Does Compression of the Fourth Ventricle Cause Preterm Labor? Analysis of Data From the PROMOTE Study

Kendi L. Hensel, DO, PhD; Brandy M. Roane, PhD

From the University of North Texas Health Science Center in Fort Worth. This manuscript was prepared in partial fulfillment of the requirements to earn the designation of Fellow of the American Academy of Osteopathy (FAAO) for Dr Hensel.

Disclaimer: Dr Hensel, a JAOA associate editor, was not involved in the editorial review or decision to publish this article.

Financial Disclosures: None reported.

Support: This study was supported by grants number K23AT003304 and K23AT3304-4S1 from the National Center for Complementary and Alternative Medicine at the National Institutes of Health and grant number 06-11-549 from the American Osteopathic Association.

Additional financial support was provided by the Medical Education Foundation of the American College of Osteopathic Obstetricians and Gynecologists, the American Academy of Osteopathy, the Osteopathic Heritage Foundations, and the Osteopathic Research Center at the University of North Texas Health Science Center. It was also supported by the UNT Health Department of Obstetrics and Gynecology and FOR HER.

Address correspondence to Kendi L. Hensel, DO, PhD, University of North Texas Health Science Center, 3500 Camp Bowie Blvd, Fort Worth, Texas 76107-2644. Email: kendi.hensel@unthsc.edu

Submitted
February 6, 2019;
accepted
March 11, 2019.

Background: The technique for the compression of the fourth ventricle (CV4) in the brain has been described as a method of reaching the physiologic centers that reside in its floor and of restoring optimal flow of the cerebrospinal fluid. However, a study published as an abstract in 1992 questioned whether CV4, when applied to pregnant women, could induce uterine contractions and possibly labor.

Objective: To further examine whether CV4 could induce uterine contractions and labor as part of the osteopathic manipulative treatment (OMT) protocol used in the Pregnancy Research in Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) study.

Methods: Labor and delivery data collected during the PROMOTE study from 2007-2011 were analyzed. The PROMOTE study was funded by the National Institutes of Health and was a randomized controlled clinical trial that measured the primary outcomes of back-specific functioning and pain in pregnant women aged 18 to 34 years. Participants were randomly divided into 3 groups—usual obstetric care only, placebo ultrasound treatment plus usual obstetric care, and OMT plus usual obstetric care. Study participants were scheduled for 7 treatment visits. Presented data were gathered from labor and delivery records.

Results: Four hundred participants were included. No significant differences were identified between treatment groups for the development of high-risk status ($P=.293$) or preterm delivery ($P=.673$). Evaluation of high-risk status by preterm delivery for the groups also showed no significant differences between groups ($P=.455$).

Conclusion: The application of CV4 as part of an OMT protocol during the third trimester caused neither a higher incidence of preterm labor nor the development of high-risk status.

J Am Osteopath Assoc. 2019;119(10):668-672
doi:10.7556/jaoa.2019.114

Keywords: compression of the fourth ventricle, CV4, obstetrics, osteopathic manipulative treatment, preterm delivery

Compression of the fourth ventricle (CV4) is an osteopathic manipulative treatment (OMT) technique that William G. Sutherland, DO, described as a way to “reach the entire system” through the physiologic centers that reside in the floor of the fourth ventricle.¹ The technique was most simply described as a way to “normalize fluctuation of the cerebrospinal fluid.”²

Sutherland¹ discussed the use of CV4 as a treatment option for various conditions relating to dysfunction of the fluids and tides within the body. In 1976, Magoun² briefly discussed the use of CV4 for uterine inertia, stating that application of the technique was “usually quite effective” at reviving uterine muscle activity. He mentioned the use of CV4 during pregnancy as perhaps assisting with contractions but not causing continuous contractions.

Gitlin and Wolf³ conducted a study to determine whether CV4 would induce uterine contractions in 8 pregnant women at 38 to 42 weeks’ gestation. Two women were eliminated from data analysis, but the remaining 6 women all experienced uterine contractions within a mean of 17.5 minutes. One of the women progressed to delivery within 24 hours and 1 felt contractions for the next 24 hours, but no mention was made of the other 4 participants.³ No larger studies have been conducted to examine this effect. However, it has been extrapolated from the Gitlin and Wolf study³ that CV4 is contraindicated during pregnancy out of a fear that it may cause preterm labor.

The treatment protocol for the Pregnancy Research in Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) Study included CV4 in the protocol to further examine this question.

Methods

This study involves analysis of labor and delivery data collected during the PROMOTE study, which was conducted from 2007 to 2011. The PROMOTE study was funded by the National Institutes of Health and was a randomized controlled clinical trial that measured the primary outcomes of back-specific functioning and pain in pregnant women aged 18 to 34 years. This study was approved by the institutional review board at the University of North Texas Health Science Center. Participants were randomly divided into 3 groups—usual obstetric care only (UCO), placebo ultrasound treatment (PUT) plus usual obstetric care, and OMT plus usual obstetric care.

Study 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. The OMT group received a protocol treatment that included all of the following techniques: seated thoracic articulation, cervical soft tissue, occipitotantal decompression, thoracic inlet myofascial release, lateral recumbent scapulothoracic soft tissue, lateral recumbent lumbar soft tissue, abdominal diaphragm myofascial release, pelvic diaphragm myofascial release, sacroiliac articulation, pubic symphysis decompression, frog-leg sacral release, and CV4. Thus, all OMT group participants received CV4. A detailed description of the protocol was previously published.⁴

In the PUT group, an ultrasound wand that did not emit any ultrasound waves was applied in similar areas as the OMT techniques. The PUT protocol was performed by the same treating physicians as the OMT protocol and lasted approximately the same amount of time. The UCO group had no treatment performed.

Labor and delivery data points were collected from medical records from the hospital birth location. Data points collected included length of labor, use of episiotomy, degree of perineal laceration, fever in mother during labor, characteristics of amniotic fluid (eg, meconium stained, bloody, clear), use of forceps, use of vacuum device, and Apgar scores. High-risk conditions that occurred during pregnancy were also collected, including gestational hypertension, gestational diabetes, preterm labor, preeclampsia, eclampsia, and oligohydramnios, among others.

Data Analyses

Data management and analyses were performed using SPSS version 20 (IBM). Demographic characteristics were described by frequencies and percentages for categorical data and by means and SDs for continuous data. Analyses of variance were run to examine significant group differences in age, gestational weeks, and total study visits. Preliminary cross-tabular analyses examined potential differences between the 3 treatment groups (UCO, PUT, and OMT) for additional

Table 1.
Use of Compression of the Fourth Ventricle in the PROMOTE Study: Participant Characteristics by Treatment Group

Variable	n	All (N=366)	Usual Care Only (n=124)	Placebo Ultrasound Treatment (n=116)	Osteopathic Manipulative Treatment (n=126)	P Value
Age, y, mean (SD)	360	24.3 (4.2)	24.5 (4.5)	24.0 (4)	24.1 (4.1)	.117
Visits made, mean (SD)	366	5.6 (1.2)	5.7 (1.2)	5.5 (1.2)	5.6 (1.1)	.514
Gestational weeks, mean (SD)	365	39.1 (1.2)	39.0 (1.1)	39.1 (1.3)	39.2 (1.2)	.149
Previous preterm birth, mean (SD)	362	0.09 (0.4)	0.10 (0.4)	0.07 (0.3)	0.09 (0.3)	.811
Nulliparous, No. (%)	366	125 (34.2)	42 (33.9)	41 (35.3)	42 (33.3)	.944

Abbreviation: PROMOTE, Pregnancy Research in Osteopathic Manipulation Optimizing Treatment Effects.

demographics, high-risk status, and preterm delivery. Multinomial logistic regression analyses were conducted to further examine statistically significant differences between the 3 groups. Statistical significance was a priori set at $P < .05$.

Results

A total of 400 participants were enrolled in the PROMOTE study and were randomly assigned to 1 of the 3 study groups. Of the 400 enrolled participants, 366 provided data on age, parity, and delivery status and attended at least 3 study visits. Of these 366 women, 124 were assigned to UCO, 116 to PUT, and 126 to OMT (Table 1). Treatment groups did not significantly differ regarding age ($P = .117$) or parity ($P = .944$). Detailed demographic data for these women has previously been published and showed no significant difference between treatment groups on demographic measures.⁵

Crosstabular analyses (Table 2) indicated no significant differences between treatment groups for high-risk status ($P = .293$) or preterm delivery ($P = .673$). Examination of high-risk status by preterm delivery for the groups (Table 3) also showed no significant differ-

ences between groups ($P = .455$). Logistic regression analyses also showed no significant differences for high-risk status or preterm delivery ($P = .920$), with the latter including high-risk status and previous preterm delivery as covariates. Both high-risk status and previous preterm delivery were significant predictors of preterm delivery. High-risk status increased the likelihood of preterm delivery by 5.2 times ($P < .001$), and previous preterm delivery increased the likelihood of preterm delivery during the current pregnancy by 1.6 times ($P = .019$).

Discussion

According to the PROMOTE data, application of CV4 as part of the PROMOTE study OMT protocol starting at week 30 of gestation did not cause any higher risk of preterm delivery. Other data relating to additional outcomes of pregnancy, labor, and delivery have been published separately and demonstrate the safety of the study protocol.⁶

The legacy of the study by Gitlin and Wolf³ is an excellent illustration of several concepts: (1) the study was generally misinterpreted and was the basis for erroneous generalizations that have become policy; (2) no

Table 2.
Use of Compression of the Fourth Ventricle in the PROMOTE Study: High-Risk and Preterm Delivery Status by Treatment Group^a

Variable	Usual Care Only (n=24)	Placebo Ultrasound Treatment (n=116)	Osteopathic Manipulative Treatment (n=126)	χ^2	P Value
High-Risk Status					
High risk	15 (12.1)	11 (9.5)	8 (6.3)	2.458	.293
Not high risk	109 (87.9)	105 (90.5)	118 (93.7)		
Preterm Delivery Status ^b					
Preterm delivery	5 (4.1)	5 (4.3)	3 (2.4)	0.791	.673
No preterm delivery	118 (95.9)	111 (95.7)	123 (97.6)		

^a Data provided as No. (%) except where otherwise indicated.

^b Data missing on preterm delivery status for 1 participant.

Abbreviation: PROMOTE, Pregnancy Research in Osteopathic Manipulation Optimizing Treatment Effects.

follow-up or larger related study was done for more than 2 decades; and (3) the misinterpretation of data from Gitlin and Wolf³ became professional dogma rather than validated evidence. Reversing the effect of these errors may take years or even decades. In the meantime, physicians who use CV4 on their pregnant patients face a medicolegal risk because osteopathic literature cites pregnancy as a contraindication for CV4.⁷

A Google search on “CV4-induce labor” retrieves multiple lectures and websites stating that CV4 may induce preterm labor.^{8,9} Resources for students, including Quizlet flash cards¹⁰ and the OMM Guide app,¹¹ state that CV4 “can induce labor” and is a “relative contraindication in pregnancy; only indicated for [labor] induction.” An online student forum¹² demonstrates that osteopathic medical students have been taught that “CV4

Table 3.
Use of Compression of the Fourth Ventricle in the PROMOTE Study: High-Risk and Preterm Delivery Status by Treatment Group^{ab}

Treatment Group	No High Risk / No Preterm Delivery	No High Risk / Preterm Delivery	High Risk / No Preterm Delivery	High Risk / Preterm Delivery
Usual obstetric care only (n=123)	107 (87)	1 (0.8)	11 (8.9)	4 (3.3)
Placebo ultrasound treatment (n=116)	105 (90.5)	0	6 (5.2)	5 (4.3)
Osteopathic manipulative treatment (n=126)	118 (93.7)	0	5 (4)	3 (2.4)

^a Data provided as No. (%) except where otherwise indicated.

^b Data missing on preterm delivery status for 1 participant.

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technique can induce labor.” *Foundations of Osteopathic Medicine*¹³ is unclear on the point, stating that “It is probably incorrect to be concerned about the use of CV4 in pregnant women.” The result of these types of statements is perpetuation of the misinformation, which may now begin to diminish with the addition of some countering evidence to the literature.

This study is not without limitations. The small sample sizes in the high-risk and preterm delivery groups likely affected the ability to ascertain significant group differences. Cell frequencies were also further lowered by the restriction to at least 3 study visits to consider realistic therapeutic effects. Future studies should address these issues, and may also consider comparing CV4 as part of a protocol to the application of a CV4 by itself.

Conclusion

Based on the data from the PROMOTE study, the application of an OMT protocol that includes CV4 during the third trimester is a safe intervention and is not associated with an increased risk of preterm delivery.

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