Osteopathic Manipulative Medicine Research
State of the Evidence

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Objectives

• State the current evidence for using OMT in osteopathic clinical practice, focusing on recently published clinical trials.
• Recall resources to keep up to date on OMM research.
• Use resources to improve patient care.
• Use resources provided to increase efficiency of coding and billing practices.
BIOPSYCHOSOCIAL

NUTRITION

TRAUMA

INFECTION

AGING

STRESSORS

ENVIRONMENT

BODY

OSTEOPATHIC STRUCTURAL EXAM

FUNCTION

POSTURE

MOTION

MUSCULO SKELETAL

RESPIRATION

CIRCULATION

FLUIDS

METABOLISM

ENERGY

NEUROLOGIC BALANCE

BEHAVIORAL ADAPTATION
Does the benefit of treatment outweigh the risk?

The use of a medical treatment must be based on the balance of evidence for risk and therapeutic efficacy.
Evidence-Based Spinal Manual Medicine Summary

Benefit > Risk for:

• Acute, subacute and chronic mechanical low back and neck pain
• Cervicogenic headaches

Increase in:

• Patient satisfaction
Evidence-Based Spinal Manual Medicine Summary

Can reduce:
- Pain
- Medication use
- PT utilization
- Hospital days

- Disability and Impairment
- Work days lost from nonspecific or mechanical LBP
Level B evidence (small clinical trials)

OMT recommended for:

- Ankle sprain
- Atelectasis
- Colic
- Fibromyalgia
- Headache
- LBP during pregnancy and labor
- Menopausal symptoms
- Reduce narcotic usage
- Neck pain
- Otitis media
- Pancreatitis
- Parkinson’s Disease
- Pneumonia
Guidelines for OMM

• AOA
• US Govt.
• International
AOA National Guideline

- OMT by D.O.s is recommended for patients with Low Back Pain and Somatic Dysfunction
- Agency for Healthcare Research and Quality (AHRQ) National Guidelines Clearinghouse (NGC) Guideline Summary NGC-7504
- Grade 1a level of evidence (Meta-analysis, systematic review of RCTs)

http://www.guideline.gov/content.aspx?id=15271
AOA Practice Recommendations

• Offer OMT for patients who have evidence of somatic dysfunction in the acute, subacute or chronic stages of mechanical low back pain
Landmark Study on OMT for Low Back Pain

- OSTEOPATHic Health outcomes In Chronic low back pain (OSTEOPATHIC)
- Osteopathic Research Center in Texas
- John Licciardone, DO et al
Osteopathic manual treatment and ultrasound therapy for chronic low back pain: a randomized controlled trial.

Methods

• Randomized, double-blind, sham-controlled, $2 \times 2$ factorial design
• 455 patients: OMT (n = 230) or sham OMT (n = 225), and to UST (n = 233) or sham UST (n = 222)
• Six treatment sessions were provided over 8 weeks.
• Intention-to-treat analysis was performed to measure moderate and substantial improvements in low back pain at week 12 (30% or greater and 50% or greater pain reductions from baseline, respectively).
• Five secondary outcomes, safety, and treatment adherence were also assessed.
### Methods

#### Factor 1

<table>
<thead>
<tr>
<th>Factor 1</th>
<th>Osteopathic manual treatment</th>
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<tbody>
<tr>
<td>Active</td>
<td>OMT + UST (n=115)</td>
</tr>
<tr>
<td>Sham</td>
<td>Sham OMT + UST (n=118)</td>
</tr>
<tr>
<td>OMT + Sham UST (n=115)</td>
<td>Sham OMT + Sham UST (n=107)</td>
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#### Factor 2

<table>
<thead>
<tr>
<th>Ultrasound therapy</th>
<th>Active</th>
<th>Sham</th>
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<td>Main effects (n=233)</td>
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<tr>
<td>Sham UST</td>
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**OMT main effects (n=230)**

**Sham OMT main effects (n=225)**
Results

• There was no statistical interaction between OMT and UST.

• Patients receiving OMT were more likely than patients receiving sham OMT to achieve moderate (response ratio [RR] = 1.38; 95% CI, 1.16-1.64; $P < .001$) and substantial (RR = 1.41, 95% CI, 1.13-1.76; $P = .002$) improvements in low back pain at week 12.

• These improvements met the Cochrane Back Review Group criterion for a medium effect size.
Results

• Back-specific functioning, general health, work disability specific to low back pain, safety outcomes, and treatment adherence did not differ between patients receiving OMT and sham OMT.

• Nevertheless, patients in the OMT group were more likely to be very satisfied with their back care throughout the study ($P < .001$).
Results

• Patients receiving OMT used prescription drugs for low back pain less frequently during the 12 weeks than did patients in the sham OMT group (use ratio = 0.66, 95% CI, 0.43-1.00; \( P = .048 \)).

• Ultrasound therapy was not efficacious.
Strengths of the study

• Largest OMT randomized clinical trial to date.
• Pragmatically assessed OMT as practiced in real-life settings to complement usual care and self-care for chronic LBP.
• Used the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) consensus statement recommendations for determining moderate and substantial improvement in low back pain.
Strengths of the study

• Sham comparator group
• Treatment fidelity training
• Externally blinded physician drug prescribers
• Safety monitoring
• Similarity of baseline patient characteristics across treatment groups
• Intention-to-treat analysis
OSTEOPATHic Trial Subgroup Analyses

• 269 (59%) patients reported low baseline pain severity (LBPS) (<50 mm/100 mm), whereas 186 (41%) patients reported high baseline pain severity (HBPS) (≥50 mm/100 mm).

• **HBPS** group had substantial (>50%) pain reduction, clinically significant improvement in back specific functioning and satisfaction with care.

• Licciardone JC, et al., Outcomes of osteopathic manual treatment for chronic low back pain according to baseline pain severity: Results from the OSTEOPATHIC Trial, Manual Therapy (2013), http://dx.doi.org/10.1016/j.math.2013.05.006
OSTEOPATHIC Trial Data Subgroup Analyses

• Interleukin 1Beta and Interleukin 6 levels correlated with number of “key” osteopathic “lesions”, i.e., significant somatic dysfunctions with TART findings.

• TNF alpha changed significantly after 12 weeks of OMT

• Associations of Cytokine Concentrations With Key Osteopathic Lesions and Clinical Outcomes in Patients With Nonspecific Chronic Low Back Pain: Results from the OSTEOPATHIC Trial, (2012) JAOA 112(9):596-605.
TNF alpha and Diabetic Neuropathy

OSTEOPATHic Trial Data Subgroup Analyses

- 34 (7%) of 455 LBP patients also had DM.
- Severe somatic dysfunction was present significantly more often in patients with DM.
- Patients with DM who received OMT had significant reductions in LBP severity during the 12-week period.
- Decreased circulating levels of TNF-α may represent a possible mechanism for OMT effects in patients with diabetes mellitus.

OMT for LBP in Pregnancy Subgroup Analysis

• 68 patients (47%) experienced progressive back-specific dysfunction during the third trimester of pregnancy.
• Patients who received UOBC+OMT were significantly less likely to experience progressive back-specific dysfunction.
• The effect sizes for UOBC+OMT vs UOBC+SUT and for UOBC+OMT vs UOBC were classified as medium and large, respectively.
• The corresponding NNTs for UOBC+OMT were 5.1 vs UOBC+SUT; and 2.5 vs UOBC.

Progressive back-specific dysfunction during the third trimester of pregnancy.

Osteopathic manual treatment has medium to large treatment effects in preventing progressive back-specific dysfunction during the third trimester of pregnancy.
The Biology of Manual Therapies

by Brian C. Clark, James S. Thomas, Stevan A. Walkowski, and John N. Howell

J Am Osteopath Assoc
Volume 112(9):617-629
September 14, 2012

Published by American Osteopathic Association
First EBM MM Book 2007

- Seffinger and Hruby
- Evidence Based Manual Medicine: A Problem Oriented Approach
- Saunders/Elsevier
<table>
<thead>
<tr>
<th>Evidence Level</th>
<th>Recommendation</th>
<th>References</th>
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</table>
| A              | Manual treatment for patients with acute or chronic mechanical low back pain is as effective as standard treatments | Assendelft 2003[^31]; 2004[^32]  
http://www.cochrane.org/cochrane/revabstr/AB000447.htm |
| A              | Manual treatment is recommended for adult patients with mechanical low back pain. | ICSI 2004[^33]; (Grade I; Classes A, M, R)  
http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=149 |
<p>| A              | Manual therapy provides more effective short-term pain relief for patients with acute or subacute low back pain and better than a placebo treatment for patients with chronic low back pain | van Tulder 2000[^27]; Bronfort 2004[^19] |
| A              | Spinal manipulation is more effective for patients with LBP of less than 3 months duration. | Ferreira 2003[^38] |</p>
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<tr>
<th>Level of Evidence</th>
<th>Recommendation</th>
<th>References</th>
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| A                 | Manipulation should be used in addition to usual care for patients with shoulder somatic dysfunction. | Hay (2003)
|                   |                                                                                                  | Bergman (2004)                                   |
| A                 | Manipulation under anesthesia should be used for frozen shoulder that is refractory to conservative treatments. | Kivimäki and Pohjolainen (2001)
|                   |                                                                                                  | Farrell et al (2005)                             |
| A                 | Manipulation plus exercise should be used for rotator cuff dysfunction.                           | Green et al (1998)                              |
| A                 | Manipulation plus exercise should be used for shoulder impingement syndrome.                     | Desmeules (2003)                                |
EVIDENCE BASED PRACTICE RECOMMENDATION FOR CERVICOCGYGENIC HEADACHE

• Grade A

• Recommendation:
  Manual treatment and physical conditioning exercises are effective for cervicogenic headache

• RCTs: Nilsson 1997; Jull 2002, Bronfort 2004
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<tr>
<th>Grade Level</th>
<th>Recommendation</th>
<th>Reference</th>
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<tr>
<td>A</td>
<td>Manipulation of the upper extremities and spine is effective as conservative</td>
<td>Davis 1998&lt;sup&gt;56&lt;/sup&gt;</td>
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<tr>
<td></td>
<td>medical care in improving symptoms and signs of CTS</td>
<td></td>
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<tr>
<td>A</td>
<td>Wrist mobilization improves symptoms and signs of CTS</td>
<td>Tak-Akabi 2000&lt;sup&gt;55&lt;/sup&gt;</td>
</tr>
<tr>
<td>C</td>
<td>Manual treatment of the thoracic outlet, upper ribs, upper back and lower</td>
<td>Ramey 1999&lt;sup&gt;50&lt;/sup&gt;;</td>
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<td></td>
<td>cervical spine, and tenderpoints in the forearm improve symptoms and signs of</td>
<td>Sucher 1995&lt;sup&gt;48&lt;/sup&gt;</td>
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<td>CTS.</td>
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<tr>
<td>C</td>
<td>Myofascial release combined with exercise of the carpal tunnel improves</td>
<td>Sucher 1993&lt;sup&gt;54&lt;/sup&gt;;</td>
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<tr>
<td></td>
<td>symptoms and signs of CTS</td>
<td>Sucher 1994&lt;sup&gt;47&lt;/sup&gt;</td>
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Osteopathic EBM References

Somatic Dysfunction in Osteopathic Family Medicine

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