CME Update EBM OMT

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WUHS COMP
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Objectives

- Review the recent research literature on OMT for patients with Mechanical Low Back and Neck Pain
- Correlate the research with National Guidelines and Policy Statements from Professional Organizations
- Discuss the ramifications of these statements to clinical practice and patient care
- State what research is ongoing and planned for the future in these areas
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
Licciardone JC, Minotti DE, Gatchel RJ, Kearns CM, Singh KP.

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

<table>
<thead>
<tr>
<th>Factor 1: Osteopathic manual treatment</th>
<th>Factor 2: Ultrasound therapy</th>
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<tbody>
<tr>
<td><strong>Active</strong></td>
<td><strong>Active</strong></td>
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<tr>
<td>OMT + UST (n=115)</td>
<td>Sham OMT + UST (n=118)</td>
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<td>OMT + Sham UST (n=115)</td>
<td>Sham OMT + Sham UST (n=107)</td>
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<td>OMT main effects (n=230)</td>
<td>Sham OMT main effects (n=225)</td>
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<td><strong>Sham</strong></td>
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<td>Sham OMT + UST (n=233)</td>
<td>Sham UST (n=222)</td>
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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.
OSTEOPATHic Trial Data Subgroup Analyses

- Patients with higher baseline pain had more significant relief and
- Patients who were treated for psoas muscle syndrome had less relapse and prolonged relief
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 Peripheral Neuropathy (DPN)


Arrow: mitochondrion in Schwann’s cell

#: nucleus of Schwann’s cell

Triangle: myelin sheath

Star: axon

Low Power

High Power

Normal

DPN

DPN + T2
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.

Osteopathic manipulative treatment for nonspecific low back pain: a systematic review and meta-analysis

Helge Franke, Jan-David Franke, and Gary Fryer

Abstract
Background: Nonspecific low back pain (LBP) is common, disabling, and costly. Therefore, we assessed the effectiveness of osteopathic manipulative treatment (OMT) in the management of nonspecific low back pain (LBP) regarding pain and functional status.

Methods: A systematic literature search was performed in October 2013 in electronic and ongoing trials databases. Searches of reference lists and personal communications identified additional studies. Only randomized clinical trials were included, specific back pain or single treatment techniques studies were excluded. Outcomes were pain and functional status. Studies were independently reviewed using a standardized form. The mean difference (MD) or standard mean difference (SMD) with 95% confidence intervals (CIs) and overall effect size were calculated at 3 months posttreatment. GRADE was used to assess quality of evidence.

Results: We identified 307 studies. Thirty-one were evaluated and 16 excluded. Of the 15 studies reviewed, 10 investigated effectiveness of OMT for nonspecific LBP, 3 effect of OMT for LBP in pregnant women, and 2 effect of OMT for LBP in postpartum women. Twelve had a low risk of bias. Moderate-quality evidence suggested OMT had a significant effect on pain relief (MD, -1.91; 95% CI, -2.11 to -1.71) and functional status (SMD, -0.36; 95% CI, 0.58 to -0.14) in acute and chronic nonspecific LBP. In chronic nonspecific LBP, moderate-quality evidence suggested a significant difference in favour of OMT regarding pain (MD, -1.56; 95% CI, -3.41 to -0.71) and functional status (SMD, -0.32; 95% CI, 0.58 to -0.07). For nonspecific LBP in pregnancy, low-quality evidence suggested a significant difference in favour of OMT for pain (MD, -1.56; 95% CI, -2.13 to -0.98) and functional status (SMD, -0.36; 95% CI, -1.36 to -0.26), whereas moderate-quality evidence suggested a significant difference in favour of OMT for pain (MD, -1.56; 95% CI, -3.41 to -0.71) and functional status (SMD, -0.32; 95% CI, -2.13 to -0.98) in nonspecific LBP postpartum.

Conclusion: Clinically relevant effects of OMT were found for reducing pain and improving functional status in patients with acute and chronic nonspecific LBP and for LBP in pregnant and postpartum women at 3 months posttreatment. However, larger, high-quality randomized controlled trials with robust comparison groups are recommended.

Keywords: Low back pain, Spinal manipulation, Osteopathic manipulative treatment, Systematic review

Published in August 2014
Used to support the 2015 AOA Guideline statement for OMT for patients with LBP
**Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects: the PROMOTE study.**

Hensel KL¹, Buchanan S², Brown SK³, Rodriguez M⁴, Cruser dA⁵.

**Abstract**

**OBJECTIVE:**
The purpose of this study was to evaluate the efficacy of osteopathic manipulative treatment (OMT) to reduce low back pain and improve functioning during the third trimester in pregnancy and to improve selected outcomes of labor and delivery.

**STUDY DESIGN:**
Pregnancy research on osteopathic manipulation optimizing treatment effects was a randomized, placebo-controlled trial of **400 women in their third trimester**. Women were assigned randomly to usual care only (UCO), usual care plus OMT (OMT), or usual care plus placebo ultrasound treatment (PUT). The study included 7 treatments over 9 weeks. The OMT protocol included specific techniques that were administered by board-certified OMT specialists. Outcomes were assessed with the use of self-report measures for pain and back-related functioning and medical records for delivery outcomes.

**RESULTS:**
There were 136 women in the OMT group: 131 women in the PUT group and 133 women in the UCO group. Characteristics at baseline were similar across groups. Findings indicate significant treatment effects for pain and back-related functioning (P < .001 for both groups), with outcomes for the OMT group similar to that of the PUT group; however, both groups were significantly improved compared with the UCO group. For secondary outcome of meconium-stained amniotic fluid, there were no differences among the groups.
Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects: the PROMOTE study. 

Hensel KL\textsuperscript{1}, Buchanan S\textsuperscript{2}, Brown SK\textsuperscript{3}, Rodriguez M\textsuperscript{4}, Cruser dA\textsuperscript{5}.

CONCLUSION:

• OMT was effective for mitigating pain and functional deterioration compared with UCO; however, OMT did not differ significantly from PUT.
• This may be attributed to PUT being a more active treatment than intended.
• There was no higher likelihood of conversion to high-risk status based on treatment group.
• Therefore, OMT is a safe, effective adjunctive modality to improve pain and functioning during the third trimester.
AHA/ASA Scientific Statement

Cervical Arterial Dissections and Association With Cervical Manipulative Therapy

A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association

Endorsed by the American Association of Neurological Surgeons and Congress of Neurological Surgeons

José Biller, MD, FAHA, Chair; Ralph L. Sacco, MS, MD, FAHA, Co-Chair; Felipe C. Albuquerque, MD; Bart M. Damerau, MD, MSc; Pierre Fayad, MD, FAHA; Preston H. Long, DC, PhD; Lori D. Noorollah, MD; Peter D. Panagias, MD, FAHA; Wouter I. Schievink, MD; Neil E. Schwartz, MD, PhD; Ashfaq Shuaib, MD, FAHA; David E. Thaler, MD, PhD, FAHA; David L. Tirschwell, MD, MSc; on behalf of the American Heart Association Stroke Council

Purpose—Cervical artery dissections (CDs) are among the most common causes of stroke in young and middle-aged adults. The aim of this scientific statement is to review the current state of evidence on the diagnosis and management of CDs and their statistical association with cervical manipulative therapy (CMT). In some forms of CMT, a high or low amplitude thrust is applied to the cervical spine by a healthcare professional.

Methods—Members of the writing group were appointed by the American Heart Association Stroke Council’s Scientific Statements Oversight Committee and the American Heart Association’s Manuscript Oversight Committee. Members were assigned topics relevant to their areas of expertise and reviewed appropriate literature, references to published clinical and epidemiology studies, morbidity and mortality reports, clinical and public health guidelines, authoritative statements, personal files, and expert opinion to summarize existing evidence and to identify gaps in current knowledge.

Results—Patients with CD may present with unilateral headaches, posterior cervical pain, or cerebral or retinal ischemia (transient ischemic or strokes) attributable mainly to artery–artery embolism, CD cranial nerve palsies, oculophasympathetic palsy, or pulsatile tinnitus. Diagnosis of CD depends on a thorough history, physical examination, and targeted ancillary investigations. Although the role of trivial trauma is debatable, mechanical forces can lead to intimal injuries of the vertebral arteries and internal carotid arteries and result in CD. Disability levels vary among CD patients with many having good outcomes, but serious neurological sequelae can occur. No evidence-based guidelines are currently available to endorse best management strategies for CDs. Antiplatelet and anticoagulant treatments are both used for prevention of local thrombus and secondary embolism. Case-control and other articles have suggested an epidemiologic association between CD, particularly vertebral artery dissection, and CMT. It is unclear whether this is due to lack of recognition of preexisting CD in these patients or due to trauma caused by CMT. Ultrasonography, computed tomographic angiography, and magnetic resonance imaging with magnetic resonance angiography are useful in the diagnosis of CD. Follow-up neuroimaging is preferentially done with noninvasive modalities, but we suggest that no single test should be seen as the gold standard.
The vertebral artery as it passes through the transverse foramina of C6 through C2 and then enters the skull base through the foramen magnum (not shown).

José Biller et al. Stroke. 2014;45:3155-3174
Schematic diagram illustrating the neutral anatomic alignment of the vertebral artery (top) and stretching of the V3 segment during lateral rotation and lateral flexion (bottom).

José Biller et al. Stroke. 2014;45:3155-3174
Thrombus from a nonocclusive dissection becoming dislodged and embolizing downstream.

José Biller et al. Stroke. 2014;45:3155-3174
THURSDAY, Aug. 7, 2014 (HealthDay News) -- Getting your neck adjusted by a chiropractor or osteopathic doctor may be associated with an increased risk of stroke, according to a scientific statement released Thursday by the American Heart Association.
In a statement released Thursday, the American Osteopathic Association had this to say about the new statement: "U.S.-trained osteopathic physicians [DOs] use osteopathic manipulative therapy to diagnose, treat and even prevent illness or injury. DOs are taught to conduct thorough evaluations using standard neurological and orthopedic examinations."

The statement noted that osteopaths should not be grouped with chiropractors and physical therapists, who are not physicians and use different techniques for cervical manipulative therapy.
Nonetheless, chiropractors and osteopathic physicians ought to warn patients of this link, the statement added.

"We strongly believe that patients should be informed of this association before undergoing neck manipulation," Biller said.

The statement was published in the Aug. 7 online edition of the journal Stroke.
OMT for Neck Pain Research Update

- American Heart Association Position Paper
- AOA House of Delegates
- American Academy of Osteopathy
- Educational Council on Osteopathic Principles
- NIH National Center for Complementary and Integrative Health
- RAND Corporation, Santa Monica, CA
- Appropriateness of Manipulation or Mobilization of the Cervical Spine in patients with Chronic Neck Pain
OMM Research at COMP

- RCTs:
  - OMM for balance in patients with vertigo
  - OMM for patients with headaches
  - OMM for patients with asthma
  - OMM for patients with diabetic foot ulcers
- Reliability and Validity of palpatory and visual assessment of pelvic landmark asymmetry and leg length discrepancy
- OMM intensive educational programs for first year students
- OMM table trainer: student ratio article
- Practice Based Research Networks: CONCORD (ORC in Texas) and DO-touch.net (Kirksville)