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

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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.

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Background and Objective

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 in many drug therapies. A majority of pregnant women and prenatal health care providers 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.

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. 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 Research Center at the University of North Texas Health Science Center. Recruitment was open from July 2003 through December 2005.

Each subject was randomized to one 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). Subjects were stratified by age and gravida number on the theoretical basis that these factors may influence response to OMT. 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 included any of the following treatment modalities: soft tissue, myofascial release, muscle energy, and range-of-motion mobilization. The protocol 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. The SUT treatments were provided by the same physicians who provided OMT. 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

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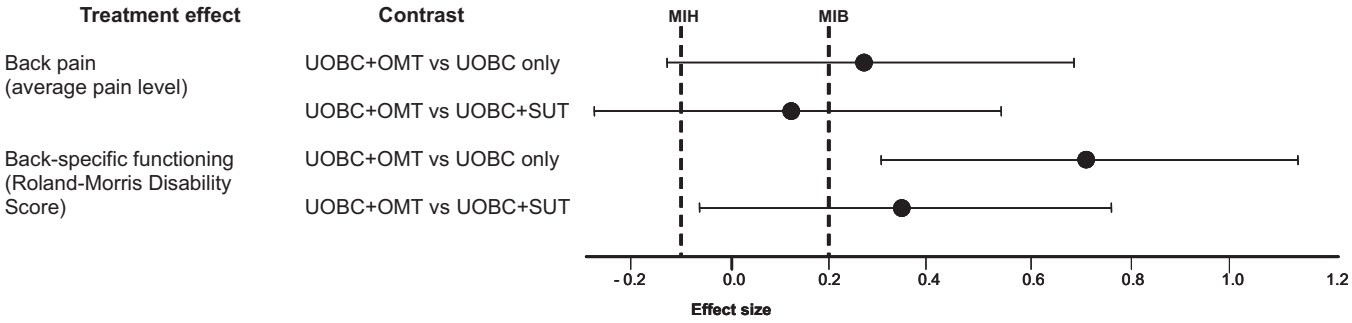
FIGURE
Graphical summary of treatment effects



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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ultrasound intended to treat musculoskeletal disorders.

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). All analyses were based on the intention-to-treat principle. Missing data were imputed using the last observation carried forward method.

Minimally important benefits were defined by effect sizes ≥0.2 based on a commonly accepted standard for small effects. Minimally important harms were more conservatively defined by effect sizes ≤−0.1.

Results

A total of 49, 48, and 49 subjects were randomized to the UOBC+OMT, UOBC+SUT, and UOBC-only groups, respectively. There were no significant baseline differences in any of the outcome measures among treatment groups.

The intention-to-treat analyses included 144 subjects. 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.

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], −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.

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.

The Figure displays a summary of treatment outcomes with regard to minimally important benefits and harms of OMT.

Comment

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. 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.

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."

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. 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. 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 bio-

mechanical 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.

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.

CLINICAL IMPLICATIONS

- This evidence-based approach clearly indicates that the clinically relevant benefits in physical functioning associated with complementary osteopathic manipulative treatment (OMT) in third-trimester obstetric care outweigh any potential harms.
- Mechanistic studies are necessary to elucidate the hormonal, circulatory, or analgesic effects that may mediate this OMT effect on physical functioning during the third trimester.
- Replication of these findings in a larger clinical trial may have important clinical and economic implications for preventing or treating back pain, functional limitations, and disabilities that occur during the third trimester. ■

Effects of calcium supplementation on uteroplacental and fetoplacental blood flow in low-calcium-intake mothers: a randomized controlled trial

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OBJECTIVE: We postulated that calcium supplementation of calcium-deficient pregnant women would lower vascular resistance in uteroplacental and fetoplacental circulations.

STUDY DESIGN: Pulsatility index (PI) and resistance index (RI) (uterine and umbilical arteries) and presence of bilateral uterine artery diastolic notching were assessed by Doppler ultrasound between 20-36 weeks' gestation in 510 healthy, nulliparous Argentinean women with deficient calcium intake in a randomized, placebo-controlled, double-blinded trial.

RESULTS: Average umbilical and uterine artery RI and PI tended to be lower in the supplemented group at each study week. Differences became statistically significant for umbilical artery RI and PI from 32 and 36 weeks, respectively. Estimated probabilities of bilateral uterine artery diastolic notching trended toward lower values in calcium-supplemented women.

CONCLUSION: Calcium supplementation of pregnant women with deficient calcium intake may affect uteroplacental and fetoplacental blood flow by preserving the vasodilation of normal gestation.

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BACKGROUND AND OBJECTIVE

Hypertensive disorders complicate approximately 9% of all pregnancies and are responsible for substantial morbidity and mortality in both mother and fetus with the majority of these bad outcomes due to pure or superimposed preeclampsia/eclampsia. Despite recent and existing progress related to causality, the etiology and pathophysiology of preeclampsia remain unclear, and we are yet to develop targeted prevention strategies.

There are reports that intracellular free calcium concentration is increased in women with preeclampsia. It has further been suggested that increased intracellular free calcium levels are a consequence of the increase in parathyroid hormone levels secondary to low calcium intake, a problem correctable by calcium supplementation and proposed as a preventive strategy for preeclampsia, specifically among low-calcium-intake women.

A plausible approach toward understanding the mechanisms linking dietary calcium intake to vasoconstriction during normal and abnormal pregnancy is to prospectively assess the effects of dif-

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This is an ancillary study performed in parallel with the World Health Organization calcium supplementation trial among low-calcium-intake women (Am J Obstet Gynecol 2006;194:639-49).

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