OMM Research Update

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Disclosures

- None

Objectives

- Discuss new osteopathic research studies that are relevant for primary care
- Discuss new osteopathic research studies from other medical fields
- Review respiratory protocol from MOPSE study that could be helpful for acute respiratory patients (Covid)

Clinical Research

PROMOTE Study

- Hensel KL, Buchanan S, Brown SK, et al. Pregnancy research on osteopathic manipulation optimizing treatment effects: the PROMOTE study, a randomized controlled trial. *Am J Obstet Gynecol*. 2015;212(1):108.e1-108.e9. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4275366/pdf/nihms626863.pdf
- Hensel KL, Roane BM, Chaphekar AV, Smith-Barbaro P. PROMOTE study: safety of osteopathic manipulative treatment during the third trimester by labor and delivery outcomes. *J Am Osteopath Assoc*. 2016;116(11):698-703. Available at: https://jaoa.org/article.aspx?articleid=2578870
- Hensel KL, Carnes MS, Stoll ST. Pregnancy research on osteopathic manipulation optimizing treatment effects: the PROMOTE study protocol. J Am Osteopath Assoc. 2016;116(11):716-724. Available at: https://www.ncbi.nlm.nih.gov/pubmed/27802557

Study Design

- Inclusion: 18-35 yo, at 30 WGA at the start of the trial, medically cleared
- Exclusion: high risk pregnancy (abruption placenta, placenta previa, severe preeclampsia or eclampsia, vaginal bleeding, gestational DM, or pregnancy-induced HTN)
- Randomized into study groups, OBs were blinded regarding the group
- Groups
  - Usual care plus OMT (n=136): each technique performed for 1-2 minutes until adequate tissue change noted by NMM/OMM boarded physicians
  - Usual care plus placebo ultrasound treatment (ultrasound machine turned off) (n=131): tactile stimulation over same regions as OMT for 2 minutes
  - Usual care only (n=133): completed study questionnaires
- Measures: Quadruple Visual Analog Scale, functional status (Roland Morris Disability Questionnaire), L&D outcomes
- Intention-to-treat analysis

Study Design Continued

- Visits after usual OB visits at 30, 32, 34, 36, 37, 38, and 39 WGA: 99 (25%) completed all 7 treatments
- OMT Protocol (Video link: https://youtu.be/TsCpcEK6rLg)
  - Seated forward-leaning thoracic spine articulation
  - Supine cervical soft tissue
  - OA decompression
  - Thoracic inlet MFR
  - Lateral recumbent scapulothoracic soft tissue
  - Lateral recumbent lumbosacral soft tissue
  - Abdominal diaphragm MFR
  - Pelvic diaphragm MFR
  - Sacroiliac articulation
  - Frog-leg sacral release
  - Posterior innominate ME (only if needed)
  - Anterior innominate ME (only if needed)
  - Pubic symphysis decompression
  - CV4

Abdominal Diaphragm MFR

- This study showed this technique as one done with the patient supine
- I find it easier to do this with the patient seated because the uterus falls away from the diaphragm and it's easier to place your hands in the appropriate position
  - You have to stand behind the patient; I usually put my knee on the table and turn to the side so they can slump into the side of my body
  - Just warn the patient that you are putting your hands under her rib cage!

Sacroiliac Articulation

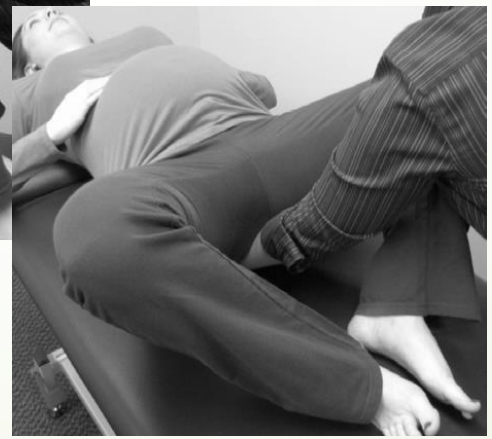
- Check ASIS compression
- Flex hip, add mild compression through femur
- The hip is internally rotated and then extended; then externally rotated and then extended
- Repeat until motion with ASIS compression improves; may repeat on both sides

SI Articulation

Frog Leg Sacral Release

- The physician's hand is under the sacrum with patient's hips flexed, knees bent, and feet side-by-side
- Sacrum brought to the myofascial point of ease, assessing for ease with respiratory inhalation and exhalation
- At the point of most ease during the respiratory cycle, the patient's knees fall to the side and she straightens out her legs. The physician adds mild inferior traction to the sacrum
- Repeat 3-5 times until sacral motion is more symmetrical with ASIS compression or when checking myofascial motion

Frogleg Sacral Articulation



Results

- UCO had worsening pain and functioning
- OMT and PUT group outcomes did not differ significantly (!)
- Secondary outcomes
  - Meconium staining not influenced by treatment group
  - Gestational age at delivery not influenced by treatment group
  - Conversion to high risk status was statistically not influenced by treatment group
    - OMT n=11
    - PUT n=19
    - UCO n=20
  - OMT group had prolonged labor (2.3x more likely than in UCO and 4x more likely than in PUT) but reporting of labor was very varied
    - Does not increase risk of conversion to c-section, use of forceps/vacuum, or episiotomy

Conclusions

- OMT is safe to use in the third trimester
- OMT and PUT groups had improved pain and functional status in comparison to UCO
- The use of sham treatments for OMT is very difficult to design; the ultrasound wand here may have caused a myofascial release type of effect
- In my experience, OMT usually helps a lot with pregnancy related back pain but as the pregnancy progresses, you usually need to see them more often. The effects of treatment don't "stay in place" as long
- "Shotgun" sacral techniques described here are very helpful if you can't remember how to do the muscle energy sacral diagnosis and treatment

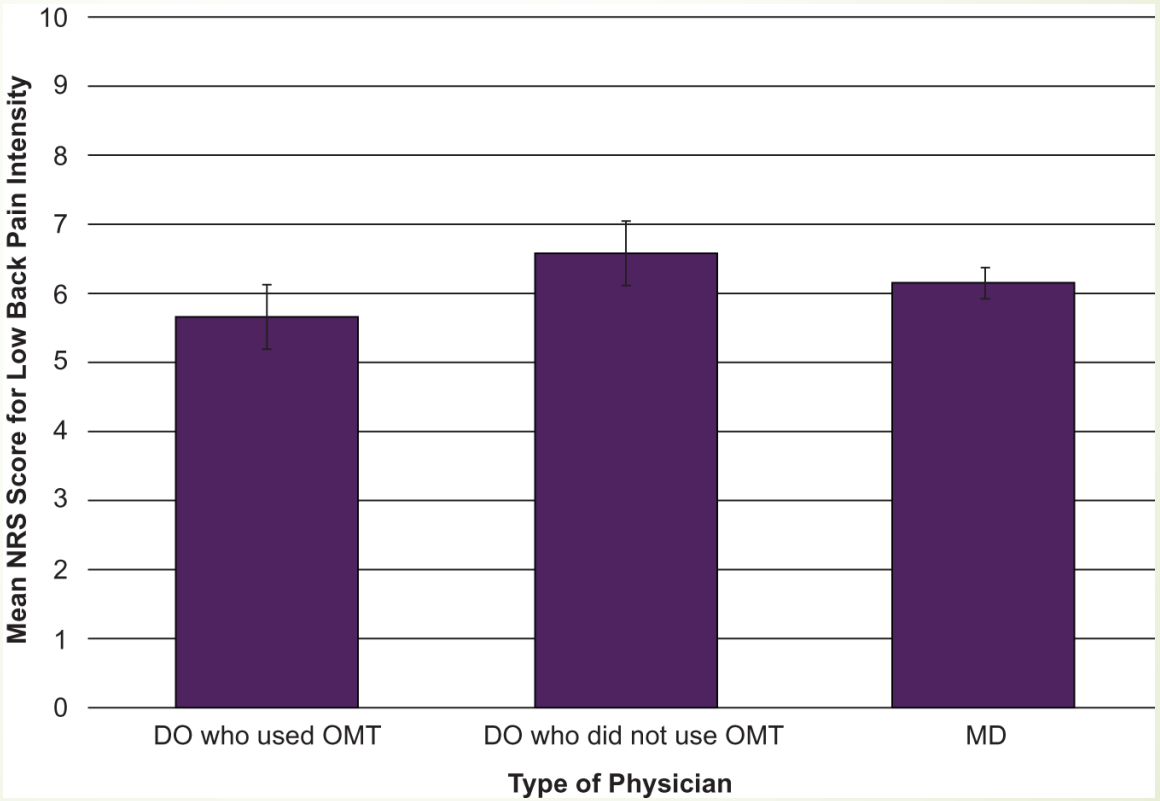
OSTEOPATHIC Low Back Pain Trial

- Licciardone JC, Gatchel RJ. Osteopathic medical care with and without osteopathic manipulative treatment in patients with chronic low back pain: a pain registry-based study. *J Am Osteopath Assoc*. 2020;120(2):64-73. Available at: https://jaoa.org/article.aspx?articleid=2760106&resultClick=1
- Patients recruited from Ft Worth area
- Inclusion criteria: self-reported chronic LBP for at least 3-6 months with frequency of pain at least half of the days, 21-79 yo, having a physician who had provided medical care for LBP.
- Exclusion criteria: pregnancy, being institutionalized
- Assessments: questionnaires, numerical pain scale, medical conditions, nonpharmalogical treatments for LBP
- Outcome Measures: LBP intensity, back-related functioning, use of NSAIDs or opioids for LBP

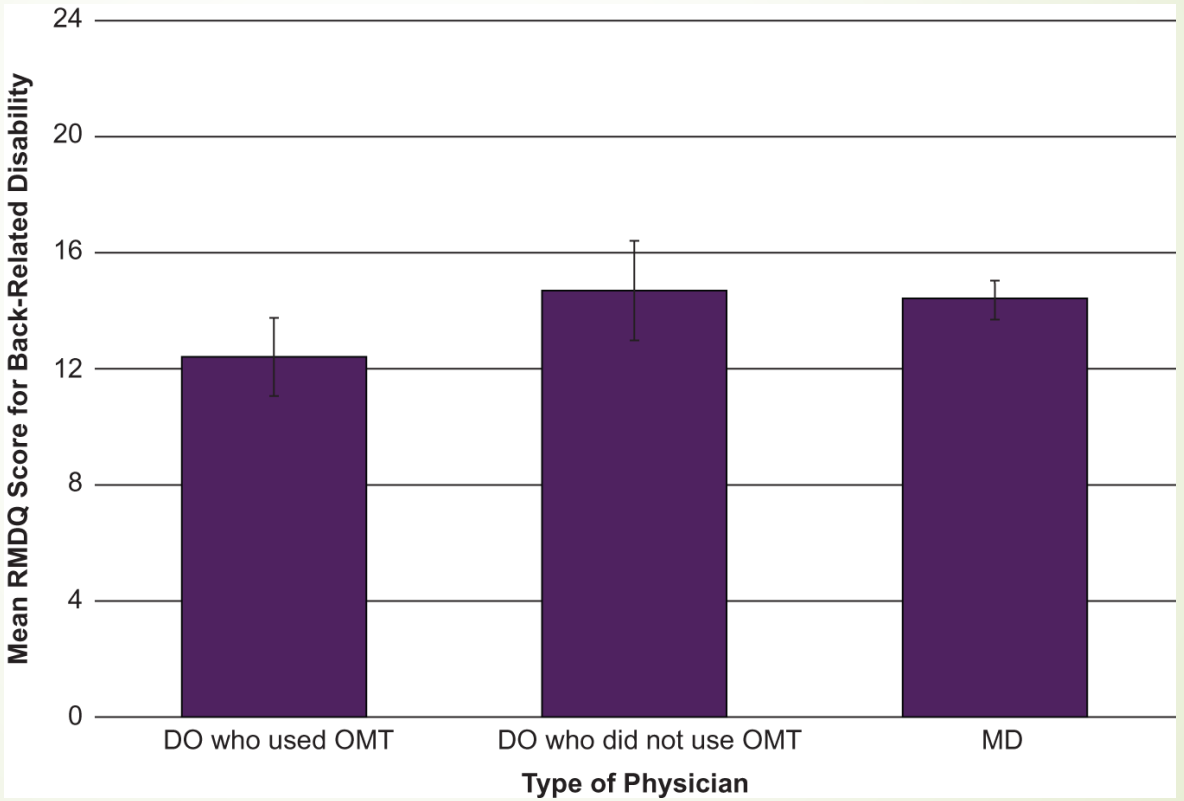
OSTEOPATHIC Trial Continued

- N=518 patients screened, 445 met eligibility criteria; mean age 54 yo; 69.2% of patients were female
- Mean low back pain intensity=6.1; mean disability score=14.1
- DOs treated 127 patients (28.5%) with OMT
- 288 patients (64.7%) used NSAIDs for LBP; 164 (36.9%) reported using opioids; 91 (20.4%) used both

Statistically significant differences in pain intensity scores between DOs who used OMT and who did not (p=0.008) and DOs who used OMT and MDs (p=0.04)



Statistically significant differences in disability scores between DOs who used OMT and who did not (p=0.03) and DOs who used OMT and MDs (p=0.009)



Use of NSAIDs and Opioids

	DOs using OMT	DOs not using OMT	MDs
NSAID use	41 (51.9%)	30 (62.5%)	217 (68.2%)
Opioid use	20 (25.3%)	17 (35.4%)	127 (39.9%)

Risk factors associated with more frequent use of opioids for LBP: current cigarette smoking, presence of widespread pain, herniated disc diagnosis, increasing levels of back related disability

Conclusions

- OMT is effective as a component of nonpharmacologic and non-opioid treatment for chronic low back pain
- DOs in this study who used OMT were less likely to prescribe NSAIDs or opioids
- Patients treated by DOs who did not use OMT did not have better results than those treated by MDs—so OMT was the crucial factor
- Self-selection of patients?

Low Back Pain Tips

- Follow LIPLSIP mnemonic—lower extremities, innominate shears, pubic shears, lumbars, sacrum, innominate rotations/flares, psoas/iliacus
- Treating lumbars first will get rid of sacral dysfunctions at least 50-60% of the time in my experience
- Think about different layers of muscles in low back—an ideal lumbar treatment would address all of these efficiently
- The PROMOTE protocol for lumbars, pelvis, and sacrum are also helpful

Post Concussion Syndrome and OMM

- Chappell C, Dodge E, Dogbey GY. Assessing the immediate effect of osteopathic manipulation on sports related concussion symptoms. *Osteopathic Family Physician*. 2015;7(4):30-35.
- Retrospective case series (n=26); no control or sham group
- Inclusion: athletes with sports-related concussion, SCAT2 before and after encounter, OMT
- Treatments done by OMM/NMM Plus-1 residents or sports medicine physician; no protocol but treatment designed individually
- 16 (64%) were male; 9 (36%) were female—1 person's gender was missing
- Ages ranged from 15-26 yo; average 19.56 yrs
- Time from injury to presentation: mean 6.5 days, range 1-9 days

Results

- Statistically significant improvements in SCAT2 ($p<0.05$), although all 22 symptoms improved
  - Headache
  - Pressure in head
  - Balance problems
  - Sensitivity to noise
  - Feeling like in a fog
  - Don't feel right
  - Difficulty concentrating
  - Fatigue or low energy
  - Irritability
  - Sadness

Conclusions

- OMT helped improve all symptoms in SCAT2, but some more than others
- No control group so hard to make broader generalizations
- Clinically, OMT can be helpful to make a quicker recovery after concussion. From my experience, if you start treatments earlier, the better the results. If the injury occurred more than a year previous to starting treatment, it is a lot harder to treat—takes longer to show improvement.
- Also important to consider adjunctive physical therapy, such as vestibular and ocular

Tension Headaches

- Deodata M, Fuolo F, Monticco A, et al. Osteopathic manipulative therapy in patients with chronic tension-type headache: a pilot study. *J Am Osteopath Assoc*. 2019;119:682-687. Available at: https://jaoa.org/article.aspx?articleid=2748603&resultClick=1
- Pilot study done in Trieste, Italy
- Two groups
  - OMT, n=10
  - Control, n=10
- Inclusion: diagnosis of chronic tension type headache, >=18 yo
- Exclusion: pregnancy, severe psychiatric disorders, severe coexisting diseases (major cranial/cervical trauma, cancer, severe infectious diseases), major surgical procedures in the previous 12 mo, PT +/- OMT in the past 3 months, pharmacologic treatment in the past 3 mo, <18 yo

Study Design

- OMT group—NSAIDS or other medications allowed but only for maximum of 2x/wk
  - 10 x 1 hr treatments
  - First 3 treatments—individualized treatment, including ME, articulatory techniques
  - Last 7 treatments—more indirect techniques, including MFR, balanced membranous tension, cranial
    - Focusing on nociceptive input of trigeminal nucleus level: MFR sacrum, diaphragm, thoracic outlet, throat; BMT and dural venous sinus release
- Control group: 30-50 mg amitriptyline based on body weight; dose not adjusted
- Patients maintained a headache diary
- Also looked at forward head posture (craniovertebral angle (line between C7 and tragus)) via software

Results

- OMT group: 8 women, 2 men, mean age 42.6 yo
- Control group: 4 women, 6 men, mean age 51.4 yo
- No differences at baseline in headache qualities between 2 groups
- Mean headache intensity
  - OMT group decreased by 1.8 (p=0.002)
  - Control group decreased by 1.7 (p=0.03)
- Mean headache frequency
  - OMT group decreased by 11.5 days (p=0.002)
  - Control group decreased by 16 days (p=0.003)
- Mean headache duration
  - OMT group decreased by 3.7 hrs
  - Control group decreased by 4.2 hrs
- Mean CVA of forward head posture decreased in OMT group by 4 deg (p=0.003); not enough control patients completed this part

Conclusions

- OMT was as effective as amitriptyline
- Decrease in CVA indicates that OMT may help with forward head posture, which contributes to chronic tension headaches
- In my experience, tension headaches usually improve with OMT
  - I also ask about pillow height, work ergonomics, and glasses
  - Neck stretches such as bringing the head forward and backwards are also helpful

Treating Adhesions

- Liedler M, Woisetschlager G. Influence of postoperative adhesions after cesarean section on chronic lower back pain—a pilot study of osteopathic manipulative treatment. *European Journal of Osteopathic Research*. 2019;1(1):38-46. Available at: https://european-journal-of-osteopathic-research.com/v1/n1/influence-of-postoperative-adhesions-after-caesarean-section-on-chronic-lower-back-pain/
- Premise: Adhesions from c-section may affect mobility of deep fascia and transference of mechanical forces in the core muscles cannot occur as well; may also affect mechanoreceptors and nociceptors in thoracolumbar fascia
- Group A: OMT, n=18
- Group B: physiotherapy, n=16
- Assessments: pain scale and Oswetry Low Back Pain Questionnaire administered right before first treatment and one week after the second treatment
- 2 visits
- Inclusion: female patients between 20-69 yo, chronic low back pain symptoms for at least 6 months, had undergone a c-section as recently as 1 year ago, and at most one other abdominal surgery
- Exclusion: >=2 abdominal surgeries, cancer, other physical or PT treatments during study, use of analgesic +/- muscle relaxers as part of chronic pain therapy

Treating Adhesions Continued

- Group A treatments: myofascial release and direct technique +/- hip movement
- Group B treatments: scar massage technique from Academy of Physiotherapy in Vienna
- Group A results
  - Low back pain intensity: from 4.6 to 2.0
  - Oswetry Disability Index: from 18.3% to 6.2%
- Group B results
  - Low back pain intensity: from 5.1 to 3.7
  - Oswetry Disability Index: from 19.1% to 14.0%
- Differences between group results were not statistically significant but it was a small pilot study

Clinical Tips

- Scar tissue can be palpated to see how much restrictions are associated with it—line your fingers up on the scar, add moderate compression, and move tissue into all planes of motions
  - Tissue that does not have a lot of restrictions/scar tissue will move freely in all planes
  - Otherwise, may have restrictions in 1+ plane(s)
- To treat, move tissue into restriction barrier in 3 planes of motion and have the patient take around 5 deep breaths, then recheck
- Patient can do this at home several times a week to improve mobility of the scar tissue
- If scar is painful to touch, subcutaneous injection of 1% lidocaine without epinephrine can be helpful to break the nociceptor cycle
- Sometimes relevant in women who complain of pain at epidural site for months or years later

Irritable Bowel Syndrome

- Muller A, Franke H, Resch KL, Fryer G. Effectiveness of osteopathic manipulative therapy for managing symptoms of irritable bowel syndrome: a systematic review. *J Am Osteopath Assoc*. 2014;114:470-479. Available at: https://jaoa.org/article.aspx?articleid=2094816&resultClick=1
- Used Cochrane guidelines for the systematic review
- RCTs only included
- 5 studies included with 204 patients in total; 1 study had a high risk of bias; significant heterogeneity for outcome measures and controls
- Only 1 study done in US; others in Europe

Study Reviews

- Visual analogue scale for pain
  - Muller et al: OMT group went from 64.5 to 12.9; control group went from 63.7 to 49.7 ($P<0.01$)
  - Brisard et al: OMT group went from 50.7 to 33.4; control group went from 56.5 to 62.3 ($p=0.02$)
- Attali et al used RCT crossover study design
- Florance et al used IBS severity score: more short-term improvement (0-7 days) in treatment group (OMT group=300 to 196, control group=275 to 244) but at day 28 severity score was almost identical
- Hundscheid et al used Functional Bowel Disorder Severity Index: OMT group went from 174 to 74; control group on standard medical care went from 171 to 119 ($p=0.02$) over 6 month time period

Conclusions

- OMT reduced abdominal pain, constipation, and diarrhea, and patients reported improved well-being
- No adverse effects
- Treatments were individualized
- Patients can be taught to do mesenteric release on their abdomens several times a week or as needed when symptomatic
- IBS is a multi-factorial syndrome so OMT is usually a part of the picture, not the whole solution
  - Also consider stress/psychological factors, dietary considerations (timing/duration of meals, low FODMAP diet, decreasing fast foods/processed foods), increasing water intake, etc

Mesenteric Release

- The physician's hands are in the RLQ with the fingers curled slightly underneath the large intestine (Figure A).
- The fingers gently push toward the patient's back and then toward the patient's left side until they meet the restrictive tissue barrier.
- This position is held until the physician palpates a release (20 to 30 seconds), and then the physician follows this movement (fascial creep) to the new barrier and continues until no further improvement is detected.

Figure A

Mesenteric Release Continued

- The physician's hands move to the ascending colon and repeats procedure (Figure B).
- The physician moves to the patient's right side and places hands on the left side of the abdomen, maneuvering under the descending colon (Figure C).
- The physician's hands move to the LLQ and repeats procedure (Figure D).

Figure B

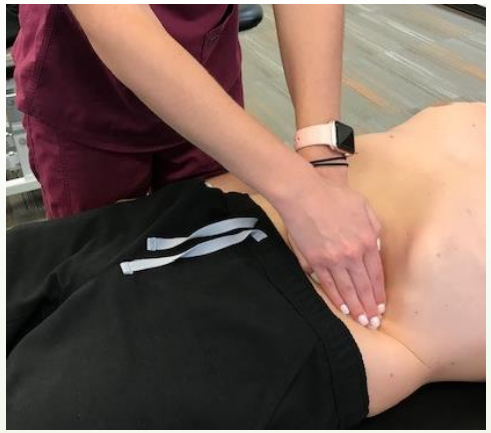


Figure C

Figure D

Revisit of MOPSE for Acute Respiratory Patients

Multicenter Osteopathic Pneumonia Study in the Elderly (MOPSE)

- Noll DR, Degenhardt BF, Fossum C, Hensel K. Clinical and research protocol for osteopathic manipulative treatment of elderly patients with pneumonia. *J Am Osteopath Assoc*. 2008;108:508-516. Available at: https://jaoa.org/article.aspx?articleid=2093709&resultClick=1
- Noll DR, Degenhardt BF, Morley TF, et al. Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized patients with pneumonia: a randomized controlled trial. *Osteopath Med Prim Care*. 2010;4:2. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2848182/

Study Design

- Multi-center (5 states)
- Inclusion: >=50 yo, acute pneumonia dx
- Excluded: nosocomial pneumonia, lung cancer, metastatic cancer, uncontrolled metabolic bone disease, bronchiectasis, pulmonary TB, lung abscess, advanced pulmonary fibrosis, current rib or vertebral fracture, previous pathologic fracture, previous study participation, or respiratory failure
- Outcome measures: length of hospital stay, time to clinical stability, reduced rate of symptomatic and functional recovery, duration of antibiotic use, number of complications (mortality and ventilator use for respiratory failure), duration and severity of fever, leukocytosis
- Randomized groups
  - OMT, n=135
  - Light touch, n=136
  - Conventional care, n=135

OMT Protocol

- Standardized protocol (10 min)
  - Thoracic soft tissue
  - Rib raising
  - Doming diaphragm with indirect myofascial release
  - Soft tissue to the cervical spine
  - Suboccipital inhibition
  - Myofascial release to the thoracic inlet
  - Thoracic lymphatic pump with activation
  - Pedal lymphatic pump
- Nonstandardized protocol (5 min)—individualized treatment

Results

- Per protocol analysis showed that OMT decreased LOS (median 3.5 days for OMT vs 4.5 for CCO), duration of IV antibiotics (median 3 days for OMT group vs 3.5 for CCO), and incidence of respiratory failure and death (0 deaths for OMT group vs 8 deaths for CCO group)
  - Intention to treat did not show difference
  - This is one of the reservations for this study because per protocol means that all treatments were given in the proscripted fashion and can introduce more biases to the study and is not as "real world" as intention to treat
  - Post hoc comparisons showed that between-group characteristics were still similar

Conclusions

- OMM for hospitalized patients >=50 yo did not have side effects and showed improvement with clinical outcomes in per protocol analysis
- The OMM service at OSUMC often gets consults for respiratory patients and anecdotally seems to improve well-being and difficulty breathing
  - Rib cage compliance and diaphragm excursion noticeably change after treatment

Of General Interest

Glymphatics

- Hitscherich K, Smith K, Cuoco JA, et al. The glymphatic-lymphatic continuum: opportunities for osteopathic manipulative medicine. *J Am Osteopath Assoc*. 2016;116(3):170-177.
- Glymphatics: recently discovered lymphatic system of the brain (Iliff, et al)

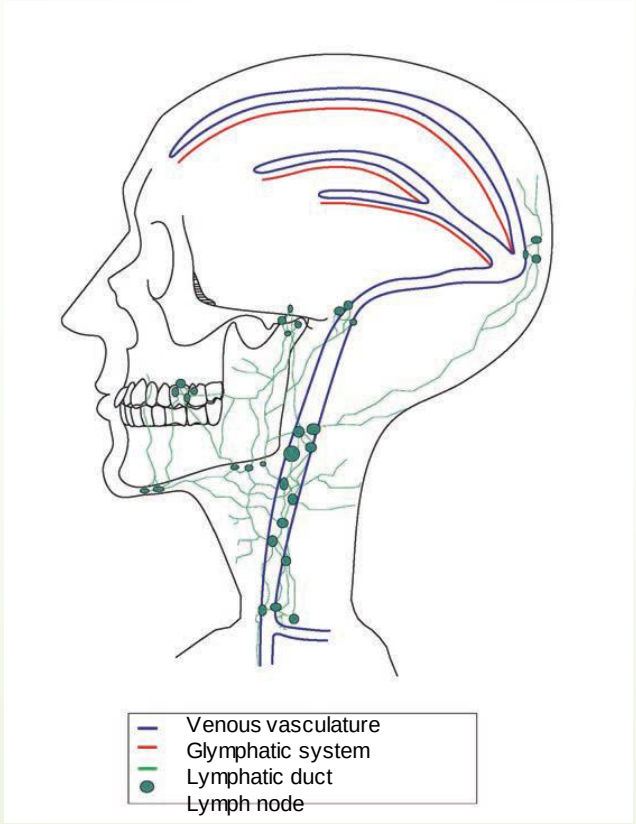


Figure 2 from Hitscherich (2016)

- https://www.youtube.com/watch?v=ci5NMscKJws

Clinical Considerations

- Potential effects on Alzheimer's and other dementias, neurodegenerative disorders, post-concussion syndrome, headaches
- OMM may be affecting the glymphatic system with cranial manipulation
  - This is speculative but may explain clinical results
  - Many basic cranial techniques like the V-spread, venous sinus drainage, and parietal/frontal lifts affect dural tension, which would affect venous and glymphatic drainage
- Proper treatment would also include lymphatic treatment, including targeting the thoracic outlet, abdominal diaphragm, and rib cage

OMT in NICU

- Lanaro D, Ruffini N, Manzotti A, et al. Osteopathic manipulative treatment showed reduction of length of stay and costs in preterm infants: a systematic review and meta-analysis. *Medicine*. 2017;96(12):e6408.
- 5 trials with 1306 infants
- Moderate heterogeneity
- Meta-analysis showed pre-term infants treated with OMT had reduction in LOS by 2.71 days (95% CI -3.99, -1.43; $p<0.001$). Reduced costs (-1,545.66 euros). Studies were done in Europe
- No adverse effects
- Variety of treatment techniques, including cranial, myofascial, visceral, balanced ligamentous tension.
- 4 trials had treatment protocols that took 20-30 min per treatment
- Frequency varied from 2-3 treatments/wk; either for entire hospitalization or 1 week

OMT in NICU Continued

- Very preterm infants (<32 WGA); n=118, 58 receiving OMT and 60 in control group
  - Meta-analysis from 2 studies: OMT group was discharged 9 days earlier on average (95% CI -13.46, -3.81 days; p<0.001)
- Moderate preterm infants; n=311, 163 receiving OMT and 148 in control group
  - Meta-analysis from 3 studies: OMT group was discharged 3.08 days earlier on average (95% CI -5.16, -0.99 days, p<0.01)
- Late preterm infants; n=477, 233 receiving OMT and 244 in control group
  - Meta-analysis from 3 studies: OMT group discharged more than 2 days earlier on average (95% CI -3.63, -0.78 days; p<0.01)

OMT in NICU Continued

- Possible mechanisms of action
  - Reduction of pro-inflammatory cytokines—preterm infants have higher pro-inflammatory cytokines
  - This also helps to deregulate the sympathetic nervous system hyperactivity—preterm infants may have abnormal autonomic nervous system reactivity
  - Improves lymphatic and immune system function
- OMT can be helpful in NICU patients with regards to length of stay, which translates to savings in health care costs
  - No adverse events noted

Just for Fun

Cannabimimetic Effects of OMT

- McPartland JM, Giuffrida A, King J, et al. Cannabimimetic effects of osteopathic manipulative treatment. *J Am Osteopath Assoc*. 2005;105(6):283-291.
- Ever wonder why you feel spacy sometimes after treatment?
- Many types of endocannabinoids
  - Anandamide (AEA); mimicked by THC; also elevated in "runner's high"
  - 2-arachidonoylglycerol (2-AG)
  - Oleylethanolamide (OEA)
- Methods
  - OMT group, n=16; this was direct osteopathic manipulation within common compensatory pattern model
  - Sham manipulation (control), n=15; this was indirect biodynamic osteopathy in the cranial field
  - Subjects blinded
  - Each group had 20 minutes of treatment or sham

Measures

- Immediately before and after treatment
- Drug Reaction Scale—has discrimination between cannabimimetic drugs and non
- Blood tests for AEA, 2-AG, and OEA
- Blinding was partially successful
  - In OMT group, 75% believed they had received treatment
  - In sham group, 40% believed they had received treatment

Results

- DRS
  - OMT group: significant changes ($p<0.05$) between pre- and post-treatments with descriptors *distractible* (5.5; 4.2), *good* (7.0; 8.3), *happy* (7.8; 8.7), *high* (4.6; 5.7), *hungry* (3.9; 5.0), *inhibited* (2.7; 2.1), *light headed* (2.8; 4.9), *sober* (8.7; 5.7), *stoned* (1.2; 2.1), *uncomfortable* (3.7; 2.1)
  - Sham group: significant changes ($p<0.05$) between pre- and post-treatments with descriptors *depressed* (2.2; 1.6), *fast* (5.4; 3.9), *good* (6.7; 7.8), *high* (4.2; 3.5), *impatient* (3.2; 2.1), *light bodied* (3.1; 4.8), *relaxed* (5.6; 8.4), *rested* (5.0; 8.0)

Lab results

Serum Level	OMT pre	OMT post	Sham pre	Sham post
AEA	2.99	8.01	2.26	2.65
2-AG	0.92	0.85	ND	0.003
OEA	15.58	11.43	13.90	14.27

- No statistically significant changes in labs (large variations)
- Changes in AEA and OEA were significantly associated with 9 DRS scores
  - Increases in AEA were associated with increased feelings of *rational, cold* and decreased feelings of *paranoid, bad*
  - Decreases in OEA were associated with increased feelings of *nausea, rough, and quiet* and decreased feelings of *rested and rational*

Comments

- Interesting theory, cannot make conclusions based on this study—further research would be interesting
- Limitations: small sample size, white and Maori populations, possibly a circadian influence in endocannabinoids that influenced results, AEA has short half life in serum
- Increased AEA levels associated with decreased psychotic symptoms in schizophrenic patients
  - AEA also causes a release of nitric oxide
  - Perhaps a mechanism for how OMM has anecdotally affected schizophrenic patients

Thank You!