Yoga for Chronic Low Back Pain

October 16, 2018
Symposium for Yoga Research

Rob Saper, MD MPH
Associate Prof. of Family Medicine, Boston Univ. School of Medicine
Director of Integrative Medicine, Boston Medical Center
This work was supported by grants from

[NIH logo]

K07 AT002915
R01 AT005956
Disclosures

No relevant financial conflicts of interest to disclose...
Harvard Medical School
“You’ve been fooling around with alternative medicines, haven’t you?”
NIH FUNDED CAM RESEARCH FELLOWSHIP
PASSION

IMPORTANCE

FEASIBILITY

Yoga for Low Back Pain
Themes to Reflect On Tonight

• What, who, and why do we study?

• As yoga investigators (and enthusiasts), how do we maintain perspective between our personal experience and our commitment to rigor and objectivity?

• How can our work have the greatest impact?
Low Back Pain

- Chronic low back pain (CLBP) is a large cause of morbidity, disability, and cost
- Approximately ¼ U.S. adults have LBP ≥ 1 day/3 mos (Deyo, ‘06)
- Estimated 5-10% experience recurring or chronic LBP (Deyo, 2006)
- 34 million office visits annually to PCPs (Licciardone, 2008)
- >$50 billion annual direct costs (Luo, 2004)
- LBP patients incur 75% more medical expenditures (Martin, 2008)
- Leading & most expensive cause of worker’s comp (Guo, 1999)
- Leading cause of disability globally (GBD Working Group, Lancet, 2016)
Effect on Lives Can Be Profound

- Impact on function: work, physical, psychosocial, ADLs & IADLs
- Loss of activities that bring joy and meaning to life
- A sense of suffering, often in isolation
- Feelings of anger, depression, and guilt
- Impact on family
  - Emotional and physical energy caring for person in chronic pain
  - They experience the same anger, depression, and guilt
  - Pain controls their lives as well

Adapted from icer-review.org/material/back-and-neck-pain-final-report
Specific Causes of Back Pain:

- Superior articular process
- Transverse process
- Spinous process
- Intervertebral foramen
- Pars interarticularis
- Defect in pars interarticularis (spondylolysis)
- Intervertebral disk
- Anterior displacement of L5 on sacrum (spondylolisthesis)
- Articular surface (sacroiliac)
- Sacrum
- Ligamentum flavum
- Normal canal
- Herniated nucleus pulposus
- Anulus fibrosus
- Herniated disk
- Hypertrophy of facets
- Thickened ligamentum flavum
- Spinal stenosis
Acute (<4 weeks) and Subacute (4-12 weeks) Nonspecific Low Back Pain

• Common
• Mechanism: Injury to ligaments, facet joints, muscle, fascia, nerve roots, or disc
• 75-90% resolve spontaneously
Nonspecific Chronic Low Back Pain
(>12 weeks)

• Complex poorly understood condition
• Different CNS patterns than acute LBP
• Contributes to most suffering and cost
• Pharmaceuticals can help but often not fully satisfactory
Health Disparities in Low Back Pain

• LBP prevalence similar among different racial groups
• Impact of LBP is greater in low-income minority populations
• Medical expenditures for LBP in minorities are 30% lower than in whites (Luo 2004)
• Minorities with LBP receive less:
  • patient education (Licciardone 2001)
  • specialty referrals (Green 2003)
  • intensive rehabilitation (Chibnall 2005)
A National Health Crisis

Every 13 minutes there is a death from opioid overdose\(^1\)

2.1M Americans suffer from an opioid use disorder\(^2\)

$504B estimated annual costs of U.S. opioid epidemic\(^3\)

---

From pain to overdose and death

Pain \rightarrow Opioid Rx \rightarrow Rx opioid addiction \rightarrow Heroin and Rx opioid addiction \rightarrow Overdose \rightarrow ED visit \rightarrow Hospitalization \rightarrow DEATH
Low Back Pain: Biopsychosocial-Spiritual Model

- **B**ody
  - Structural injury
  - Inflammation

- **M**ind
  - Depression
  - Fear avoidance

- **S**pirit
  - Loss of Faith
  - Loss of Purpose

- **S**ocial
  - Work dissatisfaction
  - Social Support
Yoga Use in U.S. Adults 1998-2012

<table>
<thead>
<tr>
<th>Year</th>
<th>Use (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998*</td>
<td>3.8</td>
</tr>
<tr>
<td>2002**</td>
<td>5.1</td>
</tr>
<tr>
<td>2007**</td>
<td>6.1</td>
</tr>
<tr>
<td>2012**</td>
<td>8.4</td>
</tr>
</tbody>
</table>

*Eisenberg JAMA 1998; **NHIS
Use of CAM by U.S. Adults for Back Pain – 2012

<table>
<thead>
<tr>
<th>CAM Type</th>
<th>n</th>
<th>Used for back pain, %</th>
<th>Perceived benefit (of those who used CAM for back pain), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any CAM n=3892</td>
<td></td>
<td>21.1</td>
<td></td>
</tr>
<tr>
<td>Acupuncture n=261</td>
<td></td>
<td>19.5</td>
<td></td>
</tr>
<tr>
<td>Chiropractic Manipulation n=1363</td>
<td></td>
<td>40.7</td>
<td></td>
</tr>
<tr>
<td>Massage n=1017</td>
<td></td>
<td>22.2</td>
<td></td>
</tr>
<tr>
<td>Yoga/Qigong/Tai chi n=905</td>
<td></td>
<td>8.1</td>
<td></td>
</tr>
</tbody>
</table>

- **Used for back pain, %**
  - Any CAM n=3892: 21.1
  - Acupuncture n=261: 19.5
  - Chiropractic Manipulation n=1363: 40.7
  - Massage n=1017: 22.2
  - Yoga/Qigong/Tai chi n=905: 8.1

- **Perceived benefit (of those who used CAM for back pain), %**
  - Great
    - Any CAM n=3892: 58.1
    - Acupuncture n=261: 64.6
    - Chiropractic Manipulation n=1363: 62.0
    - Massage n=1017: 54.7
    - Yoga/Qigong/Tai chi n=905: 53.2
  - Some
    - Any CAM n=3892: 29.1
    - Acupuncture n=261: 16.4
    - Chiropractic Manipulation n=1363: 27.2
    - Massage n=1017: 30.8
    - Yoga/Qigong/Tai chi n=905: 36.8
  - Only a little
    - Any CAM n=3892: 8.0
    - Acupuncture n=261: 11.8
    - Chiropractic Manipulation n=1363: 6.1
    - Massage n=1017: 9.4
    - Yoga/Qigong/Tai chi n=905: 8.1
  - Not at all
    - Any CAM n=3892: 4.8
    - Acupuncture n=261: 7.2
    - Chiropractic Manipulation n=1363: 4.8
    - Massage n=1017: 5.2
    - Yoga/Qigong/Tai chi n=905: 1.9

*Data from NHIS Sample Adult, Alternative Health Supplement file 2012.*

Socioeconomic Disparities in Yoga Use

- Black vs. White
- Hispanic vs. Non-Hispanic
- High School vs. College
- Low vs. High Income

2007 NHIS
Availability of Yoga Studios in Boston
Yoga vs. Exercise vs. Education (n=101)

(Sherman K et al, Ann Intern Med 2005)
Yoga vs. Usual Care (n=313)

(Tilbrook et al, Ann Intern Med. 2011)
Yoga vs. Stretching vs. Education (n=228)

(Sherman et al, Arch Intern Med. 2011)
## Meta-analysis of Yoga for LBP

<table>
<thead>
<tr>
<th>Follow-up duration</th>
<th>Outcomes</th>
<th>Number of trials (n)</th>
<th>Standardized mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-term</td>
<td>Pain</td>
<td>6 (584)</td>
<td>−0.48 (−0.65 to −0.31)</td>
</tr>
<tr>
<td></td>
<td>Back-specific disability</td>
<td>8 (689)</td>
<td>−0.59 (−0.87 to −0.30)</td>
</tr>
<tr>
<td>Long-term</td>
<td>Pain</td>
<td>5 (564)</td>
<td>−0.33 (−0.59 to −0.07)</td>
</tr>
<tr>
<td></td>
<td>Back-specific disability</td>
<td>5 (574)</td>
<td>−0.35 (−0.55 to −0.15)</td>
</tr>
</tbody>
</table>

Chronic LBP
Use nonpharmacologic treatment first
• Exercise
• Spinal manipulation
• Acupuncture
• Yoga
• MBSR
• CBT
• Tai chi

American College of Physicians Recommendations
Qaseem et al, Ann Int Med 2017

Clinical Guideline

Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Robert M. McLean, MD; and Mary Ann Forciea, MD; for the Clinical Guidelines Committee of the American College of Physicians

Description: The American College of Physicians (ACP) developed this guideline to present the evidence and provide clinical recommendations on noninvasive treatment of low back pain.

Methods: Using the ACP grading system, the committee based these recommendations on a systematic review of randomized, controlled trials and systematic reviews published through April 2015 on noninvasive pharmacologic and nonpharmacologic treatments for low back pain. Updated searches were performed through November 2016. Clinical outcomes evaluated included reduction or elimination of low back pain, improvement in back-specific and overall function, improvement in health-related quality of life, reduction in work disability and return to work, global improvement, number of back pain episodes or time between episodes, patient satisfaction, and adverse effects.

Target Audience and Patient Population: The target audience for this guideline includes all clinicians, and the target patient population includes adults with acute, subacute, or chronic low back pain.

Recommendation 1: Given that most patients with acute or subacute low back pain improve over time regardless of treatment, clinicians and patients should select nonpharmacologic treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). If pharmacologic treatment is desired, clinicians and patients should select nonsteroidal anti-inflammatory drugs or skeletal muscle relaxants (moderate-quality evidence). (Grade: strong recommendation)

Recommendation 2: For patients with chronic low back pain who have had an inadequate response to nonpharmacologic therapy, clinicians and patients should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as first-line therapy, or tramadol or duloxetine as second-line therapy. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients. (Grade: weak recommendation, moderate-quality evidence)

Ann Intern Med. doi:10.7326/M16-2567
For author affiliations, see end of text.
This article was published at Annals.org on 14 February 2017.
Rationale for our Research

1. Evidence for yoga for LBP in studies of predominantly high SES populations
2. Minority low income populations are more likely to be negatively impacted by LBP and less likely to use yoga
3. Trials for LBP should target all affected groups.
4. For integration, CAM evidence-based therapies need to be compared to evidence-based conventional approaches
Is a randomized controlled trial of yoga for chronic low back pain in predominantly low income minority populations feasible?

Yoga For Chronic Low Back Pain In A Predominantly Minority Population:
   a pilot RCT

(Saper et al, Alt Ther Health Med 2009)
Participant Flow Chart

2 months

Inquiries about study (n=234)

Eligibility Screening (n=66)

Randomized (n=30)

Ineligible (n=36)

Yoga (n=15)

Wait list Control (n=15)

(Saper et al, Alt Ther Health Med 2009)
Is a Yoga RCT of yoga for chronic LBP in low income minority populations feasible?

<table>
<thead>
<tr>
<th>Race</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>24%</td>
</tr>
<tr>
<td>Black</td>
<td>70%</td>
</tr>
<tr>
<td>Other</td>
<td>6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Social Determinants</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual household income $\leq$ $30,000</td>
<td>44%</td>
</tr>
<tr>
<td>No or public health insurance</td>
<td>50%</td>
</tr>
<tr>
<td>$\leq$ High school grad</td>
<td>33%</td>
</tr>
</tbody>
</table>

(Saper et al, Alt Ther Health Med 2009)
Pain

Week

Pain Score

Yoga

Usual care

(Saper et al, Alt Ther Health Med 2009)
What is the ideal “dose” of yoga for chronic low back pain?

The Yoga for Low Back Pain Dosing Study

Saper et al, ECAM 2013
Recruitment

Boston HealthNet
Boston Medical Center
6 community health centers

Multiple recruitment strategies
631 inquiries in 4 months
• Targeted letters (48%)
• Flyers/Brochures (28%)
• Physician referral (13%)
• Other (11%)

Of those enrolled, greatest % was from physician referral (27%)
Results: Roland Morris

Graph showing results for 1x/week and 2x/week:
- Baseline: 13.8
- 6 Weeks: 9.4
- 12 Weeks: 8.4
- Baseline: 13.7
- 6 Weeks: 10.2
- 12 Weeks: 8.7
Yoga & PT are effective but their comparative effectiveness is unknown.

If a CAM therapy like yoga is to be integrated into healthcare, it should be at least as effective as conventional therapy.
Back to Health Study Design

Recruitment & Enrollment (n=320)

Baseline Data Collection

Randomization

Yoga (n=128)
Education (n=64)
PT (n=128)

12 Week Data Collection

Re-randomization

Yoga
Education
PT

Yoga Maintenance (n=64)
No Yoga Maintenance (n=64)
PT Maintenance (n=64)
No PT Maintenance (n=64)

52 Week Data Collection

Saper et al. Trials 2014
Participants

Inclusion Criteria
• 18-64 years old
• Current non-specific cLBP >12 weeks
• Mean pain intensity >4 on 0-10 point scale

Exclusion Criteria
• Specific back pain pathologies
• Sciatica > back pain
• Yoga or PT in previous 6 months
• Pregnancy

Saper et al. Trials 2014
Hatha Yoga Protocol

• Diverse expert panel systematically reviewed lay & scientific literature
• Drafted protocol based on literature and experience
• Iterative refinements in 2 previous studies
• Weekly 75 minute group class with 1:4 instructor:participant ratio
• Fidelity assessments
• DVD for home practice

Saper et al. *Trials* 2014
- Knee to chest
- Knee to chest with twist
- Cat and Dog Pose

- Chair Pose
- Chair Pose Modified
- Mountain Pose
- Shoulder Opener

- Half Moon (Crescent)
- Child’s Pose
- Cobra and variation

- Bridge pose
- Cat and Dog Pose Variation
- Table Top Leg Extension
- Triangle at wall

- 12 weeks
- 1 class/wk
- 75 mins/class
- Variations
- World music
- Home practice
- DVD
- Handbook
- Free yoga supplies
## Baseline Characteristics (n=320)

<table>
<thead>
<tr>
<th>Sociodemographics</th>
<th>Yoga (n=127)</th>
<th>PT (n=129)</th>
<th>Education (n=64)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years</td>
<td>46</td>
<td>46</td>
<td>44</td>
</tr>
<tr>
<td>Female</td>
<td>57%</td>
<td>70%</td>
<td>66%</td>
</tr>
<tr>
<td>Non-white</td>
<td>76%</td>
<td>85%</td>
<td>83%</td>
</tr>
<tr>
<td>Income &lt; $30,000</td>
<td>60%</td>
<td>55%</td>
<td>64%</td>
</tr>
<tr>
<td>Education ≤ high school</td>
<td>39%</td>
<td>43%</td>
<td>31%</td>
</tr>
<tr>
<td><strong>Outcome Measures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean pain score</td>
<td>7.1</td>
<td>7.2</td>
<td>7.0</td>
</tr>
<tr>
<td>Mean Roland score</td>
<td>13.9</td>
<td>15.6</td>
<td>15.0</td>
</tr>
<tr>
<td>Pain medicine use</td>
<td>69%</td>
<td>73%</td>
<td>73%</td>
</tr>
<tr>
<td>% Opioid use</td>
<td>22%</td>
<td>18%</td>
<td>19%</td>
</tr>
</tbody>
</table>

Saper et al, Ann Int Med 2017
# Treatment Adherence

<table>
<thead>
<tr>
<th></th>
<th>Median Sessions Attended in Treatment Phase</th>
<th>Adherence* in Treatment Phase</th>
<th>Attending ≥1 Maintenance Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yoga</td>
<td>7</td>
<td>44%</td>
<td>49%</td>
</tr>
<tr>
<td>PT</td>
<td>7</td>
<td>36%</td>
<td>54%</td>
</tr>
<tr>
<td>Education</td>
<td>NA</td>
<td>44%</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Defined as attending ≥75% sessions

Saper et al, Ann Int Med 2017
Roland Morris – Intention to Treat

Saper et al, Ann Int Med 2017

[Graph showing the mean RMDQ score across different phases and interventions over weeks.]
Pain Intensity Intention to Treat

Treatment Phase

Maintenance Phase

Mean Back Pain Rating

- Yoga Drop-in Classes
- Yoga Home Practice
- Physical Therapy Booster Sessions
- Physical Therapy Home Practice
- Education

(days 0-52)
## Responder Analyses

(> 30% ↓ from baseline)

<table>
<thead>
<tr>
<th></th>
<th>Yoga</th>
<th>PT</th>
<th>Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roland</td>
<td>48%</td>
<td>37%</td>
<td>23%</td>
</tr>
<tr>
<td>Pain</td>
<td>35%</td>
<td>43%</td>
<td>25%</td>
</tr>
</tbody>
</table>

### Comparison

<table>
<thead>
<tr>
<th></th>
<th>Yoga vs. PT</th>
<th>Yoga vs. Education</th>
<th>PT vs. Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roland</td>
<td>1.9 (1.1,3.1)</td>
<td>3.2 (1.6,6.4)</td>
<td>1.7 (0.9,3.5)</td>
</tr>
<tr>
<td>Pain</td>
<td>0.9 (.54, 1.5)</td>
<td>1.7 (0.9,3.4)</td>
<td>1.9 (0.98,3.8)</td>
</tr>
</tbody>
</table>

Saper et al, Ann Int Med 2017
Pain Medication Use

% USING PAIN MEDICINE IN PAST WEEK

WEEK

0 6 12

Yoga  PT  Education

69%  72%  73%  60%  63%  75%  55%*  53%**

*Saper et al, Ann Int Med 2017

*p<.05 compared to education

**p<.01 compared to education
Improvement & Satisfaction at 12 Weeks

Very Improved

Very Satisfied

Yoga  PT  Education

*S* p<.05 compared to education

Saper et al, Ann Int Med 2017
Roland Morris - Per Protocol

Treatment Phase

Maintenance Phase

Mean RMDQ Score

Week

Saper et al, Ann Int Med 2017
### Adverse Events

<table>
<thead>
<tr>
<th>Symptom type</th>
<th>Yoga (N=127)</th>
<th>PT (N=129)</th>
<th>Education (N=64)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any possibly or definitely related adverse event</td>
<td>7%</td>
<td>11%</td>
<td>2%</td>
</tr>
<tr>
<td>Any serious possibly related adverse event</td>
<td>1%</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Joint pain</td>
<td>3%</td>
<td>6%</td>
<td>0</td>
</tr>
<tr>
<td>Increased back pain</td>
<td>3%</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Sciatica or leg pain</td>
<td>1%</td>
<td>1%</td>
<td>0</td>
</tr>
<tr>
<td>Neck pain</td>
<td>1%</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>1%</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0</td>
<td>1%</td>
<td>0</td>
</tr>
</tbody>
</table>

Saper et al, Ann Int Med 2017
Qualitative Data: Physical Effects

Doing yoga, it actually takes you to a place where some days there is absolutely no pain.

It’s going to have to be something that’s part of my life... So I’m looking at it as a medical treatment—it’s not just a yoga class.
Qualitative Data: Mental Effects

People can push those buttons as they used to, they can’t make you angry, because now you have something that keeps you calm regardless.

I felt good because I was doing something, not sitting around waiting for a diagnosis, not taking another pill. I was involved in my treatment.
Strengths & Limitations

Strengths
• Assessor-blinded randomized design
• Adequate power to assess noninferiority
• Standardized interventions
• Diverse population

Limitations
• Relatively low adherence rates
• Per protocol are subset analyses
• Generalizability to ‘real world’
Future Work Needed

• Cost effectiveness
• Pragmatic Trials with patient-centered choice of therapies
• Online yoga vs. in-person
Themes to Reflect On Tonight

- What, who, and why do we study?
- As yoga investigators (and enthusiasts), how do we maintain perspective between our personal experience and our commitment to rigor and objectivity?
- How can our work have the greatest impact?
Acknowledgements

All participants and staff of Boston Medical Center, Codman Square Health Center, Dorchester House, The Dimock Center, Greater Roslindale Medical & Dental Center, South Boston Community Health Center, Upham’s Corner Health Center, South End Community Health Center

Yoga Team
Anna Dunwell
Smokey Montgomery
Lisa Cahill
Deidre Alessio
Danielle Ciofani
Carol Faulkner
Victoria Garcia
Drago
Amy Goh
Beth Kacel
Karen Cullen
Sylvia Baedorf Kassis
Julie Aronis
Monica Delgado-Chaffe

Co-Investigators
Anthony Delitto
Karen Sherman
Janice Weinberg
Patricia Herman

Research Staff
Allison Marshall
Christian Cerrada
Chelsey Lemaster
Darshan Shastri
Emir Duhovic
EJ Fontana-Martinez
Huong Tran
Julia Keosaian
Kaori Sato
Kristin Trimble
Kristin Shaw
Matt McGrath
Michael Roxas
Morgan Ford
Sarah Baird
Shayna Egan
Sheba Ebnote
Shirley Gillies
Taylor Mazac

Physician Champions
Stephen Tringale
Yen Loh
Aram Kaligian
Ani Tahmassian
Katherine Gergen Barnett
Nandini Sengupta
Kristin Shaw

DSMB
Deborah Cotton
Bei Chang
Maya Breuer

Physical Therapy Team
New England PT Plus
BMC PT
Megan Poletto
Joel Stevans

Data Analysis
Kat Sadhikova
Thank You!