Title: Osteopathic Manipulative Treatment in the Third Trimester of Pregnancy

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Abstract/Intro

Osteopathic Manipulative Therapy (OMT) is a hands-on approach to treating conditions that affect all areas of the body. Physicians trained in OMT (Doctors of Osteopathic Medicine or DO) use OMT to correct structural imbalances in the body, relieve pain, and improve circulation. It is not only used as a treatment modality, but also to diagnose and prevent disease and improve overall functioning. There are over 40 OMT techniques that all involve gentle manipulation of the muscles, soft tissues, and joints in several ways to optimize alignment, improve blood flow, restore balance, and improve range of motion ("Osteopathic Manipulative Therapy & OMT." Cleveland Clinic). Research shows that manual therapy is equally or more effective in treating pain and improving function versus oral analgesics (Bodine). OMT can decrease cost and improve function in patients with a minimal adverse effect profile.

Some OMT techniques are similar to those used by chiropractors, physical therapists, and massage therapists. What makes it unique is that osteopathic physicians are trained to apply the philosophies of OMT with their comprehensive medical training of all body systems to specifically adapt the treatment to each individual patient. They incorporate their vast knowledge of pathology and physiology with the philosophy that the body can self-heal and self-regulate.

While OMT is most known for its application in treating pain, it truly involves holistic examination of the whole patient – body, mind, and spirit – and can be applied to any situation that places stress upon the body. It is also adjusted based on the patient's condition, age, weight, and other characteristics to yield personalized treatment that can be an adjunct to treatment for virtually any disease or condition (Roberts). Other OMT applications include relieving asthma, irritable bowel syndrome, fibromyalgia, migraines, carpal tunnel syndrome, and sports-related injuries. In addition to the indications listed above, there is a growing body of research surrounding the use of OMT in pregnancy and its use in treatment and prevention of complications peripartum.

Problem and/or Purpose Statement- Objective of the Research

The current practice of obstetrics does not often incorporate the use of OMT in pregnancy to treat pain or prevent complications during and after delivery, despite evidence that it is safe. We believe there is a need to focus attention on the effect of OMT on the rates of specific adverse events in labor and delivery.

Question: Does OMT during the third trimester of pregnancy improve delivery outcomes including: decreased labor times, less utilization of analgesics, fewer incidences of meconium fluid and perineal lacerations, and reduced risk of conversion to c-section or operative vaginal delivery?

Explanation of need for the study: Though all research has shown that OMT is safe in pregnancy there has been conflicting data on its benefits during the peripartum period. Additional research is needed to show its utility in decreasing labor times and need for analgesics during labor and reducing incidence of

adverse outcomes including perineal lacerations and conversion to c-section and operative vaginal delivery.

How results will contribute to existing knowledge: Our study will add to the growing body of knowledge about OMT during pregnancy and its potential benefits outside of musculoskeletal pain relief.

Background information

Hypothesis: OMT in the third trimester of pregnancy will reduce incidence of adverse outcomes including: conversion to operative vaginal deliveries (OVD) and cesarean sections (CS), decrease the use of analgesics during labor, shorten labor times and reduce the incidence of meconium fluid. Conversion to cesarean section or operative vaginal delivery is sometimes unavoidable for the safety of both the mother and baby but they do come with their own set of risks. C-sections incur the same risks of other operative procedures including hemorrhage, infection, embolism, and damage to other organs ("C-Section" Cleavland Clinic). Risks associated with operative vaginal deliveries, those performed with forceps or vacuum devices, have the risk of tears to the muscles of the vagina or rectum, which may cause difficulty urinating or urinary incontinence. Risks to the baby include scalp edema, bruising leading to jaundice, cephalohematoma, and skull fractures ("Forcep Delivery" and "Vacuum Extraction Delivery," Cleavland Clinic).

Theoretical Framework- Present Knowledge

Current data supports that OMT is safe for use in pregnant patients. Osteopathic manipulative treatment is used daily to treat patients at the Longmeadow Primary Care Residency Clinic.

Literature Review

A retrospective study published in 2003, looked at the medical records of women from 4 different cities who did receive prenatal OMT compared to women in those same cities who did not receive prenatal OMT. The study looked for the occurrence of meconium fluid, preterm delivery, operative vaginal delivery (forceps delivery) and conversion to c-section (King et al). The types of OMT used varied based on the needs of the patient and the individual osteopathic structural examination. Two of the study sites had a single physician who performed OMT on all the study participants while the other two sites used several staff physicians and residents to perform OMT on the study participants. The study found that the participants who received OMT were significantly older (28.32yo vs 26.89yo) than those who did not receive OMT and yet they had fewer complications of labor and delivery than the group that did not receive OMT (King et al). The study concluded that if older women have a higher incidence of poor labor and delivery outcomes it should be even harder to obtain favorable study outcomes among this age group. This study also found that OMT was consistently associated with favorable labor outcomes and lower rates of meconium fluid, preterm delivery, and operative vaginal delivery. While the use of several physicians could introduce error into the study the positive results suggest further validity of OMT in the setting of labor and delivery.

A literature review in 2012 by John M. Lavelle, DO, looked at the ability of OMT to improve the quality of life of pregnant women by treating somatic dysfunction caused by the rapid changes in the maternal body. He stated that data supported the benefit of OMT in lower back and pelvic pain in pregnancy but

also stated that there were not enough randomized controlled trials to support the use of OMT in the prenatal patient (Lavelle).

A systematic review of OMT in gynecology and obstetrics (Ruffini et al.) concluded that the small number of studies and high risk of bias prevented any indication on effect of OMT care. This literature review looked at 24 studies ranging in topics from low back and pelvic pain in pregnancy to infertility and dysmenorrhea. It also looked at analgesic use during labor and delivery. The authors concluded that OMT could be effective on pregnancy related back pain but was uncertain in other gynecologic and obstetric conditions. Only three studies listed adverse events following OMT, lacking sufficient data for analysis (Ruffini et al).

The Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) study from 2016 (Hensel et al) studied the application of OMT to manage pain and dysfunction in pregnant patients during their third trimester. Patients were randomized to either OMT, usual care plus placebo ultrasound, or usual care and the incidence of high-risk status and labor and delivery outcomes were analyzed. Results showed that high-risk status was less likely to develop in patients who received OMT, and the protocol was also safe regarding labor and delivery outcomes. OMT did not Increase the risk of precipitous labor, c-section or operative vaginal delivery. There was also no increase in need for episiotomy, incidence of perineal laceration or meconium fluid when compared to the usual care or the usual care plus placebo groups. Interestingly, the OMT group was 2.3 times more likely to experience prolonged labor when compared to the participants of the usual care group and 4 times more likely to experience prolonged labor when compared to the participants in the usual care plus placebo. It is important to note that the difference in labor durations were not statistically significant in relation to any of the safety outcomes (Hansel et al).

A prospective study was completed in 2019, looking at the effects of OMT on the duration of labor in the inpatient setting (Martingano et al). In this study 100 patients were enrolled, with 50 receiving adjunct OMT along with standard labor management from osteopathic physicians. These patients were matched to 50 control patients, who received standard labor management alone from allopathic physicians. Patients in the OMT group were treated once daily with a standardized protocol including: suboccipital decompression, thoracic inlet release, rib raising, paraspinal inhibition, and sacral inhibition. Every OMT patient received every treatment each day that they were admitted. The study looked at labor duration, meconium fluid, and conversion to a c-section due to failure to progress or lack of descent. All 100 patients in this study received an epidural and oxytocin augmentation of labor. The average duration of labor for controls was 16.57 hours versus 11.34 hours in the OMT group (Martingano et al). These results are in direct contradiction with the former retrospective study completed by Hansel et al in 2016.

Case Study Protocol

Background:

a. Previous research as described in above literature review
b. Does OMT in the 3rd trimester of pregnancy shorten duration of labor?
c. Does OMT in the 3rd trimester of pregnancy reduce risk of perineal laceration, meconium fluid, operative vaginal delivery, or conversion to c-section?
d. Does OMT in the 3rd trimester of pregnancy reduce analgesic use during labor?

Design:

a. Pregnant patients who are 34 weeks to delivery will be recruited through Southwest Michigan Women's Clinic and Cass Community Clinic in Niles, Intercare (Benton Harbor), South Shore Women's Health (Saint Joseph), and BellaNova (Saint Joseph, MI), using referrals and flyers distributed by providers in those offices
b. Patients who wish to participate will call the Longmeadow Primary Care Clinic (number listed on flyer) to schedule an appointment.
c. Participants must discuss their participation in the study with their obstetrical provider and provide a signed information brochure at their first appointment. Signed brochures will be scanned into the patient's chart.
d. Patients will be consented using a tablet in the lobby of the Longmeadow Primary Care Residency Clinic or with Rachelle Pichot, consent form attached
e. If patients have questions about OMT or the study, they will be directed to call the Longmeadow Primary Care Clinic where office staff will be knowledgeable in where to direct the call. Attending DO physicians or participating DO resident physicians will return calls to answer those questions.
f. OMT will be performed by Drs Schaefer, Moreno, Mather, Collingsworth, Gutierrez, and Pearson based on patient's structural exam in relation to the evaluation list below. Additional senior level residents may be included in OMT treatments as the study progresses and more participants wish to join. **OMT is performed regularly by all DO providers at the Longmeadow Primary Care Residency Clinic.**
g. Appointments will be blocked specifically for study participants
h. Study participants will not be charged for these appointments
i. Patients will receive **once weekly treatments** from 34 weeks gestation until delivery. Minimum of one OMT treatment is needed to be included in the study.
j. Exam and treatments to focus on areas commonly affecting pregnant women
    i. Evaluation to include:
        1. Chapman points for uterus and broad ligament
        2. Evaluation and treatment of the occiput using soft tissue and muscle energy techniques
        3. Evaluation and treatment of the thoracic inlet using myofascial release technique

4. Evaluation and treatment of the ribs using muscle energy and counter-strain techniques
5. Evaluation and treatment of the paraspinal musculature using soft tissue and muscle energy techniques
6. Evaluation and treatment of the sacrum using muscle energy and articulatory techniques

k. The control group will be all patients who give birth at Corewell Health – South for the duration of the study per the HIPAA Waiver of Informed Consent.
l. There will be no follow-up with the participants in the study, all data will be gathered with epic, no identifying information will be shared, and patients will not be contacted past their delivery date.

Case Inclusion:

a. Pregnant patients, ages 18-34
b. Primiparous and multiparous
c. Gestational age ≥34 weeks
d. Delivering at Corewell Health South Saint Joseph or Niles hospitals
e. Consent for treatment or as a control
f. English or Spanish speaker

Case Exclusion:

a. Absolute contraindications to OMT
b. Acute abdomen
c. BP >160/110
d. Unexplained visual disturbances
e. Heavy vaginal bleeding preceding delivery
f. <34 weeks gestational age
g. Treatment refusal
h. Magnesium sulfate received for seizure prophylaxis in setting of preeclampsia w/ severe features or severe gestational HTN
i. Scheduled c-section due to prior OB conditions

Data Collection:

a. data to be collected via EPIC charting completed by nurse and obstetrical provider
    i. maternal age
    ii. parity
    iii. gestational age
    iv. number of OMT treatments received
    v. Types of OMT treatments recieved
    vi. preterm delivery before 37 weeks (if applicable)
    vii. duration of labor
    viii. meconium amniotic fluid

ix. perineal laceration occurrence and degree
x. epidural and other analgesic use
xi. need for operative vaginal delivery
xii. need for conversion to c-section
xiii. APGAR scores

b. Data will only be available to primary and secondary investigators
c. Data will be stored in a password protected excel sheet on a protected server
d. Identifying data will not be shared or used in future write ups

Data Analysis:

Unknown at this time, dependent on available software and data

Study Limitations:

a. Propensity of OB providers to convert to CS/OVD
b. Patient preference for OMT/experience with OMT
c. Age of patient
d. Pre-existing physical activity may change outcomes and participation
e. Body habitus
f. Limited number of patients in study
g. Protections in vulnerable patient population

Ethical Considerations:

Benefits: (Carnes, Mars et al. 2010)

- Reduced pain
- Increased mobility
- Reduced lower extremity swelling
- Decreased health care cost

Risks: (Carnes, Mars et al. 2010)

- Increased muscle soreness following treatment- short term, minimal severity, diminished in days
- Localized tenderness/stiffness
- Headaches

Absolute Contraindications: (Carnes, Mars et al. 2010)

General issues

1. No permission given by patient
2. Contraindications have not been established
3. No thorough medical history and physical examination have been conducted

General Medical Conditions

1. Patient has an underlying medical/surgical emergency
2. Acute abdominal pain
3. Sudden unexplained nausea, vomiting or diarrhea

Cardiovascular disorders

1. Hypertensive crisis with BP >190/110 bpm
2. Tendency to collapse (low BP, low BMI)
3. Untreated cardiac insufficiency and arrhythmia

Neurological/Neurovascular disorders

1. Suspected vascular occlusions
2. Acute, intense headache
3. Acute neck stiffness
4. Strong unexplained vertigo
5. Acute paresthesia/paralysis
6. Cauda-Equina Syndrome
7. Sudden visual disturbances

Obstetric & Gynecological disorders

1. Symptoms that risk fetal loss such as contractions and vaginal bleeding
2. Abnormal prenatal tests during pregnancy that OB deems unsuitable

Psychiatric disorders

1. Untreated psychosis
2. Underage or mentally incompetent patients who are unable to give consent
3. Post-traumatic stress
4. Suicidal patients

Adverse Event Reporting

Adverse events that are non-serious will be reported in the Annual Report or Withdrawal of IND report to the FDA, and in the Continuing Review to the IRB. Serious or life-threatening adverse events directly attributable to the test article will be reported to the FDA and IRB in a prompt manner, based on IRB polciies. In general, a serious adverse event (SAE) will meet any of the following conditions:

1) results in death;

2) is life-threatening (places the subject at immediate risk of death from the event as it occurred);

3) results in hospitalization or prolongation of existing hospitalization;

4) results in persistent or significant disability/incapacity;

5) results in a congenital anomaly or a birth defect; or

6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent a severe outcome.

SAE reporting will be based on whether the SAE is possibly, probably or definitely related to the administration of this test article. Abnormal laboratory values will be reported if associated with a clinical abnormality.

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