

The Journal of the American Osteopathic Association



The Journal of the American Osteopathic Association (JAOA) encourages osteopathic physicians, faculty members and students at colleges of osteopathic medicine, and others within the health care professions to submit comments related to articles published in the JAOA and the mission of the osteopathic medical profession. The JAOA's editors are particularly interested in letters that discuss recently published original research.

Osteopathic Manipulative Treatment During the Third Trimester of Pregnancy

To the Editor:

Dr Hensel and colleagues recently published the Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) study protocol¹ and findings.² The protocol included 12 osteopathic manipulative treatment (OMT) techniques used to complement usual obstetric care (UOC) during the third trimester. The primary outcomes were numerical ratings of low back pain and the Roland-Morris Disability Questionnaire (RMDQ). This trial was large, with 400 women randomly assigned to OMT+UOC, placebo ultrasound therapy+UOC, or UOC only.² Nevertheless, it failed to demonstrate a significant benefit in any primary outcome in women receiving OMT as compared with those receiving placebo ultrasound therapy.²(Table 4) In fact, women who received OMT reported worse outcomes on both the composite measure of pain and RMDQ. Although significant benefits were reported for composite pain and RMDQ when comparing OMT+UOC vs UOC,²(Table 4) neither outcome reflected a treatment effect that was clinically relevant according to evidence standards.³

My colleagues and I initially reported that OMT was efficacious in achieving

statistically significant and clinically important benefits in pain reduction and back-specific functioning during the third trimester.⁴ A responder analysis of these trial data, not cited by Dr Hensel and colleagues, provides insight on OMT efficacy in preventing back-specific dysfunction.⁵ Using Cochrane Back Review Group criteria, OMT+UOC was associated with a medium treatment effect vs sham ultrasound therapy+UOC, and a large treatment effect vs UOC only. Responder analysis is now recommended in addition to reporting mean scores for back pain and related outcomes to avoid the skewing of trial results by patients who are clearly insensitive to treatment.⁶ Such responder analysis has been used to develop an OMT targeting strategy for patients with chronic low back pain.^{7,8}

The PROMOTE study findings bring into question the conclusion reached by the authors that its protocol appears to be an “effective way to manage low back pain and its associated disability during pregnancy.”¹ Although clinical trials involving well-trained practitioners have not clearly identified any safety risk in women treated with OMT during the third trimester,^{1,4,9} such risks may emerge if OMT were to become widely used in obstetrical practice or administered by less experienced practitioners under the

presumption that the techniques are “relatively simple and easily taught.”¹ Thus, it is premature to recommend that the PROMOTE study protocol be implemented in obstetrics as indicated by Dr Hensel and colleagues.¹ A safer and more practical approach would be to target treatment by experienced practitioners at pregnant women who have favorable OMT response profiles based on emerging research and evidence standards. (doi:10.7556/jaoa.2017.050)

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Response

Dr Licciardone expresses concern regarding data from a 2015 article by Hensel et al¹ that directly addressed the question of treatment effectiveness. In that Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) study, pregnant women in the OMT group showed improvement over those in the usual care only group in all but 1 measure. A subsequent PROMOTE study showed that the OMT techniques used in the study were safe for use during pregnancy.² However, when the placebo ultrasound therapy group outcomes were compared with the OMT group outcomes, no statistically significant differences were reported, as Dr Licciardone correctly states. We discussed our theories to explain this occurrence in the article.¹

Licciardone and Aryal³ previously published data that evaluated effectiveness of OMT in reducing risk of progressive back-pain dysfunction using the 2009 Cochrane Back Review Group recommendations. Their findings showed marginal benefits of OMT vs placebo ultrasound therapy in pregnant women (N=144; $P=.046$). The authors acknowledged that the sample size used in their study was small, potentially explaining why they reported a marginal difference. Direct comparison with their findings would require different analyses of the PROMOTE data. Dr Licciardone also

references an earlier analysis of his data that examined the effectiveness of OMT in pregnant women compared with sham ultrasound therapy and standard care⁴; this analysis was comparable to the 2015 study by Hensel et al¹ in that the placebo ultrasound group did not statistically differ from the OMT group in posttreatment back-specific dysfunction.

Given the findings of the current study² and previous study,¹ we stand by our conclusion that the OMT protocol used in the PROMOTE study appears to be a safe² and effective way of managing low back pain and its associated disability during pregnancy.^{1,3,4} We acknowledge the concern Dr Licciardone expresses regarding the potential risks of teaching these techniques to less experienced practitioners. Although it is not uncommon for study protocols to be published^{5,6} for both reproducibility and educational purposes, appropriate training is expected of practitioners, as is the case with any OMT technique. For this reason, training in this protocol has been conducted at colleges of osteopathic medicine and at national osteopathic meetings of the American Academy of Osteopathy, the American College of Osteopathic Obstetricians and Gynecologists, and the American Osteopathic Association. In the almost 10 years that these protocols have been taught in these settings, no adverse events have been reported to date, to our knowledge.

Although standardized OMT protocols are more frequently used, we also support the development of personalized interventions, which may be based on favorable OMT response profiles, as suggested by Dr Licciardone, or on other factors identified by scientific findings. Additional research is required to fully inform such personalization, and we hope that data from the PROMOTE studies aid in this pursuit (doi:10.7556/jaoa.2017.051)

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Correction

The *JAOA* regrets an error that appeared in the following article:

Davis GE, Gayer GG. Comparison of basic science knowledge between DO and MD students. *J Am Osteopath Assoc*. 2017;117(2):114-123. doi:10.7556/jaoa.2017.022

On page 117, in Table 1, footnote symbols should not have appeared in the row stubs under “Variables.” This correction will be made to the article online. (doi:10.7556/jaoa.2017.052)