OBSTETRICS

Osteopathic manipulative treatment of back pain and related symptoms during pregnancy: a randomized controlled trial

John C. Licciardone, DO, MS, MBA; Steve Buchanan, DO; Kendi L. Hensel, DO, PhD; Hollis H. King, DO, PhD; Kimberly G. Fulda, DrPH; Scott T. Stoll, DO, PhD

OBJECTIVE: To study osteopathic manipulative treatment of back pain and related symptoms during the third trimester of pregnancy.

STUDY DESIGN: A randomized, placebo-controlled trial was conducted to compare usual obstetric care and osteopathic manipulative treatment, usual obstetric care and sham ultrasound treatment, and usual obstetric care only. Outcomes included average pain levels and the Roland-Morris Disability Questionnaire to assess back-specific functioning.

RESULTS: Intention-to-treat analyses included 144 subjects. The Roland-Morris Disability Questionnaire scores worsened during pregnancy; however, back-specific functioning deteriorated significantly less in the usual obstetric care and osteopathic manipulative treatment group (effect size, 0.72; 95% confidence interval, 0.31–1.14; $P = .001$ vs usual obstetric care only; and effect size, 0.35; 95% confidence interval, −0.06 to 0.76; $P = .09$ vs usual obstetric care and sham ultrasound treatment). During pregnancy, back pain decreased in the usual obstetric care and osteopathic manipulative treatment group, remained unchanged in the usual obstetric care and sham ultrasound treatment group, and increased in the usual obstetric care only group, although no between-group difference achieved statistical significance.

CONCLUSION: Osteopathic manipulative treatment slows or halts the deterioration of back-specific functioning during the third trimester of pregnancy.

Key words: back pain, osteopathic manipulative treatment, physical functioning, pregnancy, randomized controlled trial

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Previous studies have found that a majority of pregnant women report low back pain during pregnancy.[1-4] Other common neuromusculoskeletal problems during pregnancy include pubic pain, hip pain, knee pain, leg cramps, carpal tunnel syndrome, and DeQuervain's tenosynovitis.[5,6] When considering such neuromusculoskeletal aspects of pregnancy, virtually all women experience symptoms during pregnancy, with an estimated one quarter having at least temporary disability.[7] Moreover, pregnancy-related back pain is often associated with sleep disturbance and may affect activities of daily living or quality of life.[1,3,4]

Complementary and alternative medicine (CAM) therapies may be considered as treatment options for back-related symptoms during pregnancy because of the real or unknown risks inherent with many drug therapies. A majority of pregnant women and prenatal health care providers alike report that they would consider using CAM therapies for low back pain during pregnancy, particularly manipulative and body-based practices such as massage and spinal manipulation.[8] Osteopathic manipulative treatment (OMT) is a form of manual therapy provided by osteopathic physicians. An intriguing aspect of OMT is that during pregnancy, unlike massage therapy or chiropractic, it potentially could be integrated with the routine prenatal visits provided by osteopathic obstetricians. However, relatively little research has been conducted on OMT during pregnancy. An observational study using medical records review at 4 sites found that prenatal OMT was associated with lowered risk of preterm delivery and meconium staining of amniotic fluid.[9] Nevertheless, corroborating evidence of OMT benefits during pregnancy from prospective studies or clinical trials is lacking. The primary purpose of this randomized controlled trial was to explore the potential effects of OMT provided exclusively during the third trimester of pregnancy on maternal back pain and related physical functioning.

Materials and Methods

This Phase II randomized controlled trial was conducted by The Osteopathic

From The Osteopathic Research Center (Drs Licciardone, Hensel, King, and Stoll), the Department of Obstetrics and Gynecology (Dr Buchanan), and the Primary Care Research Institute (Dr Fulda), University of North Texas Health Science Center, Fort Worth, TX.

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Reprints: John C. Licciardone, DO, MS, MBA, 3500 Camp Bowie Boulevard, Fort Worth, TX 76107. licciar@hsc.unt.edu.

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Research Center at the University of North Texas Health Science Center. Recruitment was open from July 2003 through December 2005 within the Department of Obstetrics and Gynecology at the University of North Texas Health Science Center. All study procedures were approved by the Institutional Review Board for Protection of Human Subjects. The study was also registered with ClinicalTrials.gov (www.clinicaltrials.gov, NCT00298935).

Obstetric clinic patients were screened up to the 30th week of pregnancy for eligibility and willingness to participate in the study. Exclusion criteria included either of the following: (1) intent to deliver at a nondesignated hospital or (2) high-risk pregnancy as determined by the attending obstetrician. The latter criterion included, but was not limited to gestational diabetes, preeclampsia, placenta previa, and abruptio placentae. Clinic patients who met the eligibility criteria and provided informed consent were enrolled as subjects between the 28th and 30th weeks of pregnancy and were then randomly assigned as trial subjects.

Each subject was randomly assigned to 1 of 3 treatment groups: (1) usual obstetric care and OMT (UOBC+OMT); (2) usual obstetric care and sham ultrasound treatment (UOBC+SUT); or (3) usual obstetric care only (UOBC only). In this trial, "usual obstetric care" refers to conventional prenatal care during pregnancy exclusive of OMT, which is generally considered a CAM therapy.[10] Subjects were stratified by age and gravida number on the theoretical basis that these factors may influence response to OMT. Twenty-four years was estimated to be the median age of clinic patients seeking obstetric care based on previous records, and we arbitrarily stratified subjects as primigravida or multigravida. Hence, the 4 age- and gravid-specific strata were as follows: (1) age ≤24 years and primigravida; (2) age ≤24 years and multigravida; (3) age ≥25 years and primigravida; and (4) age ≥25 years and multigravida. Blocked treatment assignments were then made within each of the 4 age- and gravid-specific strata.[11] Blocks of 6 subjects were used to randomly assign 2 subjects to each of the 3 treatment groups within each age- and gravid-specific stratum. Assuming continued eligibility and pregnancy, the UOBC+OMT and UOBC+SUT groups were scheduled to receive treatments at the 30th week (visit 1), 32nd week (visit 2), 34th week (visit 3), 36th week (visit 4), 37th week (visit 5), 38th week (visit 6), and 39th week (visit 7). Each treatment visit was scheduled to last 30 minutes.

The OMT protocol consisted of a standardized approach whereby each assigned subject received treatment provided by licensed physician faculty within the Department of Osteopathic Manipulative Medicine at the University of North Texas Health Science Center. The study protocol included any of the following treatment modalities: soft tissue, myofascial release, muscle energy, and range-of-motion mobilization.[12] These modalities were used in a systematic manner within a protocol that enabled the physician to identify and treat specific somatic dysfunctions in the following anatomic regions: cervical, thoracic, and lumbar spine; thoracic outlet and clavicles; ribcage and diaphragm; and pelvis and sacrum. Treatment providers met regularly to ensure consistency in the duration, type, anatomic location, and manner of manipulation provided throughout the trial. The study protocol prohibited use of high-velocity, low-amplitude techniques because the increasing ligamentous laxity that occurs in late pregnancy may pose a theoretical risk in performing such maneuvers. A cranial technique known as compression of the fourth ventricle (CV-4) was also prohibited on theoretical grounds that it may potentially induce premature labor, although the small uncontrolled study suggesting that CV-4 may initiate uterine contractions involved only postdate women.[13]

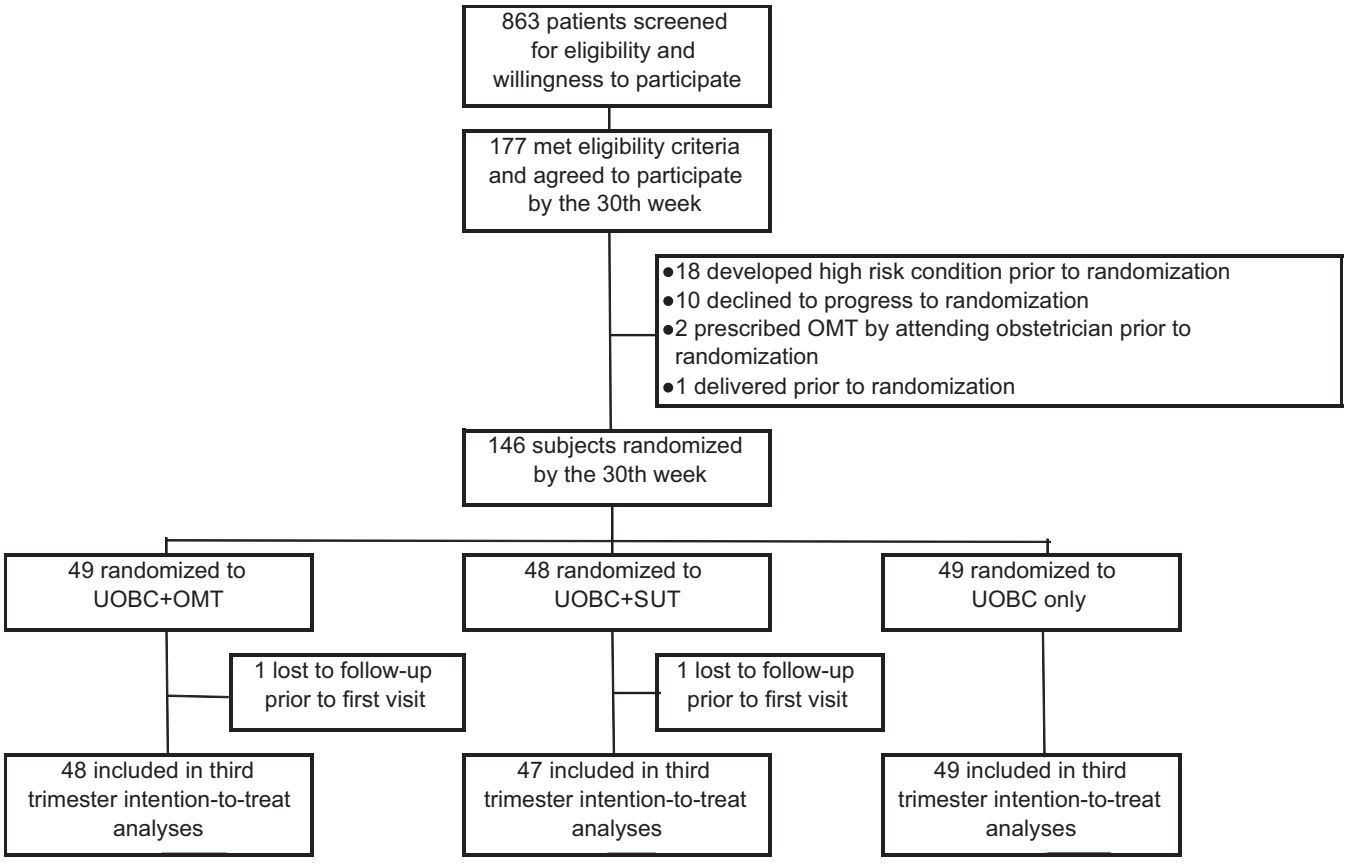
The SUT protocol was adapted from that described in a previous randomized controlled trial of manual therapy.[14] The SUT treatments were provided by the same physicians who provided OMT. In addition to controlling for physician attention during the treatment visit, the SUT used a nonfunctional ultrasound therapy unit that was modified for research purposes to provide both visible and auditory cues that could potentially elicit a placebo response. The physician provided the SUT by placing the applicator head over the subject's clothing and applying sufficient pressure for tactile stimulation of the skin and underlying tissues in the same anatomic distributions as would generally be addressed if the subject were being treated with OMT.

The subjects assigned to the UOBC-only group did not receive any study treatments beyond conventional obstetric care; however, they were expected to complete data collection forms on the same schedule as all other trial subjects. As with the UOBC+OMT and UOBC+SUT subjects, the UOBC-only subjects were allowed to receive conventional obstetric care, but not OMT, massage therapy, physical therapy, chiropractic manipulation, or therapeutic ultrasound intended to treat musculoskeletal disorders.

Data for subjects in each of the 3 treatment groups were collected by blinded clinical research personnel at the time of randomization and during third trimester visits 1-7. At each treatment visit, the blinded attending obstetrician confirmed the subject's continuing eligibility during the prenatal visit immediately before the provision of the study treatment (ie, OMT or SUT in the applicable treatment groups). The 2 outcome domains included: (1) back pain, as measured by an 11-point scale (0, 1, 2, . . . , 10) for the average level of back pain; and (2) back-specific functioning, as measured by the Roland-Morris Disability Questionnaire (RMDQ).[15] The back pain scale included interval ratings from 0 ("no pain") to 10 ("worst possible pain") with no temporal frame of reference. Responses to this item were analyzed as if obtained from a 10-cm visual analog scale for pain. The RMDQ was scored as the total number of affirmative responses to each of its 24 back-related items based on the day of data collection. A higher score was indicative of poorer back-specific functioning and a greater level of disability.

All analyses were based on the intention-to-treat principle.[11] Thus, once a particular treatment was started, each

FIGURE 1
Flow of subjects through the trial



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

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subject was included in that treatment group regardless of her adherence to the 7-visit treatment protocol during the third trimester. Subjects may have missed their assigned treatments for various reasons, including withdrawing from the study without cause, being lost to follow-up, being withdrawn by their attending obstetrician for development of a high-risk condition, or other miscellaneous reasons. In addition, subjects may have "missed" scheduled treatment visits because of delivery before visit 7 at the 39th week. Missing data were imputed using the last observation carried forward method. If a subject delivered before visit 7, to maximize statistical power, the carry-forward method was used to impute missing data for censored observations during the remaining obstetric visits that were obviated by the delivery. Because back pain was likely to increase and back-specific functioning to deteriorate as pregnancy progressed, this approach to imputation may have biased the results in favor of treatment groups with more missed visits. We analyzed the differences in frequency of missed visits among treatment groups to determine whether supplemental analyses were needed to further address this potential source of bias.

The baseline characteristics of subjects were summarized using descriptive statistics. Differences among the 3 treatment groups were assessed using the χ^2 test for categorical variables and analysis of variance for continuous variables. Life-table methods were used to assess subject flow through the trial, including the cumulative distributions of treatment-eligible subjects, treatment-withdrawn subjects because of development of high-risk status, and treatment-censored subjects because of delivery before visit 7. Treatment outcomes were assessed with repeated measures analyses of covariance (ANCOVA) using the baseline measures as covariates. The ANCOVA considered both treatment group and time (as proxied by visit number) main effects and the treatment group × time interaction. Additional analyses were performed to measure effect sizes for treatment outcomes. The latter were computed such that positive effect sizes reflected treatment outcomes in the desired directions (ie, lower pain levels and lower RMDQ scores). Effect size thresholds for minimally important benefits and harms attributable to OMT were used to supplement the conventional statistical interpretation of the results of this exploratory trial.[16] Minimally important benefits were defined by effect sizes ≥0.2 based on a commonly ac-

TABLE
Baseline characteristics of randomly assigned subjects according to treatment group[a]

Characteristics	Treatment group			*P* value
	UOBC + OMT (n = 49)	UOBC + SUT (n = 48)	UOBC only (n = 49)	
Age, y	23.8 ± 5.5	23.7 ± 4.4	23.8 ± 5.2	.99
Race/ethnicity[b]				.10
White	23 (47)	10 (21)	15 (31)	
Black	10 (20)	22 (46)	15 (31)	
Hispanic	15 (31)	14 (29)	17 (35)	
Other	1 (2)	2 (4)	2 (4)	
Education, y	12.1 ± 1.7	11.8 ± 1.8	11.9 ± 2.0	.74
Marital status				.89
Single	29 (59)	28 (58)	29 (59)	
Married	17 (35)	18 (38)	19 (39)	
Other	3 (6)	2 (4)	1 (2)	
Employment status				.57
Employed	20 (41)	21 (44)	26 (53)	
Unemployed	24 (49)	19 (40)	17 (35)	
Status unknown	5 (10)	8 (17)	6 (12)	
Health insurance type				.57
Medicaid	31 (63)	36 (75)	38 (78)	
HMO/PPO/POS	14 (29)	9 (19)	9 (18)	
Other	4 (8)	3 (6)	2 (4)	
Tobacco use				.30
Never smoked	26 (53)	36 (75)	32 (65)	
Former smoker	5 (10)	1 (2)	4 (8)	
Current smoker	5 (10)	4 (8)	6 (12)	
Status unknown	13 (27)	7 (15)	7 (14)	
Alcohol use				.10
Never drank	25 (51)	38 (79)	36 (73)	
Former drinker	3 (6)	1 (2)	2 (4)	
Current drinker	8 (16)	2 (4)	4 (8)	
Status unknown	13 (27)	7 (15)	7 (14)	
Illicit drug use				< .001
Never used	22 (45)	38 (79)	39 (80)	
Former user	11 (22)	1 (2)	2 (4)	
Current user	2 (4)	4 (8)	2 (4)	
Status unknown	14 (29)	5 (10)	6 (12)	
Gravida	2.7 ± 1.5	2.7 ± 1.3	2.7 ± 1.6	.97
Para	1.1 ± 1.0	1.1 ± 1.1	1.4 ± 1.2	.47

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TABLE
Baseline characteristics of randomly assigned subjects according to treatment group[a] *(continued)*

Characteristics	Treatment group			*P* value
	UOBC + OMT (n = 49)	UOBC + SUT (n = 48)	UOBC only (n = 49)	
Vaginal bleeding				.05
No	42 (86)	40 (83)	47 (96)	
Yes	2 (4)	6 (13)	0 (0)	
Status unknown	5 (10)	2 (4)	2 (4)	
Systolic blood pressure, mm Hg	111.9 ± 11.2	110.9 ± 10.3	115.1 ± 10.7	.15
Diastolic blood pressure, mm Hg	70.1 ± 8.4	67.7 ± 8.2	68.2 ± 11.2	.46
Weight, lb	181.7 ± 41.8	173.5 ± 36.3	186.4 ± 43.7	.31
Average back pain level	4.9 ± 2.1	4.8 ± 2.3	4.9 ± 2.3	.99
Roland-Morris Disability score	8.4 ± 4.7	8.1 ± 5.3	6.6 ± 4.5	.14

HMO, health maintenance organization; *OMT*, osteopathic manipulative treatment; *POS*, point-of-service plan; *PPO*, preferred provider organization; *SUT*, sham ultrasound treatment; *UOBC*, usual obstetric care.

[a] Table entries reported as mean ± standard deviation for continuous variables and as number (percentage) for categorical variables; [b] As self-reported on a combined race/ethnicity item.

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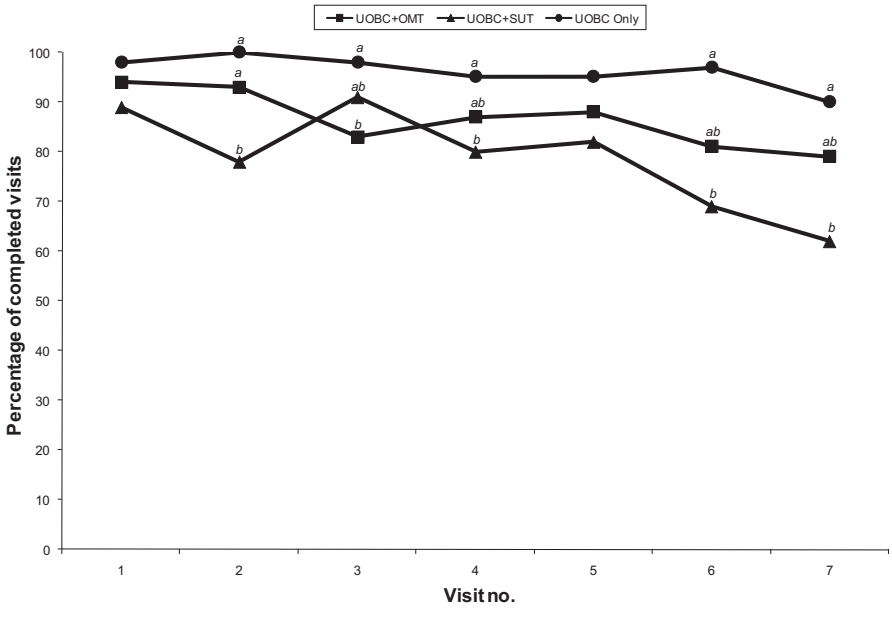
cepted standard for small effects. Minimally important harms were more conservatively defined by effect sizes ≤ −0.1. All hypotheses were assessed at the $\alpha = .05$ level of statistical significance using 2-tailed tests. The treatment group sample sizes were estimated to achieve a statistical power of 70% in conventional independent group comparisons based on a hypothesized moderate and clinically relevant effect size of 0.5 for back pain (ability to detect differences of 1.25 cm among treatment groups on a 10-cm visual analog scale for back pain) and back-specific functioning (ability to detect differences of 3 units among treatment groups on the 24-unit RMDQ).[17] Data management was performed with the SPSS version 14.0 software package (SPSS, Inc, Chicago, IL).

Results

As shown in Figure 1, 863 obstetric clinic patients were screened for eligibility and willingness to participate in the study. A total of 177 eligible patients agreed to participate; however, 31 patients did not progress to random assignment, most often because of the development of a high-risk condition (n = 18) or voluntary withdrawal from the trial (n = 10). A total of 49, 48, and 49 subjects were randomly assigned to the UOBC+OMT, UOBC+SUT, and UOBC-only groups, respectively.

The baseline characteristics of these subjects according to treatment group are presented in the Table. Subjects were similar across treatment groups with regard to most characteristics. There was a significant difference among treatment groups with regard to illicit drug use ($P < .001$). The UOBC+OMT group in-

FIGURE 2
Distribution of completed visits over time



Statistically significant differences among treatment groups were observed at visits 2, 3, 4, 6, and 7. Observations at a given visit that do not have a letter in common are significantly different than one another (eg, "a" and "b" are significantly different, but "ab" is not significantly different than "a" or "b").

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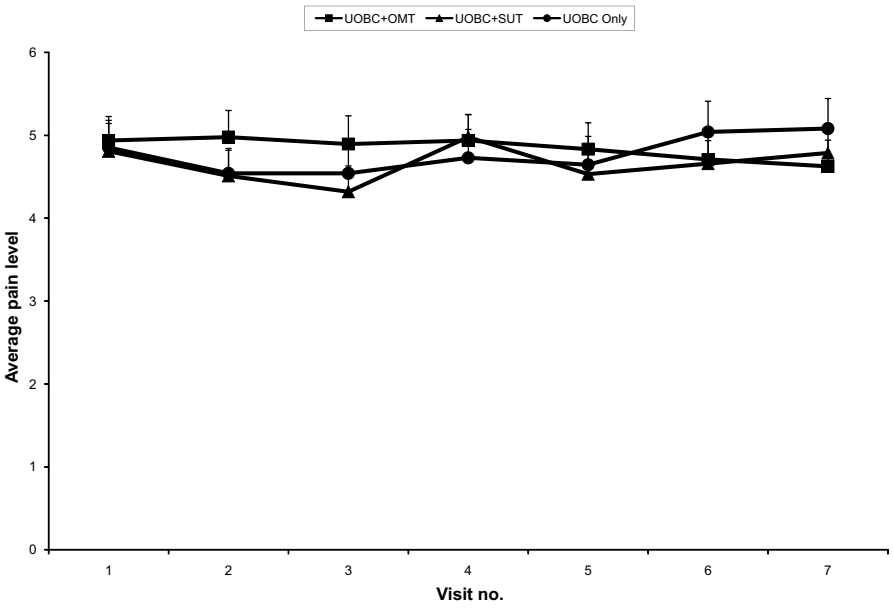
FIGURE 3
Average back pain levels over time



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.

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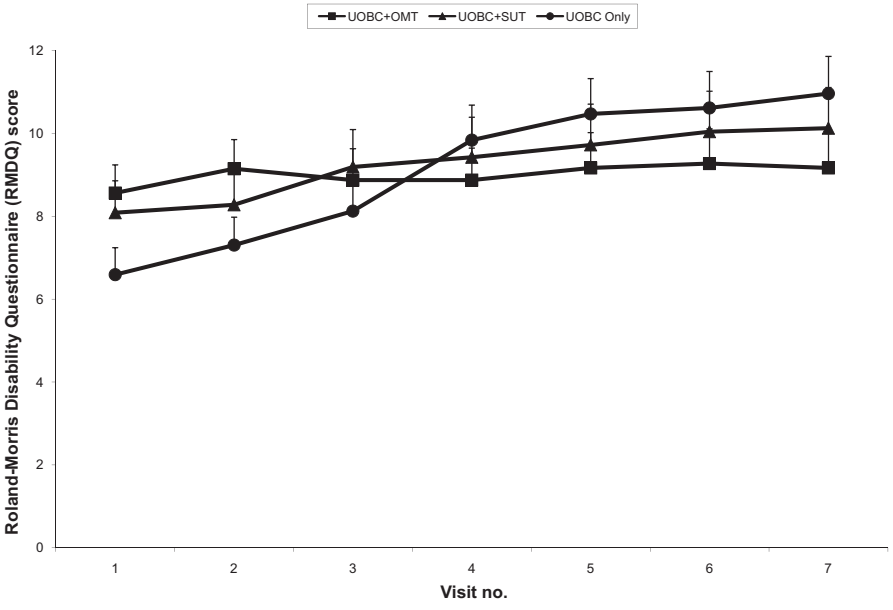
FIGURE 4
Roland-Morris Disability Questionnaire (RMDQ) scores over time



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

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

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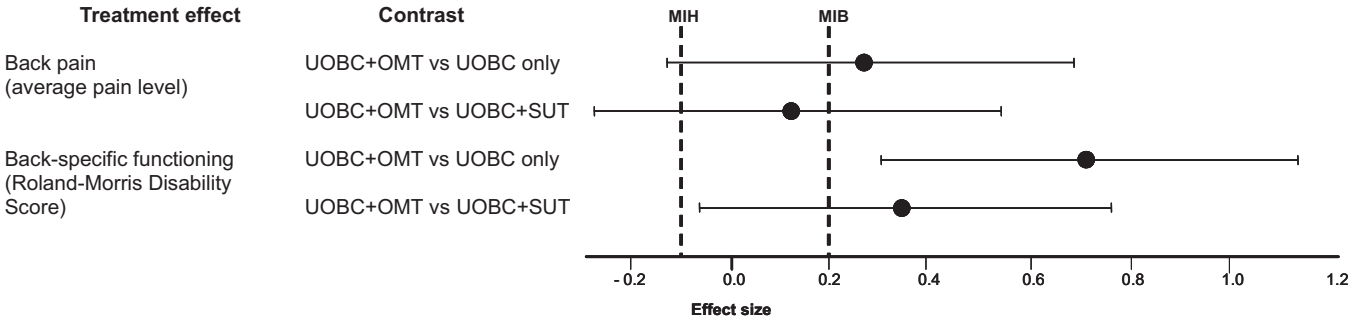
cluded substantially more former drug users and fewer never users than the other treatment groups. Also, there was a marginally significant difference among treatment groups with regard to vaginal bleeding ($P = .05$). In subtable analyses, this was attributed to the greater percentage of subjects who reported vaginal bleeding in the UOBC+SUT group compared with those in the UOBC-only group ($P = .04$). There were no significant baseline differences in any of the outcome measures among treatment groups.

Two randomly assigned subjects were lost to follow-up during the third trimester before any treatment was provided or outcomes data collected. Thus, the intention-to-treat analyses included 144 subjects. Only 4 subjects with continued eligibility missed more than half of their scheduled OMT or SUT visits (2 each in the UOBC+OMT and UOBC+SUT groups). The distribution of completed visits over time according to treatment group is displayed in Figure 2. Subjects in the UOBC-only group had the greatest completion percentage, with those in the UOBC+OMT group generally having intermediate completion percentages and those in the UOBC+SUT group having the lowest completion percentages. Significant differences in completion percentages among treatment groups were observed at 5 of the 7 treatment visits. Before visit 7, 23 (16%) subjects were withdrawn because of the development of a high-risk condition, and observations of another 60 (42%) subjects were censored because of delivery. There were no significant differences among treatment groups in the cumulative percentages of treatment-eligible subjects, treatment-withdrawn subjects because of the development of a high-risk condition, or treatment-censored subjects because of delivery before visit 7.

Average back pain levels according to treatment group are presented in Figure 3. Although there were no statistically significant differences in pain levels among treatment groups, mean pain levels decreased in the UOBC+OMT group, remained unchanged in the UOBC+SUT group, and increased in the UOBC-only group. The effect sizes were 0.27 (95% confidence interval [CI],

FIGURE 5
Graphical summary of treatment effects



Results are presented as effect size and 95% confidence interval. Positive and negative effect sizes represent benefits and harms, respectively.

MIB, minimally important benefit; *MIH*, minimally important harm; *OMT*, osteopathic manipulative treatment; *SUT*, sham ultrasound treatment; *UOBC*, usual obstetric care.

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−0.13 to 0.68; $P = .18$) for the UOBC+OMT vs UOBC-only contrast and 0.14 (95% CI, −0.26 to 0.55; $P = .48$) for the UOBC+OMT vs UOBC+SUT contrast.

The RMDQ outcomes according to treatment group are presented in Figure 4. There were significant differences in back-specific functioning among treatment groups (ANCOVA main effect, $P = .02$). Although RMDQ scores significantly increased over time (ANCOVA main effect, $P = .01$), back-specific functioning deteriorated less in the UOBC+OMT group than in the UOBC-only and UOBC+SUT groups (ANCOVA treatment group × time interaction effect, $P < .001$). The effect sizes were 0.72 (95% CI, 0.31–1.14; $P = .001$) for the UOBC+OMT vs UOBC-only contrast and 0.35 (95% CI, −0.06 to 0.76; $P = .09$) for the UOBC+OMT vs UOBC+SUT contrast.

Because there were significant differences among treatment groups in completed visits over time, as shown in Figure 2, and because the RMDQ scores increased over time, imputation using the last observation carried forward method may have biased the results in favor of the treatment groups with greater percentages of missed visits (UOBC+SUT and, to a lesser degree, UOBC+OMT) compared with the UOBC-only group. Ironically, this potential bias in favor of UOBC+SUT or UOBC+OMT is consistent with the theory that subjects may have purposely missed the SUT or OMT components of their obstetric visits because they perceived little or no benefit from these interventions. To assess this possibility, we conducted a supplemental analysis of the RMDQ outcomes using only those subjects who completed at least 6 of the 7 treatment visits (n = 68). This approach limited data imputation to no more than 1 carry forward per subject while still maintaining a modestly powered statistical analysis (estimated 40% power to detect an effect size of 0.5). The results of this analysis (treatment group main effect, $P = .04$; treatment group × time interaction effect, $P < .001$) corroborated the originally observed treatment group main effect and interaction effect, although the time main effect was not statistically significant ($P = .47$).

A summary of treatment outcomes with regard to minimally important benefits and harms of OMT is displayed in Figure 5. The latter clearly demonstrates important clinical benefits without appreciable harms in back-specific functioning when OMT is provided as complementary therapy during the third trimester of pregnancy. The outcomes with regard to back pain also suggest an important clinical benefit when OMT is provided as complementary therapy; however, the possibility of minimally important harms cannot be ruled out.

Comment

To our knowledge, this is the first randomized, placebo-controlled trial to explore the potential effects of OMT provided during the third trimester of pregnancy. Our results indicate that OMT lessens or halts the deterioration in back-specific functioning that often characterizes the third trimester of pregnancy and thereby provides an important clinical benefit when used as complementary therapy (Figure 5). Although there is evidence that OMT may provide an important clinical benefit in reducing back pain, the results are not as conclusive as they are for back-specific functioning. Thus, taken together, these findings suggest that the beneficial effects of OMT on physical functioning during the third trimester of pregnancy may not be related simply to an analgesic effect on back pain, but may possibly involve other mechanisms.

According to osteopathic philosophy, OMT may be used at various stages of pregnancy to complement conventional obstetric care and thereby to ameliorate the effects of somatic dysfunction, including back-related symptoms. Somatic dysfunction is an osteopathic concept defined as "impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodial, and myofascial structures, and related vascular, lymphatic, and neural elements."[12] Changes during advancing pregnancy may contribute to the development or worsening of somatic dysfunction. Specifically, 3 changes that occur during pregnancy are commonly thought to contribute to somatic

dysfunction: (1) hormonal changes; (2) changes in body fluid circulation; and (3) structural and biomechanical changes related to the developing fetus.[18] Previous research involving OMT during pregnancy has most often addressed structural and biomechanical changes. Typically, the back-related changes that occur during the third trimester of pregnancy include increased lumbar lordosis with pelvic tilt, increased thoracic kyphosis, and anterior tilt of the pelvic brim.[18] Although the results of our trial suggest that some of the benefits of OMT may be mediated by analgesic effects, which would most likely impact on the structural and biomechanical aspects of somatic dysfunction, other mechanisms that alleviate the hormonal and circulatory aspects of somatic dysfunction during pregnancy may also explain the effects of OMT on physical functioning.

Our trial also demonstrates the feasibility of providing OMT as a complement to conventional obstetric care during the third trimester of pregnancy. Although OMT was provided by specialists in osteopathic manipulative medicine rather than by the attending obstetricians, subjects were generally compliant in receiving OMT immediately after their obstetric visits. By comparison, compliance in receiving OMT during our trial was similar to that recently reported by pregnant women in taking a daily multimicronutrient supplementation tablet.[19]

Our randomized controlled trial has several strengths, including the use of a SUT control, blinded measurement of outcomes, repeated outcome measures throughout the third trimester of pregnancy, and analysis that used the intention-to-treat principle. However, there are several limitations of this trial that should be mentioned. First, despite the blocked randomization strategy used, subjects were not adequately randomized on illicit drug use, vaginal bleeding, and race/ethnicity. Thus, the potential for important confounding by these factors cannot be ruled out. Control for these potential confounders by use of stratified analyses or multivariate statistical techniques was not feasible because of the relatively small number of subjects enrolled in the trial. Second, the statistical power of the trial, originally estimated at 70% to detect moderately sized and clinically relevant treatment effects with regard to reducing back pain and improving back-specific functioning, may have been diluted to some degree because of these and other potential confounders. Third, the OMT protocol was limited to the third trimester of pregnancy. Theoretically, in clinical practice, it would be desirable to implement OMT earlier in the pregnancy to prevent or slow the progression of somatic dysfunction and back-related symptoms. Finally, the OMT protocol involved a standardized approach to treatment that may not adequately reflect the potential benefits seen in clinical practice, in which there is a more individualized treatment approach for each patient.

The results of our exploratory trial indicate that a larger Phase III trial with greater statistical power and better control of potential confounders is warranted to better assess the effects of OMT on back pain and related physical functioning during the third trimester of pregnancy. If our findings are replicated in such a trial, it may have important clinical and economic implications for treating common back-related symptoms and consequent functional disabilities that appear during the third trimester of pregnancy. ■

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