To the Editor:

I congratulate Dr Wieting and colleagues for their original contribution from May 2013. The authors have successfully brought a well-designed study to publication, which is no easy task. The osteopathic medical profession needs many more such projects completed to the publication stage if osteopathic manipulative treatment (OMT) is to be realized to its full potential. I particularly appreciate that the authors published power analyses to provide guidance for future studies.

Nevertheless, I am puzzled by the authors’ assertion that OMT had a more positive effect on the postoperative recovery of patients who underwent coronary artery bypass grafting when none of the outcomes were statistically significant. In other words, I do not believe it is correct to characterize the intervention as “beneficial, though not statistically significant.” For example, the authors report that the mean length of stay for the OMT group was 0.6 days shorter than the conventional care control group. However, the \( P \) value for this datum is .49, which to my understanding means that they were 51% confident something other than random chance is occurring. This result does not inspire confidence, nor does it justify implying a beneficial effect. As is well known, it requires a \( P \) value of .05 or less to say with confidence that something other than random chance has influenced the outcome. Despite the authors’ enthusiasm, these results are not persuasive for using OMT as a standard therapeutic treatment for patients with the condition studied.

We should remember this was an exploratory study. If the treatment protocol was tweaked and the study size increased, then OMT might be shown to be efficacious after coronary artery bypass grafting in the future. Publishing the study’s protocol, design, preliminary results, and power analysis is the real value of the study. The authors do not need to settle the question of benefit in 1 step. The results are encouraging enough for future projects to build upon the work. The ultimate goal is not to prove OMT, but to discover what helps people. This distinction may be subtle but is important to remember.

The authors also wrote, “A 1976 study by Rogers and Rogers has shown potential changes in autonomic nervous system function in coronary heart disease after OMT is performed.” This statement is a classic example of how myths percolate through the osteopathic medical profession. The reference is impressive and I am certain was given in good faith. Enthusiastic proponents of osteopathic principles and practice will no doubt read this statement and repeat it to students, who in turn will take it at face value. Few will check the reference because the study by Rogers and Rogers is available online as a citation only. “The Role of Osteopathic Manipulative Therapy in the Treatment of Coronary Heart Disease,” the title of the Rogers and Rogers article, is also misleading.

In fact, the Rogers and Rogers article is not technically a study. It is a well-written review of the literature and case report of 2 individuals who had definite symptoms of ischemic heart disease but no abnormalities at coronary angiography.
the patients had transient coronary artery spasms in coronary arteries that were free of atherosclerosis. In these 2 case reports, Rogers and Rogers did not report use of OMT or somatic dysfunction measurements; nor did they include information about the autonomic nervous system function of the patients. As enthusiastic advocates of OMT, however, the authors speculated, “It is logical to assume that manipulative treatment, by normalizing the action of the autonomic nervous system, might influence both cellular metabolism and the vasomotor dynamics of the coronary arteries.” Nevertheless, assuming is a long way from reporting hard data.

Lastly, I believe the study by Wieting et al is a good illustration of the limits of the 3-arm study design for small, exploratory clinical trials of OMT. I can speak with more authority than most because I was one of the first to use a 3-arm design for OMT and gained much experience with it during the Multicenter Osteopathic Pneumonia Study in the Elderly. The principal problem with a 3-arm study design—which encompasses an OMT group, a sham or placebo treatment group, and a conventional care only control group—is that the statistical power of the study is invariably reduced.

Hróbjartsson and Gøtzsche, who conducted a systematic review of the literature on the systemic effects of placebo in clinical trials, questioned the power of the placebo. Preliminary, exploratory, or pilot projects are often statistically underpowered, and the 3-arm study design exacerbates this problem. A 2-arm trial (ie, experimental treatment vs conventional care—only control group) is a reasonably good design for a preliminary project. This study design addresses the question I most frequently ask: Does OMT improve standard care? Such a design is also technically easier to implement because it saves the investigators the trouble of performing a sham or placebo treatment. The mystical effects of touch can be sorted out later.

On the other hand, analyzing the effect of OMT vs sham or placebo may work well in some instances because the use of a non-treatment arm allows the investigator to offer some type of treatment to all the prospective participants, which can facilitate recruitment. A placebo treatment also controls for attention, touch, and other theoretically beneficial aspects of a physician treating a patient. All the same, a 3-arm study design should be reserved for large, well-funded, definitive projects where each group is adequately powered. (doi:10.7556/jaoa.2013.018)

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References

Response
To the Editor:
My colleagues and I thank Dr Noll for taking the time, first, to read our original contribution and, second, to compose such a constructively critical letter pointing out the weaknesses in our project and how potential future studies might be designed.

We freely admit that, despite positive and encouraging results, there were limitations to our study, namely the following:

■ Several osteopathic physicians (ie, DOs) and students performed osteopathic manipulative treatment (OMT) on our study’s patients. We attempted to decrease the variation in OMT skills, however, by enlisting 1 physician (S.G.) to train all operators.

■ The study population was limited to patients from the practice of 1 surgeon (Gary L. Roth, DO). Although we believed that this limitation worked to decrease and counter variables and to standardize the preoperative evaluation and consent process, it may have also inadvertently led to the enrollment of a smaller population of patients in our study.

■ The study population was confined to patients who underwent coronary artery bypass graft surgical procedures only and thus did not include patients who also underwent other surgical interventions, such as valve replacements.

As we stated, “We are aware that these limitations in our study sample may decrease the ability to extrapolate these findings to other, more heterogeneous populations.”
Dr Noll states that it is not correct to characterize the intervention as “beneficial, though not statistically significant.” We respectfully believe, however, that the OMT was beneficial. The following factors should be considered:

- The 17 patients in the OMT group were discharged 0.6 days sooner postoperatively than the 18 patients in the control group. Though not statistically significant, this result—if extrapolated to McLaren Greater Lansing (where Dr Roth and I practice and where the study was conducted)—could have saved our hospital at least $1000 per patient. For some hospitals, $17,000 may not seem substantial. If these savings are seen in light of 50, 100, or 400 surgical procedures per year, however, the savings quickly multiply.

- A reason for the decrease in length of stay was the return of bowel function 0.5 days sooner for patients in the OMT group than for patients in the control group. This correlation is especially relevant to general surgeons, who perform OMT—or have their residents or students perform it—postoperatively on patients to prevent or manage bowel obstruction.

- Patients in the OMT group also had the highest average total FIM (formerly known as Functional Independence Measure) score on postoperative day 3. This group’s mean score was 19.3 compared with 15.4 for the placebo group and 18.6 for the control group.

We acknowledge that our study was small and “exploratory,” as described by Dr Noll. We are grateful to The Journal of the American Osteopathic Association for allowing its publication. Many people worked with the authors—including Gayle Durnin, PT—putting in many hours during and after the study to prepare it for submission. We are proud of our efforts even as we appreciate Dr Noll’s comments regarding its shortcomings. Furthermore, our study has contributed to the following improvements at McLaren Greater Lansing:

- The Osteopathic Manipulative Medicine Consultation, Treatment, and Teaching Service has been resurrected. For the past 8 years, DOs have been consulted to treat patients undergoing coronary artery bypass graft, valve repair or replacement, and thoracotomies performed by a study colleague (G.L.R.) and several of his associates, all of whom are allopathic physicians (ie, MDs). As DOs, we appreciate and respect the fact that our allopathic colleagues believe our skills to be valuable for their patients. Other DOs and MDs ask that we use our skills in osteopathic manipulative medicine, including OMT, to treat patients in other areas of our hospital with many different complaints and conditions.

- During the course of the study, we as researchers and DOs developed a more collegial bond with the nursing staff in the intensive care unit, as well as with nurses in general medical, surgical, oncological, and labor and delivery units. We always ask permission of the intensive care unit nurses before performing OMT on patients in their wards. Nurses on other units are consulted as well. We believe that nurses have a better understanding of what DOs do and what OMT is used to accomplish, from a services’ standpoint.

- Physicians—both DOs and MDs—are cultivating osteopathic thinking, wherein OMT is considered for many patients. Osteopathic medical students and resident DOs are also encouraged to perform OMT with permission when applicable.

Dr Noll suggested that a 3-arm study should be reserved for large, well-funded, definitive projects where each group is adequately powered. We agree and indeed wrote in our article that we hoped further, larger scale investigations (preferably multicenter) would be conducted to confirm the benefits that our patients experienced. McLaren Greater Lansing would be unable to participate, however, because OMT is now part of the standard of care in the postoperative recovery of this patient population. (doi:10.7556/jaoa.2013.019)

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References


Relighting the Fire in Our Bellies

To the Editor:
If you are reading this letter, you are most likely an osteopathic physician (ie, DO) or osteopathic medical student. As such, you are witnesses to the struggle of patients to overcome illness, and you understand firsthand the challenges they can face.

Think for a moment about the last time you placed your hands on the abdomen of a patient after a surgical procedure, felt the distention caused by an ileus, then waited for the return of bowel function.

Think for a moment about the last time you watched a patient with chronic obstructive pulmonary disease (COPD) struggle to walk down a hallway and then wished you could do more.

In a 2006 letter, Mychaskiw wrote that OMT is overemphasized by the American Osteopathic Association (AOA). I continue to hear this sentiment expressed by both DO clinicians and educators. He also noted, “Osteopathic medicine and osteopathic principles do not start and end with OMT.”

Where has the fire in our bellies gone?
Does anyone notice when research appears that can feed that fire? A recent retrospective study by Baltazar et al concluded that OMT applied after a major gastrointestinal operation is associated with decreased time to flatus and decreased hospital length of stay (LOS). A 2012 pilot study by Zanotti et al reported that OMT performed on patients with COPD who underwent pulmonary rehabilitation may improve exercise capacity as determined by a 6-minute walk.

These studies suggest that low-cost, low-harm OMT has a positive impact on otherwise difficult-to-treat conditions. Why does our profession not hunger for more research of this kind? Why do we instead frequently hear comments from osteopathic colleagues that there is little or no place for OMT—save for managing a limited number of complaints (such as neck pain or back pain) in primary care?

If you are facing, for example, the prospect of a gastrointestinal surgical procedure, would you not opt for treatment that hastens your recovery and shortens your LOS? If the answer is yes, should your patients not also have access to the same level of care?

As an educator I am intrigued by the way that DOs, particularly those in training, apply evidence in the real world. Confirmation bias seems to run rampant at times, particularly with OMT. It is sometimes said that the absence of evidence to support OMT is a reason not to use it. But who is to blame for that absence?

Adhering to the osteopathic oath, DOs have pledged to “be ever alert ... to develop the principles of osteopathy which were first enunciated by Andrew Taylor Still.” In other words, advancing the profession is a task for all of us.

Ileus is a common postoperative complication and treatment options have not changed substantially over the years. Is the role of OMT in managing ileus unclear after decades of studies since the founding of this profession? Why is the question of performing OMT on patients postoperatively not of interest to every resident in osteopathic general surgery residency approved by the AOA?

Likewise, COPD is a common disorder. Shouldn’t DOs in every residency or fellowship program—whether in family medicine, internal medicine, or pulmonary medicine—discuss the article by Zanotti et al and determine how to apply the results to patients in their care or to the design of future, larger-scale studies?

Instead, we overlook the benefits revealed by decades of observational reports of OMT. We fail to conduct subsequent research that might confirm previous investigators’ findings. This lack of initiative erodes the distinct foundation of osteopathic medicine. Why are we still awaiting the definitive prospective study of OMT?
Do we think someone else will conduct the study for us?

Where is the fire to demonstrate that our unique form of care does in fact lead to better outcomes? Perhaps we should ask if such research would even change the opinion of those who see no modern place for osteopathic medicine regarding its practice as 19th century therapy.

If the practice of osteopathic medicine is to continue its focus on the patient, then the findings about OMT must give fuel to our inner fire. I argue as a board-certified pulmonologist that walking an additional 49 meters in 6 minutes can have a profound meaning for a patient with stage 3 COPD. This is particularly true if it enables that patient to do something of importance, such as walking to the mailbox or bathroom, or crossing a room to meet a grandchild. From an evidence-based practice standpoint, the findings of the study by Zanotti et al matter a great deal and can easily be applied to patient-centered practice.

Is OMT overemphasized by the AOA? Perhaps it is not emphasized enough.

Our duty as DOs is to help our patients realize their health potential, not simply to manage their diseases. This profession can end the decades-old debate about osteopathic distinctiveness if it will simply decide to follow a path that reminds us that our duty is to provide health care.
The first step in osteopathic decision making should be to identify and remove all impediments to a patient’s full recovery—structural, social, spiritual, nutritional, bacterial, or surgical. Our knowledge and our hands allow us to both clear an obstructed bowel and promote recovery of function in the bowel. Such follow-through helps to define holistic care and to keep us patient centered.

If we produce superior outcomes through the delivery of truly holistic care—as reflected by the results of the 2 aforementioned studies—\textsuperscript{3,4}—we could solidify the role of osteopathic medicine and redefine the US health care system.

There remain many unanswered questions about human health. Sadly, we seem to balk at the work of determining how to implement osteopathic manipulative medicine for maximum impact. Or we have balked at publishing such effects. Are our principles and practices a myth or reality? Only we can answer such questions, guided by the knowledge gained while earning an osteopathic medical degree.

Many individuals in the osteopathic medical profession have spent decades working to gain the acceptance of others. In that time, such efforts moved us further from the core beliefs of our profession. I offer that osteopathic concepts have not been proven wrong; they have been neglected in an effort to be more like our allopathic colleagues.

What if that neglect has failed patients and the health care system by limiting (or, in many specialties, eliminating) a form of treatment that may in fact alter the course of disease and contribute to maintenance of health?

Think about this neglect the next time you place your hands on a distended abdomen or listen to a patient tell you about his or her struggle to breathe and do nothing to incorporate your osteopathic skills when treatable dysfunction is present.

We have an opportunity to change the course of this profession. It begins by determining if there is something our form of training and decision making adds to patient care that is not easily replicated by others.

Some will worry about perception, wondering what patients will think if we perform OMT as part of their treatment plan. Pomykala et al\textsuperscript{5} found in a survey-based study that 98% of 168 hospitalized patients believed that OMT improved their overall comfort level, 94% felt it was helpful to their recovery, and 98% would recommend it for other hospitalized patients. Similar results were found in a survey-based study\textsuperscript{6} of patients in the outpatient setting.

Putting aside for a moment the osteopathic tenets\textsuperscript{7} and their focus on interrelations of structure-function and mind-body-spirit: who wouldn’t want to improve the patient experience in this era of pay for performance and value-based purchasing? A savvy hospital executive might start by asking medical staff why they aren’t using OMT to treat patients, particularly in hospitals that sponsor AOA-accredited residency training programs.

What if, 5 years ago, an influential figure had noticed these positive findings on OMT in 2 of the studies\textsuperscript{3,4} I mentioned? Imagine the ways in which our profession could have provided leadership as ideas for health care reform were taking shape. An old proverb attributed to many cultures states, “The best time to plant a tree was 20 years ago. The second best time is now.” It is not too late for our profession to make a difference in health care reform. The opportunity will pass, however, if we keep debating what it means to be osteopathic and putting off a decision to act on the core competencies described by our tenets.\textsuperscript{7}

We must relight the fire in our bellies and search for answers that help us carry out our duty as osteopathic physicians.

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\textbf{References}


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