



OMM and Evidence Based Medicine

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Objectives

By the end of this educational activity, participants will be able to

- Discuss the clinical conditions in which integration of OMM into the management is supported by clinical evidence
- Discuss the clinical practice guidelines that recommend the inclusion of manual treatments as part of management
- Describe the evidence base for the safety of OMM
- Discuss the type and timing of adverse events associated with OMM
- Discuss the decision-making process for performing OMM

Manual Medicine Disciplines

- Osteopathic
- Chiropractic
- Massage
- Physical therapy
- Other
 - Craniosacral therapies
 - Rolfing
 - Reiki
- Many US manual medicine disciplines started with involvement of DOs
- Many techniques are shared across disciplines
- Osteopathic manipulative medicine (OMM) is the diagnosis of somatic dysfunction and treatment of the somatic dysfunction using osteopathic manipulative treatment (OMT)

Osteopathic Neuromusculoskeletal Medicine (ONMM)

Specialized expertise in the indications, risks, benefits, and application of OMM in treatment of patients with neuromusculoskeletal and visceral disorders



OMM Research to Establish the Evidence Base

OMM Research

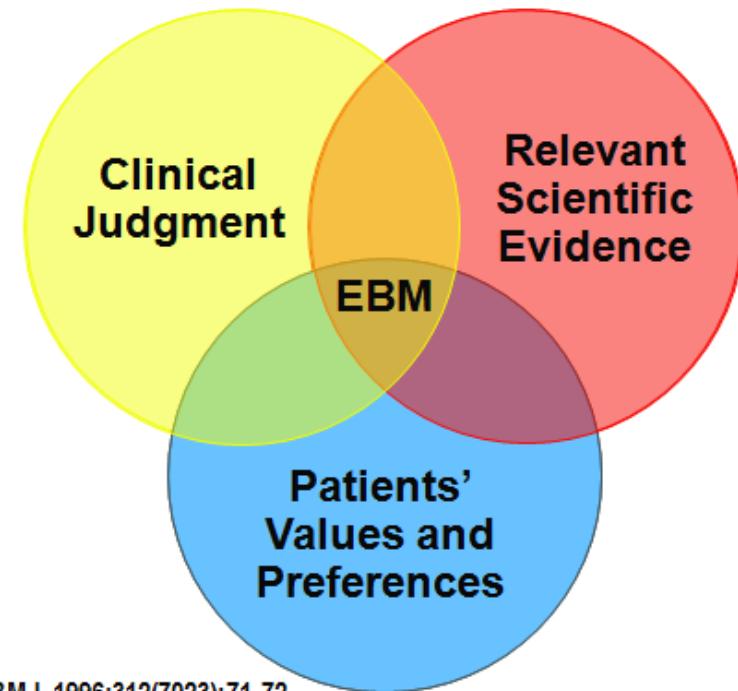
- Long history of OMM research
 - IM Korr PhD
 - Louisa Burns DO
 - Stedman Denslow DO
 - Viola Fryman DO
- New research strategies
 - RTCs
 - Practice base research networks
 - International osteopaths are strong contributors



Evidence Base

- Evidence-based Medicine (EBM)
 - Conscientious, explicit, and judicious use of current best evidence in making appropriate clinical decisions
 - Clinical decisions **must also include**
 - Clinical expertise of provider
 - Patient's values, preferences, and unique circumstances

What Is Evidence-Based Medicine?



Sackett DL, et al. BMJ. 1996;312(7023):71-72.

Types of OMM Studies

- Clinical Research
- Educational Research
- Basic Science (Mechanistic)

- Clinical Research
 - Case studies
 - Case series
 - Retrospective
 - Prospective observational
 - Randomized controlled studies
 - Meta-analyses
 - Combines data from multiple similar studies
 - May contain multiple manual medicine disciplines

Evidence Base

- Preponderance of evidence base **supports** manual medicine
 - Musculoskeletal conditions
 - Many visceral conditions
 - Some pediatric conditions
 - Some psychiatric conditions
- Most RTC OMM studies use a protocol of OMT techniques for consistency
- **Procedural studies**
 - Small compared to pharma studies
 - Methodologically prone to bias
 - treating clinician cannot be blinded
 - study participants cannot be blinded if they have had OMT before
 - Practice-based research provided real world data on treatment outcomes

Osteopathic Manipulative Treatment - EBM



- Achilles tendinitis
- Ankle injuries (acute)
- Athletes: cardiovascular autonomic parameters (rugby players)
- Athletes: anaerobic performance and lactate clearance (male athletes)
- Athletes: lower limb function (professional soccer players)
- Athletes: musculoskeletal complaints and disorders (musicians)
- Athletes: patellofemoral pain (runners)
- Athletes: prevention of stress fracture (collegiate cross-country athletes)
- Balance disorders
- Cancer-related symptoms: breast cancer patients (undergoing chemotherapy)
- Cancer-related symptoms: geriatric patients (not undergoing chemotherapy)
- Carpal tunnel syndrome
- Chronic obstructive pulmonary disease
- Depression
- Dizziness (associated with neuro-otologic disorders)
- Fibromyalgia
- Generalized anxiety disorder
- Geriatric health (nursing home residents)
- Headaches: migraine
- Headaches: tension type
- Heart failure
- Irritable bowel syndrome (IBS)
- Low back pain (acute and chronic)
- Lower urinary tract symptoms (women)
- Musculoskeletal pain (chronic noncancer pain)
- Neck pain (acute, chronic, and nonspecific)
- Pancreatitis
- Parkinson disease
- Pediatrics: asthma
- Pediatrics: infant colic
- Pediatrics: newborn and preterm (stable, neonatal ICU)
- Pediatrics: otitis media
- Pediatrics: plagiocephaly (nonsynostotic)
- Plantar fasciitis
- Pneumonia
- Pregnancy: hemodynamic control
- Pregnancy: prenatal care
- Pregnancy: intrapartum care
- Pregnancy: pelvic girdle, low back, and postpartum low back pain
- Postoperative: cardiac surgery
- Postoperative: ileus after abdominal or gastrointestinal surgery
- Postoperative: hysterectomy
- Postoperative: knee replacement surgery
- Shoulder pain

Patient Care Context of OMT

1. Primary treatment for the patient's condition
2. Adjuvant or adjunctive treatment
 - As part of a multimodal approach
 - Surgery, pharmaceutical, life-style changes, etc
3. Palliative care
 - Provides relief but will not cure the patient's condition
 - Decrease pain and improve function and quality of life



Sample of Newborn Hospital Studies



Evidence Base -NICU

Lanaro D, Ruffini N, Manzotti A, Lista G. Osteopathic manipulative treatment showed reduction of length of stay (LOS) and costs in preterm infants: A systematic review and meta-analysis. *Medicine*. 2017;96(12):e6408.

Meta-analysis of 5 trials (1306 infants) in the **NICU**

Preterm infants treated with OMT had a **significant reduction of LOS** by 2.71 days (95% CI -3.99, -1.43; $P < 0.001$). Considering costs, meta-analysis showed **reduction cost of stay** in the OMT group ($P < 0.0001$).

Evidence Base – Newborn Nursery

Mills MV. The use of osteopathic manipulative treatment in the newborn nursery and its effect on health in the first six months of life: A retrospective observational case-control study. Complementary Therapies in Clinical Practice. 2021;43. doi:10.1016/j.ctcp.2021.101357

58 newborns that received OMT in the newborn nursery were compared to 58 case matched controls.

Over the first 6 months of life, those that received **OMT had significantly less documented food intolerance (P = .04), colic (P = .04), spitting/vomiting (P = .003), and antibiotic usage (P = .012).**

Sample of Hospital Studies



Evidence Base – Pneumonia

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.

MOPSE Study: RCT of hospitalized patients with pneumonia (406 patients) comparing OMT vs sham OMT vs control

OMT resulted in **significantly decreased hospital length of stay, duration of IV antibiotics, respiratory failure, and death**

Evidence Base - Pancreatitis

Radjieski JM, Lumley MA, Cantieri MS. Effect of osteopathic manipulative treatment on length of stay for pancreatitis: a randomized pilot study [published correction appears in J Am Osteopath Assoc. 1998;98:408]. J Am Osteopath Assoc. 1998;98:264–272.

Hospitalized adult patients with uncomplicated pancreatitis who were randomized to received OMT (n=6) spent significantly fewer days in the hospital before discharge (**mean reduction of 3.5 days**, $p < .039$) compared to those patients that did not receive OMT (n=6).

OMT resulted in **significantly shorter length of stay**

Evidence Base – Post Cardiac Surgery

Rorris FP, Skouteli EAT, Papakonstantinou K, Kokotsaki L, Skotiniotis E, Kokotsakis J. Osteopathic manipulative treatment in cardiac surgery patients: a systematic review. *Int J Osteopath Med.* 2022;46:29-35.

Systematic review of 4 studies (244 patients) comparing OMT in postoperative period to those that did not receive OMT.

OMT resulted in **significantly reduced postoperative pain; improved pulmonary function; increased cardiac index; decreased hospital length of stay**

Evidence Base – Post Operative Ileus

Baltazar GA, Betler MP, Akella K, Khatri R, Asaro R, Chendrasekhar A. Effect of osteopathic manipulative treatment on incidence of postoperative ileus and hospital length of stay in general surgical patients. *J Am Osteopath Assoc.* 2013;113(3):204-209.

Crow WT, Gorodinsky L. Does osteopathic manipulative treatment (OMT) improves outcomes in patients who develop postoperative ileus: a retrospective chart review. *Int J Osteopath Med.* 2009;12(1):32-37.

Herrmann EP. Postoperative adynamic ileus: its prevention and treatment by osteopathic manipulation. *DO.* 1965;6(2):163-164.

Multiple retrospective studies assessing return of bowel function after abdominal surgery .

OMT resulted in **significantly decreased time to flatus and shorter length of stay**



Sample of Outpatient Studies

Evidence Base - Lower Urinary Tract Symptoms

Franke H, Hoesel K. Osteopathic manipulative treatment (OMT) for lower urinary tract symptoms (LUTS) in women. *J Bodyw Mov Ther.* 2013;17(1):11-18.

Meta-analysis of 5 studies (207 patients) comparing OMT to no treatment or pelvic floor training

OMT resulted in **significantly improved urologic symptom severity level in voiding dysfunction; improved stress** ($P < 0.008$ to 0.00001)

Evidence Base – Irritable Bowel

Lotfi C, Blair J, Jumrukova A, Grubb M, Glidden E, Toldi J. Effectiveness of osteopathic manipulative treatment in treating symptoms of irritable bowel syndrome: a literature review. Cureus. 2023;15(7):e42393.

Meta-analysis of 5 studies (150 patients) comparing OMT (mostly visceral) to no treatment or sham

OMT resulted in **significantly reduced pain and IBS severity index score; decreased rectal sensitivity; reduced abdominal distention**

Evidence Base - Dizziness

Rehman, Y., Kirsch, J., Wang, M. Y.-F., Ferguson, H., Bingham, J., Senger, B., Swogger, S. E., Johnston, R., & Snider, K. T. Impact of osteopathic manipulative techniques on the management of dizziness caused by neuro-otologic disorders: systematic review and meta-analysis. *J Osteopath Med.* 2023;123(2):91-101.

Meta-analysis of 12 studies (367patients) comparing OMT techniques to physical therapy (vestibular rehab) or medications

OMT (articular techniques) resulted in **significantly reduced disability associated with dizziness; reduced dizziness severity and frequency**

Evidence Base – Generalized Anxiety Disorder

Dixon L, Fotinos K, Sherifi E, et al. Effect of osteopathic manipulative therapy on generalized anxiety disorder. *J Am Osteopath Assoc.* 2020;120(3):133-143.

Patient with generalized anxiety disorder (n=26) comparing anxiety scores pre and post OMT

OMT resulted in **significantly reduced Hamilton Anxiety Rating Scale score and Intolerance for Uncertainty Scale score**

Evidence Base – Sleep

Cutler MJ, Holland BS, Stupski BA, Gamber RG, Smith ML. Cranial manipulation can alter sleep latency and sympathetic nerve activity in humans: a pilot study. J Altern Complement Med. 2005;11(1):103-108.

20 healthy people randomly assigned to CV4, sham or no treatment

OMT resulted in **significantly Decreased sleep latency**

Evidence Base – LBP and Diabetes

Licciardone JC, Kearns CM, Hodge LM, Minotti DE. Osteopathic manual treatment in patients with diabetes mellitus and comorbid chronic low back pain: subgroup results from the OSTEOPATHIC Trial. *J Am Osteopath Assoc.* 2013;113(6):468-478.

As part of a larger trial of 455 patients with low back pain, **patients with DMII** (n=34) had **significantly more somatic dysfunction** than those who did not have DMII (P=.01).

OMT resulted in **significant reductions in LBP severity** (P=.04) **in the DMII patients and tumor-necrosis factor (TNF)- α** (P=.03) compared to those that received sham OMT

Evidence Base – MSK Headaches

Rehman, Yasir, Kirsch, Jonathon, Ying-Fang Wang, Mary, Johnston, Robert, Will, Meadow, Gibson, Emily, Spencer, David, Garcia, Claudio and Snider, Karen T. Osteopathic manipulative treatment in the management of headaches associated with musculoskeletal dysfunction: systematic review and meta-analysis. *Journal of Osteopathic Medicine*. <https://doi.org/10.1515/jom-2025-0075>

Systematically evaluated the effectiveness of **OMT** for managing headaches associated with musculoskeletal dysfunction (18 RCTs)

Moderate quality evidence that protocols of direct techniques (articular + HVLA; soft tissue + articular + HVLA) resulted, **significant reduced headache frequency** ($p<0.01$). Moderate quality evidence that articular and HVLA **significantly improved quality of life** ($p<0.01$).

All OMT significantly **decreased headache severity** ($p<0.01$)

No evidence of OMT causing harms

Practice Guidelines

- Practice guidelines are algorithms for management of specific conditions
- Manual Medicine is included in practice guidelines when evidence is strong for benefit and safety is good
- Guidelines typically include multimodal approach
- OPP = multimodal treatment

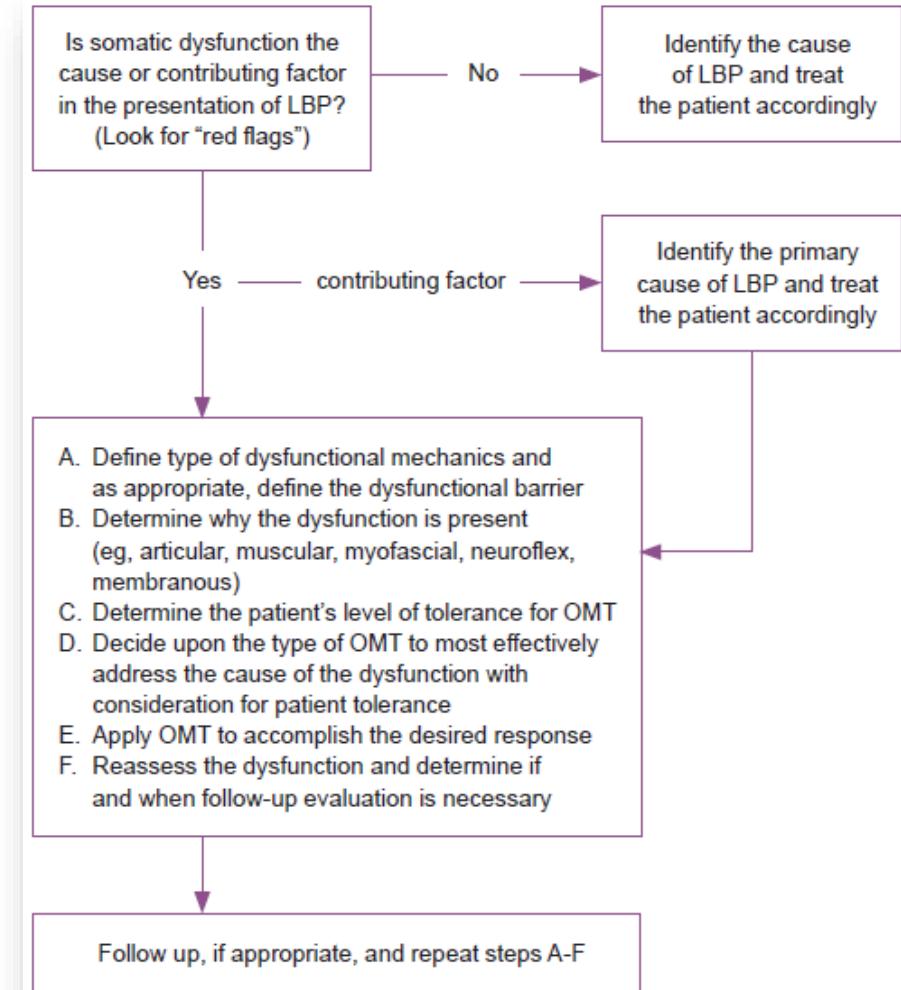


Figure.

Algorithm for osteopathic manipulative treatment (OMT) for low back pain (LBP) decision making.
Source: Adapted from: Nelson KE. The manipulative prescription. In: Nelson KE, Glonek T, eds. *Somatic Dysfunction in Osteopathic Family Medicine*. Baltimore, MD: Lippincott, Williams & Wilkins; 2007:27-32.

Practice Guidelines that include Manual Medicine

- **Acute MSK pain**
- Carpal tunnel syndrome
- Headaches
- **Low back pain**
- Lumbar stenosis with neurogenic claudication
- Lymphedema
- Neck pain
- Osteoarthritis of the knee
- Osteoarthritis of the hip
- Plantar fasciitis
- Shoulder rotator cuff disorders

Guidelines typically include multimodal approach

OMM Safety



Safety Terms

- **Adverse event (AE)**
 - any unfavorable or unintended disease, sign, symptom, or other medical occurrence that is ***temporally*** associated with a treatment or procedure
 - AE may or may not be related to the treatment or procedure
 - AE after OMT may be related to a medication, another procedure, or specific activities undertaken by the patient
- AE is not the same as side effect
- **Side effect**
 - secondary, unintended **beneficial** **or** **harmful** effect of an intervention
 - Term ***side effect*** is not recommended because it refers to both unintended harm and benefit

OMM Safety

- No serious adverse events (AEs) attributable to OMT have been reported in **prospective** studies
- Serious AEs only anecdotal or in case studies
 - Most involve chiropractic HVLA
- ***Serious*** AEs are Grade 4-5 AEs - life threatening, disabling or death



Common Terminology Criteria for Adverse Events (CTCAE) Grades of Adverse Events

Grade	Level	Classification	Description
1	Mild	Nonserious	The event is usually transient, does not typically interfere with activities of daily living, and requires no special treatment or intervention.
2	Moderate	Nonserious	The event impacts usual daily activities but is alleviated with simple noninvasive, therapeutic treatments. Laboratory evaluation indicates injury but without long-term risk or permanent harm.
3	Severe	Nonserious	The event requires intensive therapeutic intervention and interrupts usual daily activities. It may require brief hospitalization or prolong an existing hospitalization but does not result in a persistent or significant disability or incapacity.
4	Life-threatening or disabling	Serious	A medically significant event or its immediate sequelae, which places the patient at imminent risk of death or is associated with physical or mental disabilities that affect or limit the ability of a person to perform activities of daily living. The event may result in inpatient hospitalization or prolong an existing hospitalization.
5	Death	Serious	The event is associated with termination of life.

OMT Adverse Events

2018 Degenhardt

- Prospective study practice-based research network (1800 encounters)
- AEs immediately after OMT
 - 2.5% reported AE
 - mild to moderate pain/discomfort, tiredness/fatigue, lightheadedness, nausea/vomiting, headache, numbness/tingling, and stiffness
 - HVLA lowest AEs
 - BLT/LAS highest AEs
 - **No serious AEs related to OMT**



OMT Adverse Events

2022 Bagagiolo

- Multinational national systematic review of OMT clinical trials (55 trials)
 - Transient mild to moderate stiffness, tiredness, and muscle spasticity
 - **No serious AEs related to OMT**



Manual Medicine Adverse Events Timing

2010 Carnes

- Multinational systematic review of AE timing in 42K encounters
 - Physiotherapy, osteopathic, and chiropractic
 - **Most AEs occur within 24 hours and resolve within 48 hours**
 - Mild to moderate local pain and discomfort/aggravation of presenting complaint, stiffness, headache, pain outside the area of treatment, muscle spasm, radiating pain, tiredness and fatigue, lightheadedness, nausea, vomiting, numbness, and tingling
 - **No serious AEs reported**

OMT Adverse Events

2017 Lanaro

- Multinational national systematic review of NICU OMT (newborn)
 - One AE reported: 1 of 1306 preterm infants experienced longer time to full enteral feeding (nutrition via GI)
 - **No serious AEs related to OMT**

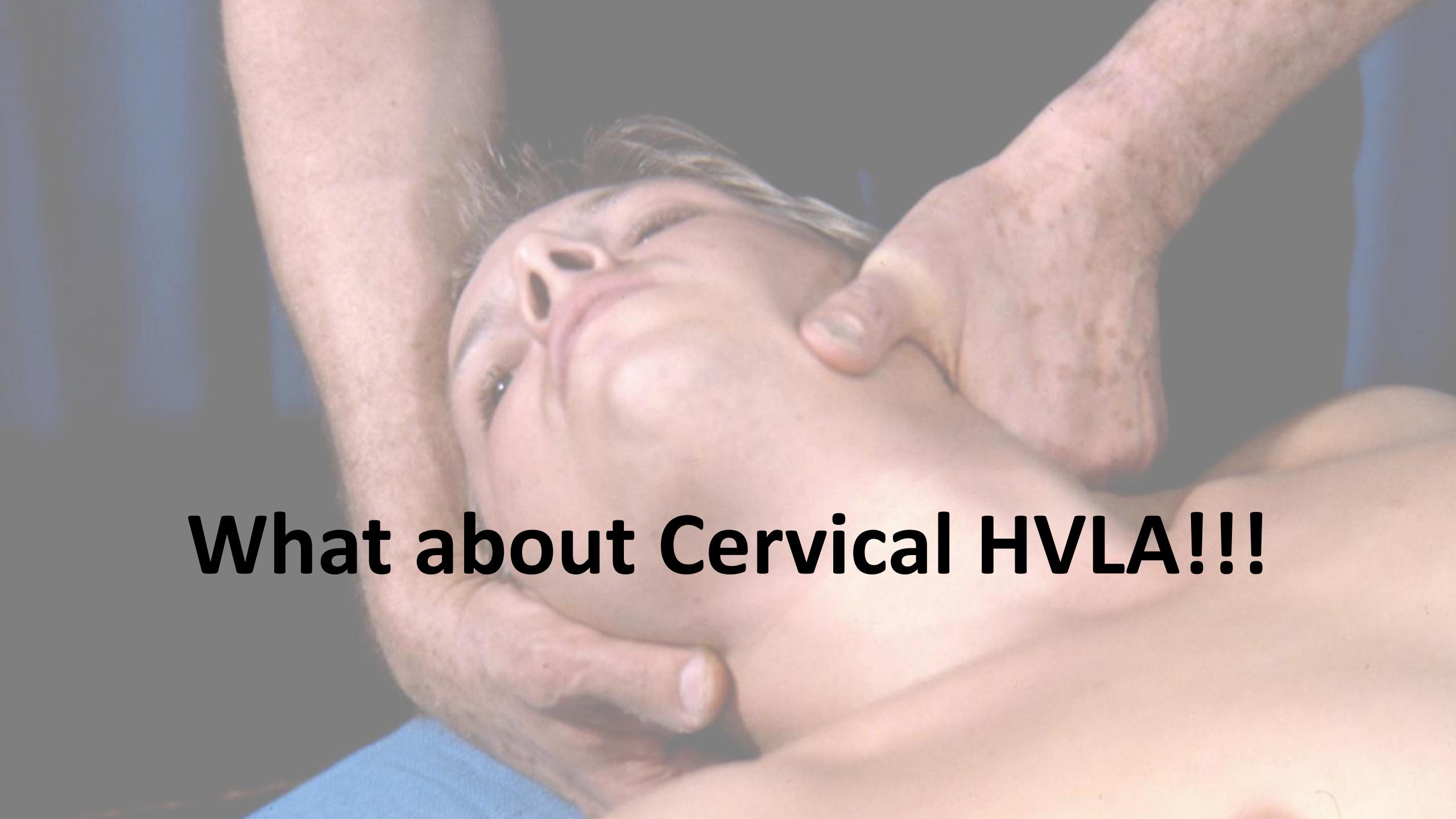


Manual Medicine Adverse Events Timing

2019 Parnell Prevost

- Multinational systematic review of AE timing in **pediatric** patients
 - Physiotherapy, osteopathic, and chiropractic
 - **Most AEs occur within 24 hours and resolve within 48 hours**
 - Dizziness, and increased symptoms in infants (such as vomiting or crying) for up to 48 hours
 - **No serious AEs reported**



A close-up photograph of a man's head and neck. He is lying on his back with his head tilted back. A person's hands are visible, applying pressure to the back of his head and neck, likely performing a cervical HVLA adjustment. The man has short, light-colored hair and is wearing a blue shirt.

What about Cervical HVLA!!!

Manual Medicine Risk

- Serious AEs
 - Cervical spinal manipulation (HVLA or HVHA) causing neurovascular accidents
 - cervical artery dissection leading to stroke (Grade 4 Serious [permanent harm]AE)
 - Estimates range widely from 1 in 20,000 to 1 in 250 million cervical HVLA manipulations (Nielsen 2017, FIMM 2013)
- NSAIDs
 - Increased Risk of Myocardial Infarction - odds ratio 1.24 celecoxib to 1.53 naproxen (Bally 2017)
 - 1 in 2400 incidence of myocardial infarction associated with use of NSAIDs (Straube 2009)
 - 18.8% mortality (grade 5 serious AE)
 - Increased Risk of gastrointestinal bleed - odds ratio 2.39 (first time) to 4.76 (repeat) (Venerito 2010)
 - 1 in 87 incidence of gastrointestinal bleed associated with NSAIDs (Straube 2009)
 - 20.9% estimated mortality (grade 5 serious AE) from a gastrointestinal bleed associated with NSAID (1997-2008)

Medicare Review of 23 Million Patients

Whedon 2022

Age 65 and older

- Compared patients
 - 1 week after PCP visit vs.
 - 1 week after cervical HVLA*
- Those that had cervical HVLA
 - Odds Ratio 0.73 for vertebral artery dissection
 - Odds Ratio 0.79 for carotid artery dissection

*Chiropractic Spinal Manipulation (HVLA)

- **Finding: those that received spinal manipulation were LESS likely to have vertebral or carotid artery dissection** than those that were seen by PCP
- Perhaps patients who receive manual treatment are healthier than those that do not receive manual treatment?
- Perhaps people who present with neck pain are more likely to have neurovascular events that originate in the neck?

Relative Risk Comparison

- Medicare E&M services
 - Medical Decision Making (MDM)
 - Risk of morbidity or mortality associated with management plan
- Manual Therapies Relative Risk
 - Consistent with exercise, physical therapy, joint injections, over the counter medications
 - **OMT is same level of risk as PT or exercise and OTC NSAIDs**



Relative Risk Reduction

- Basal risk refers to the degree of risk of AE in an untreated group
- Relative risk refers to the degree of risk for AE in the treated group
- Relative risk reduction refers to actions that can be taken to reduce the risk of the AE in the treated group to bring the risk closer to basal risk

OMT Relative Risk Reduction

- Reduce the relative risk of OMT by adhering to indications and contraindications
- OMT indication is the presence of somatic dysfunction

OMT Contraindications

- Contraindications are based on **common sense**
 - Consider anatomy, physiology, pathophysiology, and the forces applied with type of technique
- Contraindications are not evidence based

General Rules

- OMT should not be used when the patient or guardian does not provide verbal or written informed consent for the procedure.
- OMT should not be used in the presence of an unstable condition that involves rapid life-threatening deterioration.
- OMT should not be used if performing OMT will delay definitive diagnosis and treatment of an urgent or emergent condition.
- OMT should not be used without performing an appropriate history and physical evaluation, including evaluation for somatic dysfunction.
- OMT should not be specifically applied to sites of unstable anatomy if the application of forces used with the technique presents a high risk of a deleterious consequence.
- OMT should not be used when the physician's skill level makes it likely they will apply a force that overwhelms the integrity of the tissues.

Shared Decision-Making

- Obtain consent for OMT
- Explain OMT
 - “OMT is a hands-on form of treatment to joints and soft tissues to improve joint and muscle biomechanics, and improve nerve, blood vessel and immune function”
- Explain risks and benefits of OMT
 - “Most people report that OMT helps with their pain (or other issue)”
 - “Some people may experience soreness after OMT that is similar to post-exercise soreness which may last 1-2 days”
- Technique specific issues
 - Explain if technique known to cause other issues
 - HTP and triggerband techniques can cause bruising
- Patient specific issues
 - Patient on blood thinners may experience bruising from OMT techniques that use minimal forces

(Rushton 2023)

Patient Satisfaction

- Patients who participate in management decisions have greater patient satisfaction
- When patients receive OMT from trained clinicians, they perceive OMT to be holistic and patient-centered
- OMT associated with a positive patient–clinician partnership
- Patient satisfaction with OMT is generally reported as very good

Fawkes 2021, Lam 2019, Licciardone 2002, Tramontano 2018



Summary

- EBM supports OMT and other manual treatments to be included as part of multimodal management of many conditions
- Most AEs are transient and mild to moderate in severity
- Most AEs occur within 24 hours and resolve within 48 hours
- Shared decision making should be practiced
- Patient satisfaction with OMM is high
- Need more OMM research (AOA)
- OMM research needs to be published

please

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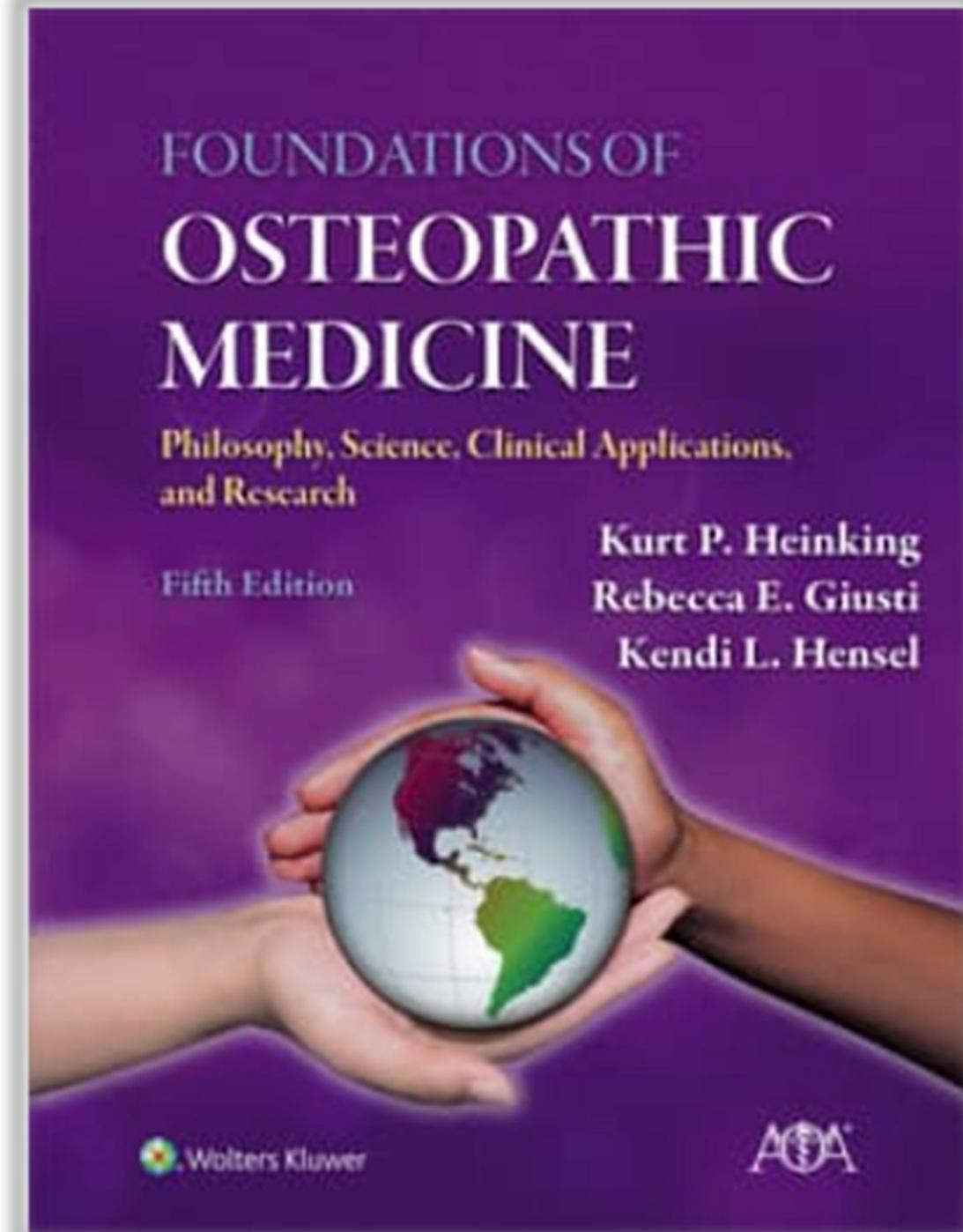
Chapter 95

Effectiveness and Safety of Osteopathic Manipulative Treatment

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