COMP Alumni CME OMM EBM
Update 2017

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Upon completion of this educational activity, participants will be able to answer the following questions:

1. What is the evidence for the benefit for OMT in patients hospitalized with pneumonia?
2. What is the evidence for the benefit of OMT for pregnant patients?
3. What is the evidence for the number of OMT visits needed to receive maximum benefit for patients with low back pain?
4. What is the difference between the 2016 American Osteopathic Association Guidelines for use of OMT in patients with low back pain and the 2017 American College of Physician's Guideline for spinal manipulative therapy (SMT) for patients with low back pain?
5. What is the evidence for cost effectiveness of OMT for musculoskeletal problems?
6. What is the evidence in support of OMT for post open heart surgery patients?
Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized patients with pneumonia: a randomized controlled trial.
Noll et al. Osteopathic Medicine and Primary Care 2010, 4:2
http://www.om-pc.com/content/4/1/2
* “MOPSE”
The Multicenter Osteopathic Pneumonia Study in the Elderly (MOPSE)

* 406 subjects aged ≥ 50 years hospitalized with pneumonia
* 7 community hospitals

RCT 3 groups:
* Conventional Care Only (CCO)
* + light-touch treatment (LT)
* + OMT
OMT and LT groups received group-specific protocols for 15 minutes, twice daily until one of the following:

- Discharge
- Cessation of antibiotics
- Respiratory failure
- Death
- Withdrawal from the study
The primary outcomes were:

* Hospital length of stay (LOS)
* Time to clinical stability
* Symptomatic and functional recovery scores
Conclusions:

* ITT analysis found no differences between groups.
* PP analysis found significant reductions in LOS, duration of intravenous antibiotics, and respiratory failure or death when OMT was compared to CCO.
* Given the prevalence of pneumonia, adjunctive OMT merits further study.
Comparison of treatment groups in ventilator-dependent respiratory failure rate and in-hospital mortality rate for age subgroups using intention-to-treat (ITT) analysis (A, aged 50-74 years; C, aged ≥75 years) and per-protocol (PP) analysis (B, aged 50-74 years; D, aged ≥75 years) analysis in older adults hospitalized for pneumonia. Abbreviations: CCO, conventional care only; LT, light touch; OMT, osteopathic manipulative treatment.
Subgroup Analysis found that **Adjunctive OMT and Light Touch:**

* Reduced LOS in adults aged 50 to 74 years
* Lowered in-hospital mortality rates in adults aged 75 years or older
* May also reduce LOS and in-hospital mortality rates in older adults with more severe pneumonia

Noll DR, Degenhardt BF, Johnson JC. Multicenter Osteopathic Pneumonia Study in the Elderly: Subgroup Analysis on Hospital Length of Stay, Ventilator-Dependent Respiratory Failure Rate, and In-hospital Mortality Rate. J Am Osteopath Assoc. 2016 Sep;116(9):574-87
OMT for LBP During Pregnancy

References

OMT for LBP in Pregnancy

* Licciardone JC, Buchanan S, Hensel KL, King HH, Fulda KG and Stoll ST.
* Osteopathic manipulative treatment of back pain and related symptoms during pregnancy: a randomized controlled trial.
Conclusion

* Osteopathic manipulative treatment slows or halts the deterioration of back-specific functioning during the third trimester of pregnancy.

OMT for LBP in Pregnancy Subgroup Analysis

• 68 patients (47%) experienced progressive back-specific dysfunction during the third trimester of pregnancy.
• OMT group: significantly less likely to experience progressive back-specific dysfunction.
• 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.

Licciardone J, Aryal S. J Am Osteopath Assoc 2013;113:728-736
400 women in third trimester

* Usual care only (UCO) n=133
* Usual care plus OMT (OMT) n=136
* Usual care plus placebo ultrasound (PUT) n=131

Back pain and back related functioning improved in both OMT and PUT groups!

OMT was shown to be safe with no adverse events reported or measured in mother, fetus, or newborn.

Osteopathic manual treatment and ultrasound therapy for chronic low back pain: a randomized controlled trial.


- **Subgroup analysis** of the OSTEOPATHic Trial: Randomized, double-blind, sham-controlled trial involving 455 patients (2006 to 2011)
- OMT 15-minute sessions provided by
  - Osteopathic physicians, fellows, or residents
  - at weeks 0, 1, 2, 4, 6, and 8
- Sham OMT involved
  - hand contact, active and passive range of motion
  - techniques that simulated OMT but used such maneuvers as
    - light touch,
    - improper patient positioning,
    - purposely misdirected movements, and
    - diminished force by the treatment provider
Definitions

• **Risk Ratio (RR)** for recovery from LBP using OMT
  – <1, negative effect or harm;
  – 1 ≤ RR < 1.25, small effect;
  – 1.25 ≤ RR ≤ 2, medium effect;
  – RR > 2, large effect.

• The **numbers-needed-to-treat (NNTs)**
  – the reciprocal of the absolute difference in proportion of patients reporting recovery with OMT relative to sham OMT
  – NNTs less than 10 represents clinically relevant treatment effects based on a systematic review of clinical trials involving oral analgesics

• 100-mm visual analog pain scale
• Substantial improvement was defined as 50% or greater reduction at week 12 compared with baseline.

• Results: Medium treatment effects for LBP intensity were observed overall
  – (RR, 1.41; 95% CI, 1.13-1.76; P=.002; NNT, 6.9; 95% CI, 4.3-18.6).

• However, large treatment effects were observed in patients with baseline VAS scores of 35 mm or greater.

• Although OMT was not associated with overall substantial improvement in back-specific functioning,
• Patients with baseline RMDQ scores of 7 or greater experienced medium effects, and
• Patients with baseline scores 16 or greater experienced large effects that were significant.

Conclusions:
• OMT outcomes are best when patients have higher baseline level of pain intensity and lower level of back-specific functioning.
• I.e., The worse they are the better they will respond.
Another Subgroup analysis of OSTEOPATHic Trial: A randomized double-blind, sham-controlled trial

- 6 OMT sessions over 8 weeks
- Recovery was assessed at week 12 using a composite measure of pain recovery (10 mm or less on a 100-mm visual analog scale) and functional recovery (2 or less on the Roland-Morris Disability Questionnaire for back-specific functioning).
- The Risk Ratio RRs and numbers needed-to-treat (NNTs) for recovery with OMT were measured, and corresponding cumulative distribution functions were plotted according to baseline LBP intensity and back-specific functioning.
- Multiple logistic regression was used to compute the Odds Ratio (OR) for recovery with OMT while simultaneously controlling for potential confounders.

- 455 randomized patients
- 230 (51%) were assigned to the OMT group and
- 225 (49%) were assigned to the sham OMT group
- The primary analyses conducted herein included 345 of 455 randomized patients (76%) who met neither of the dual recovery criteria at baseline (i.e., baseline VAS scores were greater than 10 mm and RMDQ scores were greater than 2).
- Ave age 42, 65% F
- Median baseline scores were 50/100 (IQR, 34-64) mm on the VAS for LBP intensity and 6/24 (IQR, 4-11) on the RMDQ for back-specific functioning.

- **Risk Ratio (RR)** for recovery from LBP using OMT
  - $<1$, negative effect or harm;
  - $1 \leq RR < 1.25$, small effect;
  - $1.25 \leq RR \leq 2$, medium effect;
  - $RR > 2$, large effect.

- **The numbers-needed-to-treat (NNTs)**
  - the reciprocal of the absolute difference in proportion of patients reporting recovery with OMT relative to sham OMT
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- Clinically relevant NNTs were observed in 273 patients (79%) with baseline VAS scores of 30 or greater, and in 245 patients (71%) with RMDQ scores of 4 or greater.

- There was a large treatment effect for recovery with OMT (RR, 2.36; 95% CI, 1.31-4.24; P=.003), which was associated with a clinically relevant NNT (8.9; 95% CI, 5.4-25.5).

- This significant finding persisted after adjustment for potential confounders (OR, 2.92; 95% CI, 1.43-5.97; P=.003).

- There was also a significant interaction effect between OMT and co-morbid depression \((P=.02)\), indicating that patients without depression were more likely to recover from chronic LBP with OMT \((RR, 3.21; 95\% CI, 1.59-6.50; P<.001)\) \((NNT, 6.5; 95\% CI, 4.2-14.5)\).

- Greatest effect was in the **50- to 69-year-old patient** subgroup \((RR, 7.50; 95\% CI, 1.00-56.47; P=.03)\)\((NNT, 6.9; 95\% CI, 3.9-39.2)\)

- The cumulative distribution functions demonstrated optimal RR and NNT responses in patients with moderate to severe levels of LBP intensity and back-specific dysfunction at baseline. Similar results were observed in the sensitivity analyses.

TAKE HOME MESSAGE

6 sessions over 8 weeks of OMT is most efficacious for patients between the ages of 50-69 with moderate to severe levels of low back pain intensity and back-specific dysfunction without co-morbid depression!
Licciardone JC, Gatchel RJ, Aryal S.
Recovery From Chronic Low Back Pain After Osteopathic Manipulative Treatment: A Randomized Controlled Trial.

Watch the YouTube video about this study! – Welcome to multimedia research publications!

https://www.youtube.com/watch?v=3fbK6KGNqhA&feature=youtu.be
Prevent Relapse After OMT

- Treat hypertonic psoas muscles.
- Encourage OTC analgesics.
- Treat depression.
- Identify “responders” by response of at least 50% reduction in pain upon initial OMT, or after 3 OMT sessions in 4 weeks.
- Patients who were the most dysfunctional for the longest time responded best.
The American Osteopathic Association approves the attached Guidelines for Patients with Low Back Pain. 2009; referred 2014; reaffirmed as amended 2015

American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients with Low Back Pain

Executive Summary:

The American Osteopathic Association recommends that osteopathic physicians use Osteopathic Manipulative Treatment (OMT) in the care of patients with low back pain. Evidence from systematic reviews and meta-analyses of randomized clinical trials (Evidence Level 1a) supports this recommendation.
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

Grade 1a level of evidence (Meta-analysis, systematic review of RCTs)
AOA Practice Recommendations

• Offer OMT for patients who have evidence of somatic dysfunction in the acute or chronic stages of mechanical low back pain.

• Long term benefits proven.
American College of Physicians
2017 Non-pharmacologic Guidelines for Patients with LBP

No OMT studies reviewed!
Excluded!
“OMT consists of more than one type of manual intervention”
American College of Physicians 2017 Non-pharmacologic Guidelines for Patients with LBP

- Chiropractic Spinal Manipulation has short term effects for Acute LBP and Chronic LBP
- Also beneficial:
  - Acupuncture
  - Exercise therapy
  - Massage
  - Mindfulness-based stress reduction
  - Multidisciplinary rehabilitation
  - Psychological therapies
  - Tai chi
  - Yoga

• Cost and comparative effectiveness of osteopathic manipulative treatment (OMT) is under researched.
• Most comparative effectiveness studies examining OMT do not comply with the reporting guidelines.
• Economic analyses of OMT are limited but promising in some areas.
• Future osteopathic research needs to prioritize quality cost and comparative effectiveness research.
Systematic review of comparative effectiveness and health economics research relating to osteopathic manipulative treatment

Steel and colleagues recently reviewed the literature on comparative effectiveness and health economics research relating to osteopathic manipulative treatment (OMT) and concluded that the published studies were of insufficient quality and quantity to inform policy and practice (Steel et al., 2015). However, there were several limitations, inconsistencies, and inaccuracies in their review that should be noted. First, a large, cost-effectiveness study published prior to their final database search in September 2015 was not included (Wilson et al., 2015). This study used the Medical Expenditure Panel Survey in the United States from 2003 to 2012 to examine 16,545 patients with back pain or neck problems. This sample rate for comparison and the inclusion of patients included in all the economic analyses reviewed by Steel and colleagues. These patients treated themselves from physicians within a specific specialty (family medicine, internal medicine, orthopedic medicine, or osteopathic medicine, and rheumatology) or Terry from other provider types (chiropractor, physiotherapists, acupuncturists, and massage therapists). Outcomes were evaluated using the Osteopathic Medicine Index scores to assess the health-related quality of life of the pain, neck, shoulder, arm, shoulder, and hand problems. The overall results indicated that OMT was associated with a lower cost-effectiveness ratio using the Osteopathic Medicine Index scores to assess the health-related quality of life of the pain, neck, shoulder, arm, shoulder, and hand problems. The overall results indicated that OMT was associated with a lower cost-effectiveness ratio using the Osteopathic Medicine Index scores to assess the health-related quality of life of the pain, neck, shoulder, arm, shoulder, and hand problems.

• Medical Expenditure Panel Survey in the United States from 2002 to 2012: 16,546 patients with back pain or joint problems.
• Assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.
• Osteopathic medicine, family medicine, and internal medicine were more cost effective than chiropractors, physiotherapists, acupuncturists, and physicians in the specialties of orthopedics, neurology, and rheumatology.
Post Sternotomy OMTh RCT (Italy)

METHODS

• 80 post-sternotomy adult inpatients
  – standardized cardiorespiratory rehabilitation program alone (control group) or
  – combined with OMT

• Pain intensity (VAS)

• Respiratory functional capacity

• OMTh = Italian Osteopaths used MFR to Diaphragm, Thoracic inlet, Sternum for five days, 15 minutes each session

Post Sternotomy OMTh RCT (Italy)

RESULTS

• Comparable pain and respiratory function at onset of rehab between groups.

• At the end of rehabilitation OMT group had
  
  — **lower Visual Analog Scale median score**
  (controls 3, IQR: 2 to 4; OMT 1, IQR: 1 to 2; p < 0.01)
  
  — **higher mean inspiratory volume**
  (controls 1,400 ± 588 mL; OMT 1,781 ± 633 mL; p < 0.01)
  
  — **Shorter LOS**
  (19.1 ± 4.8 versus 21.7 ± 6.3 days; p < 0.05)

• The analgesic drug intake was similar in the two groups.
CONCLUSIONS

The combination of standard care with OMT is effective in inducing pain relief and functional recovery, and significantly improves the management of patients with sternotomy after heart surgery.
What research is the AOA funding now?
**Quick Review**

**Focus on 5 Research**

1. Chronic Disease and Conditions
2. Pain Management
3. OMM/OMT
4. Osteopathic Philosophy
5. Musculoskeletal Injuries & Prevention

**# of Applications**
- Prior to 2016: 18 per yr.
- FY 2016: 29

**$ Supporting Research**
- Prior to 2016: $300,000
- FY 2016: $1,050,000
RESEARCH GRANTS & AWARDS (2016)

OMM/OMT
- Parkinson’s disease (2 projects)
- OMM/OMT in inflammatory bowel disease
- Low Back Pain (LBP)
- OMM/OMT and arthritis
- Changes in emotional quotient traits during training

Chronic Disease
- Obesity and women

OP
- Value of osteopathic care (Cost-effectiveness study)
- Patient experience/satisfaction

MSK

Pain Mgmt.

$1,040,182.22 in awards
## FY 2016 AOA GRANT RECIPIENTS

<table>
<thead>
<tr>
<th>Grantee (Principal Investigator)</th>
<th>Project Title</th>
<th>Focus Areas Covered</th>
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<tbody>
<tr>
<td><strong>John Licciardone, DO, MS, MBA</strong> (University of North Texas Health Science Center)</td>
<td>The osteopathic difference in treating patients with low back pain.</td>
<td>Osteopathic Philosophy, Musculoskeletal Injuries &amp; Prevention, Pain Management</td>
</tr>
<tr>
<td><strong>Jennifer Berglind, PhD</strong> (Edward Via College of Osteopathic Medicine)</td>
<td>Use of the lymphatic pump technique as a novel therapy for IBD.</td>
<td>OMM/OMT</td>
</tr>
<tr>
<td><strong>Diana Speelman, PhD</strong> (Lake Erie College of Osteopathic Medicine)</td>
<td>Use of osteopathic principles for nonpharmacologic, therapeutic interventions in obese women with polycystic ovary syndrome.</td>
<td>Chronic Disease</td>
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<td>Kendi Hensel, DO, PhD (University of North Texas Health Science Center)</td>
<td>Effects of OMT on gait kinematics and postural control in Parkinson Disease.</td>
<td>OMM/OMT, Chronic Disease, Musculoskeletal Injuries &amp; Prevention</td>
</tr>
<tr>
<td>Walter Hartwig, PhD (Touro University California)</td>
<td>Patient experience of osteopathic physician distinction and empathy.</td>
<td>Osteopathic Philosophy</td>
</tr>
<tr>
<td>Gail Singer-Chang, PsyD, MS, PPS (Western University of Health Sciences College of Osteopathic Medicine of the Pacific)</td>
<td>Identifying risk factors associated with declining EQ traits during DO training.</td>
<td>Osteopathic Philosophy</td>
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<td><strong>Michael Volin, PhD</strong>&lt;br&gt;(Midwestern University, Chicago College of Osteopathic Medicine)</td>
<td>Lymphatic pump treatment of inflammation in rat-adjuvant-induced arthritis.</td>
<td>OMM/OMT Musculoskeletal Injuries &amp; Prevention</td>
</tr>
<tr>
<td><strong>Sheldon Yao, DO</strong>&lt;br&gt;(New York Institute of Technology)</td>
<td>Effect of osteopathic manipulation on balance function, and biomarkers in Parkinson's Disease.</td>
<td>OMM/OMT Chronic Disease</td>
</tr>
<tr>
<td><strong>Mark Speicher, PhD, MHA</strong>&lt;br&gt;(Midwestern University, Arizona College of Osteopathic Medicine)</td>
<td>The value of osteopathic clinical care: A multi-level analysis.</td>
<td>Osteopathic Philosophy</td>
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LET’S PRACTICE!