Pregnancy Research in Osteopathic Manipulation Optimizing Treatment Effects: The PROMOTE Study

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Musculoskeletal Changes in Late Pregnancy

- Center of gravity shifted anteriorly
- Altered head angle
- Increase in kypholordotic strain at cervicodorsal junction
- Compression of thoracic inlet
- Stretch in diaphragm required
- Sacral nutation induced
- Lumbosacral strain
- Changes in load bearing and alignment in legs and feet
Common Conditions in Pregnancy

• Low back pain
  • Compensatory lordosis
  • Stress across vertebral facets of lumbar spine
  • Increases shear forces across intervertebral disc spaces
  • Shortened paraspinal muscles

• Sacroiliac joint pain
  • Excessive connective tissue stretch & microtrauma
  • Increased mobility at SI joint due to distention of pelvis (relaxin)

• Posterior pelvic pain
  • Radiation of pain in posterior part of thigh, extends down below knee*

• Muscle cramps

• Sluggish venous return
  • Lower extremity edema & congestion
  • Hemorrhoids, Varicosities
  • Breast soreness
  • Fluid retention (progesterone)
  • Carpal tunnel syndrome
  • De Quervain’s

• Joint pains

• CNS congestion:
  • Nausea
  • Headaches

• Vomiting

• Progesterone
  • Constipation (decreased peristalsis)
  • Reflux esophagitis (decreased esophageal sphincter tone)

• Expanding uterus
  • Urinary frequency
  • Various paresthesias or radicular symptoms
    • Direct pressure on nerve roots/plexi by gravid uterus or lumbar lordosis
    • Ilioinguinal & iliofemoral nerve distribution
  • Round ligament pain
Pubic pain

Tenderpoints AL5
Inguinal Adductors
Chapman’s Urethra Uterus Ovaries Cystitis

http://paulhead.co.uk/tag/public-clock/
OMM Considerations

**SNS** $T_{10}$-$L_2$
- ↑ vasoconstriction → poor nutrition & O2 exchange
- ↑ uterine contraction
- ↓ threshold for pain for the uterus

**PNS** $S_2$-$4$
- ↑ stimulation:
  - ↑ relaxation of uterine muscle
  - ↑ vasodilation
- ↓ threshold for pain for the cervix

- Lymphatic:
  - Impaired lymphatic flow
    - ↑ tissue congestion
    - Bloating and discomfort

OCSD p.141
Why treat the sacrum and pelvis?
Research on OMT’s effects on pregnancy, labor & delivery

• Decreased labor time
• Decreased pain medication use during delivery
• Decreased nausea/vomiting of pregnancy
• Decreased use of forceps
• Decreased incidence of meconium-staining of the amniotic fluid
• Decreased preterm delivery
OMT & Pregnancy


• 160 women from 4 cities who received prenatal OMT vs 161 from same cities who did not receive prenatal OMT

• In pregnant patients who received prenatal OMT, there were lower rates of:
  • Occurrence of meconium-stained amniotic fluid (6% vs 26%)
  • Preterm delivery (4% vs 12%)
  • Lower use of forceps (0% vs 2%)

• **Prospective study was recommended**
Pilot study design

Subject Recruitment and Consent

Random Assignment

Standard Care Plus OMM

Standard Care Plus Placebo ultrasound

Standard Care Only

Regular visit to OB/GYN clinic
Screening and clearance for study participation

Study Visit: OMM Questionnaires

Study Visit: Placebo Ultrasound Questionnaires

Study Visit: No Intervention Questionnaires

DELIVERY

Regular visit to OB/GYN clinic at 2 and 6 weeks post-partum

Complete Questionnaires.

Funding by the AOA and Osteopathic Heritage Foundation 2002-2005
Results are presented as mean and standard error. There were no statistically significant differences in pain levels among treatment groups.

OMT, osteopathic manipulative treatment; SUT, sham ultrasound treatment; UOBC, usual obstetric care.

Results are presented as mean and standard error. The treatment group ($P = .02$) and time ($P = .01$) main effects and the treatment group $\times$ time interaction effect ($P < .001$) were all statistically significant.

*OMT*, osteopathic manipulative treatment; *SUT*, sham ultrasound treatment; *UOBC*, usual obstetric care.

Summary- pilot study

• N=144

• Pre-delivery outcomes
  • Substantially favorable findings with respect to functional disability
  • Some trends in favorable findings with respect to VAS pain scores

• Labor and delivery outcomes
  • Some trends in favorable findings at delivery (MSAF)
  • No trends in obstetrical complications (sample size too small to assess relatively rare events)

• Larger study needed to evaluate rarer clinical outcomes
PROMOTE study

Pregnancy Research in Osteopathic Manipulation Optimizing Treatment Effects
NIH (NCCAM) study design (part of K23 grant)

1. Subject Recruitment and Consent
2. Random Assignment:
   - Standard Care Plus OMM
   - Standard Care Plus Placebo ultrasound
   - Standard Care Only
3. Regular visit to OB/GYN clinic for screening and clearance for study participation
4. Study Visit:
   - OMM Questionnaires
   - Placebo Ultrasound Questionnaires
   - No Intervention Questionnaires
5. DELIVERY
   - Regular visit to OB/GYN clinic at 2 and 6 weeks post-partum
6. Complete Questionnaires.
Acute improvement in hemodynamic control after osteopathic manipulative treatment in the third trimester of pregnancy

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Summary
Objectives: The physiological changes that occur during pregnancy, including increased blood volume and cardiac output, can affect hemodynamic control, most profoundly with positional changes that affect venous return to the heart. By using Osteopathic Manipulative Treatment (OMT), a body-based modality theorized to affect somatic structures related to nervous and circulatory systems, we hypothesized that OMT acutely improves both autonomic and hemodynamic control during head-up tilt and heel raise in women at 30 weeks gestation.

Design: One hundred subjects were recruited at 30 weeks gestation.

Setting: The obstetric clinics of UNT Health in Fort Worth, TX.

Intervention: Subjects were randomized into one of three treatment groups: OMT, placebo ultrasound, or time control. Ninety subjects had complete data (N = 25, 31 and 34 in each group respectively).

Main outcome measures: Blood pressure and heart rate were recorded during 5 min of head-up tilt followed by 4 min of intermittent heel raising.

Results: No significant differences in blood pressure, heart rate or heart rate variability were observed between groups with tilt before or after treatment (p > 0.36), and heart rate variability was not different between treatment groups (p > 0.55). However, blood pressure increased significantly (p = 0.02) and heart rate decreased (p < 0.01) during heel raise after OMT compared to placebo or time control.
NIH/AOA Physiology Substudy

• Before and after treatment
  • 30 weeks gestation
  • 36 weeks gestation

• Autonomic and hemodynamic measures
  • Heart rate variability
  • Blood pressure variability
  • Leg volume
  • Supine venous flow rate
  • Orthostatic challenge and skeletal muscle pump as physiologic stimuli
Baseline (15 min) → Tilt (5 min) → Tilt and heel raise (4 min)

ΔΔ
OBJECTIVE: The purpose of this study was to evaluate the efficacy of osteopathic manipulative treatment (OMT) to reduce low back pain and improve functioning during the third trimester in pregnancy and to improve selected outcomes of labor and delivery.

STUDY DESIGN: Pregnancy research on osteopathic manipulation optimizing treatment effects was a randomized, placebo-controlled trial of 400 women in their third trimester. Women were assigned randomly to usual care only (UCO), usual care plus OMT (OMT), or usual care plus placebo ultrasound treatment (PUT). The study included 7 treatments over 9 weeks. The OMT protocol included specific techniques that were administered by board-certified OMT specialists. Outcomes were assessed with the use of self-report measures for pain and back-related functioning and medical records for delivery outcomes.

RESULTS: There were 136 women in the OMT group, 131 women in the PUT group, and 133 women in the UCO group. Characteristics at baseline were similar across groups. Findings indicate significant treatment effects for pain and back-related functioning ($P < .001$ for both groups), with outcomes for the OMT group similar to that of the PUT group; however, both groups were significantly improved compared with the UCO group. For secondary outcome of meconium-stained amniotic fluid, there were no differences among the groups.

CONCLUSION: OMT was effective for mitigating pain and functional deterioration compared with UCO; however, OMT did not differ significantly from PUT. This may be attributed to PUT being a more active treatment than intended. There was no higher likelihood of conversion to high-risk status based on treatment group. Therefore, OMT is a safe, effective adjunctive modality to improve pain and functioning during the third trimester.

Key words: low back pain, osteopathic manipulation, pregnancy

Table 4. Primary Outcomes Estimated in a Linear Mixed Effects Model

<table>
<thead>
<tr>
<th></th>
<th>OMT (n=136)</th>
<th>USP (n=131)</th>
<th>SCO (n=133)</th>
<th>Difference Between OMT and SCO Groups</th>
<th>Difference Between OMT and USP Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Now</td>
<td>-.299</td>
<td>-.034</td>
<td>.707</td>
<td>-1.01 (-1.44 to -0.57)</td>
<td>&lt;.001</td>
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<td></td>
<td>-0.26 (-0.7 to 0.17)</td>
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<tr>
<td>Pain Average</td>
<td>-.205</td>
<td>-.364</td>
<td>.175</td>
<td>-0.38 (-0.77 to 0.02)</td>
<td>.065</td>
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<tr>
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<td></td>
<td></td>
<td>0.16 (-0.24 to 0.56)</td>
</tr>
<tr>
<td>Pain Best</td>
<td>-.202</td>
<td>-.154</td>
<td>.478</td>
<td>-0.68 (-1 to -0.36)</td>
<td>&lt;.001</td>
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<tr>
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<td></td>
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<td></td>
<td>-0.05 (-0.38 to 0.28)</td>
</tr>
<tr>
<td>Pain Worst</td>
<td>-.482</td>
<td>-.641</td>
<td>.296</td>
<td>-0.78 (-1.15 to -0.4)</td>
<td>&lt;.001</td>
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<tr>
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<td></td>
<td></td>
<td>0.16 (-0.22 to 0.54)</td>
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<tr>
<td>RMDQ</td>
<td>.676</td>
<td>.469</td>
<td>2.926</td>
<td>-2.25 (-3.18 to -1.32)</td>
<td>&lt;.001</td>
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<td></td>
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<td></td>
<td>0.21 (-0.73 to 1.14)</td>
</tr>
</tbody>
</table>

CI, confidence interval; OMT, Osteopathic Manipulative Treatment; RMDQ, Roland Morris Disability Questionnaire; SCO, Standard Care Only; USP, Ultrasound Placebo.
Values are estimates for mean change in pain and P values are pairwise comparisons using Bonferroni adjustment.

Hensel, KL et al.
AJOG
Placebo potency and effect

- Light-moderate massage
  - Less pain
  - Shorter labor times
  - Lower rates of prematurity

- Placebo effect
  - Assessment and observation
  - Therapeutic ritual (placebo)
  - Supportive patient-practitioner relationship
  - Harvard’s *Program in Placebo Studies and the Therapeutic Encounter*
Growing APAP controversy

• Wheezing and asthma
• Cryptorchidism
• Neurodevelopment
  • Gross motor development
  • Communication
  • Internalizing and externalizing behavior
  • Activity levels
• Systematic Reviews and Meta-analysis
  • Clinical & Experimental Allergy, 2011
    • 93,039 subjects
  • Chest, 2009
    • 425,140 subjects
• FDA Drug Safety Communication 1-9-15
  • Quotes study on APAP and ADD
Incidence of High-risk Status

- SCO
- USP
- OMT

P = .03
<table>
<thead>
<tr>
<th>Table 1: Participant Characteristics by Treatment Group</th>
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<tbody>
<tr>
<td><strong>All</strong></td>
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<tr>
<td>---------</td>
</tr>
<tr>
<td>380</td>
</tr>
<tr>
<td>Age, y* (n = 380)</td>
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<tr>
<td>Nulliparous (n = 380)</td>
</tr>
<tr>
<td>High risk (n = 380)</td>
</tr>
<tr>
<td>Episiotomy or Perineal Laceration (n = 372)</td>
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<tr>
<td>Converted to C-section (n = 379)</td>
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<tr>
<td>Assistive Device used (n = 338)</td>
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<tr>
<td>Meconium Stain (n = 377)</td>
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<tr>
<td>Precipitous Labor (n = 321)</td>
</tr>
<tr>
<td>Prolonged Labor (n = 320)</td>
</tr>
<tr>
<td>Complications (n = 375)</td>
</tr>
<tr>
<td>APGARS Score @ 1 min* (n = 373)</td>
</tr>
<tr>
<td>APGARS Score @ 5 min* (n = 374)</td>
</tr>
</tbody>
</table>

*Data are given in mean (standard deviation).
So what does this mean for my practice?

- Data from this study showed that the application of the OMT protocol does not result in increased risk of high-risk status, in fact, women who received OMT were less likely to develop high risk status.

- The OMT protocol also did not increase risk of precipitous labor, conversion to caesarian section, perineal laceration, meconium-stained amniotic fluid, or requiring the use of forceps or a vacuum device.

- In all the maternal outcomes examined, no difference was reported among the three study groups with the exception of incidence of prolonged labor. Women receiving OMT were able to successfully labor longer and vaginally deliver with no increased incidence of complications, including perineal laceration, episiotomy, and use of forceps or vacuum device.

- The addition of body-based therapies, such as OMT or massage, appears to be a safe intervention to reduce the progression of back pain and decreasing functional status throughout the third trimester.
Bottom line

• These results suggest that the OMT protocol as applied in PROMOTE is a safe intervention during the third trimester, and is effective at slowing the progression of back pain and disability through the end of pregnancy.
PROMOTE Study OMT Protocol

• Sitting
  – Forward-leaning articulatory T-spine
• Supine
  – Cervical ST/MFR
  – OA decompression
  – Thoracic Inlet MFR
• Lateral Recumbent (R and L)
  – Scapulothoracic MFR
  – Lumbosacral ST
• Supine
  – Ab diaphragm MFR
  • Pelvis
    – AP pelvic diaphragm MFR
    – SI articulation
    – Frogleg sacral articulation
    – Innominate rotations
    – Pubic decompression
  • CV4

Video available
http://web.unthsc.edu/info/200677/osteopathic_manipulative_medicine/1490/research
Billing and coding for OMT

• After evaluating a patient and arriving at a diagnosis (which may include somatic dysfunction), it is appropriate to report an evaluation and management (E/M) code to describe the service.
  • Document the following for E/M service code:
    • Chief Complaint • History • Examination • Medical Decision Making

• Append Modifier-25 to the E/M service code
  • (E/M) service is separate and separately identifiable service from the OMT procedure and should be reported separately.
  • The decision to use or not to use OMT is made at each visit, based on the patient’s presentation at that time.

• Document the procedure of OMT
  • Somatic dysfunctions
  • Techniques
  • Response to treatment
Billing and coding for OMT

• Document somatic dysfunction diagnoses
  • M99.00 Segmental and somatic dysfunction of head region
  • M99.01 Segmental and somatic dysfunction of cervical region
  • M99.02 Segmental and somatic dysfunction of thoracic region
  • M99.03 Segmental and somatic dysfunction of lumbar region
  • M99.04 Segmental and somatic dysfunction of sacral region
  • M99.05 Segmental and somatic dysfunction of pelvic region
  • M99.06 Segmental and somatic dysfunction of lower extremity
  • M99.07 Segmental and somatic dysfunction of upper extremity
  • M99.08 Segmental and somatic dysfunction of rib cage
  • M99.09 Segmental and somatic dysfunction of abdomen and other regions

• OMT billed by number of regions treated
  • 98925 1-2 body regions
  • 98926 3-4 body regions
  • 98927 5-6 body regions
  • 98928 7-8 body regions
  • 98929 9-10 body regions
- **PROMOTE Protocol**
  - Forward-leaning articulatory T-spine
  - Cervical ST/MFR
  - OA decompression
  - Thoracic Inlet MFR
  - Scapulothoracic MFR
  - Lumbosacral ST
  - Ab diaphragm MFR
  - AP pelvic diaphragm MFR
  - SI articulation
  - Innominate rotations
  - Pubic decompression
  - CV4

- **Billable regions**
  - Thoracic region (may also be rib if rib S/D diagnosed)
  - Cervical region
  - Head region
  - Thoracic region
  - Upper extremity
  - Lumbar region
  - Abdominal region
  - Pelvic region
  - Sacral region
  - Pelvic region
  - Pelvic region
  - Head region
  - 7-8, or 9-10 regions billable
Protocol video

• [http://jaoa.org/article.aspx?articleid=2578872&resultClick=1](http://jaoa.org/article.aspx?articleid=2578872&resultClick=1)

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Protocol video

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