Prevention of Progressive Back-Specific Dysfunction During Pregnancy: An Assessment of Osteopathic Manual Treatment Based on Cochrane Back Review Group Criteria

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Context: Back pain during pregnancy may be associated with deficits in physical functioning and disability. Research indicates that osteopathic manual treatment (OMT) slows the deterioration of back-specific functioning during pregnancy.

Objective: To measure the treatment effects of OMT in preventing progressive back-specific dysfunction during the third trimester of pregnancy using criteria established by the Cochrane Back Review Group.

Design: A randomized sham-controlled trial including 3 parallel treatment arms: usual obstetric care and OMT (UOBC+OMT), usual obstetric care and sham ultrasound therapy (UOBC+SUT), and usual obstetric care (UOBC).

Setting: The Osteopathic Research Center within the University of North Texas Health Science Center in Fort Worth.

Participants: A total of 144 patients were randomly assigned and included in intention-to-treat analyses.

Main Outcome Measures: Progressive back-specific dysfunction was defined as a 2-point or greater increase in the Roland-Morris Disability Questionnaire (RMDQ) score during the third trimester of pregnancy. Risk ratios (RRs) and 95% confidence intervals (CIs) were used to compare progressive back-specific dysfunction in patients assigned to UOBC+OMT relative to patients assigned to UOBC+SUT or UOBC. Numbers needed to treat (NNTs) and 95% CIs were also used to assess UOBC+OMT vs each comparator. Subgroup analyses were performed using median splits of baseline scores on a numerical rating scale for back pain and the RMDQ.

Results: Overall, 68 patients (47%) experienced progressive back-specific dysfunction during the third trimester of pregnancy. Patients who received UOBC+OMT were significantly less likely to experience progressive back-specific dysfunction (RR, 0.6; 95% CI, 0.3-1.0; $P=.046$ vs UOBC+SUT; and RR, 0.4; 95% CI, 0.2-0.7; $P<.0001$ vs UOBC). The effect sizes for UOBC+OMT vs UOBC+SUT and for UOBC+OMT vs UOBC were classified as medium and large, respectively. The corresponding NNTs for UOBC+OMT were 5.1 (95% CI, 2.7-282.2) vs UOBC+SUT; and 2.5 (95% CI, 1.8-4.9) vs UOBC. There was no statistically significant interaction between subgroups in response to OMT.

Conclusion: Osteopathic manual treatment has medium to large treatment effects in preventing progressive back-specific dysfunction during the third trimester of pregnancy. The findings are potentially important with respect to direct health care expenditures and indirect costs of work disability during pregnancy.

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Back pain is commonly reported during pregnancy[1-7] and may lead to deficits in physical functioning and disability.[3,5] The management of back pain and related problems during pregnancy is complicated by potential or unknown risks of drug therapies and other interventions. Multimodal interventions involving patient education, exercise, muscle strengthening, or manual therapy during pregnancy have reportedly reduced pain and achieved other favorable outcomes[8] and decreased work loss due to back and pelvic pain.[9] In such studies, however, it is impossible to determine the treatment effect specifically attributable to manual therapy. A systematic review[10] of studies through 2008 specifically aimed at evaluating the effects of spinal manipulative therapy on back pain and other related symptoms during pregnancy found no randomized controlled trials of osteopathic manual treatment (OMT) or chiropractic manipulation.Nevertheless, a majority of patients and providers alike report that they would consider using or prescribing complementary and alternative medicine therapies, including manual therapies, for back pain during pregnancy.[11]

The osteopathic literature includes physician accounts[12] and observational data[13,14] supporting the benefits of OMT during pregnancy. In 2010, however, the first randomized controlled trial of OMT for back pain and related symptoms during pregnancy was reported.[15] This study concluded that OMT slows or halts the deterioration of back-specific functioning during the third trimester of pregnancy. Since then, other standards of evidence have gained increasing visibility and acceptance, particularly guidelines established by the Cochrane Back Review Group for determining the clinical relevance of study results.[16] In light of these guidelines on clinical relevance, we conducted this updated assessment of OMT in preventing progressive back-specific dysfunction during the third trimester of pregnancy.

Methods

A randomized controlled trial of OMT during the third trimester of pregnancy was conducted from 2003 through 2006 at The Osteopathic Research Center on the campus of the University of North Texas Health Science Center in Fort Worth. The institutional review board approved all study procedures. Additionally, the study was registered with ClinicalTrials.gov (NCT00298935), and its methodological details have been provided therein[17] and reported elsewhere.[15] The trial aimed to assess the efficacy of OMT delivered during the third trimester, as measured by an 11-point numerical rating scale (NRS) for typical level of back pain and the Roland-Morris Disability Questionnaire (RMDQ)[18] for back-specific functioning. Given the significant findings previously reported,[15] this updated assessment primarily focuses on using guidelines from the Cochrane Back Review Group to more clearly delineate the clinical relevance of OMT in preventing progressive back-specific dysfunction.

Patients without high-risk obstetric conditions were recruited and subsequently enrolled between weeks 28 and 30 of pregnancy. Blocked randomization according to age ($\leq$24 years vs $\geq$25 years) and gravida status (primigravida vs multigravida) was used to assign patients to 1 of 3 parallel treatment arms: usual obstetric care and OMT (UOBC+OMT), usual obstetric care and sham ultrasound therapy (UOBC+SUT), or usual obstetric care (UOBC). Up to 7 treatment sessions were provided in conjunction with standard obstetric visits at weeks 30, 32, 34, 36, 37, 38, and 39.

Osteopathic manual treatment was delivered by physicians within the Department of Osteopathic Manipulative Medicine at the University of North Texas Health Science Center Texas College of Osteopathic Medicine. The OMT protocol included the following techniques: soft tissue, myofascial release, range-of-motion, and muscle energy.[19] These techniques were aimed at somatic

dysfunction involving the cervical, thoracic, and lumbar spine; sacrum and pelvis; thoracic outlet and clavicles; and ribcage and diaphragm. The OMT protocol precluded use of high-velocity, low-amplitude thrusts and compression of the fourth ventricle[20] on the theoretical grounds that these techniques may pose risks to the patient or fetus or may induce premature labor, respectively.

The same physicians also delivered the SUT protocol using a nonfunctional ultrasound therapy unit that provided visible and auditory cues to help elicit a placebo response. The SUT applicator head was applied over the patient's clothing to provide sensory stimulation within the anatomical distribution corresponding to the OMT protocol. Patients were precluded from externally seeking OMT, chiropractic manipulation, physical therapy, massage therapy, or therapeutic ultrasound. Both OMT and SUT treatments were withheld from patients if they developed a high-risk obstetric condition following randomization.

Blinded research personnel collected patient self-reported outcomes data at each protocol visit. The RMDQ was scored as the total number of affirmative responses on each of its 24 items, with higher scores reflecting greater levels of back-specific disability. This updated assessment of the clinical relevance of OMT during the third trimester of pregnancy is based on guidelines established by the Cochrane Back Review Group.[16] We measured changes in the RMDQ score from baseline (week 30) through the last scheduled protocol visit prior to delivery, or through the final protocol visit (week 39) in women who had not yet delivered. Missing RMDQ values because of incomplete protocol adherence or study attrition were imputed using the last-observation-carried-forward method. Progressive back-specific dysfunction was defined as a 2-point or greater increase on the RMDQ score from baseline to final relevant observation. This criterion was based on published correspondence with the Editorial Board of the Cochrane Back Review Group.[21]

The baseline patient characteristics were assessed using the χ^2 test for categorical variables and parametric statistics for continuous variables. We computed risk ratios (RRs) and 95% confidence intervals (CIs) for progressive back-specific dysfunction for UOBC+OMT relative to both UOBC+SUT and UOBC. The effect size attributable to OMT in preventing progressive back-specific dysfunction was determined on the basis of method guidelines for systematic reviews recommended by the Cochrane Back Review Group: small, $RR>0.8$; medium, $0.5\leqslant RR\leqslant 0.8$; or large, $RR<0.5$.[16] We also computed the numbers needed to treat (NNTs) for prevention of back-specific dysfunction for UOBC+OMT relative to both comparator groups. The 95% CIs for NNTs were computed using the Wilson score method.[22] Finally, we conducted subgroup analyses by dichotomizing the baseline NRS scores for back pain and the RMDQ scores for back-specific functioning using a median split for each variable. The *P* value for interaction[23] was used to assess the risk of progressive back-specific dysfunction within the back pain and back-specific functioning subgroups. Data were managed and analyzed with the SPSS Statistics version 20 software (IBM Corporation). All study outcomes were assessed by intention-to-treat analysis with hypotheses tested at the .05 level of statistical significance using 2-tailed methods.

Results

The CONSORT diagram summarizing the flow of patients through the trial is presented in *Figure 1*. The baseline characteristics of the 146 randomly assigned patients are presented in *Table 1*. A total of 144 patients were included in the intention-to-treat analysis because 2 patients were lost to follow-up after randomization but before the first protocol visit. Overall adherence to the OMT and SUT protocols exceeded 80% among patients with continuing trial eligibility. There was no statistically significant difference in treatment adherence between study groups at any protocol visit except for week 32, wherein

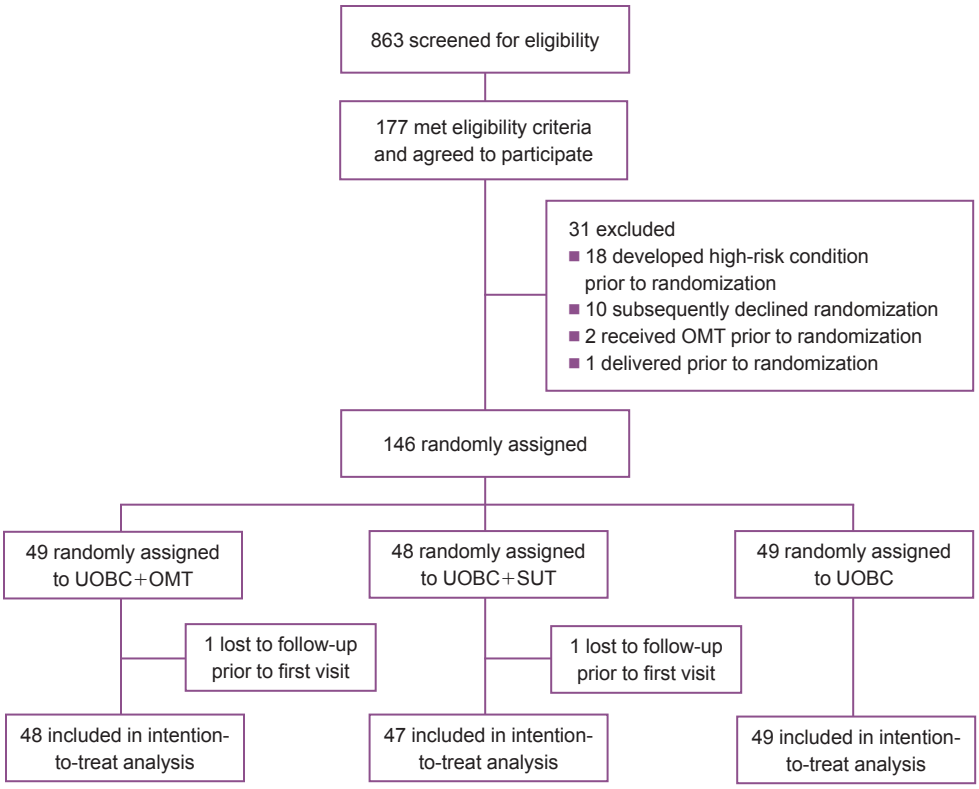

Figure 1.
CONSORT diagram illustrating the flow of patients through the trial. *Abbreviations:* OMT, osteopathic manual treatment; SUT, sham ultrasound therapy; UOBC, usual obstetric care.

a greater percentage of patients in the UOBC+OMT group received treatment as compared with patients in the UOBC+SUT group (adherence ratio, 1.2; 95% CI, 1.0-1.4; $P=.03$). Neither was there any statistically significant difference between study groups in the rates of development of high-risk obstetric conditions or delivery prior to week 39.

The frequency distributions of NRS scores for back pain and RMDQ scores for the 144 patients immediately prior to the first protocol visit at week 30 are presented in *Figure 2*. A total of 141 patients (98%) reported typically having some level of back pain, and 138 (96%) reported some deficit in back-specific functioning. The median values on the NRS for back pain and the RMDQ were 5 and 7, respectively.

Overall, 68 patients (47%) experienced progressive back-specific dysfunction during the third trimester of pregnancy. The risk of progressive back-specific dysfunction according to study group is presented in *Figure 3*. These results are further summarized and classified in *Table 2*. Therein, statistically significant reductions in RRs were observed for the contrasts

Table 1.
Baseline Patient Characteristics According to Treatment Group (N=146)

Characteristic	Treatment Group			*P* Value
	UOBC+OMT (n=49)	UOBC+SUT (n=48)	UOBC (n=49)	
Age, y, mean (SD)	23.8 (5.5)	23.7 (4.4)	23.8 (5.2)	.99
Race/Ethnicity,[a] No. (%)				.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, mean (SD)	12.1 (1.7)	11.8 (1.8)	11.9 (2.0)	.74
Marital Status, No. (%)				.89
Single	29 (59)	28 (58)	29 (59)	
Married	17 (35)	18 (38)	19 (39)	
Other	3 (6)	2 (4)	1 (2)	
Employment Status, No. (%)				.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, No. (%)				.57
Medicaid	31 (63)	36 (75)	38 (78)	
HMO/PPO/POS	14 (29)	9 (19)	9 (18)	
Other	4 (8)	3 (6)	2 (4)	
Gravida, mean (SD)	2.7 (1.5)	2.7 (1.3)	2.7 (1.6)	.97
Para, mean (SD)	1.1 (1.0)	1.1 (1.1)	1.4 (1.2)	.47
Weight, lb, mean (SD)	181.7 (41.8)	173.5 (36.3)	186.4 (43.7)	.31
NRS Score for Back Pain, mean (SD)	4.9 (2.1)	4.8 (2.3)	4.9 (2.3)	.99
RMDQ Score, mean (SD)	8.4 (4.7)	8.1 (5.3)	6.6 (4.5)	.14

[a] Self-reported on a combined race/ethnicity item.

Abbreviations: HMO, health maintenance organization; NRS, numerical rating scale; OMT, osteopathic manual treatment; POS, point-of-service plan; PPO, preferred provider organization; RMDQ, Roland-Morris Disability Questionnaire; SUT, sham ultrasound therapy; UOBC, usual obstetric care.

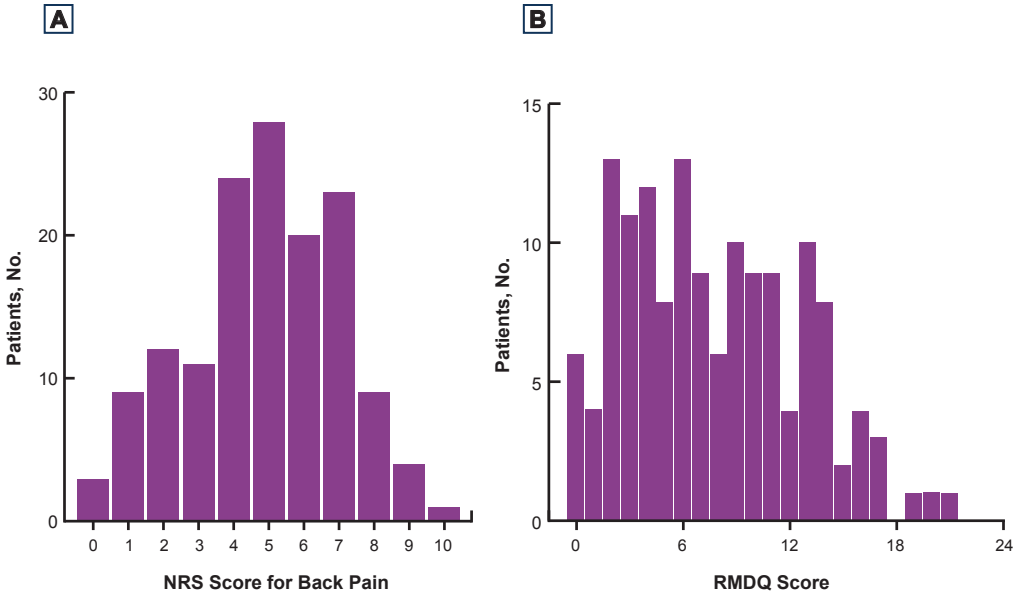

Figure 2.
Frequency distributions of (A) numerical rating scale (NRS) scores for back pain and (B) Roland-Morris Disability Questionnaire (RMDQ) scores immediately prior to the first visit at week 30.

involving UOBC+OMT vs both UOBC+SUT and UOBC, although only marginally so for the former contrast. The effect sizes for UOBC+OMT are classified as medium in comparison with UOBC+SUT and as large in comparison with UOBC. Correspondingly, the NNT profiles for UOBC+OMT demonstrate significantly better outcomes than for either UOBC+SUT or UOBC, although the former contrast involves a wide 95% CI because of the marginally significant difference in outcomes and the relatively small sample sizes of each study group. There was no statistically significant interaction between subgroups in response to OMT.

Comment

This updated assessment sheds greater light on the efficacy and clinical relevance of OMT in preventing progressive back-specific dysfunction during the third trimester of pregnancy. Large treatment effects were attributable to OMT when it was used to complement

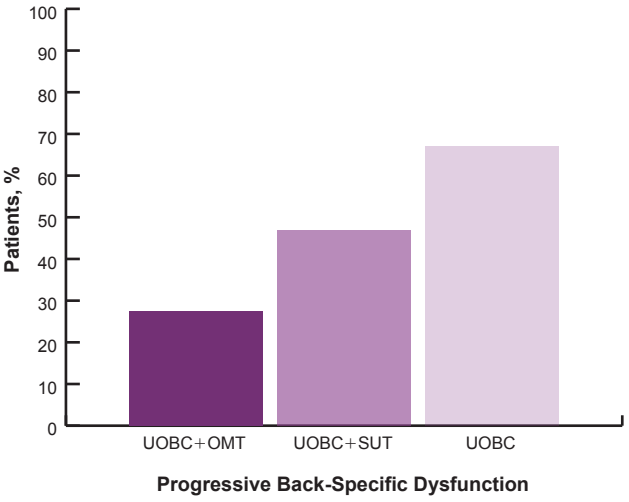

Figure 3.
Progressive back-specific dysfunction during the third trimester of pregnancy. Progressive back-specific dysfunction was defined as a 2-point or greater increase on the Roland-Morris Disability Questionnaire score during the third trimester. *Abbreviations:* OMT, osteopathic manual treatment; SUT, sham ultrasound therapy; UOBC, usual obstetric care.

Table 2.
Efficacy and Clinical Relevance of Osteopathic Manual Treatment in Preventing Progressive Back-Specific Dysfunction During the Third Trimester of Pregnancy[a]

	Osteopathic Manual Treatment (n=48)			
Control Group	Risk Ratio (95% CI) for Progressive Back-Specific Dysfunction	*P* Value	NNT (95% CI) to Prevent Progressive Back-Specific Dysfunction	Effect Size
UOBC+SUT (n=47)	0.6 (0.3-1.0)	.046	5.1 (2.7-282.2)	Medium
UOBC (n=49)	0.4 (0.2-0.7)	<.0001	2.5 (1.8-4.9)	Large

[a] The risk ratios are for UOBC+OMT vs each control group based on intention-to-treat analyses. Risk ratios (RRs) less than 1 indicate some level of benefit with OMT in preventing progressive back-specific dysfunction. The effect size is based on the *P* value and RR, as interpreted using the Cochrane Back Review Group recommendations.[16] Using these criteria, treatment effects for prevention of progressive back-specific dysfunction that are statistically significant are further classified as small (RR>0.8), medium (0.5≤RR≤0.8), or large (RR<0.5).

Abbreviations: CI, confidence interval; NNT, number needed to treat; OMT, osteopathic manual treatment; SUT, sham ultrasound therapy; UOBC, usual obstetric care.

UOBC. Medium treatment effects were attributable to OMT in comparison with SUT. Thus, in the absence of previously reported trials specifically addressing the efficacy of OMT or chiropractic manipulation,[10] these results begin to build an evidence base for the clinical relevance of OMT in preventing deficits in physical functioning and disability during the third trimester of pregnancy. Additionally, these results may have potentially important economic implications with respect to direct health care expenditures and the indirect costs of work disability related to deterioration of back-specific functioning during the third trimester of pregnancy.

These results generally mirror the medium to large treatment effects observed for OMT in achieving moderate to substantial improvements in patients with chronic low back pain in the OSTEOPATHIC Trial.[24] Also, our NNT results for UOBC+OMT vs UOBC (NNT, 2.5; 95% CI, 1.8-4.9) compare favorably with those reported in the UK BEAM trial, wherein spinal manipulation for back pain was similarly compared with general practice care over 3 months (NNT, 5.2; 95% CI, 3.7-8.8).[25] While such between-trial comparisons of NNTs should be viewed cautiously, it is important to note that both trials computed NNT on the basis of absolute changes in the RMDQ score and both used the Wilson score method to compute the corresponding 95% CIs. In more practical terms, our NNT results suggest that for every 100 pregnant women who receive OMT to complement their UOBC during the third trimester, about 40 cases of progressive back-specific dysfunction would be prevented.

The previously reported study[15] results indicated that back pain decreased with UOBC+OMT, remained unchanged with UOBC+SUT, and increased with UOBC during the third trimester, although the results failed to achieve statistical significance.Unlike common "nonspecific" low back pain, the back pain experienced by pregnant women may be related to very specific changes that occur during the third trimester, including increased lumbar lordosis with pelvic tilt, increased thoracic kyphosis, and anterior tilt of the pelvic brim.[26] It is possible that the irreversible demands of advancing pregnancy, including fetal growth in length and weight, place a progressively increasing mechanical load on somatic tissues that evokes a nociceptive response that is resistant to analgesia.[27] Nevertheless, our present results suggest that

OMT may work by some mechanism to counter the factors that promote deficits in back-specific functioning during the third trimester. A recent study[28] concluded that mild but significant inflammatory activity, including presence of interleukin-6 and tumor necrosis factor-α, is involved in the development and progression of normal pregnancy, and that such inflammation may have important physiological roles.The OSTEOPATHIC Trial[29] found decreased serum concentrations of tumor necrosis factor-α in patients with chronic low back pain who received OMT, thereby suggesting a possible mechanism for the results observed herein.

The strengths of our randomized controlled trial included use of a sham comparator, blinded outcome assessors, imputation of missing data, intention-to-treat analysis, and consistency with method guidelines for systematic reviews recommended by the Cochrane Back Review Group. Limitations of the study included relatively small samples sizes within each study group, a standardized OMT treatment protocol that may not have adequately reflected the variety of techniques used by community-based osteopathic physicians, and absence of data with which to perform cost-effectiveness analyses within the trial. Additionally, there was no consensus on the criterion for progressive back-specific dysfunction based on the RMDQ. Several sets of criteria for interpreting RMDQ change scores have been proposed since 2000[21,30,31]; however, these criteria generally focused on identifying thresholds for clinical improvement rather than deterioration. Because pregnant women are considered a vulnerable population, we elected to use the change score on the RMDQ that would be most sensitive in detecting progressive back-specific dysfunction. Consequently, in line with the Editorial Board of the Cochrane Back Review Group,[21] we elected to use a 2-point or greater increase on the RMDQ during the third trimester as the criterion for progressive back-specific dysfunction. This change score corresponded to 30% deterioration for the typical patient in our study.

Conclusion

The present study indicates that OMT has a medium to large treatment effect in preventing progressive back-specific dysfunction during the third trimester of pregnancy. The economic implications of these findings are unclear but potentially important. A larger pragmatic trial, including a cost-effectiveness analysis component, is needed to determine the generalizability of these results and to assess the economic impact of OMT on direct health care expenditures and the indirect costs of work disability.

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Editor's Note: In this article, the authors use the term *osteopathic manual treatment* to describe the techniques used to treat patients with somatic dysfunction. The style guidelines of *The Journal of the American Osteopathic Association* and AOA policy prefer the term *osteopathic manipulative treatment*. Given the context of this article, the authors believe that the term *osteopathic manual treatment* is more appropriate because it is more encompassing than *osteopathic manipulative treatment*.