbody>
<tr>
<td><strong>Age, mean</strong></td>
<td>50.1</td>
<td>49.1</td>
</tr>
<tr>
<td><strong>Female, %</strong></td>
<td>58%</td>
<td>60%</td>
</tr>
<tr>
<td><strong>RMDQ Disability</strong></td>
<td>9.8</td>
<td>9.7</td>
</tr>
<tr>
<td><strong>Low Risk</strong></td>
<td>148</td>
<td>73</td>
</tr>
<tr>
<td><strong>Medium Risk</strong></td>
<td>263</td>
<td>131</td>
</tr>
<tr>
<td><strong>High Risk</strong></td>
<td>157</td>
<td>79</td>
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</table>
## Results

**RMDQ - 12 month results**

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Intervention RMDQ (change)</th>
<th>Control RMDQ (change)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
<td>3.0 (-1.6)</td>
<td>3.0 (-1.2)</td>
</tr>
<tr>
<td>Medium Risk</td>
<td>4.0 (-4.9)</td>
<td>6.2 (-3.6)</td>
</tr>
<tr>
<td>High Risk</td>
<td>7.5 (-5.9)</td>
<td>8.9 (-4.8)</td>
</tr>
<tr>
<td>Risk Level</td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------</td>
<td>---------</td>
</tr>
<tr>
<td>Low Risk</td>
<td>7%</td>
<td>49%</td>
</tr>
<tr>
<td>Medium Risk</td>
<td>98%</td>
<td>60%</td>
</tr>
<tr>
<td>High Risk</td>
<td>100%</td>
<td>65%</td>
</tr>
</tbody>
</table>
## Results

Days off work - 12 months

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
<td>0.4</td>
<td>3.0</td>
</tr>
<tr>
<td>Medium Risk</td>
<td>4.1</td>
<td>18.4</td>
</tr>
<tr>
<td>High Risk</td>
<td>9.9</td>
<td>10.6</td>
</tr>
</tbody>
</table>
Cost-effectiveness

• Intervention had greater mean QALY (0.039) at lower mean health costs

• Costs £240.01 vs. £274.40
  – saving 34.4 British pounds
All secondary outcomes favored intervention

- Back pain intensity
- Change to lower risk group
- Global Change
- Pain-catastrophizing
- Anxiety
- Depression
- SF12 PCS, MCS
- Satisfaction with care
What these studies add

Author Conclusions

• Targeted screening and treatment for back pain improved primary care efficiency

• Underlying reductions in control group unexpectedly high, making even more dramatic the intervention results

• Economics perspective- improved QALYs, reduced health care use, fewer days off work.

• Pattern of referral matched risk group
How should I change practice?

• Use STaRT Back Screening tool with back pain patients

• Consider referral to PT (or other effective modality) for patients with medium or high risk patients

• Consider psychological/physical intervention for patients with high risk profiles
Multiple Choice

How to improve overall care for back pain in the clinic?

D. Refer patients based on a risk stratification assessment.

- Develop a system to have patients fill out questionnaire when seeing clinician for back pain of any type
- Develop referral network to evidence-based treatment options
Questions?

Dan Alford  
Matthew Bair  
William Becker  
Joseph Frank  
Erin Krebs  
Jane Liebschutz

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Erin.Krebs@va.gov
Jane.Liebschutz@bmc.org
Additional Reading
INTERVENTIONAL PAIN MEDICINE

• **Featured:**

• **Additional Reading:**
  - Iverson et al. Effect of caudal epidural steroid or saline injection in chronic lumbar radiculopathy: multicentre, blinded, randomised controlled trial. *BMJ.* 2011 Sep 13;343:d5278.. PMID: 21914755

OPIOIDS

• **Featured:**

• **Additional Reading:**

### CENTRAL SENSITIZATION/NEUROPATHIC PAIN

**Featured:**

**Additional Reading:**
YOGA, OTHER NON-PHARMACOLOGIC

• Featured:

• Additional Reading:

COGNITIVE BEHAVIORAL THERAPY

• Featured:

• Additional Reading:
SYSTEMS APPROACHES

• Featured:

• Additional Reading: