Osteopathic Manipulative Medicine Research: Where We're At

Rebecca J. Bowers, D.O., C-NMM/OMM

2019 SOUTHEAST
Savannah, GA, June 13 – 16

Conflict of Interest Disclosure

I have no conflicts and nothing to disclose

2019 SOUTHEAST
Savannah, GA, June 13 – 16

Objectives

By the end of the presentation, the learner should be better able to:

- Communicate some of the various challenges and approaches to Osteopathic Manipulative Medicine (OMM) Research
- Discuss areas of potential research that are likely to improve upon the understanding of and clinical application of OMM
- Recall some of the larger OMM studies of the past few years and discuss their findings
- List the current evidence-based OMM guidelines

Osteopathic Manipulative Medicine (OMM)

- **Not** the same thing as Osteopathic Manipulative Treatment (OMT)
- **Not** the same thing as Osteopathic Principles and Practice (OPP)

Goals of Clinical Research

- Explore the effectiveness & safety of an intervention
- Justify the resources required to provide the intervention

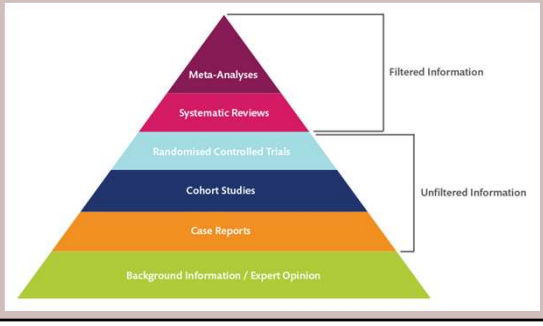
Some of the Challenges to Researching OMM

- "Objective" findings that can only be appreciated by a subjective experience
- Variability in the skills of those applying OMM or OMT
- What is OMT?
- Resources required to administer OMT to enough patients to achieve a well powered study
- Randomized Controlled Trials work well for studying a small number of known variables that are easily measured
- Pressure to show clinical relevance now
- OMM is often confused with OMT

Differential Diagnosis for Chest Pain

- Acute myocardial infarction
- Stable angina/CAD
- Vasospastic angina
- Pericarditis
- Pneumonia
- Pulmonary embolism
- Pleurisy
- Heart failure
- Thoracic aortic dissection
- Sickle cell disease
- Neoplasms
- Somatic Dysfunction
- Costochondritis
- Referred pain from thoracic spine/costovertebral joints
- Sternalis syndrome
- Fracture
- Tietze's syndrome
- Gastroesophageal reflux disease
- Esophageal motility disorders
- Perforation of the esophagus
- Anxiety
- Fibromyalgia
- Rheumatoid arthritis
- Axial spondyloarthritis
- Psoriatic arthritis
- Sternoclavicular hyperostosis
- Systemic lupus erythematosus
- Septic arthritis of the chest wall
- Relapsing polychondritis

Study Design



Study Design: OMT vs. OMM

- Most OMT can be appropriately studied by RCTs
  - Fewer variables and outcomes
  - Techniques effect on **somatic dysfunction**
- Most OMM is better studied with observational, cohort studies
  - Allows for greater control of confounding factors
  - **Somatic dysfunction's** effect on a patient

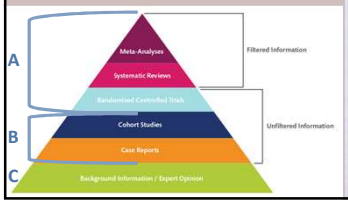
OMM: Areas of Potential Research

- Anatomy
- Neurophysiology
- OMM
  - Education
  - Diagnosis of Somatic Dysfunction (SD)
    - Diagnostic imaging or other tools that can evaluate SD?
    - Which SD matters the most- causative vs. compensatory?
    - Which are associated with which comorbid disease states?
  - Treatment
    - Technique types and conceptual models
    - Are some OMT types more effective for certain types of SD?
    - Are some OMT types more effective for certain populations of patients?
    - Does timing of treatment matter?
  - Clinical outcomes
    - Subjective & Objective measures
    - Treatment flares and complications

Common Problems with OMM Research

- Small sample sizes
- Underqualified/inexperienced technicians (students & residents)
- Suboptimal controls
  - No control
  - Shams applied to areas relevant to the disease process
- Suboptimal protocols
  - OMT to "treat" a symptom
  - OMT w/o diagnosis of SD
- Subjective outcomes
- Short-term follow up

Effectiveness of OMT in Patient Care Categories According to the Five Models



Condition	Highest Level of Evidence
Neurological and Structural Models	
Acute and chronic low back pain in adult patients, even during pregnancy, or in the military	A
Pain control in postoperative care	A
Acute or chronic mechanical neck pain with or without headache	B
Postoperative ileus in gastrointestinal surgery patients	A
Tension-type headaches and migraines	B
Shoulder pain and dysfunction	A
Carpal tunnel syndrome	B
Fibromyalgia	B
Pain in spinal cord injured patients	A
Metabolic and Respiratory/Circulatory Models	
Pneumonia in hospitalized elderly patients	A
Pain and costal cage dysfunction in heart surgery patients with sternotomy	B
Pediatric acute otitis media	A
Pancreatitis in hospitalized patients	B
Acute ankle sprain	B
Premature infant in NICU	A
Asthma	B
Biopsychosocial Model	
Sleep	B
Depression	B

American Osteopathic Association (AOA) Guidelines for OMT for Patients With Low Back Pain- 2010

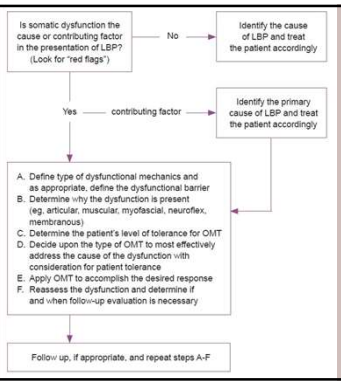
- There was a significant reduction in low back pain associated with OMT in trials vs active treatment or placebo control (effect size, -0.26; 95% CI, -0.48 to -0.05; P=.02),
  - This is comparable to nonsteroidal anti-inflammatory drugs, including cyclo-oxygenase-2 inhibitors
  - OMT also significantly reduced pain during the 3- to 12-month period following randomization
- There were significant reductions in low back pain associated with OMT during the:
  - short-term (effect size, -0.28; 95% CI, -0.51 to -0.06; P=.01)
  - intermediate-term (effect size, -0.33; 95% CI, - 0.51 to -0.15; P<.001)
  - long-term (effect size, -0.40; 95% CI, -0.74 to -0.05; P=.03)

AOA Guidelines for OMT for Patients With Low Back Pain- 2016

- OMT has a significant effect on:
  - LBP (acute and chronic)
  - LBP in pregnant women
  - LBP in postpartum women
- OMT may have a larger effect on pain than functional status.
- According to the criteria recommended by the Cochrane Back Review Group:
  - the significant effects found are also clinically relevant

AOA Guidelines for OMT for Patients With Low Back Pain- 2016:

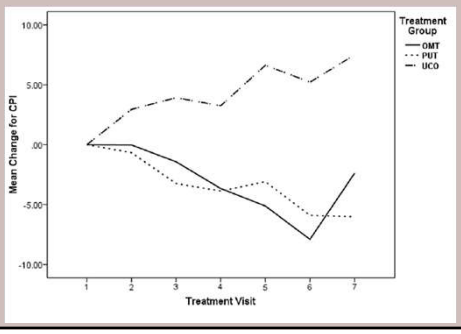
The AOA recommends that osteopathic physicians use OMT in the care of patients with low back pain



PROMOTE Study- 2015

- N=400
- 3 groups
  - OMT + usual care
  - PUT (placebo U/S tx) + usual care
  - UCO (usual care only)
- OMT & PUT applied to the same body areas by an OMM specialist ~20mins w/in 24hrs of routine OB visits at weeks 30, 32, 43, 36, 37, 38, & 39
- Only 99 women completed all 7 visits
- Primary Outcomes:
  - Quadruple visual analog scale (now, average, worst, best) that was used to calculate a characteristic pain intensity (CPI) (0-100)
  - Roland-Morris Low Back Pain and Disability Questionnaire
- Secondary Outcome:
  - Safety- no statistical difference in conversion to high-risk pregnancy was found between groups

PROMOTE Study-2015



The OSTEOPATHIC Trial- 2013

- N=455 (21-69yo, non-pregnant, LBP 3+ months)
- 4 groups
  - OMT + UST
  - OMT + Sham UST
  - Sham OMT + UST
  - Sham OMT + Sham UST
- Pt. randomized to receive interventions from either faculty DO, Resident, or NUFA Student (15 individuals) at weeks 0, 1, 2, 4, 6, & 8
- Standard Diagnostic Evaluation done prior to OMT
- Used a range of OMT techniques aimed at the lumbosacral, iliac, & pubic areas (15 mins)
- Sham OMT= hand contact, AROM, PROM, light touch, misdirected movements, & diminished force applied to the same regions (15 mins)
- UST & Sham UST (subtherapeutic intensity) applied to the low back

Figure 1. Allocation of patients to osteopathic manual treatment and ultrasound therapy interventions using a 2×2 factorial design.

	Osteopathic Manual Treatment (OMT)		
	Active	Sham	
Ultrasound Therapy (UST) Active	OMT + UST	Sham OMT + UST	UST Main Effects
	OMT + Sham UST	Sham OMT + Sham UST	Sham UST Main Effects
	OMT Main Effects	Sham OMT Main Effects	

The OSTEOPATHIC Trial- 2013

- Primary Outcomes:
  - Used a 100mm visual analog pain scale measured just prior to OMT/Sham OMT & at week 12
  - Looked for moderate improvement (30% or greater) or Substantial improvement (50% or greater)
- Results:
  - Significant reduction in pain scores for OMT vs. sham OMT (p=0.002), but not for UST vs. sham UST (p=0.99)

At Week 12	OMT	Sham OMT
• Moderate improvement obtained	63%	46%
• Substantial improvement obtained	50%	35%

Table 3. Secondary Outcomes by Main Effects Group

The OSTEOPATHIC Trial- 2013

Outcome	OMT vs Sham OMT			UST vs Sham UST		
	OMT (n = 230)	Sham OMT (n = 225)	*P* Value	UST (n = 233)	Sham UST (n = 222)	*P* Value
Lost 1 or more work days in past 4 weeks because of LBP, % (95% CI)[a]						
Week 4	10 (4-16)	14 (7-21)	.41	16 (9-23)	7 (2-12)	.04
Week 8	6 (2-11)	19 (12-27)	.005	17 (10-24)	8 (3-14)	.054
Week 12	11 (5-17)	8 (3-13)	.41	13 (6-19)	6 (1-11)	.11
Very satisfied with back care, % (95% CI)[a]						
Week 4	52 (46-59)	34 (28-41)	<.001	41 (35-48)	45 (38-52)	.44
Week 8	61 (54-67)	39 (33-46)	<.001	49 (43-56)	51 (44-58)	.77
Week 12	66 (60-73)	43 (36-50)	<.001	55 (48-61)	55 (48-62)	.99
LBP co-treatment during study, % (95% CI)[a]						
Exercise programs	19 (14-24)	20 (14-25)	.82	20 (15-25)	18 (13-24)	.73
Lumbar supports	1 (0-3)	1 (0-2)	>.99	1 (0-2)	1 (0-3)	.68
Nonprescription drugs	46 (39-52)	45 (39-52)	.95	46 (40-53)	45 (38-51)	.71
Prescription drugs	13 (9-18)	20 (15-26)	.048	16 (11-21)	18 (13-23)	.54
CAM therapies	15 (11-20)	17 (12-22)	.63	16 (12-21)	16 (11-21)	.87
Physical therapy	11 (7-15)	8 (4-11)	.17	9 (5-13)	10 (6-14)	.74
Hospitalization	0 (0-0)	0 (0-1)	.49	0 (0-1)	0 (0-0)	>.99
Surgery	0 (0-1)	0 (0-0)	>.99	0 (0-0)	0 (0-1)	.49

CAM = complementary and alternative medicine; IQR = interquartile range; LBP = low back pain; OMT = osteopathic manual treatment; RMDQ = Roland-Morris Disability Questionnaire; SF-36 GH = Medical Outcomes Study Short Form-36 Health Survey general health scale; UST = ultrasound therapy.

[a] Higher scores on the RMDQ represent greater disability. *P* values at each endpoint based on the Mann-Whitney test; N = 455 for all endpoints.
[b] Higher scores on the SF-36 GH represent better health. *P* values at each endpoint based on the Mann-Whitney test; N = 455 for all endpoints.
[c] Work disability analyses limited to the 215 patients employed full-time at baseline; n = 207, 211, and 211 at the successive endpoints.
[d] n = 415, 425, and 420 at the successive endpoints.

Shoulder Pain & Dysfunction

Improving Functional Ability in Elderly with Spencer Technique- 2002

- N=29
- 2 groups
  - Spencer technique (w/ Muscle Energy- ME)
  - **Supposedly** SHAM Spencer technique (regular Spencer technique)
- Treatment done at weeks 1, 3, 5, 7, 11, & 15
- Primary Outcomes:
  - Modified physical functioning scale: dressing, bathing, and grooming
  - Shoulder Range of Motion (goniometer)
  - Pain level (0-10 scale)
  - Assessed at entry (week 0), then 1 week s/p each treatment, & then at week 19
- Results:
  - Don't mention the functioning scale
  - 1 week s/p last treatment, both groups had improvement of ROM & decreased pain ($p<0.01$)
  - Week 19, showed a trend towards reversal of ROM improvement in the sham group, while the treatment group continued to have improvement of ROM
  - Week 19, showed trend towards increase in pain level in both groups

Manipulative therapy (MT) for shoulder pain and disorders: expansion of a systematic review- 2011

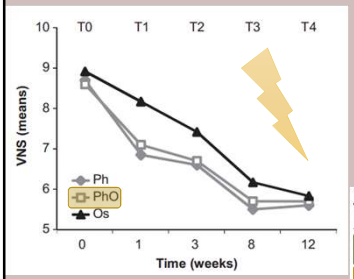
- Authors=Chiropractors
- Searched for any manual therapy (chiropractic, osteopathic, PT)
- Out of 211 citations, 35 deemed useful
- Used Physiotherapy Evidence Database Scale
  - A= good evidence
  - B= fair evidence
  - C= limited evidence
  - I= Insufficient evidence
- Results
  - MT applied to the shoulder, shoulder girdle, &/or Full Kinetic Chain (+/- exercise, +/- multi-modal approach) is helpful for a variety of common rotator cuff disorders, shoulder disorders, adhesive capsulitis, & ST disorders. **B (except for OA of shoulder= I)**
  - MT applied to the shoulder, shoulder girdle, &/or Full Kinetic Chain (+/- exercise, +/- multi-modal approach) is helpful for peripheral nerve injuries/entrapment. **C**

Pain in Spinal Cord Injured Patients

OMT for Spinal Cord Injury-Associated Pain Control- 2011

- N=26 + 21 (18-60yo w/ traumatic SCI between C5-L5 that had been stable for 6 months)
- Started with 2 groups (N=26)
  - **Os:** Anti-depressant + OMT (MFR, ST, SCS, ME, & Cranial-Sacral) (7 OMT sessions/3 months)
  - **Ph:** Anti-depressant + pharmacologic pain management (pregabalin 600mg/day or paracetamol 2-4g/day)
- Primary Outcomes:
  - Pain Intensity (0-10 verbal numeric scale)

OMT for Spinal Cord Injury-Associated Pain Control- 2011



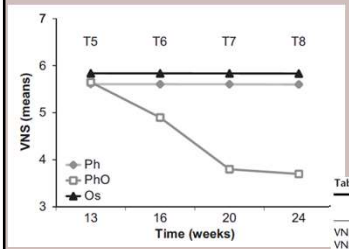
Results:

- From 0-3 weeks: Ph group was having a more rapid reduction in pain than Os group
- From 0-8weeks: there was a statistical difference between the Ph & Os groups

Table 5 Comparison of the three groups per each time interval

Time interval	P[a]
T0–T1	<0.01
T1–T2	<0.05
T2–T3	<0.01
T3–T4	0.57

OMT for Spinal Cord Injury-Associated Pain Control- 2011



Results Cont.

- Only PhO group had further statistically significant change in pain score (from T5-T8)

Table 6 VNS scores from *T5* to *T8*

	Ph	*PhO*	*Os*	P
VNS *T5* (mean ± s.d.)	5.60 ± 1.07	5.65 ± 0.75	5.83 ± 0.75	0.17
VNS *T6* (mean ± s.d.)	5.72 ± 0.97	4.90 ± 1.07	5.65 ± 0.46	0.25
VNS *T7* (mean ± s.d.)	5.89 ± 1.2	3.80 ± 1.14	5.97 ± 0.2	0.16
VNS *T8* (mean ± s.d.)	5.65 ± 1.3	3.70 ± 1.06	6.01 ± 0.9	0.28
P (*T8* versus *T5*)	0.88	<0.01	0.9	

Pain Control in Post-operative Care

Pre-op Morphine Sulfate & Post-op OMT: Analgesic Use s/p Total Abdominal Hysterectomy 2005

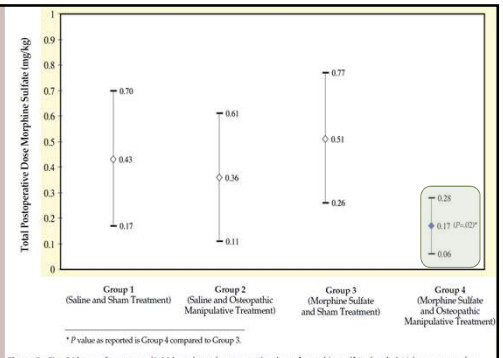


Figure 2. *First 24 hours after surgery (0–24 hours): total postoperative dose of morphine sulfate (mg/kg). Values presented are averages with 95% confidence intervals.*

Pre-op Morphine Sulfate & Post-op OMT: Analgesic Use s/p Total Abdominal Hysterectomy 2005

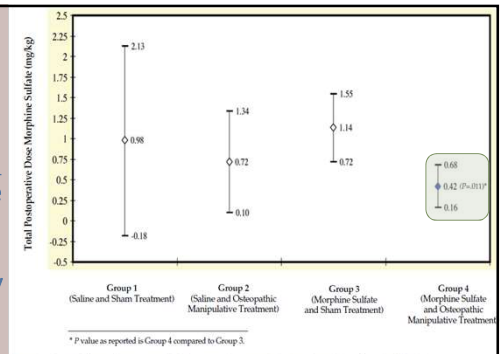


Figure 3. *Second 24 hours after surgery (25–48 hours): total postoperative dose of morphine sulfate (mg/kg). Values presented are averages with 95% confidence intervals.*

Post-operative Ileus

Baltazar GA, Betler MP, Akella K, et al. Effect of osteopathic Manipulative treatment on incidence of postoperative ileus and hospital stay in general surgery. *J Amer Osteopath Assoc.* 2013;113:204-209

Table 1.
Characteristics and Outcomes in General Surgical Patients Who Did or Did Not Receive Postoperative OMT (n=55)

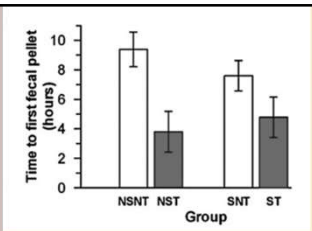
Characteristic or Outcome	Mean (SD) OMT Group (n=17)	Mean (SD) Non-OMT Group (n=38)	*P* Value
Age, y	60.3 (17.7)	62.1 (15.8)	.70
ASA Physical Status Class[a]	2.5 (0.6)	2.7 (0.7)	.31
Time to Flatus, d	3.1 (0.6)	4.7 (0.4)	.035
Time to Clear Liquid Diet, d	4.6 (3.8)	5.6 (7.0)	.59
Time to Bowel Movement, d	4.8 (2.3)	5.8 (4.9)	.43
Postoperative Hospital LOS, d	6.1 (1.7)	11.5 (1.0)	.006

[a] Physical status was classified on a scale of 1 to 6, with 1 being healthy and 6 being brain dead.

Abbreviations: ASA, American Society of Anesthesiologists; LOS, length of stay; OMT, osteopathic manipulative treatment; SD, standard deviation.

Do patients with postoperative ileus that receive OMT have improved outcomes?- 2009

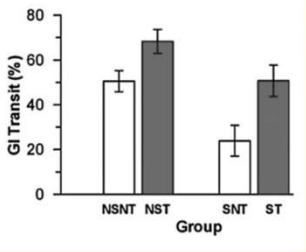
- **Retrospective Chart Review**
- **331** patients met inclusion criteria and had undergone abdominal surgery
- **172 received OMT**
- **139 did not receive OMT**
- Patients who received **OMT had statistically significant shorter hospital stays** (11.8 vs. 14.6 days; *P*=.029).



NST = no surgery, treatment
NSNT = no surgery, no treatment
ST = surgery, treatment
SNT = surgery, no treatment

Post-Op Ileus- Rat Model

Visceral massage significantly reduced the time to first fecal pellet discharge. (P<0.01)



NST = no surgery, treatment
NSNT = no surgery, no treatment
ST = surgery, treatment
SNT = surgery, no treatment

Post-Op Ileus- Rat Model

Visceral massage significantly increased gastrointestinal transit (P<0.001)

Post-Op Ileus/Intraperitoneal protein and inflammation

- In the Rat Model study, revealed that abdominal visceral massage resulted in decreased total intraperitoneal protein and numbers of intraperitoneal inflammatory cells in the ST group compared to the SNT group (P<0.05).
- Mouse-model study published in the World Journal of Surgery in 2005 "concluded that both inhibition of inflammation and increased gastrointestinal motility during the early postoperative period have a positive effect on decreasing the formation of adhesions."
- Hence, Post-op abdominal manipulation should theoretically reduce the incidence of post-op ileus as well as adhesions

Post-Op Ileus Prevention

Postoperative Adynamic Ileus: Its Prevention and Treatment by Osteopathic Manipulation. The DO. 1965:163-4

- 317 patients received routine OMM s/p surgery
  - 0.3% developed Ileus
- 92 patients did not received OMM
  - 7.6% developed Ileus

Pneumonia in Hospitalized Elderly Patients

Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized elderly patients with pneumonia (MOPSE trial)- 2010

- N= 387
- 3 groups:
  - Conventional Care Only (CCO)
  - OMT
  - Light touch
- Primary Outcomes:
  - Length of Stay (LOS)
  - Time to Clinical Stability

MOPSE Trial-2010

Primary Outcomes	OMT	LT	CCO	p value[a]
Hospital Length of Stay (days)				
ITT Analysis	(n = 130)	(n = 124)	(n = 133)	
mean (SD)	4.5 (2.7)	4.9 (2.7)	4.5 (2.6)	
median (95% CI)	3.9 (3.4-4.7)	4.5 (3.8-4.9)	4.3 (3.9-4.9)	0.53
PP Analysis	(n = 96)	(n = 95)	(n = 127)	
mean (SD)	4.0 (2.0)	4.4 (2.4)	4.5 (2.6)	
median (95% CI)	3.5 (3.2-4.0)	3.9 (3.5-4.8)	4.5 (3.9-4.9)	0.01 (OMT<CCO)
Time to Clinical Stability (days)				
ITT Analysis	(n = 121)	(n = 118)	(n = 130)	
mean (SD)	2.5 (1.6)	2.5 (1.4)	2.6 (1.6)	
median (95% CI)	2.0 (2.0-2.0)	2.0 (2.0-3.0)	2.0 (2.0-2.0)	0.97
PP Analysis	(n = 90)	(n = 90)	(n = 124)	
mean (SD)	2.3 (1.4)	2.5 (1.5)	2.6 (1.6)	
median (95% CI)	2.0 (2.0-2.0)	2.0 (2.0-2.0)	2.0 (2.0-2.0)	0.47

MOPSE Trial

Secondary Outcomes				
Duration of Intravenous Antibiotic Use(days)				
ITT Analysis	(n = 130)	(n = 124)	(n = 133)	
mean (SD)	3.7 (2.6)	3.9 (2.5)	3.9 (2.5)	
median (95% CI)	3.3 (2.9-3.7)	3.7 (2.9-3.9)	3.5 (3.1-3.9)	0.44
PP Analysis	(n = 96)	(n = 95)	(n = 127)	
mean (SD)	3.4 (1.9)	3.7 (2.5)	3.9 (2.5)	
median (95% CI)	3.0 (2.7-3.5)	3.3 (2.7-3.8)	3.5 (3.2-3.9)	0.05 (OMT<CCO)
Duration of Total (Intravenous+Oral) Antibiotic Use (days)				
ITT Analysis	(n = 130)	(n = 124)	(n = 133)	
mean (SD)	4.2 (2.7)	4.6 (2.5)	4.5 (2.5)	
median (95% CI)	3.6 (3.2-4.3)	4.1 (3.7-4.8)	4.0 (3.6-4.8)	0.43
PP Analysis	(n = 96)	(n = 95)	(n = 127)	
mean (SD)	4.0 (2.0)	4.4 (2.4)	4.5 (2.5)	
median (95% CI)	3.5 (3.0-3.9)	3.7 (3.1-4.6)	4.0 (3.6-4.8)	0.08
Treatment Endpoint				
ITT Analysis	(n = 124)	(n = 124)	(n = 132)	
n (%) Death	2 (2)	3 (3)	8 (6)	0.08
n (%) Respiratory Failure	4 (3)	4 (3)	10 (8)	
n (%) Discharge	118 (95)	117 (94)	114 (86)	
PP Analysis	(n = 96)	(n = 95)	(n = 127)	
n (%) Death	0 (0)	3 (3)	8 (6)	0.006 (OMT<CCO)
n (%) Respiratory Failure	1 (1)	2 (2)	9 (7)	
n (%) Discharge	95 (99)	90 (95)	110 (87)	

Benefits of Osteopathic manipulative treatment for hospitalized elderly patients with pneumonia-2000

Duration of Antibiotic Therapy and Length of Hospital Stay*

Measurement	Treatment group	Control group	*P* value
■ Duration of antibiotic therapy, d			
☐ Oral antibiotics	1.4±1.4	1.4±1.8	.952
☐ Intravenous antibiotics	5.3±2.2	7.3±2.8	.002
☐ All antibiotics	6.1±2.3	8.1±2.5	.003
■ Length of stay, d	6.6±2.9	8.6±2.9	.014

*Data were analyzed using one-way analysis of variance and are presented as mean ± SD for each measurement. Duration of antibiotic therapy and length of stay were measured in days.

Post-Operative Pulmonary Complications-1963

1031 surgical patients evaluate for Somatic Dysfunction (SD) at C3-C5
- 109 had SD at C3-C5 (10.6%)
- 109 split in to 2 groups:
  - OMT group= (75) received OMT to correct the C3-C5 dysfunction(s) prior to surgery
  - No OMT group= (34) did not have their C3-C5 dysfunction(s) corrected

Results:
- Of all the 1031 surgical patients evaluated:
  - **3.1%** rate of post-op pulmonary complications
- No OMT group:
  - **85.3%** rate of post-op pulmonary complications
- OMT group:
  - **5.3%** rate of post-op pulmonary complications

Pediatric Acute Otitis Media

OMT as Adjuvant Therapy in Children with Recurrent Acute Otitis Media- 2003

- N= 57 (6mm-6yo w/ hx of 3 AOM/6mm or 4AOM/1yr)
- 2 groups:
  - Routine pediatric care
  - Routine pediatric care + OMT
- Outcomes:
  - Incidence of AOM
  - Antibiotic use
  - Surgical intervention
  - Tympanometric & audiometric performance
  - Behaviors

OMT as Adjuvant Therapy in Children with Recurrent Acute Otitis Media- 2003

Variable	Intervention, Mean ± SD	Control, Mean ± SD	Group Difference,† Mean (95% Confidence Interval)
Monthly No. of episodes of acute otitis media during the study	0.19 ± 0.21	0.27 ± 0.26	−0.14 (−0.27 to 0.00)‡
Monthly No. of antibiotic prescriptions during the study	0.30 ± 0.35	0.42 ± 0.47	−0.17 (−0.38 to 0.05)
Months in study surgery free	6.00 ± 0.00	5.25 ± 1.46	0.75 (0.16 to 1.34)‡
Audiologic data, dB			
Final speech awareness threshold (n = 51)	16.59 ± 10.84	14.58 ± 7.91	−0.97 (−6.10 to 4.16)
Final response to 500-Hz stimulus (n = 51)	20.43 ± 13.14	21.52 ± 11.80	−1.45 (−8.64 to 5.73)
Final response to 1000-Hz stimulus (n = 49)	16.74 ± 12.02	17.88 ± 8.62	−1.31 (−6.59 to 3.98)
Final response to 2000-Hz stimulus (n = 49)	18.26 ± 15.35	20.00 ± 10.15	−2.63 (−10.31 to 5.05)
Final response to 4000-Hz stimulus (n = 49)	22.05 ± 15.63	23.64 ± 13.89	−1.59 (−10.55 to 7.37)
Tympanometric data§ (n = 52)			
Final mean sum of types A and C tympanograms obtained by the audiologist	1.41 ± 0.80	1.00 ± 0.96	0.55 (0.08 to 1.02)‡

‡$P<.05$

Premature Infants in NICU

OMT for Premature Infants: Systematic Review & Meta-analysis- 2017

- Journal: Medicine
- Comprehensive database search from journal inception (1922) to May 2015 for quasi-RCTS that treated preterm infants in the crib or bed with OMT by Osteopaths.
- Results:
  - 5 studies (1306 infants) met inclusion criteria

OMT for Premature Infants: Systematic Review & Meta-analysis- 2017

Summary of results of meta-analysis.

Outcome	No of studies included in the meta-analysis (no of patients)	Mean effect of OMT on preterm infants versus usual care group (95% CI)	P
LOS (days)	5 (1306)	Decrease in preterm infants treated by OMT by 2.71 (95% CI −3.99, −1.43)	<0.001
Cost (Euros)	3 (915)	Preterm infants costs decreased in the OMT group (−1545.66 €; −1888.03, −1203.29€)	<0.0001
Subgroup analysis: LOS (days) <32 weeks	2 (118)	Decrease in preterm infants with severe prematurity treated with OMT (−8.64 days; 95% CI −13.46, −3.81 days)	<0.001
Subgroup analysis: LOS (days) >32; <35 weeks	3 (311)	Shorten in moderate preterm infants allocated to OMT group (−3.08 days; 95% CI −5.16, −0.99 days)	<0.01
Subgroup analysis: LOS (days) >35; <37 weeks	3 (477)	Diminish in late preterm infants treated by OMT (−2.21 days; 95% CI −3.63, −0.78 days)	<0.01

LOS = length of stay, OMT = osteopathic manipulative treatment.

OMT Safety

- Stratification of Potential Complications
  - Dire
    - Ex. death, spinal injury, cerebrovascular accident
  - Serious
    - Ex. fracture, dislocation, dissemination of infection or neoplasm, significant aggravation of pain or disability
  - Less consequential
    - Ex. local discomfort, numbness/tingling, headache, dizziness/light-headedness
- HVLA has been shown to be associated with dire or serious issues

Random Manual Sham

- Would not involve/incorporate knowledge of Osteopathic Principles and Practice or Osteopathic Manipulative Medicine
- Could be given by students or anyone with an appropriate license to place their hands on a patient

Example

- OMT group= DO administers
  - Directed at pertinent areas
  - 15-20 minute session
    - Fix as much of the pertinent SD as possible
- Sham group= DO, or student or other
  - Randomized Sham protocol
    - Computer generated or pull a variable out of different envelopes
      - Variables= region + left, right or bilateral
  - 15-20 minute session
    - Light touch or Soft Tissue or placebo ultrasound

Online Search for OMT/OMM Studies

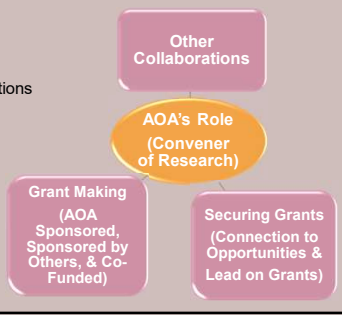
Source: VCOM Library Advanced Search of World-Wide Libraries
In English, peer-reviewed articles
In Title: "Osteopathic Manipulation" or "Osteopathic Manipulative"

2009-2014= 65 articles
2014-2019= 285 articles

AOA- Bureau of Clinical Education and Research

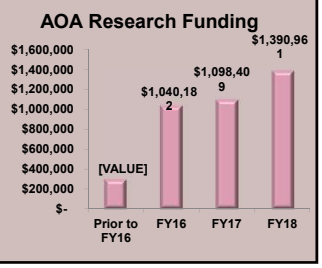
Five Research Focus Areas

- Chronic Diseases & Conditions
- Osteopathic Philosophy
- Musculoskeletal Injuries & Prevention
- Impact of OMM & OMT
- Pain Management

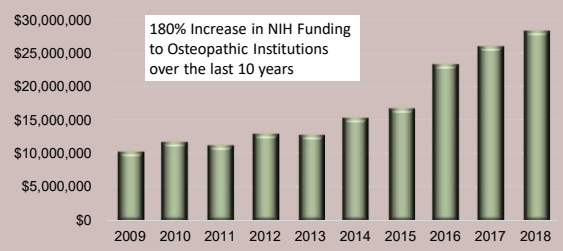


AOA as the Funder of Research

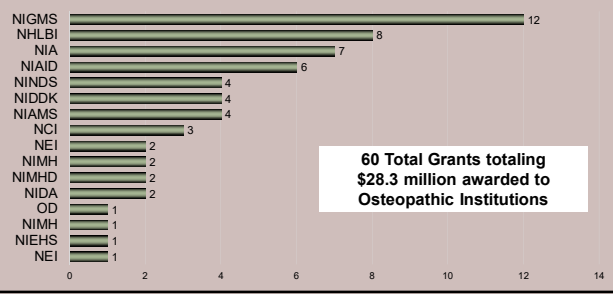
Grant Categories	FY16	FY17	FY18
OMM/OMT	4	2	2
Musculoskeletal Inj. & Prev.		2	1
Pain Management		2	1
Chronic Disease	1	1	2
Osteopathic Philosophy	4	1	2
Student Grant			4
Physicians in Training Grant			1
Total # of Grants	9	8	13



NIH Awards to Osteopathic Institutions (2009-18)



NIH Projects Awarded to Osteopathic Institutions by Institute/Center (2018)



OMT/OMM Research Funding & Ways to Get Involved

- Reach out to:
  - AOA & JAOA
  - AAO & AAOJ
  - FORCE
  - Practice-Based Research Networks
    - DO-Touch.net
    - Consortium for Collaborative Osteopathic Research Development
  - COMs
  - NIH

References

- Seffinger, Michael A., et. al. *Foundations of Osteopathic Medicine,4th Ed.* Philadelphia: Wolters Kluwer. 2018.
- Bordoni, B, et al. Emission of Biophotons and Adjustable Sounds of the Fascial System: Review and Reflections for Manual Therapy. J of EVB Integrative Medicine. 2018; vol. 23:1-6.
- Herrmann E. Postoperative Adynamic Ileus: Its Prevention and Treatment by Osteopathic Manipulation. The DO. 1965:163-4
- http://files.academyofosteopathy.org/convo/2017/Presentations/King_OMTandGITract.pdf
- Crow WT, Gorodinsky L. Does osteopathic manipulative treatment (OMT) improves outcomes in patients who develop postoperative ileus: a retrospective review. *Intern J Osteopath Med.*2009;(2):32-37.
- Chapelle SL, Bove GM. Visceral massage reduces postoperative ileus in a rat model. *J BodywMovTher.*2013;17(1):83-88.
- Fu et al., 2005. Fu F , Hou Y., Jiang W., Wang R., and Liu K.: Escin: inhibiting inflammation and promoting gastrointestinal transit to attenuate formation of postoperative adhesions. World J. Surg. 2005, 29: pp. 1614-1620
- Ernst, 1999. Ernst E.: Abdominal massage therapy for chronic constipation: a systematic review of controlled clinical trials. Forsch. Komplementarmed. 1999; 6: pp. 149-151.
- Noll DR, et. al. (2000) Benefits of Osteopathic manipulative treatment for hospitalized elderly patients with pneumonia. J Am Osteopath Assoc 100: 776–782.
- Clinical Guideline Subcommittee on Low Back Pain. American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients With Low Back Pain. JAOA 110; 11, 653-666
- Task Force on the Low Back Pain Clinical Practice Guidelines. American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients With Low Back Pain. JAOA 116; 8, 536-549
- Furlan AD, Pennick V, Bombardier C, van Tulder M; Editorial Board, Cochrane Back Review Group. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. Spine (Phila Pa 1976). 2009;34(18):1929-1941. Asked Bill to get
- Noll DR, et. Al. **Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized patients with pneumonia: a randomized controlled trial.** Osteopath Med Prim Care. 2010 Mar 15;4:2. doi: 10.1186/1750-4732-4-2. (commonly referred to as the MOPSE trial)
- Xu Z, et. al. **Fine architecture of the fascial planes around the lateral femoral cutaneous nerve at its pelvic exit: an epoxy sheet plastination and confocal microscopy study.** J Neurosurg. 2018 Dec 1:1-8.
- Licciardone JC, et. al. Osteopathic Manual Treatment and Ultrasound Therapy for Chronic Low Back Pain :A Randomized Controlled Trial . Annals of FM, vol. 11; 2. March/April 2013.
- Licciardone JC, Kearns CM, Crow WT. Changes in biomechanical dysfunction and low back pain reduction with osteopathic manual treatment: results from the osteopathic trial. Manual therapy. 2014;19(4):324-330.
- Henshaw R E. Manipulation and Postoperative Pulmonary Complications. The DO. September 1963, 132-133.

References

- Biller J, et. Al. Cervical Arterial Dissections and Association With Cervical Manipulative Therapy A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke. October 2014. 3156-3174.
- http://files.academyofosteopathy.org/MemberResourceGuide/AOAPositionPaperOMTCervicalSpine.pdf
- Checkoway H, et. Al. Selecting appropriate study designs to address specific research questions in occupational epidemiology. Occup Environ Med. 2007 Sep; 64(9): 633–638.
- Haidich A B. Meta-analysis in medical research. Hippokratia. 2010 Dec; 14 (Suppl 1): 29–37.
- Uman L S, PhD. Systematic Reviews and Meta-Analyses. J Can Acad Child Adolesc Psychiatry. 2011 Feb; 20(1): 57–59.
- Kabisch M, et. al,. Review Article: Randomized Controlled Trials (Part 17 of a Series on Evaluation of Scientific Publications). Dtsch Arztebl Int. 2011 Sep; 108(39): 663–668.
- Mitchell MA, Wartinger DD. Validation of a Functional Pyelocalyceal Renal Model for the Evaluation of Renal Calculi Passage While Riding a Roller Coaster. The Journal of the American Osteopathic Association, October 2016, Vol. 116, 647-652.
- Mills MV, Henley CE, Barnes LLB, Carreiro JE, Degenhardt BF. The use of osteopathic manipulative treatment as adjuvant therapy in children with recurrent acute otitis media. Archives of pediatrics & adolescent medicine. 2003;157(9):861-861.
- Lanaro D, Ruffini N, Manzotti A, Lista G. Osteopathic manipulative treatment showed reduction of length of stay and costs in preterm infants: a systematic review and meta-analysis. Medicine. 2017;96(12):6408.
- Goldstein FJ, et. Al. Preoperative Intravenous Morphine Sulfate With Postoperative Osteopathic Manipulative Treatment Reduces Patient Analgesic Use After Total Abdominal Hysterectomy. The Journal of the American Osteopathic Association, June 2005, Vol. 105, 273-279.
- Hensel KL, et. al. Pregnancy research on osteopathic manipulation optimizing treatment effects: the promote study. *American journal of obstetrics and gynecology.* 2015;212(1):1-9.
- Knebl JA, Shores JH, Gamber RG, Gray WT, Herron KM. Improving functional ability in the elderly via the spencer technique, an osteopathic manipulative treatment: a randomized, controlled trial. The journal of the american osteopathic association. 2002;102(7):387-396.
- Mills MV, Henley CE, Barnes LLB, Carreiro JE, Degenhardt BF. The use of osteopathic manipulative treatment as adjuvant therapy in children with recurrent acute otitis media. Archives of pediatrics & adolescent medicine. 2003;157(9):861-861.
- Brantingham JW, Cassa TK, Bonnefin D, et al. Manipulative therapy for shoulder pain and disorders: expansion of a systematic review. Journal of manipulative and physiological therapeutics. 2011;34(5):334-346.
- Email correspondence 5-20-19: Gloria Dillard, MPH, Assistant Director of Grants, Department of Research and Development at the AOA
- https://osteopathic.org/life-career/research/research-grants/
- Email correspondence 5-15-19: Kendi Hensel, DO, AAO President, member of the NIH-NCCIH Advisory Council.
- AOA Research slides from January 2019