

THE JOURNAL *of the* AMERICAN OSTEOPATHIC ASSOCIATION



The Journal of the American Osteopathic Association

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The JAOA's editors are particularly interested in letters that discuss recently published original research.

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Although the JAOA welcomes letters to the editor, these contributions have a lower publication priority than other submissions. As a consequence, letters are published only when space allows.

Observational Study Fails to Demonstrate the Effectiveness of OMT in Decreasing Low Back Pain

To the Editor:

I wish to thank Prinsen and colleagues for their response¹ to my recent letter to the editor,² which commented on their observational study of osteopathic manipulative treatment (OMT) in patients with low back pain.³ Although we agree on several key points, including the value of OMT in managing low back pain and the need for more pragmatic alternatives to randomized controlled trials, I am obliged to comment further on several aspects of their response.

First, the authors stated that it would have been impossible for them to reference the OSTEOPATHIC Health outcomes In Chronic low back pain (OSTEOPATHIC) Trial findings that I reported in my letter² because the results were either unpublished or in press when their manuscript was ac-

cepted for publication. However, a careful review of the chronology of the relevant publications reveals that their contention is incorrect. The primary results of the OSTEOPATHIC Trial were published in the March/April 2013 issue of *Annals of Family Medicine*⁴ and were freely available via the journal's website. The subgroup results for patients with moderate to severe baseline low back pain severity⁵ were initially published online in *Manual Therapy*, and the article was indexed as an "epub" in the National Library of Medicine's PubMed database on June 10, 2013, and was available at that time via open access. Thus, the OSTEOPATHIC Trial findings were easily accessible prior to the authors' submission of their revised manuscript on August 24, 2013. Moreover, the authors erroneously claimed that I frequently cite the results of a Consortium for Collaborative Osteopathic Research Development–Practice-Based Research Network (CONCORD-PBRN) observational study⁶ to support my comments relative to the OSTEOPATHIC Trial.

Although Prinsen and colleagues¹ acknowledged that 45% of their pain outcome measures were missing, they provided a lengthy discussion in their response of reasons why imputation of these missing data may have been undesirable, including that Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting clinical trials discourage using the last-observation-carried-forward method of imputation.⁷ However, the updated CONSORT guideline extension for patient-reported outcomes (such as the missing pain scores in question) states that "statistical approaches for dealing with missing data should be explicitly stated for patient-reported outcomes prespecified as primary or important secondary outcomes."⁸ Although no method of imputation is perfect, given the large proportion of missing data it would have been prudent to perform 1 or more types of imputation in a sensitivity analysis to determine the concordance of the results with those that they observed. As it is, the validity of the results remains in question and the impact of their study is diminished by not addressing these missing data in a manner consistent with the CONSORT guideline for patient-reported outcomes.⁸

Prinsen and colleagues¹ stated that they addressed the potential bias attributable to clustering in their original publication; however, a word search of their article for "cluster" or "clustering" failed to detect any use of these terms. Moreover, their response contends that clustering would theoretically increase the type I error rate while simultaneously decreasing the "strength of the statistical difference," presumably between patients receiving and not receiving OMT. In reality, the type I error rate is increased because intracluster correlation of results

within participating sites artificially decreases variance in the data (eg, decreases standard errors) and thereby increases the statistical significance of differences between study groups when performing hypothesis testing without adjustment for clustering. Interestingly, while disregarding the decreased variance and standard errors attributable to clustering, the authors invoked “underestimated standard errors” as an argument against performing imputation for missing data on pain outcomes.¹

Finally, in clinical practice, analgesic medication is usually prescribed in response to antecedent pain and its severity. The findings reported by Prinsen and colleagues³ and by Andersson and colleagues⁹ of decreased analgesic medication use in patients receiving OMT relative to those not receiving OMT, without corresponding disparities in pain status between these 2 groups, do not appear to be plausible. Observational studies in particular, and even randomized controlled trials at times, are vulnerable to biases that may yield such implausible results. Lack of physician blinding to OMT use in the American Osteopathic Association Clinical Assessment Program could have easily biased analgesic prescribing patterns in the study by Prinsen and colleagues.³ Their inability to demonstrate the superiority of OMT over conventional treatment in decreasing pain was unlikely due to insensitivity of the visual analog scale used, as had been suggested by the authors.³ In fact, the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain now recommends a comparable numerical rating scale to measure pain.¹⁰ The best explanation for greater medication use by control patients not receiving OMT in the study by Andersson and colleagues⁹ is the excessively

large number of standard medical care visits that were artificially imposed upon their physicians by the research protocol (8 visits over 12 weeks).¹¹

Notwithstanding many osteopathic studies performed over more than 3 decades, including that of Andersson and colleagues,⁹ the OSTEOPATHIC Trial has been recognized as a large high-quality clinical trial¹² that fills an important gap in the evidence for OMT.¹³ Unlike these previous studies, the OSTEOPATHIC Trial has shown straightforwardly that low back pain severity is significantly decreased with OMT as compared with control treatments, and that it is this improvement in pain after OMT that results in significantly decreased use of prescription analgesic medication. (doi:10.7556/jaoa.2014.167)

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Impact of the Single Accreditation Agreement on GME Governance and the Physician Workforce

To the Editor:

I commend Cynthia S. Kelley, DO, on her learned article “Impact of the Single Accreditation Agreement on GME [Graduate Medical Education] Governance and the Physician Workforce” in the July issue of *The Journal of the American Osteopathic Association*.¹ I call it *learned* because it is an erudite analysis of the arrangement

plus it includes a reasonable discussion of some of the negative aspects of the single accreditation system.

I have been privileged for the past 70 years to personally observe and play an active role in the slow but steady progress of our profession toward full equality. That does not make me smarter or authoritative but merely gives me broad experience. And this negotiation may be a step forward for our profession.

However, I would like to add some thoughts about the political (that is, organizational and management) aspects, a must because they will eventually determine the success of the project. That immediately brings forth concerns about cost and risks. That all of our graduates will be attending Accreditation Council for Graduate Medical Education (ACGME) residencies is very attractive—no, astounding. But we must stop to ask first, “What is the cost? What are the risks?” These are the questions one would ask in any contract situation—one that would be posed by our attorneys when we present any proposition to them. Financial costs may be known only to our negotiators, and they have not said. There are possible costs of time, effort, effects on memberships—and Kelley¹ has discussed several of them.

A Major Risk

One major risk that rears its ugly head immediately is the prospect of a strengthening call from some quarters for a merger with the American Medical Association. At several episodes in our history, circumstances have arisen that prompted such an uprising among a small minority of our osteopathic physicians (ie, DOs)—always ready to seek that goal. Among other instances, the California episode was followed by a little surge in this activity. But, in spite of the single GME agreement’s advantages, it creates another potential battle for us to fight.

The old cry of “Why do we need 2 separate medical professions?” may reappear and become, “NOW, why do we need 2 separate medical professions? There is very little difference between us.” My answer is a question saved from years past: “Considering Macy’s and Bloomingdale’s carry much of the same merchandise, service much of the same segment of the public, and often have similar pricing, why do they have to be separate?”

To be clear, I am unalterably opposed to such a merger. We have come a long, long way from almost obscurity to almost equality in status; we have always had equality in ability and service. All that fine progress was achieved without selling our birthright or being forced into joining some special group or society.

Other Risks

According to the agreement, the ACGME will make the AOA and the American Association of Colleges of Osteopathic Medicine member organizations. Each member organization is entitled 2 representatives on the Board of Directors; thus, there will be 4 designated DO representatives—2 each from the AOA and the American Association of Colleges of Osteopathic Medicine—on the ACGME Board of Directors. Assuming total integrity on the part of the present negotiators, could different personnel, in 5 years or 10, just eliminate those positions or the DOs?

Hidden Risks

There are hidden risks all around us and we cannot always discern them or prevent them or forecast them. One danger that has surfaced in other situations is being seduced by false promises. In one instance that I was able to observe, both sides to a merger-like agreement seemed to be satisfied. But a couple of years later, one of the negotiators bragged,

“Boy, did we put it over on them, by promising....” Fortunately for both sides, that empty promise did not disrupt the unity and both groups fared well. But those incidents, even though relatively rare, could always be disruptive.

My Opinion

In a single GME system, the goal is admirable and outstanding. But always—that means always—we must be guarded, careful, alert, and on an unrelenting lookout for stumbling blocks when the promises seem greatest. And that means every step of the way!

We have struggled long to rise from near-obscurity to unbelievable growth and to an enviable position in medical circles; we did it all by dint of producing numbers of competent DOs providing excellent medical care to the public. Essentially, we “pulled ourselves up by own bootstraps.” I am proud of what we have done. Now, we are facing another administrative situation with “prospects” of another milestone achievement. But manholes are still there; we must exert every human effort to avoid them. (doi:10.7556/jaoa.2014.168)

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1. Kelley CS. Impact of the single accreditation agreement on GME governance and the physician workforce. *J Am Osteopath Assoc.* 2014;114(7):518-523. doi:10.7556/jaoa.2014.102.

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