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

Task Force on the Low Back Pain Clinical Practice Guidelines

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Disclaimer: Drs Seffinger and Hensel, *JAOA* associate editors, were not involved in the editorial review or decision to publish these guidelines.

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Background: Osteopathic manipulative treatment (OMT) is a distinctive modality commonly used by osteopathic physicians to complement conventional management of musculoskeletal disorders, including those that cause low back pain (LBP). Osteopathic manipulative treatment is defined in the *Glossary of Osteopathic Terminology* as "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" (*eAppendix*). 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 Task Force on the Low Back Pain Clinical Practice Guidelines discovered the 2014 systematic literature review conducted by Franke et al[2]; this study serves as the basis for this updated guideline and further builds upon the literature used to support the previous guidelines. Findings from other eligible studies published after the search parameters of the Franke et al systematic review were also incorporated.

Results: The authors of the systematic review identified 307 studies. Thirty-one were evaluated and 16 were 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. Two additional studies published after the Franke et al review were also included.

Osteopathic manipulative treatment 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 nonspecific LBP, moderate-quality evidence suggested that OMT had a significant effect on pain relief (mean difference [MD], −12.91; 95% CI, −20.00 to −5.82) and functional status (standard mean difference [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; 95% 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).[2]

Conclusion: The conclusions of Franke et al further strengthen the findings that OMT reduces LBP. In a 2005 systematic review conducted by Licciardone et al[3] 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 3 months after treatment. Larger randomized controlled trials 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, as well as the cost-effectiveness of such treatment.

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Executive Summary

The American Osteopathic Association (AOA) 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 controlled trials (evidence level 1a; *Table 1*) 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 May 20, 2016. These guidelines are available on the AOA website and will be posted to the National Guidelines Clearinghouse. The guidelines are partially based on the following study:

> Franke H, Franke J-D, Fryer G. Osteopathic manipulative treatment for nonspecific low back pain: a systematic review and meta-analysis. *BMC Musculoskelet Disord*. 2014;15:286. doi:10.1186/1471-2474-15-286.

The format used for these guidelines is in accordance with the 2013 (Revised) Criteria for Inclusion of Clinical Practice Guidelines in the National Guidelines Clearinghouse and uses the 2011 definition of clinical practice guidelines developed by the Institute of Medicine (https://www.guideline.gov/about/inclusion-criteria.aspx): "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."

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:

> Chou R, Qaseem A, Snow V, et al; Clinical Efficacy Assessment Subcommittee of the American College of Physicians, American College of Physicians, American Pain Society Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med.* 2007;147(7):478-491.

Background

A majority of patients who visit osteopathic physicians seek treatment for musculoskeletal conditions, particularly low back pain.[4-6] 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 in the United States found that patients with acute low back problems without radiculopathy benefited from spinal manipulation if administered within the first month that symptoms occurred.[7]

In addition to these findings,[7] the investigators of the UK Back pain Exercise and Manipulation (UK BEAM) trial,[8-10] 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 3 professional groups.[8] Although 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 or any differences in outcomes.[9,10] Additionally, OMT and its range of techniques[11] 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 that may oversimplify findings that appear to be similar but are based on differing professions.[12] 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.[13]

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.[2] Additionally, they build upon the 2009 AOA clinical practice guidelines for low back pain[1] and the 2005 systematic review by Licciardone et al[3] 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 is 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 AOA does not believe it is appropriate for other professionals to create guidelines for utilization of OMT because it is not a procedure or approach used by those physicians. It is, however, the purview and duty of the AOA to inform its members and the public about the appropriate utilization of OMT.

4. Users/setting: Describe the intended users of the guideline (eg, 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 the application of OMT to patients in the ambulatory setting with nonspecific low back pain, which can

be defined as tension, soreness, or stiffness in the lower back region with an unidentified cause.[2]

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 disks, 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.

The AOA Bureau of Osteopathic Clinical Education and Research, Task Force on the Low Back Pain Clinical Practice Guidelines: Richard J. Snow, DO, MPH (chair); Michael A. Seffinger, DO; Kendi L. Hensel, DO, PhD; and Rodney Wiseman, DO.

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 AOA. 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. In August 2014, a member of the Task Force conducted a literature search using keywords including *back pain*, *low back pain*, *osteopathic manipulative treatment (OMT)*, *osteopathic, manual therapy*, and *randomized controlled trials (RCT)* in PubMed, CINAHL, Science Direct, and Springer Link databases from 2003-2014. During this search, the systematic review by Franke et al[2] published in August 2014 was discovered and a determination was made to base the revised guidelines on this publication.

Franke et al[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, Franke et al[2] tracked citations of identified trials and manually searched reference lists for other relevant papers.

Franke et al[2] reviewed all of the studies using a standardized form, and all mean differences (MD) and standard mean differences (SMD) were calculated with 95% CIs. Overall effect size was calculated at the 3-month posttreatment follow-up. The GRADE approach

Table 1.
Levels of Evidence

Strength of Evidence	Type of Study	Comment
1a	Systematic review with homogeneity of randomized controlled trials	Individual trials should be free of substantial variations in the directions and magnitudes of results
1b	Individual randomized controlled trial with narrow confidence interval	Confidence interval should indicate a clinically important OMT effect
1c	Differential frequency of adverse outcomes	An adverse outcome was frequently observed in patients who did not receive OMT, but it was infrequently observed in patients who did receive OMT (equivalent to a small number needed to treat)
2a	Systematic review with homogeneity of cohort studies	Individual studies should be free of substantial variations in the directions and magnitudes of OMT effects
2b	Individual cohort study or low-quality randomized controlled trial	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
3a	Systematic review with homogeneity of case-control studies	Individual studies should be free of substantial variations in the directions and magnitudes of OMT effects
3b	Individual case-control study	These should be free of substantial evidence of selection bias, information bias, or confounding variables
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

Abbreviation: OMT, osteopathic manipulative treatment.

Source: Adapted from Straus SE, Glasziou P, Richardson WS, Haynes RB. *Evidence-Based Medicine: How to Practice and Teach It*. 3rd ed. London, England; Churchill Livingstone; 2005.

(Grading of Recommendations Assessment, Development and Evaluation), as recommended by the updated Cochrane Back Review Group method guidelines, was used to assess quality of evidence.

Franke et al[2] searched electronic databases, reference lists, and personal communications. Their inclusion criteria consisted of randomized clinical trials of adults (aged >18 years) 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 in which co-interventions were not performed on both comparison groups; the OMT intervention could not be assigned an effect size; participants had specific low back pain from pathology (ie, fracture, tumor, metastasis, inflammation, infection); or the intervention consisted of a single manual technique.

The primary outcomes for the Franke et al review[2] were pain and functional status. The authors measured pain using the visual analog scale (VAS), number rating scale (NRS), or 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.

Of the 15 studies[14-28] included in the review, 6 were retrieved from Germany,[17,18,20,25-27] 5 from the United States,[14,15,21-23] 2 from the United Kingdom,[16,19] and 2 from Italy.[24,28] Ten studies investigated the effectiveness of OMT for LBP (*Table 2*),[14-17-19,22-24,28] 3 studies examined the effect of OMT for LBP in pregnant women,[20,21,25] and 2 studied the effect of OMT for LBP in postpartum women (*Table 3*).[26,27] All studies reported on the effect of OMT on pain, and all but 1 reported on back pain–specific functional status. There were a total of 1502 participants included in the qualitative and quantitative analysis.

Also in August 2014, personal communications yielded 2 additional articles by Hensel et al[29] and Licciardone and Aryal[35] published after Franke et al conducted their systematic review. No other studies were identified.

Two members of the Task Force reviewed the research design of these studies according to the methods used in the Franke et al systematic review and determined that both articles met the rigorous criteria applied by Franke et al. As stated by Franke et al,[2] "Only randomized clinical trials were included; specific back pain or single treatment techniques studies were excluded. Outcomes were pain and functional status. GRADE was used to assess quality of evidence." Franke et al[2] also concluded that "larger, high-quality randomized controlled trials with robust comparison groups are recommended."

Both the studies by Hensel et al[29] and Licciardone and Aryal[35] were larger than any previous studies and were high-quality randomized controlled trials with robust comparison groups. The Task Force concluded that these 2 articles were of high quality and low bias in the sense that they incorporated randomization, blinding, and baseline comparability between groups, and they addressed and accounted for patient compliance and dropouts. The Task Force agreed that these 2 recently published articles would have met the inclusion criteria of the Franke et al team and would have been included in the Franke et al systematic review had they been published earlier. The Task Force believes that the conclusions of these 2 studies supported the guidelines and were not contradictory to them.

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[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 (eg, a dropout rate over 50%). Disagreements about the quality of the studies were resolved through discussion and consensus. Franke et al[2] 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 pain measurement, and they calculated the MD with 95% CIs for the random effects model.

Franke et al[2] conducted other noteworthy analyses. The 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 4 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[2] 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.

Table 2.
Studies on Acute and Chronic Nonspecific LBP Included in the Systematic Review by Franke et al[2]

Study	Purpose	Type of LBP	OMT Comparison	Outcomes	Findings	OMT Effect		OMT vs Other	
						Pain	Function	Pain	Function
Adorjan-Schaumann[18] (Germany, 1999)	Can OMT provide a specified effect on the functional impairment and pain of patients with chronic lumbar back pain?	Chronic	SMT	1. Roland-Morris life quality score 2. VAS pain 3. SF-36 (modified) 4. Side effects	OMT—in comparison with SMT—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
Andersson[15] (US, 1999)	Comparison of OMT with standard care for patients with LBP	Acute and chronic	Usual care	1. VAS pain 2. RMDQ 3. Oswestry Pain Questionnaire 4. Range of Motion 5. Straight-leg raising	OMT and standard medical care have similar clinical results in patients with subacute LBP. However, the use of medication is greater with standard care.	Nonsignificant effect in favor of OMT	Nonsignificant effect in favor of OMT		
Chown[19] (UK, 2008)	Is one-to-one physiotherapy or physiotherapy-led group exercise as effective as one-to-one osteopathy for patients with chronic LBP?	Chronic	Physiotherapy	1. ODI 2. EuroQol EQ-5D 3. VAS pain 4. Shuttle walk test	All 3 treatments indicated comparable reductions in mean (95% CI) ODI at 6-week follow-up. One-to-one therapies provided evidence of greater patient satisfaction.	Nonsignificant effect in favor of control treatment	Nonsignificant effect in favor of OMT	Significant effect in favor of OMT	Nonsignificant effect in favor of OMT
Cruser[14] (US, 2012)	Examination of efficacy of OMT in relieving acute LBP and improving functioning in military personnel	Acute	Usual care	1. Quadruple VAS 2. RMDQ 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	Nonsignificant effect in favor of OMT		

(continued)

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

Owing to the applicability of the Franke et al review[2] to these updated guidelines and, consequently, the reliance thereon, the AOA will describe how the authors synthesized their evidence. See *Table 2* and *Table 3* for summaries of the 15 studies included in the Franke et al review.[2]

OMT vs Other Interventions for Acute and Chronic Nonspecific Low Back Pain

Franke et al[2] analyzed the effect of OMT for pain in acute and chronic LBP using 10 studies (*Table 2*) with 12 comparison groups and 1141 participants. Six studies reported a significant effect of OMT on pain,[14,17,18,22,24,28] 3 studies showed a nonsignificant effect,[15,16,23] and 3 studies reported a nonsignificant effect in favor of the control treatment.[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 comparison 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,[17,18,24,28] 3 studies reported a nonsignificant effect,[14,15,19] and 1 study reported a nonsignificant effect in favor of the control group.[23]

OMT vs Other Interventions for Chronic Nonspecific Low Back Pain

For nonspecific LBP (*Table 2*), Franke et al[2] analyzed 6 studies[18,19,22-24,28] 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.[18,24,28] One study reported a nonsignificant effect for OMT,[19] and 1 study reported an effect for the control group.[23] Collectively, the analysis showed moderate-

Table 2 (continued).
Studies on Acute and Chronic Nonspecific LBP Included in the Systematic Review by Franke et al[2]

Study	Purpose	Type of LBP	OMT Comparison	Outcomes	Findings	OMT Effect		OMT vs Other	
						Pain	Function	Pain	Function:
Gibson[16] (UK, 1985)	Comparison of OMT with SWD and placebo SWD in nonspecific LBP	Acute and chronic	Sham SWD	1. VAS pain (daytime and nocturnal scores) 2. Spinal flexion 3. Return to work 4. Recovery 5. Analgesic consumption	These observations indicate that neither OMT nor SWD was superior to placebo treatment.	Nonsignificant effect in favor of OMT[a]	Nonsignificant effect in favor of control treatment		
Heinze[17] (Germany, 2006)	Determination of the efficacy of OMT applied to subacute lumbar back pain	Acute and chronic	Physical therapy and heat	1. Numeric rating scale for current and average level of pain 2. RMDQ	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		
Licciardone[23] (US, 2003)	Determination of the efficacy of OMT as a complementary treatment for chronic nonspecific LBP	Chronic	Untreated and sham manipulation	1. SF-36 2. VAS pain 3. RMDQ 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 management of chronic nonspecific LBP.	Nonsignificant effect in favor of OMT and control treatment[a]	Nonsignificant effect in favor of control treatment	Significant effect in favor of OMT	Effect in favor of control group intervention
Licciardone[22] (US, 2013)	To study the efficacy of OMT and UST for chronic LBP	Chronic	Sham OMT	1. VAS pain 2. RMDQ 3. SF-36 general health 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 LBP. It was safe, parsimonious, and well accepted by patients.	Significant effect in favor of OMT		Significant effect in favor of OMT	
Mandara[24] (Italy, 2008)	To compare the effects of OMT with SMT on patient's self-reported pain and disability	Chronic	SMT	1. VAS pain 2. ODI	OMT appears to provide benefits over and above usual care for the management of chronic LBP. The improvement in the OMT group compared with the SMT group 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
Vismara[28] (Italy, 2012)	Is OMT combined with specific exercises more effective than specific exercises alone in obese female patients with chronic LBP?	Chronic	Specific exercises	1. Kinematic of thoracic/lumbar spine/pelvis during forward flexion 2. VAS pain 3. RMDQ 4. LBP-Disability Questionnaire	OMT and specific exercises 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

[a] Nonsignificant effect in favor of control treatment was also found.

Abbreviations: LBP, low back pain; ODI, Oswestry Disability Index; RMDQ, Roland-Morris Disability Questionnaire; SF-36, 36-Item Short Form Survey; SMT, sham manipulative treatment; SWD, short-wave diathermy; UK, United Kingdom; US, United States; UST, ultrasound therapy; VAS, visual analog scale.

Source: Adapted from Franke et al. Osteopathic manipulative treatment for nonspecific low back pain: a systematic review and meta-analysis. *BMC Musculoskelet Disord.* 2014;15:286.[2] Permission provided under the Creative Commons Attribution License.

Editor's Note: The term *osteopathic manipulative treatment (OMT)* refers to manipulative care provided by US-trained osteopathic physicians. By contrast, *osteopathic manipulative therapy (OMTh)* is typically used in the *JAOA* to describe manipulative care provided by foreign-trained osteopaths. For the purposes of the publication of these guidelines, *OMT* refers to all care provided by osteopathic physicians and osteopaths.

Table 3.
Studies on Pregnancy and Postpartum LBP Included in the Systematic Review by Franke et al[2]

Study	Purpose	Type of LBP	OMT Comparison	Outcomes	Findings	Pregnancy LBP: OMT Effect	Postpartum: OMT vs Untreated
Gundermann[20] (Germany, 2013)	To evaluate the effectiveness of OMT in pregnant women with LBP	Pregnancy, nonspecific	Untreated	1. VAS pain 2. Frequency of pain 3. RMDQ 4. Questionnaire (postpartum)	Four OMT sessions over 8 weeks led to statistically significant and clinically relevant positive changes of pain intensity and frequency in pregnant women with LBP.	Significant improvement after OMT	
Licciardone[21] (US, 2009)	Examination of OMT for back pain and related symptoms during the third trimester of pregnancy	Pregnancy, nonspecific	Usual obstetric care and sham ultrasound treatment	1. Back pain on an 11-point scale, analyzed like a 10-cm VAS pain 2. RMDQ	OMT slows or halts the deterioration of back-specific functioning during the third trimester of pregnancy.	Nonsignificant improvement after OMT	
Peters[25] (Germany, 2006)	Assessment whether OMT influences the ainsymptom-atology of women with pregnancy-related LBP	Pregnancy, nonspecific	Untreated	1. VAS pain 2. Quebec Back Pain Disability Scale	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.	Significant improvement after OMT	
Recknagel[26] (Germany, 2007)	Investigation whether OMT had an effect on women with postpartum persistent unspecific backache	Chronic, postpartum	Untreated	1. VAS pain 2. Oswestry Pain Questionnaire 3. Regions of dysfunction	OMT for women with persistent, unspecific backache postpartum brings about a clinically relevant improvement of the pain symptoms and a reduction of the impediment on daily life.		Significant improvement after OMT
Schwerla[27] (Germany, 2012)	To evaluate the effectiveness of OMT in women with persistent LBP after childbirth	Chronic, postpartum	Untreated	1. VAS pain 2. Oswestry Pain Questionnaire 3. Different specific health problems	Four OMT sessions over 8 weeks led to statistically significant and clinically relevant positive changes of pain intensity and effects of LBP pain on everyday activities in women with LBP after childbirth.		Significant improvement after OMT

Abbreviations: LBP, low back pain; RMDQ, Roland-Morris Disability Questionnaire; US, United States; VAS, visual analog scale.

Source: Adapted from Franke et al. Osteopathic manipulative treatment for nonspecific low back pain: a systematic review and meta-analysis. *BMC Musculoskelet Disord*. 2014;15:286.[2]

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quality evidence for a significant difference in favor of OMT (SMD, −0.32; 95% CI, −0.58 to −0.07).

OMT vs Usual Obstetric Care, Sham Ultrasound, and Untreated for Nonspecific Low Back Pain in Pregnant Women

For LBP in pregnant women, Franke et al[2] reviewed 3 studies with 4 comparisons and 242 participants (*Table 3*). Two studies showed a significant improvement after OMT,[20,25] and 1 study showed a nonsignificant improvement.[21] The final analysis of these studies resulted in low-quality evidence for a significant difference in favor of OMT for LBP (MD, −23.01; 95% CI, −44.13 to −1.88) and functional status (SMD, −0.80; 95% CI, −1.36 to −0.23) in pregnant women.[2]

Two other important studies[29,35] published subsequent to when Franke et al conducted their systematic review[2] addressed LBP in pregnant women and enhance the findings of Frank et al (*Table 4*). Hensel et al[29] 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. Hensel et al[29] 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 and Aryal,[35] the investigators found that during the third trimester of pregnancy, OMT has medium to large treatment effects in preventing progressive back-specific dysfunction.

OMT vs Untreated for Nonspecific Low Back Pain in Postpartum Women

Franke et al[2] reviewed 2 studies[26,27] focusing on OMT for LBP in postpartum women (*Table 3*). Both studies reported significant improvement after 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).

Table 4.
Studies on Pregnancy and LBP Published After the Systematic Review by Franke et al[2]

Study	Purpose	Type of LBP	OMT Comparison	Outcomes	Findings	Pregnancy LBP: OMT Effect
Hensel[29] (US, 2014)	To evaluate the efficacy of OMT to reduce low back pain and improve functioning during the third trimester in pregnancy and to improve selected outcomes of labor and delivery	Pregnancy	UCO and usual care plus PUT	1. VAS pain 2. RMDQ	Findings indicate significant treatment effects for pain and back-related functioning ($P<.001$ for both groups), with outcomes for the OMT group similar to that of the PUT group; however, both were significantly improved compared with the UCO group.	Significant improvement after OMT
Licciardone[35] (US, 2013)	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	Pregnancy	UOBC+OMT, UOBC+SUT, and UOBC	1. 11-point NRS for typical level of back pain 2. RMDQ for back-specific functioning	Patients who received UOBC+OMT were significantly less likely to experience progressive back-specific dysfunction ($P<.0001$ vs UOBC). The effect sizes for UOBC+OMT vs UOBC+SUT and for UOBC+OMT vs UOBC were classified as medium and large, respectively.	Significant improvement after OMT

Abbreviations: LBP, low back pain; NRS, numerical rating scale; OMT, osteopathic manipulative treatment; PUT, placebo ultrasound treatment; RMDQ, Roland-Morris Disability Questionnaire; SUT, sham ultrasound therapy; UCO, usual care only; UOBC, usual obstetric care; VAS, visual analog scale.

Source: Adapted from Franke et al. Osteopathic manipulative treatment for nonspecific low back pain: a systematic review and meta-analysis. *BMC Musculoskelet Disord*. 2014;15:286.[2] Permission provided under the Creative Commons Attribution License.

Discussion

According to our review and the Franke et al systematic review and meta-analysis,[2] OMT has a significant effect on LBP (acute and chronic), LBP in pregnant women, and LBP in postpartum women. Osteopathic manipulative treatment seems 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,[30] the significant effects are also clinically relevant.

The Franke et al review,[2] on which these guidelines are based, enhanced the 2005 Licciardone review[3] on which the previous guidelines were based.[1] There are slight differences as noted in the Franke et al discussion section. For example, Frank et al excluded 2 studies[31,32] that were included in the 2005 Licciardone et al review[3] 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[2] also did not include studies with specific causes of LBP.[33] The Franke et al review[2] also included studies of LBP associated with pregnant and postpartum women that were pooled and analyzed separately. Despite these differences in the 2 systematic reviews, the results of the both reviews[2,3] are similar, concluding that OMT may be an effective treatment for patients with LBP.

Limitations of the studies included in these guidelines are the small sample sizes and difference in comparison groups. For Franke et al,[2] the majority of the included studies had relatively small sample sizes,[14-28] but collectively, there were more than 400 participants included in each comparison group, which consisted of a chronic and acute pain group and a chronic pain group. Unfortunately, the separate analysis of LBP in pregnant and postpartum women was collectively a smaller sample (<400 participants), which indicated an imprecision of results and a downgrading of the level of evidence.[34] Also, as Franke et al[2] alluded to in their article, the control groups included in studies need to be more compatible with the OMT intervention groups.

Another limitation of the studies in the Franke et al review[2] 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.

Osteopathic manipulative treatment 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 the Franke et al systematic review[2] (evidence level 1a; *Table 1*) of randomized controlled trials 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 (ie, to treat the diagnoses of somatic dysfunctions related to low back pain).

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. The use of 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 have low back pain. Osteopathic manipulative treatment 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.

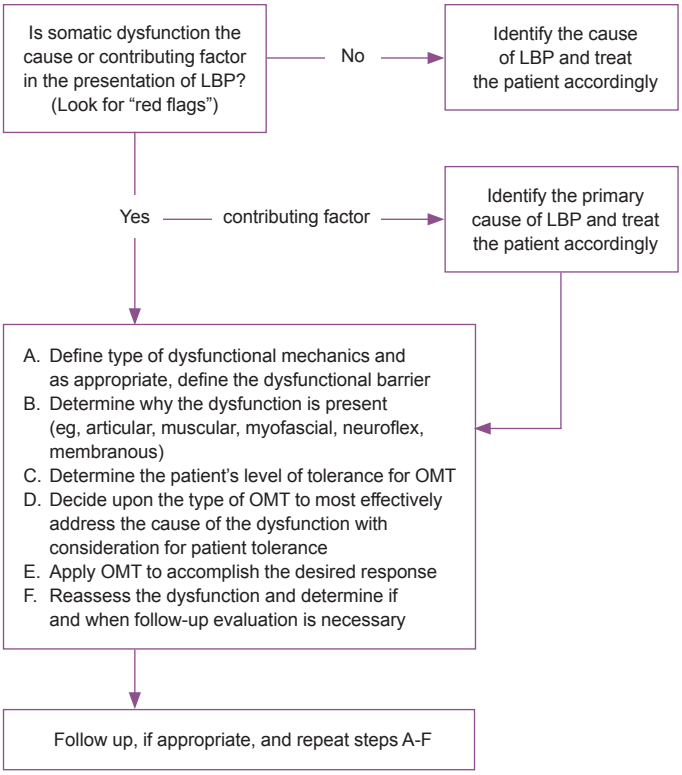

Figure.
Algorithm for osteopathic manipulative treatment (OMT) for low back pain (LBP) decision making. *Source:* Adapted from: Nelson KE. The manipulative prescription. In: Nelson KE, Glonek T, eds. *Somatic Dysfunction in Osteopathic Family Medicine*. Baltimore, MD: Lippincott, Williams & Wilkins; 2007:27-32.

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

Once a patient with low back pain is diagnosed with somatic dysfunction as the cause of, or contributing factor to, low back pain, OMT should be utilized by the osteopathic physician. The diagnosis of somatic dysfunction entails a focal or complete history and physical examination, including an osteopathic structural examination that provides evidence of asymmetrical anatomical landmarks, restriction or altered range of joint motion, and palpatory abnormalities of soft tissues. Osteopathic manipulative treatment is used to manage somatic dysfunction after other potential causes of low back pain are ruled out or considered improbable by the treating physician (ie, vertebral fracture; vertebral joint dislocation; muscle tears or lacerations; spinal or vertebral joint ligament rupture; inflammation of intervertebral disks, 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).

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.[36] However, Medicare has reimbursed osteopathic physicians for this procedure for more than 30 years. Many osteopathic physicians do not utilize OMT in clinical practice because of a number of barriers, including time constraints, lack of confidence, loss of skill over time from disuse, and inadequate office space.[36] Some specialists (ie, pathologists and radiologists) do not use OMT as it is not applicable to their duties within their specialty. The AOA believes that 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 among 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.

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