

PROMOTE Study: Safety of Osteopathic Manipulative Treatment During the Third Trimester by Labor and Delivery Outcomes

Kendi L. Hensel, DO, PhD; Brandy M. Roane, PhD; Anita Vikas Chaphekar, OMS III; and Peggy Smith-Barbaro, PhD

From the Departments of Osteopathic Manipulative Medicine (Dr Hensel), Internal Medicine (Dr Roane), and Obstetrics and Gynecology (Dr Smith-Barbaro) at the University of North Texas Health Science Center Texas College of Osteopathic Medicine (Student Doctor Chaphekar) in Fort Worth.

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Address correspondence to Kendi L. Hensel, DO, PhD, 3500 Camp Bowie Blvd, Fort Worth, TX 76107-2644.

E-mail: kendi.hensel@unthsc.edu

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Background: Few quality data exist on the safety of osteopathic manipulative treatment (OMT) during pregnancy. The Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) study was a randomized controlled clinical trial that studied the application of an OMT protocol to manage pain and dysfunction in pregnant patients during their third trimester.

Objective: To evaluate the safety of an OMT protocol applied during the third trimester of pregnancy by analyzing incidence of high-risk status and labor and delivery outcomes.

Methods: In the PROMOTE study, 400 pregnant patients were randomly assigned to 1 of 3 study groups: usual care plus OMT (OMT), usual care plus placebo ultrasound treatment (PUT), or usual care only (UCO). The incidence of high-risk status of participants and outcomes of labor and delivery, including length of labor, fever in mother during labor, operative vaginal delivery, conversion to cesarean delivery, need for forceps or vacuum device, need for episiotomy, incidence of perineal laceration, meconium-stained amniotic fluid, and infants' Apgar scores, were analyzed.

Results: Data from 380 participants were studied. High-risk status was less likely to develop in participants who received OMT (95% CI, 0.16-0.91; $P=.03$). The OMT protocol also did not increase risk of precipitous labor, operative vaginal delivery, conversion to cesarean delivery, need for forceps or vacuum device, need for episiotomy, incidence of perineal laceration, or meconium-stained amniotic fluid when compared with participants in the other 2 groups ($P>.05$). Of all other maternal outcomes examined, no difference was reported among the 3 treatment groups with the exception of incidence of prolonged labor in the OMT group. Participants receiving OMT had longer durations of labor than participants in the other groups ($P=.002$).

Conclusion: These results suggest that the OMT protocol given during the third trimester of pregnancy as applied in the PROMOTE study is safe with regard to labor and delivery outcomes. The increased duration in labor in the OMT group needs further study. (ClinicalTrials.gov number NCT00426244)

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Since the founding of osteopathic medicine in the late 19th century, osteopathic manipulative treatment (OMT) has been used for patients of all ages, including pregnant women.^{1,2} Given the nonpharmaceutical option of treatment, a case could be made that OMT would be preferable as a means for managing pregnancy-related pain and dysfunction. However, safety data on OMT use in pregnant women are lacking and, therefore, informed clinical decision making is difficult. Data collected by Whiting³ in the early 1900s suggests a benefit from OMT, showing that women who received OMT during their pregnancy had shorter labor duration than the national average at the time.³ A more recent study indicate that OMT may lessen the incidence of some commonly occurring complications of labor and delivery, such as meconium-staining of the amniotic fluid, precipitous labor, and the need for forceps use.⁴

A high-risk pregnancy is one in which an increased risk of health complications develops in the mother or fetus. Complications may include gestational hypertension, gestational diabetes, preeclampsia, or eclampsia. Gestational hypertension, defined as an increase in blood pressure at or after the 20th week of gestation, is estimated to occur in about 10% of pregnant women.^{5,6} Pregnant women are considered to have preeclampsia if their hypertension is accompanied by proteinuria or signs of organ function impairment.⁵ Preeclampsia occurs in about 3.8% of pregnancies, and it puts both the mother and fetus at risk for long-term health complications and possibly death.⁷ Gestational diabetes is another complication that manifests in 2% to 10% of pregnancies⁸ and, if not well controlled, can lead to preeclampsia, hypertension, and preterm labor.⁹

Labor and delivery can also be associated with complications in mother and fetus. Precipitous labor is labor and delivery that occurs quickly, typically less than 3 hours after the onset of contractions.¹⁰ Precipitous labor

can lead to uterine atony, which puts the mother at risk for postpartum hemorrhage.¹⁰ Possible fetal complications include deprivation of oxygen, brachial palsy, and, rarely, intracranial trauma.¹⁰ Conversely, prolonged second-stage labor is associated with an increase in postpartum hemorrhage, perineal lacerations, and chorioamnionitis; however, a prolonged second-stage labor does not seem to have deleterious consequences in newborns.¹¹

Vaginal delivery itself has associated risks, such as the need for episiotomy or instrument-aided delivery. Risks after episiotomy include pain, fistula formation, and incontinence, all of which could negatively affect long-term health and well-being.¹² Perineal laceration is another potential complication of vaginal birth. Risk factors associated with perineal laceration include episiotomy and use of forceps or vacuum device during delivery.¹³ A delivery in which forceps or a vacuum device is used is known as an operative vaginal delivery and occurs in 3.3% of all deliveries in the United States.¹⁴ Operative vaginal deliveries have recognized maternal and fetal complications, similar to those seen with episiotomy. An additional complication during labor and delivery is meconium-stained amniotic fluid, which could lead to meconium aspiration syndrome in a newborn. Infants with meconium aspiration syndrome present with respiratory distress and potential long-term complications of pulmonary hypertension.¹⁵

Clinical studies have shown that OMT used during pregnancy improves musculoskeletal pain, such as low back pain, and may positively affect some labor and delivery outcomes.^{4,16} The primary objective of the current study was to compare the incidence of high-risk status as well as labor and delivery outcomes in pregnant women who received an OMT protocol during the third trimester. Labor and delivery outcomes analyzed were length of labor, perineal lacerations, operative vaginal delivery, meconium-stained amniotic fluid, and infants' Apgar scores.

Methods

This study analyzed participant status at term and labor and delivery data collected during the Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) Study (ClinicalTrials.gov number NCT00426244) conducted from 2007 to 2011. The PROMOTE study was a randomized controlled clinical trial that measured the primary outcomes of back-specific pain and functioning in participants aged 18 to 34 years. This study was approved by the University of North Texas Health Science Center Institutional Review Board. Participants were randomly divided into 3 groups—usual care plus OMT (OMT), usual care plus placebo ultrasound treatment (PUT), and usual care only (UCO).

Participants were scheduled for 7 treatment visits at 30, 32, 34, 36, 37, 38, and 39 weeks of gestation. The OMT and PUT visits lasted approximately 20 minutes. Participants in the OMT group were evaluated for severity of dysfunction in body regions typically associated with pregnancy-related pain and dysfunction and then underwent an OMT protocol. The protocol included the following techniques: seated forward-leaning thoracic spine articulator; supine cervical soft tissue myofascial release (MFR), occipitoatlantal decompression, thoracic inlet MFR, lateral recumbent scapulothoracic MFR, lumbosacral soft tissue, abdominal diaphragm MFR, pelvic diaphragm MFR, sacroiliac articulation, frog-leg sacral release, pubic symphysis decompression, and compression of the fourth ventricle.¹⁷

Participants in the PUT group were treated with an ultrasound wand that did not emit any ultrasound waves. The wand was applied with no gel over the clothing to body regions similar to those targeted with the OMT protocol. The PUT was performed by the same physicians who provided the OMT protocol, and the session was approximately the same length as the OMT protocol. The UCO group received no additional treatment.

Labor and delivery data points were collected from the participants' medical records at the hospital where they gave birth. Data included high-risk status; length of labor; fever in mother during labor, operative vaginal

delivery, conversion to cesarean delivery, need for forceps or vacuum device, need for episiotomy, incidence of perineal laceration, meconium-stained amniotic fluid, and infants' Apgar scores. High-risk status was defined as any clinical factor that required a change in evaluation frequency, medications, or activity level, including gestational hypertension, gestational diabetes, preeclampsia, eclampsia, precipitous labor, or oligohydramnios.

For our purposes, precipitous labor was defined as labor lasting less than 3 hours, and prolonged labor, labor lasting more than 20 hours. We attempted to capture hours and minutes of labor, but because of inconsistent reporting, we had to default to the categorization of precipitous or prolonged. For example, roughly one-third of participants delivered at a teaching hospital, and in reviewing the medical records, the time noted for labor onset would vary widely between the documentation of the medical students, residents, nurses, and attending physicians. For consistent data collection, we recorded the nurses' documentation, because the labor and delivery nurses usually provided the most complete intake information.

Data management and analyses were performed with SPSS version 20 (IBM Corporation). Demographic characteristics were described by frequencies and percentages for nominal data and by means and SDs for continuous data. Logistic regression analyses examined differences between the 3 treatment groups for safety outcomes with nulliparous and age as covariates. Posthoc analyses were run examining treatment group differences for significant findings. Significance was a priori set at $P < .05$, and trending findings were set at $P < .10$.

Results

A total of 400 participants were enrolled in PROMOTE and randomly assigned to groups, and 380 of these women provided data on parity status and age. As shown in the *Table*, 129 women were assigned to OMT, 122 participants to PUT, and 129 participants to UCO. Treatment groups did not statistically differ on nulliparous status ($P = .991$) or age ($P = .299$). Detailed demographic

Table.
Participant Characteristics by Treatment Group in the PROMOTE Study^a

Characteristic	No. of Patients	All (N=380)	UCO (n=129)	PUT (n=122)	OMT (n=129)	P Value
Age, mean (SD), y	380	24.3 (4.2)	24.8 (4.5)	24.1 (4)	24.1 (4.1)	.299
Nulliparous	380	131 (34.5)	45 (34.4)	42 (32.1)	44 (33.6)	.991
High risk ^b	380	43 (11.3)	19 (44.2)	16 (37.2)	8 (18.6)	.030
Precipitous labor	321	10 (2.6)	5 (50)	2 (20)	3 (30)	.537
Prolonged labor	320	47 (12.4)	14 (29.8)	8 (17.0)	25 (53.2)	.003
Complications	375	48 (12.6)	18 (37.5)	15 (31.3)	15 (31.3)	.835
Converted to cesarean delivery	379	38 (10.0)	14 (36.8)	10 (26.3)	14 (36.8)	.714
Forceps or vacuum device	338	10 (3)	5 (50)	1 (10)	4 (40)	.235
Episiotomy or perineal laceration	372	152 (40.9)	57 (37.5)	44 (28.9)	51 (33.6)	.487
Meconium-stained amniotic fluid	377	68 (18.0)	21 (30.9)	24 (35.3)	23 (33.8)	.786
Apgar score at 1 min, mean (SD)	373	8.5 (1.1)	8.4 (1.2)	8.4 (1)	8.6 (1)	.158
Apgar score at 5 min, mean (SD)	374	8.9 (0.5)	8.9 (0.3)	8.9 (0.6)	8.9 (0.6)	.702

^a Data are given as No. (%) unless otherwise indicated. Percentages are calculated across rows rather than by columns.

^b Defined as any clinical factor requiring a change in evaluation frequency, medications, or activity level, including gestational hypertension, gestational diabetes, preeclampsia, eclampsia, preterm labor, or oligohydramnios.

Abbreviations: OMT, osteopathic manipulative treatment; PROMOTE, Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects; PUT, placebo ultrasound treatment; UCO, usual care only.

data for these participants have been published, and no significant differences were found in demographic measures between treatment groups.¹⁶

Logistic regression analyses found no significant difference between treatment groups, with UCO as the reference group, for all outcomes except high-risk classification ($P=.03$) and prolonged labor ($P=.003$). Posthoc analyses showed that participants who received OMT were 2.6 times less likely to be classified as high risk compared with participants in the UCO group (95% CI, 0.16-0.91; $P=.03$), and trend findings showed that participants in the OMT group were 2.3 times less likely to be classified as high risk compared with participants in the PUT group (95% CI, 0.18-1.06; $P=.068$). For prolonged labor, posthoc analyses showed that participants

who received OMT were 2.3 times more likely to experience prolonged labor compared with participants in the UCO group (95% CI, 1.10-4.89; $P=.028$) and 4 times more likely to experience prolonged labor compared with participants in the PUT group (95% CI, 1.70-9.84; $P=.002$). Participants in the PUT and UCO groups showed no significant difference in likelihood to experience prolonged labor ($P=.23$). Owing to the higher likelihood of prolonged labor in the OMT group, posthoc analyses were performed to compare treatment groups by prolonged labor status for safety outcomes except the need for forceps or vacuum device (because of insufficient sampling across the 3 treatment groups for prolonged labor). Logistic regression analyses showed no statistically significant differences between treatment groups

for length of labor on any of the safety outcomes ($P=.16$ to $P=.71$). Two trend findings did emerge for conversion to cesarean delivery and episiotomy or perineal laceration; however, the span of the CIs for these findings suggests that they have questionable validity.

Analyses of covariance examining Apgar scores showed no statistically significant differences between treatment groups at 1 minute ($F_{2,371}=1.85$; $P=.159$) and 5 minutes ($F_{2,371}=0.39$; $P=.675$); however, pairwise comparisons revealed a trend difference between the OMT and UCO group scores at 1 minute (8.6 vs 8.4; $P=.061$). No other statistically significant or trend findings were found between groups. Posthoc analyses of Apgar scores at 1 minute and 5 minutes did not differ significantly between treatment groups in participants who experienced prolonged labor ($P=.972$ and $P=.454$, respectively) or in participants who did not experience prolonged labor ($P=.237$ and $P=.402$, respectively).

Discussion

With any new treatment, studies must first be conducted to assess the safety and effectiveness of the treatment. Although OMT has been used in pregnant patients for over a century,^{1,2} few safety data exist. The primary outcome measures of the PROMOTE study were pain and functional status, and the findings demonstrated that OMT was effective at improving those measures during the third trimester compared with UCO.¹⁶ The current study aimed to demonstrate that OMT as applied in the PROMOTE study is also safe.

Data from the current study show that the application of PROMOTE's OMT protocol does not cause an increased risk in high-risk status, defined as any clinical factor that requires a change in evaluation frequency, medications, or activity level, including gestational diabetes, gestational hypertension, precipitous labor, preeclampsia, or oligohydramnios, nor does it increase the risk of precipitous labor, conversion to cesarean delivery, need for forceps or vacuum device, need for

episiotomy, incidence of perineal laceration, or meconium-stained amniotic fluid. With many of the high-risk conditions occurring infrequently, with insignificant differences between groups, we gathered them into 1 category. In all maternal outcomes examined, results from our study showed no difference among the 3 study groups with the exception of incidence of prolonged labor (*Table*).

The finding of an increased incidence of prolonged labor is contradictory with the finding of shorter labor times reported by Whiting.³ Some methodologic issues may at least partially explain this finding. Whiting³ was the delivering physician for all of the participants in her study, and she also documented the labor times. She was internally consistent as to how she assisted her patients during labor. In the PROMOTE study,¹⁶ multiple history-takers were involved, and a notable discrepancy in labor times was found in the medical records. Therefore, we decided not to analyze specific labor times, but instead to focus on the 2 categories of precipitous (<3 hours) and prolonged (>20 hours). Longer labor durations have been reported to carry a risk of maternal fatigue and ensuing fetal distress, which may lead to a higher risk of conversion to cesarean delivery as well as increased risk of chorioamnionitis and postpartum hemorrhage.¹⁸ Data from our study showed that participants who received OMT had longer labor duration and successfully delivered vaginally with no increased incidence of complications, including need for forceps or vacuum device, need for episiotomy, perineal laceration, or meconium-stained amniotic fluid (*Table*).

Another potential limitation of these data is that previous findings have suggested that prolonged labor is most often due to inefficient uterine contraction.¹⁹ Our OMT protocol could be theorized to optimize uterine tone and contractions by targeting the origin of the autonomic supply to the uterus. Yet, prolonged labor occurred at an increased rate in the OMT group. A full exploration of that question is not within the scope of the captured data.

Conclusion

When using high-risk status and labor and delivery outcomes as an index for safety, no greater risk in the OMT group was found. Rather, there was a trend toward a mild protective effect of the OMT protocol on the development of high-risk status. This trend would indicate that the OMT protocol as applied in the PROMOTE study is a safe intervention during the third trimester.

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Author Contributions

Drs Hensel and Roane provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; Student Doctor Chaphekar and Dr Smith-Barbaro drafted the article or revised it critically for important intellectual content; all authors gave final approval of the version of the article to be published; and all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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