JAOA LETTERS

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Are Clinical Protocols for Osteopathic Manipulative Procedures Truly "Osteopathic"?

To the Editor:

Clinical protocols for osteopathic manipulative treatment (OMT) procedures have been used in "technique" studies to examine the effects of specific procedures. Such studies, writes Michael M. Patterson, PhD,[1] are "useful in instances where there may be reason to suspect that a specific manipulative technique would change a particular condition." I would like to raise a concern regarding whether these technique studies, which are not based on medical histories or physical examinations, are ideal in terms of supporting osteopathic concepts and the practice of distinctive osteopathic medicine. In my opinion, in technique studies based on protocols for OMT procedures, manipulations are not delivered in a manner consistent with osteopathic principles, and there may be unforeseen consequences of such research—whether findings for the procedures are positive or negative.

Dr Patterson[2] has explained that "there are basically two types of studies of osteopathic manipulation: (1) *technique* studies ... and (2) studies of osteopathic manipulative *treatment*." In a technique study, a specific OM procedure is studied for its effects on a target problem. By contrast, in a study of OMT, the full range of OMT procedures are available, and the application of a specific technique depends on a thorough physical examination of the patient by the osteopathic physician.

Osteopathic manipulative treatment is defined as the "therapeutic application of manually guided forces by an osteopathic physician to improve physiologic function and/or support homeostasis that has been altered by somatic dysfunction."[3] American Osteopathic Association (AOA) protocols for the use of OMT state that the "diagnosis must be specific."[4] Once a diagnosis is made, the osteopathic physician "determine(s) the appropriate techniques and treatment." Furthermore, an evaluation and management service code requires a "history, examination, and medical decision making," all of which must be documented in the medical record.[4] Thus, by definition, OMT is directed toward removing the somatic dysfunctions that are inhibiting the body's function and self-healing mechanisms. When treatment in a clinical technique study is not based on the findings of a patient's medical history and physical examination, how can we be practicing osteopathic medicine or be studying the effects of a truly *osteopathic* manipulative procedure?

In the present letter, I examine each of the tenets of osteopathic medicine[5] as they relate to standardized clinical protocols for OMT procedures.

1. The body is a unit; the person is a unit of body, mind, and spirit.

The first part of this tenet notes that the body is a unit, meaning that the body's structure and systems function together as a unit. Structure and function interact and are unified through myriad relationships and mechanisms, and in some cases, the real source of the patient's

problem is anatomically distant from the area prompting the complaint. Although there are many parts to the body, "the osteopathic physician refrains from selecting any part above the whole."[6]

How can a technique study adequately address specific somatic dysfunctions that are inhibiting the body's ability to function when those dysfunctions are not included in the protocol used in the study—or when the dysfunctions are not even located in the area of complaint?

2. The body is capable of self-regulation, self-healing, and health maintenance.

Irvin M. Korr, PhD,[7] discusses this tenet as recognizing the inherent healing power of the body as well as the body's ability to maintain homeostasis and to defend itself from outside challenges through immunity. Dr Korr terms this combination of abilities the "internal healthcare system."[7] Certain OMT protocols support these self-healing mechanisms through the use of manipulative procedures that correct somatic dysfunction or assist the autonomic or lymphatic systems.

However, an OMT protocol may not address the areas of the somatic dysfunctions—whether primary or secondary—that are most inhibiting to the patient's self-regulatory mechanisms. For example, in lymphatic OMT procedures, treatment "should begin with the removal of all restrictions resulting from tissue hypertonicity that may be affecting lymph flow."[8] Without the guidance of a medical history and physical examination of the patient, how can the osteopathic physician direct treatment specific to that patient?

3. Structure and function are reciprocally interrelated.

This tenet addresses the interaction of the musculoskeletal system with the physiologic systems of the body. The tenet broadly states that the structure of the body affects its function, and the function of the body affects the structure. As noted by DiGiovanna et al,[6] "As structure governs function, similarly, abnormal structure brings about dysfunction." Clinical protocols for OMT procedures will certainly affect the musculoskeletal system. However, depending on the locations of the somatic dysfunctions, the main structural elements that are in need of change and that are affecting the patient's function most may be completely untouched by the protocol.

In addition, if standardized amounts of force are stipulated by a given protocol, there may not be sufficient personalized application of force to correct a somatic dysfunction in a patient. For example, if 15 pounds of force were required to lift a section of ribs and affect change at the sympathetic chain ganglia of a patient, but the clinical protocol stipulated 5 pounds of force be used in the rib-raising procedure, then the technique would not be effective.

4. Rational treatment is based upon an understanding of the basic principles of body unity, self-regulation, and the interrelationship of structure and function.

Clinical protocols for OMT procedures face a challenge in adhering to this tenet. By their very nature, standardized protocols are not able to meet the specific clinical needs of a patient because patients cannot be standardized. Protocols cannot fully address a patient's body unity because they are not based on the patient's physical examination or medical history. Protocols cannot fully address the structure-function tenet because they are not necessarily aimed at the key structural issues involved in each case. Protocols cannot fully assist the patient's self-healing mechanisms and abilities because they do not adequately address the structure and function of the body as a unit.

Reimbursement Considerations

If clinical protocols do not represent truly osteopathic treatment, then technique studies using protocols for OMT procedures may not accurately reflect the efficacy of the procedures. Negative outcomes in technique studies may not be conclusive relative to the value of those same techniques when applied in the context of a visit to an osteopathic physician. Nevertheless, although the difference between technique studies and OMT studies has been discussed in the literature,[2] it seems clear that results from technique studies are generally seen as reflective of the actual efficacy of those treatments when used in practice. If this perception occurs, then negative results in a technique study could create a negative impression regarding the efficacy of OMT and distinctive osteopathic practice, which could have insurance reimbursement ramifications.

Furthermore, positive outcomes in technique studies may send the message that a medical diagnosis of somatic dysfunction is not necessary when applying an OMT procedure in the clinical setting. Osteopathic physicians billing for OMT routinely receive insurance statements denying evaluation and management codes, often accompanied by the explanation that a diagnosis is not necessary to deliver OMT. Research outcomes that inadvertently support this mistaken argument would seem to work against efforts made by our state and national associations to improve access to distinctive osteopathic healthcare.

Conclusion

The application of standardized clinical protocols for OMT procedures may not be consistent with personalized treatment in osteopathic medicine that is customized for each patient and his or her specific dysfunctions. Breaking down each of the elements in the overall clinical approach to OMT may be akin to

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trying to separate out the ingredients of a therapeutic herb in order to discover which ingredient is the active one. By isolating individual OMT techniques from a comprehensive osteopathic approach, the techniques may cease to be osteopathic treatment at all.

I agree with Dr Korr[9] that "[i]t is essential ... that assessments of effectiveness of OMT be of OMT *as it is practiced*, as an integral part of the total interaction between physician and patient, and not as an isolated, contrived, and standardized procedure." In my view, only by studying truly *osteopathic* manipulative treatment—based on an understanding of the tenets of osteopathic medicine[5] and directed by a patient's medical history and physical examination—do we have the opportunity to demonstrate, with evidence, the true power of the unique healthcare approach that we in osteopathic clinical practice see every day.

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Response

I appreciate Dr Kirsch's comments on the concept of technique studies vs treatment studies. I certainly agree that to be a study of osteopathic manipulative treatment (OMT), the treatment must stem from a full physical and structural examination. It was with this requirement in mind that I wrote the editorial comment to which Dr Kirsch refers[1] and on which I have recently further elucidated.[2]

It is important to recognize that technique studies are not OMT studies. A technique study covers only a specific subset of the procedures used during OMT. In my editor's message,[1] I tried to make it clear that both researchers and consumers of the research must understand this difference. Technique studies ask very different questions than do full OMT studies. Technique studies also have limitations as to how they can be generalized to the practice of OMT, for some of the reasons expressed by Dr Kirsch. The distinction made in the editor's message[1] was meant to highlight these limitations so that technique studies would not be confused with full OMT studies.

Dr Kirsch argues that technique studies do not involve a physical and structural examination. However, although some technique studies may not involve a full physical and structural examination, most such studies do involve examinations of at least the areas to be treated, as well as some form of medical history of the patient. Again, these studies are not meant to be OMT studies and must not be held out as such.

Two of the hallmarks of scientific research are that studies be conducted according to a protocol and that studies be reproducible. When a protocol is established for a study, choices must be made as to what can and what cannot be done during the study. These choices are necessary for reproducibility, both within the study (ie, from patient to patient) and for replication in other studies. With each choice made, certain doors are closed.

Selection of study participants is one such choice. Participants are included in a study only after meeting certain inclusion and exclusion criteria. Such criteria are used in all clinical studies, including full OMT studies. One could make the argument that all studies that have inclusion and exclusion criteria are not conducted according to osteopathic principles, because OMT is useable on essentially all patients. However, even the landmark study by Andersson et al[3] comparing osteopathic care with standard care for patients with low back pain had such limiting criteria in its protocol. Without such criteria, a study would not produce useable data and, indeed, it would not even be a "study" but rather an observational exercise.

In any scientific study, the more controlled the protocol and the less the variability, the more one can conclude about the connection between the variable being studied and the outcome (ie, the cause and the effect). With less variability, fewer patients need to be enrolled to have a chance at yielding a positive result (if such a result exists). Thus, the best studies are those that have well-defined protocols and as little variability as possible.

Technique studies are attempts to test certain aspects of manipulative treatment—not to test OMT. How the results of these studies relate to OMT can be debated and, of course, there is always the potential problem of generalizing the results too freely. However, as previously pointed out, all studies (both

technique and treatment) have limitations on generalizability to practice because of the need for study protocols.

As to concerns about reimbursement, there is a danger that if studies are not clearly specified as technique studies, they could be taken as representative of OMT as a whole. This danger is exactly why the distinction between technique and treatment—and the limitations of any technique or treatment study—must be made clear. However, an even greater danger is that we will not properly examine OMT through either study type, thereby losing the distinctiveness of osteopathic medical practice because of failure to demonstrate its beneficial effects.

Dr Kirsch's analogy of breaking down OMT into parts for study is similar to separating out the ingredients of a therapeutic herb. Although in some herbal remedies there may be interactions among ingredients that are necessary for the total effect, in many other herbal remedies, a single "active" (ie, most dramatically effective) ingredient has been found. A few examples of such herbal remedies are quinine, atropine, and curare. These substances were all initially used in their whole forms as herbal remedies before the major, active ingredient in each was isolated, purified, and processed into an important medication.

Osteopathic manipulative treatment obviously consists of many components—such as touch, patient-physician interactions, and specific movements—all of which combine to produce the final result. Although it is important to examine the efficacy of the total treatment, it is also important to study the effects of the individual components so that the total effect can be fully understood.

Both treatment and technique studies are necessary if we are to maintain the uniqueness of osteopathic medicine. The distinctions between these 2 study types and the limitations of each must be clearly recognized and spelled out.

I agree with Dr Kirsch's quotation of Dr Korr, that "[i]t is essential ... that assessments of effectiveness of OMT be of OMT *as it is practiced*."[4] However, technique studies are not studies of OMT, but only parts of it. By clearly recognizing this distinction, technique studies can be effective in helping to understand the totality of osteopathic practice according to osteopathic philosophy and, in that way, help to maintain the distinctiveness of osteopathic medicine.

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Acknowledgments

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DOs Should Endorse an Evidence-Based National Healthcare Policy

To the Editor:

I read with interest the adulatory review by Donald W. Brown, Jr, DO,[1] of *Healthcare Solved—Real Answers, No Politics*, the treatise by Debra A. Smith, DO, about reforming the US healthcare system. A key assumption of the review warrants response and discussion.

Dr Brown[1] rejects public and universal healthcare plans, and he laments the putative struggles of private finance insurers by asking, "can we realistically expect the government to do better?" One of my osteopathic attendings as an intern was fond of repeating, "You can have your own opinions, but not your own facts." This same perspective can help provide an answer to Dr Brown's rhetorical question.

Medicare already performs better than private insurers, consuming approximately 2% to 3% of funding in administrative overhead.[2,3] Private insurers' overhead, by contrast, averages more than 12%—and often greater than 30%.[2,3] Furthermore, private insurances add no medical value by diverting dollars from patient care into advertising and profit.

At the physician end of the equation, the cost of pursuing hundreds of different payer sources falls squarely upon US physicians' practices,[4] a burden that would not exist in a single-payer system. The total expenditures of public health insurance systems throughout the developed nations is below that of US private insurers, and these systems deliver more effective healthcare to all citizens of those nations at a fraction of US costs.[5]

Private insurers' profits climbed through 2009 and 2010 as a result of premium increases[6] rather than the nebulous "underwriting ... and interest rates" described in Dr Brown's review.[1] The profitability of private finance insurers and the value of the Morgan Stanley Healthcare Payor Index (an index of insurance companies' performance) have both risen through the last 3 years—while private insurers have covered fewer Americans.[6]

Osteopathic physicians' endorsements of different public health policies will impact our patients, our communities, and our own practices. Our support for public health policy warrants the same rigorous evidence-based scrutiny as do our prescribing choices. Our patient care and our professionalism both pivot on the integrity to place

data before ideology. In the end, we as osteopathic physicians serve the health of patients—not that of insurance companies. The majority of US physicians support a comprehensive public healthcare plan for all,[7] and the available data support this endorsement.

Osteopathic medicine sprang from A.T. Still's insight that the medical practices of his contemporaries stood upon little more than the empty repetition of traditional dogmas. Similarly, Dr Still's stand against slavery helped reverse another unsupportable social dogma. Today, data consistently demonstrate higher performance and lower costs of care with national health insurance for all.[5] As the professional descendents of Dr Still, osteopathic physicians should endorse health policy that places data over dogma.

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Response

Dr Graham cites studies implying that Medicare performs better than private insurers and that it is a burden for physicians to pursue multiple payer sources.

However, Medicare is rapidly running out of money,[1] and the recently passed healthcare reform law (ie, Patient Protection and Affordable Care Act of 2010) will only add to the rolls.[2,3] Can we as a nation afford this new law when we are already more than $14 trillion in debt[4] and when entitlement spending, of which Medicare and Medicaid are a part, compromise more than 60% of the federal budget?[5]

There are 2 possible outcomes to this problem: (1) raise taxes and cut benefits or (2) institute true free-market reforms. Allowing the purchase of insurance across state lines, eliminating individual mandates, and expanding the use of health savings accounts could be a good start to such free-market reforms. These steps would help control costs and make it easier for patients to afford their own healthcare.[6]

By making the patient the single payer, all would benefit, and we would not be enslaving future generations to pay for someone else's healthcare.

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One Osteopathic Physician's Path Through an ACGME-Accredited Residency

To the Editor:

As a new faculty member in the Department of Osteopathic Manipulative Medicine at Midwestern University/Arizona College of Osteopathic Medicine (MWU/AZCOM), I am often asked this question: How did you maintain your osteopathic philosophy and your osteopathic manipulative skills at an allopathic (ie, American College of Graduate Medical Education-accredited) residency? As many graduates of osteopathic medical schools will attend allopathic residencies, I would like to use the present letter to answer that question and to help these individuals find their path.

The answer to how I maintained my osteopathic skills and osteopathic philosophy is simple: I wanted to. I developed an appreciation of osteopathic principles and practice (OPP) early on. At the beginning of my first year in osteopathic medical school, I purchased a treatment table—a purchase that I highly recommend because it opens up the opportunity to practice one's osteopathic manipulative treatment (OMT) skills. I began treating my friends with OMT, as well as my wife through her first pregnancy. My treatments, even with my limited abilities, seemed to help my "patients" quite a lot. The beneficial results started me on my path and I never looked back.

I had several additional early experiences that solidified my commitment to osteopathic medicine, a couple of which I will mention here.

The first of these experiences came during my first year of osteopathic medical school, when my daughter was born with torticollis and a suckling dysfunction after a traumatic delivery. She looked in only 1 direction, and her latch was very poor. After only 2 OMT sessions with Jane Carreiro, DO, my daughter's condition improved substantially. It was amazing to see this change right in front of my eyes! At that point, I knew that osteopathic medicine could make a big difference for patients and their families.

After my first 2 years of osteopathic medical school, I started my clinical years and was fortunate to work with a director of graduate medical education in Watertown, New York, who demonstrated a true passion for osteopathic medicine. He supervised us (medical students and residents) while we treated patients who had various musculoskeletal problems at an OMT clinic 1 to 2 evenings a month. It was a great experience to put osteopathic principles into practice, and it gave me the foundation I needed for my residency.

For graduates of colleges of osteopathic medicine who wish to perform OMT in an allopathic residency, I offer the following suggestions, which I found helpful during my own residency.

First, if at all possible, choose a residency program in which there is at least 1 osteopathic physician on faculty. If your residency program does not have a procedural competency form for OMT, create one. Next, get signed off on your competency to perform OMT. Once you have been signed off, you can perform OMT procedures independently, and you can start treating patients and fellow residents.

During my first year of residency, my opportunities to perform OMT were somewhat limited. However, I kept looking for more opportunities. As a second-year resident, I was able to treat more of my patients with OMT, and I began getting referrals from other residents. The patients were happy, and the other residents learned about the benefits of OMT.

At the end of my second year of residency, I used 1 of my elective months to do a rotation in the Department of Osteopathic Manipulative Medicine at MWU/AZCOM. I learned a tremendous amount in this rotation, and it gave me a whole new skill set. I also began to read much more literature about osteopathic medicine.

During my third year as a resident, the osteopathic portion of my residency practice blossomed, and I began getting referrals from multiple residents, faculty members, and patients. I looked for opportunities to integrate osteopathic medicine into the treatment of my patients. Of course, I did not perform OMT on all my patients, but I incorporated it into my practice whenever possible.

There is a common misconception among some osteopathic physicians that DOs who perform OMT tend to neglect more traditional medical practices. That is simply not true. I always performed thorough histories and physical examinations and ordered the appropriate workups for my patients. However, I found that OPP helped me narrow down my differential diagnoses. These days, the physical examination has become something of a lost art, having been replaced by technology. Performing a thorough physical examination based on OPP made the diagnosis more times than I could say.

In summary, to maintain one's osteopathic philosophy and skills while participating in an allopathic residency program, I suggest the following 6 steps:

1. Develop a solid foundation in OPP.
2. Choose a residency that has osteopathic faculty members, and get signed off on your ability to perform OMT.
3. Start using OMT to treat patients within your comfort level.
4. Use at least 1 elective month to do a rotation in OMT.
5. Read literature on osteopathic medicine so you know how to use it in diagnosis and treatment.
6. Be patient with yourself as you develop your OMT skills.

I have learned more in the past 6 months of doing primarily osteopathic manipulation in my practice than in all my previous years of education and training. Moreover, I still learn daily from my patients, who are the real teachers.

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