American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients with Low Back Pain

Executive Summary:
The American Osteopathic Association recommends that osteopathic physicians use Osteopathic Manipulative Treatment (OMT) in the care of patients with low back pain. Evidence from systematic reviews and meta-analyses of randomized clinical trials (Evidence Level 1a) supports this recommendation.

1. Overview material: Provide a structured abstract that includes the guideline’s release date, status (original, revised, updated), and print and electronic sources.

Release Date (expected) May 1, 2016. These Guidelines are available through the AOA website and the National Guidelines Clearinghouse, AHRQ. The guidelines are partially based upon the following study:

The format used for these guidelines are in accordance with the 2013 (Revised) Criteria for Inclusion of Clinical Practice Guidelines in NGC and uses the 2011 definition of clinical practice guidelines developed by the Institute of Medicine (IOM): “Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options”.

ABSTRACT

Background
Osteopathic manipulative treatment (OMT) is a distinctive modality commonly used by osteopathic physicians to complement conventional treatment of musculoskeletal disorders, including those that cause low back pain. OMT is defined in the Glossary of Osteopathic Terminology as: “The therapeutic application of manually guided forces by an osteopathic physician (US Usage) to improve physiologic function and/or support homeostasis that has been altered by somatic dysfunction. OMT employs a variety of techniques” (see Appendix 1 for list). Somatic dysfunction is defined as: “Impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodial and myofascial structures, and their related vascular, lymphatic, and neural elements. Somatic dysfunction is treatable using osteopathic manipulative treatment.”

These guidelines update the AOA guidelines for osteopathic physicians to utilize OMT for patients with nonspecific acute or chronic LBP published in 2010 on the National Guideline Clearinghouse.¹

Methods
This update process commenced with literature searches that included electronic databases, personal contact with key researchers of OMT and low back pain, and internet search engines. Early in the process, the AOA discovered the systematic literature review conducted by Franke, Franke and Fryer (2014)² which serves as the basis for this updated guideline and further builds upon the literature used to support the prior guidelines. Findings from other eligible studies...
published after the search parameters of the Franke et al. systematic review and December 2014 were also incorporated.

**Results**
The authors of the systematic review identified 307 studies. Thirty-one were evaluated and 16 excluded. Of the 15 studies included in the review, 6 were retrieved from Germany, 5 from the United States, 2 from the United Kingdom, and 2 from Italy.

OMT significantly reduces pain and improves functional status in patients, including pregnant and postpartum women, with nonspecific acute and chronic LBP. Franke et al. found that in acute and chronic non-specific LBP, moderate-quality evidence suggested OMT had a significant effect on pain relief (MD: -12.91, 95% CI: -20.00 to -5.82) and functional status (SMD: -0.36, 95% CI: -0.58 to -0.14). More specifically, in chronic nonspecific LBP, the evidence suggested a significant difference in favor of OMT regarding pain (MD: -14.93, 95% CI: -25.18 to -4.68) and functional status (SMD: -0.32, CI: -0.58 to -0.07). When examining nonspecific LBP in pregnancy, low-quality evidence suggested a significant difference in favor of OMT for pain (MD: -23.01; 95% CI: -44.13 to -1.88) and functional status (SMD: -0.80; 95% CI: -1.36 to -0.23). Conversely for nonspecific LBP postpartum, Franke et al. found that moderate-quality evidence suggested a significant difference in favor of OMT for pain (MD: -41.85; 95% CI: -49.43 to -34.27) and functional status (SMD: -1.78; 95% CI: -2.21 to -1.35).

**Conclusions**
Franke et al.'s conclusions further strengthen the findings that OMT reduces LBP. In a previous systematic review conducted by Licciardone et al. (2005) and the basis of the LBP guidelines published in 2010, it was determined that OMT reduces pain more than expected from placebo effects alone and these results had the potential to last beyond the first year of treatment. Franke et al. specifically stated that clinically relevant effects of OMT were found for reducing pain and improving functional status in patients with acute and chronic nonspecific LBP and for LBP in pregnant and postpartum women at 3 months post treatment. Larger randomized controlled trials (RCTs) with robust comparison groups are needed to further validate the effects of OMT on LBP. In addition, more research is needed to understand the mechanics of OMT and its short and long-term effects, and the cost-effectiveness of such treatment.

2. Focus: Describe the primary disease/condition and intervention/service/technology that the guideline addresses. Indicate any alternative preventive, diagnostic or therapeutic interventions that were considered during development.

These guidelines are intended to assist osteopathic physicians in appropriate utilization of OMT for patients with low back pain. Other alternative preventive, diagnostic and therapeutic interventions considered during development of these guidelines were those noted in the following published guidelines for physicians caring for patients with low back pain:

BACKGROUND

A majority of patients that visit osteopathic physicians seek treatment for musculoskeletal conditions, in particularly, low back pain. Osteopathic manipulative treatment (OMT) is a distinctive approach to patient care used by osteopathic physicians to complement conventional treatment of musculoskeletal disorders, including low back pain.

The Agency for Health Care Policy and Research (AHCPR) in the United States found that patients suffering from acute low back problems without radiculopathy benefited from spinal manipulation if administered within the first month that symptoms occurred. In addition to the AHCPR’s findings, there was the UK Back pain Exercise and Manipulation (UK BEAM) trial. The investigators of this study, with guidance from the professional organizations that represent osteopaths, chiropractors, and physiotherapists in the United Kingdom, developed a spinal manipulation package consisting of common manual techniques used by all three professional groups. While the study used the common manual techniques, it did not provide any data that assessed the differences of each profession in the use of these techniques and any differences in outcomes. Additionally, OMT and its range of techniques are not adequately addressed in the UK BEAM trial package.

It has been noted that manipulation approaches cannot be generalized from one profession to the next. Clinicians have been discouraged from adapting conclusions from systematic reviews which may oversimplify findings that appear to be similar but are based on differing professions. Moreover, with regard to OMT and osteopathic physicians, not only is there variability in the manual techniques from other health professions, but also, osteopathic physicians combine both conventional and complementary approaches to treat low back pain. This philosophically different approach to LBP requires more empirical data to determine the efficacy of OMT.

These guidelines are based on a systematic review of the literature on OMT for patients with low back pain and a meta-analysis of all randomized controlled trials of OMT for patients with low back pain in ambulatory settings. Additionally, they build upon the 2009 AOA Clinical Practice Guidelines for Low Back Pain and the 2005 systematic review by Licciardone et al. on which the previous guidelines were based.

3. Goal: Describe the goal that following the guideline is expected to achieve, including the rationale for development of a guideline on this topic.

The goal of these guidelines are to enable osteopathic physicians as well as other physicians, other health professionals, and third party payers, to understand the evidence underlying recommendations for appropriate utilization of OMT, which is not detailed in the current sets of guidelines developed by other physicians. The American Osteopathic Association does not believe it is appropriate for other professionals to create guidelines for utilization of OMT since it is not a procedure or approach used by those physicians. It is, however, the purview and duty of the American Osteopathic Association to inform its members and the public about the appropriate utilization of OMT.

4. Users/setting: Describe the intended users of the guideline (e.g., provider types, patients) and the settings in which the guideline is intended to be used.
These guidelines are to be used by osteopathic physicians in application of OMT to patients with nonspecific low back pain, which can be defined as tension, soreness, or stiffness in the lower back region with an unidentified cause\(^2\), in the ambulatory setting.

5. Target population: Describe the patient population eligible for guideline recommendations and list any exclusion criteria.

Patients with nonspecific low back pain of musculoskeletal origin are eligible for guideline recommendations. Patients with visceral disease conditions that refer pain to the low back are excluded from these guidelines. Other conditions of exclusion are when the following are the identified source of the low back pain: vertebral fracture; vertebral joint dislocation; muscle tears or lacerations; spinal or vertebral joint ligament rupture; inflammation of intervertebral discs, spinal zygapophyseal facets joints, muscles or fascia; skin lacerations; sacroiliitis; ankylosing spondylitis; or masses in or from the low back structures that are the source of the pain. Exclusion from this guideline does not imply that OMT is contraindicated in these conditions.

6. Developer: Identify the organization(s) responsible for guideline development and the names/credentials/potential conflicts of interest of individuals involved in the guideline’s development.


7. Funding source/sponsor: Identify the funding source/sponsor and describe its role in developing and/or reporting the guideline. Disclose potential conflict of interest.

This project was funded by the American Osteopathic Association. The AOA Bureau of Osteopathic Clinical Education and Research convened a Task Force on the Low Back Pain Clinical Practice Guidelines to revise the guidelines. Upon approval of these recommendations by the AOA Board of Trustees and the AOA House of Delegates, the guidelines will be submitted to the National Guidelines Clearinghouse for public record and access. As the guidelines were developed based on the peer reviewed scientific literature, no conflict of interest is claimed by the developers. A well rounded, objective perspective is presented. Any view from an osteopathic perspective that is not supported by the scientific literature is stated and clearly identified so the reader is able to discern any potential for bias.

8. Evidence collection: Describe the methods used to search the scientific literature, including the range of dates and databases searched, and criteria applied to filter the retrieved evidence.

This guideline update process commenced with literature searches that included electronic databases, personal contact with key researchers of OMT and low back pain, and internet search engines. Early in the process, the AOA discovered the systematic literature review conducted by Franke, Franke and Fryer (2014) which serves as the basis for this updated guideline.
Franke et al\textsuperscript{2} searched electronic reference databases, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, CINAHL, PEDro, OSTMED.DR, and Osteopathic Web Research using the following search terms: low back pain, back pain, lumbopelvic pain, dorsalgia, osteopathic manipulative treatment, OMT, and osteopathic medicine. In addition to the listed databases, the authors conducted searches in an ongoing trial database (metaRegister of Controlled Trials). To enhance their search, the authors tracked citations of identified trials, and manually searched reference lists for other relevant papers.

The authors reviewed all the studies using a standardized form, and all mean differences (MD) and standard mean differences (SMD) were calculated with 95% confidence intervals (CIs). Overall effect size was calculated at the 3 month post treatment follow-up. GRADE approach, as recommended by the updated Cochrane Back Review Group method guidelines, was used to assess quality of evidence.

Franke et al searched electronic databases, reference lists and personal communications. Their inclusion criteria consisted of randomized clinical trials of adults (>18 years of age) with nonspecific back pain treated by osteopathic physicians or osteopaths who used their clinical judgment as opposed to a standard predetermined protocol. Studies with pregnant and postpartum participants were also included. Studies excluded from the review were those where co-interventions were not performed on both comparison groups; the OMT intervention could not be assigned an effect size; participants had specific back pain from pathology (i.e., fracture, tumor, metastasis, inflammation, infection); or the intervention consisted of a single manual technique.

The primary outcomes for the Franke et al review were pain and functional status. The authors measured pain using the visual analogue scale (VAS), number rating scale (NRS), or the McGill Pain Questionnaire. Functional status was measured using the Roland-Morris Disability Questionnaire, Oswestry- Disability Index, or other valid instrument. The point of measurement for both outcomes was the first 3 month interval.

Studies were independently reviewed using a standardized form. The mean difference (MD) or standard mean difference (SMD) with 95% confidence intervals (CIs) and overall effect size were calculated at 3 months post treatment. GRADE approach, as recommended by the updated Cochrane Back Review Group method guidelines, was used to assess quality of evidence.

Of the 15 studies\textsuperscript{14-28} included in the review, 6 were retrieved from Germany,\textsuperscript{17,18,20,25,26,27} 5 from the United States,\textsuperscript{14,15,21,22,23} 2 from the United Kingdom,\textsuperscript{16,19} and 2 from Italy.\textsuperscript{24,26} (see Appendix 2) Ten studies investigated effectiveness of OMT for LBP,\textsuperscript{14-17,18,19,22-24,28} 3 studies examined the effect of OMT for LBP in pregnant women,\textsuperscript{20,21,25} and 2 studied the effect of OMT for LBP in postpartum women.\textsuperscript{26,27} All studies reported on the effect of OMT on pain, and all but one reported on back pain specific functional status. There were a total of 1502 participants included in the qualitative and quantitative analysis.

9. Recommendation grading criteria: Describe the criteria used to rate the quality of evidence that supports the recommendations and the system for describing the strength of the recommendations. Recommendation strength communicates the importance of adherence to a recommendation and is based on both the quality of the evidence and the magnitude of anticipated benefits or harms.
Franke et al.\textsuperscript{2} evaluated the methodological quality of the studies using the Risk of Bias tool of the Cochrane Back Review Group. Studies were scored as ‘low risk’, ‘high risk’, or ‘unclear’, and included assessments of randomization, blinding, baseline comparability between groups, patient compliance, and dropping out. Per the Cochrane Back Review Group, studies received a ‘low risk’ score when a minimum of 6 criteria were met and it was determined that the study had no serious flaws (e.g., a drop-out rate over 50%). Disagreements about the quality of the studies were resolved through discussion and consensus. Franke et al. used Review Manager to analyze the data for the meta-analysis. The authors converted the NRS and VAS scores from the included studies to a 100-point scale for the pain measurement, and calculated the mean difference (MD) with 95% Confidence Intervals (CIs) for the random effects model.

Franke et al. conducted other noteworthy analyses. The standard mean difference (SMD) was used in a random effects model to determine functional status. The authors grouped the 1 study examining acute LBP and the 3 studies examining patients with both acute and chronic LBP together for the purpose of their meta-analyses. Overall, they created four groups: (1) acute and chronic LBP; (2) chronic LBP (duration of pain more than 3 months); (3) LBP in pregnant women; and (4) LBP in postpartum women.

Franke et al. also assessed the clinical relevance of each study using the Cochrane Back Review Group recommendations. A small effect was defined as MD less than 10% of the scale and SMD less than 0.5. A medium effect was defined as MD 10% to 20% of the scale and SMD from 0.5 to 0.8. A large effect was defined as MD greater than 20% of the scale and SMD greater than 0.8.

10. Method for synthesizing evidence: Describe how evidence was used to create recommendations, e.g., evidence tables, meta-analysis, decision analysis.

Due to the applicability of the Franke et al. review to these updated guidelines and consequently, the reliance thereon, the AOA will describe how the authors synthesized their evidence. See Appendix 2 for a summary of the 15 studies included in Franke et al.

**OMT versus other interventions for acute and chronic nonspecific low back pain**

Franke et al.\textsuperscript{2} analyzed the effect of OMT for pain in acute and chronic LBP using ten studies with 12 comparison groups and 1141 participants. Six studies reported a significant effect of OMT on Pain,\textsuperscript{14,17,18,22,24,28} 3 studies showed a non-significant effect,\textsuperscript{15,16,23} and 3 studies reported a non-significant effect in favor of the control treatment.\textsuperscript{16,19,23} Collectively, the studies showed moderate-quality evidence that OMT had a significant effect on pain relief (MD: -12.91, 95% CI: -20.00 to -5.82).

For functional status, the authors based their results on 9 studies with 10 comparisons groups and 1046 participants. The studies revealed moderate-quality evidence that a significant difference in favor of OMT existed (SMD: -0.36, 95% CI: -0.58 to -0.14). Four studies reported a significant effect of OMT,\textsuperscript{17,18,24,28} 3 studies reported a non-significant effect,\textsuperscript{14,15,19} and 1 study reported a non-significant effect in favor of the control group.\textsuperscript{23}
OMT versus other interventions for chronic nonspecific low back pain

For nonspecific LBP, Franke et al. analyzed 6 studies with 7 comparisons and 769 participants. This analysis revealed moderate-quality evidence that a significant difference in favor of OMT existed (MD: -14.93, 95% CI: -25.18 to -4.68).

For functional status outcomes, the authors reviewed 3 studies which reported a significant improvement for OMT. One study reported a non-significant effect for OMT, and 1 study reported an effect for the control group. Collectively, the analysis showed moderate-quality evidence for a significant difference in favor of OMT (SMD: -0.32, CI: 0.58 to -0.07).

OMT versus usual obstetric care, sham ultrasound, and untreated for nonspecific low back pain in pregnant women

For LBP in pregnant women, the authors reviewed three studies with 4 comparisons and 242 participants. Two studies showed a significant improvement following OMT, and 1 study showed a non-significant improvement. The final analysis of these studies resulted in low-quality evidence for a significant difference in favor of OMT for LBP in pregnant women (MD: -23.01; 95% CI: -44.13 to -1.88) and functional status (SMD: -0.80; 95% CI: -1.36 to -0.23).

Two other important studies published subsequent to the Franke et al. systematic review address LBP in pregnant women and enhance the findings of Frank et al. Hensel et al. found that OMT was effective for mitigating pain and functional deterioration compared with usual care only; however, OMT did not differ significantly from placebo ultrasound treatment. The authors concluded that OMT is a safe, effective adjunctive modality to improve pain and functioning during the third trimester. In yet another study conducted by Licciardone et al., the investigators found that during the third trimester of pregnancy OMT has medium to large treatment effects in preventing progressive back-specific dysfunction. (See Appendix 2)

OMT versus untreated for nonspecific low back pain in postpartum women

Franke et al. reviewed two studies focusing on OMT for LBP in postpartum women. Both studies reported significant improvement following OMT. The moderate-quality evidence showed a significant difference in favor of OMT for pain (MD: -41.85; 95% CI: -49.43 to -34.27) and functional status (SMD: -1.78; 95% CI: -2.21 to -1.35).

DISCUSSION

According to our review and Franke et al.’s systematic review and meta-analysis, OMT has a significant effect on LBP (acute and chronic), LBP in pregnant women, and LBP in postpartum women. OMT appears to have a larger effect on pain than functional status. This result may be attributed to the lapse of time between the intervention and when outcomes were measured. The majority of the studies measured outcomes 3 months after the intervention, and the subjective experience of pain may respond to treatment sooner than function. According to the criteria recommended by the Cochrane Collaboration, the significant effects are also clinically relevant.

The Franke et al. review, on which these guidelines are based, enhanced the Licciardone 2005 systematic review on which the previous guidelines were based. There are slight differences as
noted in the Franke discussion section. For example, Frank et al. excluded two studies\textsuperscript{31,32} that were included in the 2005 Licciardone et al. review because they involved single techniques rather than an osteopathic intervention where the clinician was free to use clinical judgment for each patient, as occurs in clinical practice. Franke et al. also did not include studies with specific causes of LBP.\textsuperscript{33} The Franke review also included studies of LBP associated with pregnant and postpartum women which were pooled and analyzed separately. Despite these differences in the two systematic reviews, the results of the Franke et al.\textsuperscript{2} study and the Licciardone et al.\textsuperscript{3} study are similar, concluding that OMT may be an effective treatment for LBP.

Limitations of the studies included in these guidelines are the small sample sizes and difference in comparison groups. For Franke et al., the majority of the included studies had relatively small sample sizes,\textsuperscript{14-28} but collectively, there were over 400 participants included in the analysis of chronic and acute pain and for chronic pain. Unfortunately, the separate analysis of LBP in pregnant and postpartum women was collectively a smaller sample (less than 400 participants), which indicated an imprecision of results and a downgrading of the level of evidence.\textsuperscript{34} Also, as Franke et al. alluded to in their article, the control groups included in studies need to be more compatible to the OMT intervention groups.

Another limitation of the studies included in the Franke review was the absence of reporting on the exact OMT interventions performed for each patient; only a range of manual techniques for OMT were included. The lack of specific information on the delivery of OMT results in the inability to ascertain the treatment received by different patient groups or to identify the most effective OMT interventions for LBP.

11. Prerelease review: Describe how the guideline developer reviewed and/or tested the guidelines prior to release.

Guidelines were reviewed by the Bureau of Osteopathic Clinical Education and Research, the AOA Board of Trustees, and the AOA House of Delegates.

12. Update plan: State whether or not there is a plan to update the guideline and, if applicable, an expiration date for this version of the guideline.

The guidelines will be updated every 5 years.

13. Definitions: Define unfamiliar terms and those critical to correct application of the guideline that might be subject to misinterpretation.

OMT referred specifically to manual treatment provided by osteopathic physicians, or other physicians who had demonstrated training and proficiency in OMT, such as those practitioners in Europe who may have undertaken osteopathic conversion programs.

14. Recommendations and rationale: State the recommended action precisely and the specific circumstances under which to perform it. Justify each recommendation by describing the linkage between the recommendation and its supporting evidence. Indicate the quality of evidence and the recommendation strength, based on the criteria described in 9.
Based on this meta-analysis (evidence level 1a – see Table 2) of RCTs on OMT for patients with low back pain, it is recommended that OMT be utilized by osteopathic physicians for musculoskeletal causes of low back pain, i.e., to treat the diagnoses of somatic dysfunctions related to low back pain.

**Table 1  Levels of Evidence**

<table>
<thead>
<tr>
<th>Strength of evidence</th>
<th>Type of Study</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>1a</td>
<td>Systematic review with homogeneity of randomized controlled trials</td>
<td>Individual trials should be free of substantial variations in the directions and magnitudes of results</td>
</tr>
<tr>
<td>1b</td>
<td>Individual randomized controlled trial with narrow confidence interval</td>
<td>Confidence interval should indicate a clinically important OMT effect</td>
</tr>
<tr>
<td>1c</td>
<td>Differential frequency of adverse outcomes</td>
<td>An adverse outcome was frequently observed in patients who did not receive OMT, but was infrequently observed in patients who did receive OMT (equivalent to a small number needed to treat)</td>
</tr>
<tr>
<td>2a</td>
<td>Systematic review with homogeneity of cohort studies</td>
<td>Individual studies should be free of substantial variations in the directions and magnitudes of OMT effects</td>
</tr>
<tr>
<td>2b</td>
<td>Individual cohort study or low-quality randomized controlled trial</td>
<td>Low quality may be indicated by such factors as important differences in baseline characteristics between groups, lack of concealment of treatment allocation, and excessive losses to follow-up</td>
</tr>
<tr>
<td>3a</td>
<td>Systematic review with homogeneity of case-control studies</td>
<td>Individual studies should be free of substantial variations in the directions and magnitudes of OMT effects</td>
</tr>
<tr>
<td>3b</td>
<td>Individual case-control study</td>
<td>These should be free of substantial evidence of selection bias, information bias, or confounding variables</td>
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</table>
4  |  Case series and low quality cohort and case-control studies  |  Low quality of cohort and case control studies may be indicated by such factors as important sources of selection bias, information bias, or confounding variables  
5  |  Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"  |  These generally will have limited empirical data relevant to OMT effects in human populations  

*Adapted from Straus SE, Richardson WS, Glasziou P, and Haynes RB, Evidence-Based Medicine. How to Practice and Teach EBM (3rd ed.), 2005

15. Potential benefits and harms: Describe anticipated benefits and potential risks associated with implementation of guideline recommendations.

Potential benefits include but are not limited to improved care for patients seeing osteopathic physicians or practitioners for somatic dysfunctions causing low back pain. Harms have not been identified in randomized clinical trials on OMT for patients with low back pain. OMT for somatic dysfunction has not demonstrated harm in any clinical trials to date.

16. Patient preferences: Describe the role of patient preferences when a recommendation involves a substantial element of personal choice or values.

Patients have a choice of provider and services when they suffer from low back pain. OMT offers another option for care for low back pain from somatic dysfunction and can be provided by osteopathic physicians. It is utilized as adjunct or complementary to conventional or alternative methods of treatment.

17. Algorithm: Provide (when appropriate) a graphical description of the stages and decisions in clinical care described by the guideline.

Once a patient with low back pain is diagnosed with somatic dysfunction as the cause, or contributing factor, of the low back pain, OMT should be utilized by the osteopathic physician. The diagnosis of somatic dysfunction entails a focal or complete history and physical exam, including an osteopathic structural exam that provides evidence of asymmetrical anatomical landmarks, restriction or altered range of joint motion, and palpatory abnormalities of soft tissues. OMT is used to treat somatic dysfunction after other potential causes of low back pain are ruled out or considered improbable by the treating physician (i.e., vertebral fracture; vertebral joint dislocation; muscle tears or lacerations; spinal or vertebral joint ligament rupture; inflammation of intervertebral discs, spinal zygapophyseal facets joints, muscles or fascia; skin lacerations; sacroiliitis; ankylosing spondylitis; masses in or from the low back structures; or organic (visceral) disease referring pain to the back or causing low back muscle spasms).

Algorithm for OMT LBP decision making

Is Somatic dysfunction the cause, or a contributing factor, in the presentation of LBP (Look for “Red Flags”)?

No

Identify cause of LBP and treat accordingly.

Contributing factor: Identify primary cause of LBP and treat accordingly. Treat contributing somatic dysfunction using the same decision making as followed if the LBP is solely the result of somatic dysfunction.

Yes

Cause:

A) Define type of dysfunctional mechanics and as appropriate, define the dysfunctional barrier.

B) Determine why the dysfunction is present (e.g., articular, muscular, myofascial, neuroreflex, membranous).

C) Determine the patient’s level of tolerance for OMT.

D) Decide upon the type of OMT to most effectively address the cause of the dysfunction with consideration for patient tolerance.

E) Apply OMT to accomplish the desired response.

F) Reassess the dysfunction and determine if and when follow-up evaluation is necessary.

Follow-up, if appropriate, and repeat steps A-F.

18. Implementation considerations: Describe anticipated barriers to application of the recommendations. Provide reference to any auxiliary documents for providers or patients that are intended to facilitate implementation. Suggest review criteria for measuring changes in care when the guideline is implemented.
One of the barriers to application of the recommendations cited by osteopathic physicians has been poor reimbursement for OMT. However, Medicare has reimbursed osteopathic physicians for this procedure for over 30 years. Many osteopathic physicians apparently do not utilize OMT in clinical practice due to a number of barriers, including time constraints, lack of confidence, loss of skill over time from disuse, and inadequate office space. Some specialists (i.e., pathologists and radiologists) do not use OMT as it is not applicable to their duties within their specialty. The AOA believes patients with low back pain should be treated with OMT given the high level of evidence that supports its efficacy. Changes in care when these guidelines are implemented will be determined by physician and patient surveys, billing and coding practice patterns amongst osteopathic physicians, data gathered from osteopathic physicians via the AOA’s Clinical Assessment Program, and other registry data gathering tools currently being developed by researchers.

ACKNOWLEDGMENT

The AOA would like to thank the Task Force on the Low Back Pain Clinical Practice Guidelines (Richard J. Snow, DO, MPH, (chair), Michael Seffinger, DO, Kendi Hensel, DO, PhD, and Rodney Wiseman, DO) for their work on this project, John C. Licciardone, DO, MBA for his comments on the guidelines, and Helge Franke, DO (Germany), MSc, Jan-David Franke, and Gary Fryer, PhD, BSc for allowing us to use their systematic review as the basis for the guidelines.

REFERENCES


Appendix 1

DEFINITION OF TERMS USED

Glossary of Osteopathic Terminology, Revised November 2011. Reprinted with permission from the American Association of Colleges of Osteopathic Medicine. All rights reserved.

To download the complete Glossary, please go to http://www.aacom.org/news-and-events/publications/glossary-of-osteopathic-terminology

**osteopathic manipulative treatment (OMT):** The therapeutic application of manually guided forces by an osteopathic physician (U.S. usage) to improve physiologic function and/or support homeostasis that has been altered by somatic dysfunction. OMT employs a variety of techniques including:

**active method,** technique in which the person voluntarily performs an osteopathic practitioner-directed motion.

**articulatory treatment,** (Archaic). See osteopathic manipulative treatment, articulatory treatment system.

**articulatory (ART),** a low velocity/ moderate to high amplitude technique where a joint is carried through its full motion with the therapeutic goal of increased range of movement. The activating force is either a repetitive springing motion or repetitive concentric movement of the joint through the restrictive barrier.

**balanced ligamentous tension (BLT),** 1. According to Sutherland’s model, all the joints in the body are balanced ligamentous articular mechanisms. The ligaments provide proprioceptive information that guides the muscle response for positioning the joint, and the ligaments themselves guide the motion of the articular components. (Foundations) 2. First described in “Osteopathic Technique of William G. Sutherland,” that was published in the 1949 Year Book of Academy of Applied Osteopathy. See also ligamentous articular strain.

**Chapman reflex,** See Chapman reflex.

**combined method,** 1. A treatment strategy where the initial movements are indirect; as the technique is completed the movements change to direct forces. 2. A manipulative sequence involving two or more different osteopathic manipulative treatment systems (e.g., Spencer technique combined with muscle energy technique). 3. A concept described by Paul Kimberly, DO.

**combined treatment,** (Archaic). See osteopathic manipulative treatment, combined method.

**compression of the fourth ventricle (CV-4),** a cranial technique in which the lateral angles of the occipital squama are manually approximated slightly exaggerating the posterior convexity of the occiput and taking the cranium into sustained extension.
counterstrain (CS), 1. A system of diagnosis and treatment that considers the dysfunction to be a continuing, inappropriate strain reflex, which is inhibited by applying a position of mild strain in the direction exactly opposite to that of the reflex; this is accomplished by specific directed positioning about the point of tenderness to achieve the desired therapeutic response. 2. Australian and French use: Jones technique, (correction spontaneous by position), spontaneous release by position. 3. Developed by Lawrence Jones, DO in 1955 (originally “Spontaneous Release by Positioning,” later termed “strain-counterstrain”).

cranial treatment (CR), See primary respiratory mechanism. See osteopathy in the cranial field.

CV-4, abbreviation for compression of the fourth ventricle. See osteopathic manipulative treatment, compression of the fourth ventricle.

Dalrymple treatment, See osteopathic manipulative treatment, pedal pump.

direct method (D/DIR), an osteopathic treatment strategy by which the restrictive barrier is engaged and a final activating force is applied to correct somatic dysfunction.

exaggeration method, an osteopathic treatment strategy by which the dysfunctional component is carried away from the restrictive barrier and beyond the range of voluntary motion to a point of palpably increased tension.

exaggeration technique, an indirect procedure that involves carrying the dysfunctional part away from the restrictive barrier, then applying a high velocity/low amplitude force in the same direction.

facilitated oscillatory release technique (FOR), 1. A technique intended to normalize neuromuscular function by applying a manual oscillatory force, which may be combined with any other ligamentous or myofascial technique. 2. A refinement of a long-standing use of oscillatory force in osteopathic diagnosis and treatment as published in early osteopathic literature. 3. A technique developed by Zachary Comeaux, DO.

facilitated positional release (FPR), a system of indirect myofascial release treatment. The component region of the body is placed into a neutral position, diminishing tissue and joint tension in all planes, and an activating force (compression or torsion) is added. 2. A technique developed by Stanley Schiowitz, DO.

fascial release treatment, See osteopathic manipulative treatment, myofascial release.

fascial unwinding, a manual technique involving constant feedback to the osteopathic practitioner who is passively moving a portion of the patient's body in response to the sensation of movement. Its forces are localized using the sensations of ease and bind over wider regions.

functional method, an indirect treatment approach that involves finding the dynamic balance point and one of the following: applying an indirect guiding force, holding the position or adding compression to exaggerate position and allow for spontaneous readjustment. The osteopathic practitioner guides the manipulative procedure while the dysfunctional area is
being palpated in order to obtain a continuous feedback of the physiologic response to induced motion. The osteopathic practitioner guides the dysfunctional part so as to create a decreasing sense of tissue resistance (increased compliance).

**Galbreath treatment**, See osteopathic manipulative treatment, mandibular drainage.

**haptic pump**, rhythmic compression applied over the liver for purposes of increasing blood flow through the liver and enhancing bile and lymphatic drainage from the liver.

**high velocity/low amplitude technique (HVLA)**, an osteopathic technique employing a rapid, therapeutic force of brief duration that travels a short distance within the anatomic range of motion of a joint, and that engages the restrictive barrier in one or more planes of motion to elicit release of restriction. Also known as thrust technique.

**Hoover technique**, 1. A form of functional method. 2. Developed by H.V. Hoover, DO. See also osteopathic manipulative treatment, functional technique.

**indirect method (I/IND)**, a manipulative technique where the restrictive barrier is disengaged and the dysfunctional body part is moved away from the restrictive barrier until tissue tension is equal in one or all planes and directions.

**inhibitory pressure technique**, the application of steady pressure to soft tissues to reduce reflex activity and produce relaxation.

**integrated neuromusculoskeletal release (INR)**, a treatment system in which combined procedures are designed to stretch and reflexly release patterned soft tissue and joint-related restrictions. Both direct and indirect methods are used interactively.

**Jones technique**, See osteopathic manipulative treatment, counterstrain.

**ligamentous articular strain technique (LAS)**, 1. A manipulative technique in which the goal of treatment is to balance the tension in opposing ligaments where there is abnormal tension present. 2. A set of myofascial release techniques described by Howard Lippincott, DO, and Rebecca Lippincott, DO. 3. Title of reference work by Conrad Speece, DO, and William Thomas Crow, DO.

**liver pump**, See hepatic pump.

**lymphatic pump**, 1. A term used to describe the impact of intrathoracic pressure changes on lymphatic flow. This was the name originally given to the thoracic pump technique before the more extensive physiologic effects of the technique were recognized. 2. A term coined by C. Earl Miller, DO.

**mandibular drainage technique**, soft tissue manipulative technique using passively induced jaw motion to effect increased drainage of middle ear structures via the eustachian tube and lymphatics.
mesenteric release technique (mesenteric lift), technique in which tension is taken off the attachment of the root of the mesentery to the posterior body wall. Simultaneously, the abdominal contents are compressed to enhance venous and lymphatic drainage from the bowel.

muscle energy, a form of osteopathic manipulative diagnosis and treatment in which the patient’s muscles are actively used on request, from a precisely controlled position, in a specific direction, and against a distinctly executed physician counterforce. First described in 1948 by Fred Mitchell, Sr, DO.

myofascial release (MFR), a system of diagnosis and treatment first described by Andrew Taylor Still and his early students, which engages continual palpatory feedback to achieve release of myofascial tissues.

- **direct MFR**, a myofascial tissue restrictive barrier is engaged for the myofascial tissues and the tissue is loaded with a constant force until tissue release occurs.

- **indirect MFR**, the dysfunctional tissues are guided along the path of least resistance until free movement is achieved.

myofascial technique, any technique directed at the muscles and fascia. See also osteopathic manipulative treatment, myofascial release. See also osteopathic manipulative treatment, soft tissue technique.

myotension, a system of diagnosis and treatment that uses muscular contractions and relaxations under resistance of the osteopathic practitioner to relax, strengthen or stretch muscles, or mobilize joints.

Osteopathy in the Cranial Field (OCF), 1. A system of diagnosis and treatment by an osteopathic practitioner using the primary respiratory mechanism and balanced membranous tension. See also primary respiratory mechanism. 2. Refers to the system of diagnosis and treatment first described by William G. Sutherland, DO. 3. Title of reference work by Harold Magoun, Sr, DO.

passive method, based on techniques in which the patient refrains from voluntary muscle contraction.

pedal pump, a venous and lymphatic drainage technique applied through the lower extremities; also called the pedal fascial pump or Dalrymple treatment.

percussion vibrator technique, 1. A manipulative technique involving the specific application of mechanical vibratory force to treat somatic dysfunction. 2. An osteopathic manipulative technique developed by Robert Fulford, DO.

positional technique, a direct segmental technique in which a combination of leverage, patient ventilatory movements and a fulcrum are used to achieve mobilization of the dysfunctional segment. May be combined with springing or thrust technique.
progressive inhibition of neuromuscular structures (PINS), 1. A system of diagnosis and treatment in which the osteopathic practitioner locates two related points and sequentially applies inhibitory pressure along a series of related points. 2. Developed by Dennis Dowling, DO.

range of motion technique, active or passive movement of a body part to its physiologic or anatomic limit in any or all planes of motion.

soft tissue (ST), A system of diagnosis and treatment directed toward tissues other than skeletal or arthrodial elements.

soft tissue technique, a direct technique that usually involves lateral stretching, linear stretching, deep pressure, traction and/or separation of muscle origin and insertion while monitoring tissue response and motion changes by palpation. Also called myofascial treatment.

Spencer technique, a series of direct manipulative procedures to prevent or decrease soft tissue restrictions about the shoulder. See also osteopathic manipulative treatment (OMT), articulatory treatment (ART).

splenic pump technique, rhythmic compression applied over the spleen for the purpose of enhancing the patient’s immune response. See also osteopathic manipulative treatment (OMT), lymphatic pump.

spontaneous release by positioning, See osteopathic manipulative treatment, counterstrain.

springing technique, a low velocity/ moderate amplitude technique where the restrictive barrier is engaged repeatedly to produce an increased freedom of motion. See also osteopathic manipulative treatment, articulatory treatment system.

Still Technique, 1. Characterized as a specific, non-repetitive articulatory method that is indirect, then direct. 2. Attributed to A.T. Still. 3. A term coined by Richard Van Buskirk, DO, PhD.

Strain-Counterstrain®, 1. An osteopathic system of diagnosis and indirect treatment in which the patient’s somatic dysfunction, diagnosed by (an) associated myofascial tenderpoint(s), is treated by using a passive position, resulting in spontaneous tissue release and at least 70 percent decrease in tenderness. 2. Developed by Lawrence H. Jones, DO, in 1955. See osteopathic treatments, counterstrain.

thoracic pump, 1. A technique that consists of intermittent compression of the thoracic cage. 2. Developed by C. Earl Miller, DO.

thrust technique (HVLA), See osteopathic manipulative treatment, high velocity/low amplitude technique (HVLA).

toggle technique, short lever technique using compression and shearing forces.
traction technique, a procedure of high or low amplitude in which the parts are stretched or separated along a longitudinal axis with continuous or intermittent force.

v-spread, technique using forces transmitted across the diameter of the skull to accomplish sutural gapping.

ventral techniques, See osteopathic manipulative treatment, visceral manipulation.

visceral manipulation (VIS), a system of diagnosis and treatment directed to the viscera to improve physiologic function. Typically, the viscera are moved toward their fascial attachments to a point of fascial balance. Also called ventral techniques.

somatic dysfunction: Impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodial and myofascial structures, and their related vascular, lymphatic, and neural elements. Somatic dysfunction is treatable using osteopathic manipulative treatment.
<table>
<thead>
<tr>
<th>ref # in LBP guidelines</th>
<th>Author</th>
<th>Year</th>
<th>Country</th>
<th>Purpose</th>
<th>Type of LBP Pain</th>
<th>OMT Comparison</th>
<th>Outcomes</th>
<th>Findings</th>
<th>Pain: OMT Effect</th>
<th>Function: OMT Effect</th>
<th>Pain: OMT v. Other Function: OMT v. Other</th>
</tr>
</thead>
</table>
| 18                      | Adorján-Schaumann    | 1999 | Germany          | Can OMT provide a specified effect on the functional impairment and pain of patients with chronic lumbar back pain? | Chronic                 | Sham Manipulative Treatment                  | 1. Roland Morris life quality score  
2. Visual analogue scale pain  
3. SF-36 (modified)  
4. Side effects | ‘OMT – in comparison to the sham treatment - shows statistically significant and clinically important improvements regarding primary and secondary outcome measures.’ | Significant effect in favor of OMT | Significant effect in favor of OMT | Significant effect in favor of OMT | Significant improvement in favor of OMT |
2. Roland Morris Disability Questionnaire  
3. Oswestry Pain Questionnaire  
4. Range of Motion  
5. Straight-leg raising | ‘Osteopathic manual care and standard medical care have similar clinical results in patients with favor of OMT subacute low back pain. However, the use of medication is greater with standard care.’ | Non-significant effect in favor of OMT | Non-significant effect in favor of OMT | Non-significant effect in favor of OMT | Non-significant effect in favor of OMT |
| 19                      | Chown               | 2008 | U.K.             | Is one to one physiotherapy or physiotherapy - led group exercise as effective as one to one osteopathy for patients with chronic low back pain? | Chronic                 | Physiotherapy                                 | 1. Oswestry Disability Index  
2. EuroQol EQ-5D  
3. Visual analogue scale pain  
4. Shuttle walk test | ‘All three treatments indicated comparable reductions in mean [95% CI] ODI at 6-week follow-up … One-to-one therapies provided evidence of greater patient satisfaction.’ | Non-significant effect in favor of control treatment | Non-significant effect in favor of OMT | Significant effect in favor of OMT | Non-significant effect in favor of OMT |
| 14                      | Cruser              | 2012 | U.S.             | Examination of efficacy of OMT in relieving acute low back pain and improving functioning in military personnel. | Acute                   | Usual Care                                    | 1. Quadruple Visual Analogue Scale  
2. Roland Morris Disability Questionnaire  
3. SF-36  
4. Patient expectation questionnaire | The study supports the effectiveness of OMT in reducing acute LBP pain in active duty military personnel. | Significant effect in favor of OMT | Non-significant effect in favor of OMT | Non-significant effect in favor of OMT | Non-significant effect in favor of OMT |
| 16                      | Gibson              | 1985 | U.K.             | Comparison of OMT with SWD and placebo SWD in nonspecific low back pain | Acute & Chronic         | Sham Short-Wave Diathermy                     | 1. Visual analogue scale pain (daytime and nocturnal scores)  
2. Spinal flexion  
3. Return to work  
4. Recovery  
5. Analgesic consumption | ‘These observations indicate that neither osteopathic manipulation nor SWD was superior to placebo treatment.’ | Non-significant effect in favor of OMT | Non-significant effect in favor of control treatment | Non-significant effect in favor of control treatment | Non-significant effect in favor of OMT |
| 17                      | Heinze              | 2006 | Germany          | Determination of the efficacy of OMT applied to subacute lumbar back pain | Acute & Chronic         | Physical Therapy & Heat                       | 1. Numeric rating scale for current and average level of pain  
2. Roland Morris Disability Questionnaire | ‘In the area of pain, as well as in the area of the disabilities a clinically relevant improvement could be achieved.’ | Significant effect in favor of OMT | Significant effect in favor of OMT | Significant effect in favor of OMT | Non-significant effect in favor of OMT |
| 23                      | Licciardone         | 2003 | U.S.             | Determination of the efficacy of OMT as a complementary treatment for chronic nonspecific LBP. | Chronic                 | Untreated & Sham Manipulative Treatment       | 1. SF-36  
2. Visual analogue scale pain  
3. Roland Morris Disability Questionnaire  
4. Work disability  
5. Satisfaction with back care | OMT and sham manipulation ‘both appear to provide some benefits when used in addition to usual care for the treatment of chronic nonspecific low back pain’. | Non-significant effect in favor of OMT | Non-significant effect in favor of control treatment | Non-significant effect in favor of control treatment | Significant effect in favor of control group intervention |
22 Licciardone 2013 U.S. To study the efficacy of OMT and UST for chronic low back pain. Chronic: Sham Osteopathic Manipulative Treatment 1. Visual analogue scale pain 2. Roland Morris Disability Questionnaire 3. SF-36 general health score 4. Lost work days 5. Satisfaction with back care 6. Cotreatments 'The OMT regimen met or exceeded the Cochrane Back Review Group criterion for a medium effect size in relieving chronic low back pain. It was safe, parsimonious, and well accepted by patients.' Significant effect in favor of OMT Significant effect in favor of OMT

24 Mandara 2008 Italy To compare the effects of OMT with sham manipulative treatment (SMT) on patient’s self-reported pain and disability. Chronic: Sham Manipulative Treatment 1. Visual analogue scale pain 2. Oswestry Disability Index 'OMT appears to provide benefits over and above usual care for the treatment of CLBP. The improvement in the OMT compared to the SMT demonstrated that placebo effects... do not justify per se the results of this study.' Significant effect in favor of OMT Significant effect in favor of OMT Significant improvement in favor of OMT

28 Vismara 2012 Italy Is OMT combined with specific exercises more effective than specific exercises alone in obese female patients with chronic low back pain? Chronic: Specific Exercises 1. Kinematic of thoracic/ lumbar spine/ pelvis during forward flexion 2. Visual analogue scale pain 3. Roland Morris Disability Questionnaire 4. LBP-Disability Questionnaire 'OMT + SE showed to be effective in improving biomechanical parameters of the thoracic spine in obese patients with chronic LBP...' Significant effect in favor of OMT Significant effect in favor of OMT Significant effect in favor of OMT Significant improvement in favor of OMT

Studies on pregnancy and post partum back pain included in the Franke et al systematic review

<table>
<thead>
<tr>
<th>ref # in LBP guidelines</th>
<th>Author</th>
<th>Year</th>
<th>Country</th>
<th>Purpose</th>
<th>Type of LPB Pain</th>
<th>OMT Comparison</th>
<th>Outcomes</th>
<th>Findings</th>
<th>Pregnancy LBP: OMT Effect</th>
<th>Post-Partum: OMT v. Untreated</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 Gundermann 2013</td>
<td>Germany</td>
<td>2013</td>
<td>Germany</td>
<td>To evaluate the effectiveness of osteopathic treatment in pregnant women suffering from LBP</td>
<td>Pregnancy</td>
<td>Short-Wave Diathermy</td>
<td>1. Visual analogue scale pain, 2. Frequency of pain, 3. RMDQ, 4. Questionnaire (postpartum).</td>
<td>'Four osteopathic treatments over a period of 8 weeks led to statistically significant and clinically relevant positive changes of pain intensity and frequency in pregnant women suffering from low back pain.'</td>
<td>Significant Improvement after OMT</td>
<td></td>
</tr>
<tr>
<td>21 Licciardone 2009</td>
<td>U.S.</td>
<td>2009</td>
<td>U.S.</td>
<td>Examination of OMT for back pain and related symptoms during the third trimester of pregnancy.</td>
<td>Pregnancy</td>
<td>Usual Obstetric Care &amp; Sham Ultrasound Treatment</td>
<td>1. Back pain on an 11-point scale, analyzed like a 10-cm Visual analogue scale pain 2. Roland Morris Disability Questionnaire</td>
<td>'Osteopathic manipulative treatment slows or halts the deterioration of back-specific functioning during the third trimester of pregnancy.'</td>
<td>Non-significant improvement after OMT</td>
<td></td>
</tr>
<tr>
<td>25 Peters 2006</td>
<td>Germany</td>
<td>2006</td>
<td>Germany</td>
<td>Assessment whether OMT influences the ainsymptomatology of women with pregnancy related low back pain.</td>
<td>Pregnancy</td>
<td>Untreated</td>
<td>1. Visual analogue scale pain 2. Quebec Back Pain Disability Scale</td>
<td>'Four osteopathic treatments... could cause a clinically relevant influence on the pain-symptomatology and on the interference of daily life of pregnant women with pain in the pelvic and/or lumbar area'.</td>
<td>Significant Improvement after OMT</td>
<td></td>
</tr>
<tr>
<td>26 Recknagel 2007</td>
<td>Germany</td>
<td>2007</td>
<td>Germany</td>
<td>Investigation whether OMT had an effect on women with post-partum persistent unspecific backache.</td>
<td>Chronic, Post Partum</td>
<td>Untreated</td>
<td>1. Visual analogue scale pain 2. Oswestry Pain Questionnaire 3. Regions of dysfunction</td>
<td>OMT 'for women with persistent, unspecific backache post-partum brings about a clinically relevant improvement of the pain symptoms and a reduction of the impediment on daily life'.</td>
<td>Significant Improvement after OMT</td>
<td></td>
</tr>
</tbody>
</table>
Studies on pregnancy and back pain published after the Franke et al systematic review

<table>
<thead>
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<th>ref # in LBP guidelines</th>
<th>Author</th>
<th>Year</th>
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<th>Purpose</th>
<th>Type of LPB Pain</th>
<th>OMT Comparison</th>
<th>Outcomes</th>
<th>Findings</th>
<th>Pregnancy LBP: OMT Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>Hensel</td>
<td>2014</td>
<td>U.S.</td>
<td>To evaluate the efficacy of OMT to reduce low back pain and improve functioning during the third trimester of pregnancy and to improve selected outcomes of labor and delivery.</td>
<td>Pregnancy</td>
<td>Usual Care Only (UCO) &amp; Usual Care plus Placebo Ultrasound Treatment (PUT)</td>
<td>1. Visual analogue scale pain 2. Roland Morris Disability Scale</td>
<td>Findings indicate significant treatment effects for pain and back-related functioning (P &lt; .001 for both groups), with outcomes for the OMT group similar to that of the PUT group; however, both groups were significantly improved compared with the UCO group.</td>
<td>Significant Improvement after OMT</td>
</tr>
<tr>
<td>35</td>
<td>Licciardone</td>
<td>2013</td>
<td>U.S.</td>
<td>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.</td>
<td>Pregnancy</td>
<td>Usual obstetric care and OMT (UOBC+OMT), usual obstetric care and sham ultrasound therapy (UOBC+SUT), and usual obstetric care (UOBC)</td>
<td>1. Eleven-point numerical rating scale (NRS) for typical level of back pain 2. Roland Morris Disability Questionnaire for back-specific functioning</td>
<td>Patients who received UOBC+OMT were significantly less likely to experience progressive back-specific dysfunction (P&lt;0.0001 vs UOBC). The effect sizes for UOBC+OMT vs UOBC+SUT and for UOBC+OMT vs UOBC were classified as medium and large, respectively.</td>
<td>Significant Improvement after OMT</td>
</tr>
</tbody>
</table>