As the premier scholarly publication of the osteopathic medical profession, JAOA—The Journal of the American Osteopathic Association encourages osteopathic physicians, faculty members and students at osteopathic medical colleges, and others within the healthcare 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.

Letters to the editor are considered for publication in the JAOA with the understanding that they have not been published elsewhere and that they are not simultaneously under consideration by any other publication.

All accepted letters to the editor are subject to copyediting. Letter writers may be asked to provide JAOA staff with photocopies of referenced material so that the references themselves and statements cited may be verified.

Readers are encouraged to prepare letters electronically in Microsoft Word (.doc) or in plain (.txt) or rich text (.rtf) format. The JAOA prefers that letters be e-mailed to jaoa@osteopathic.org. Mailed letters should also be sent electronically, in one of the aforementioned electronic formats on an IBM-compatible compact disk or a 3 1/2-inch diskette, and addressed to Gilbert E. D’Alonzo, Jr, DO, Editor in Chief, American Osteopathic Association, 142 E Ontario St, Chicago, IL 60611-2864.

Letter writers must include their full professional titles and affiliations, complete preferred mailing addresses, day and evening telephone numbers, fax numbers, and preferred e-mail addresses. Authors are responsible for disclosing financial associations and other conflicts of interest.

Although the JAOA cannot acknowledge the receipt of letters, a JAOA staff member will notify writers whose letters have been accepted for publication. Mailed submissions and supporting materials will not be returned unless authors provide self-addressed, stamped envelopes with their submissions.

All osteopathic physicians who have letters published in the JAOA receive continuing medical education (CME) credit for their contributions. Writers of original letters receive 5 hours of AOA Category 1-B CME credit. Authors of published articles who respond to letters about their research receive 3 hours of Category 1-B CME credit for their responses.

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

Postmastectomy Lymphedema: A Call for Osteopathic Medical Research

To the Editor:

Up to 40% of patients with breast cancer who have undergone traditional mastectomy with axillary lymph node dissection can experience postmastectomy lymphedema.1 Postmastectomy lymphedema most commonly presents as an obvious swelling of the upper arm on the side of the mastectomy, with impaired functionality of the limb. In addition to commonly noted local infections, this condition can lead to severely debilitating consequences if left untreated.1

It is generally understood that imbalances between capillary filtration and lymphatic drainage are responsible for the physical manifestation of lymphedematous states.2 When the lymphatic flow is impaired (owing to events such as surgery, trauma, infection, and/or inflammation), excess fluid and protein accumulate in the interstitial space. However, the literature demonstrates additional evidence that hemodynamic factors at the site of lymphedema may also play a role in postmastectomy lymphedema.2–4

Swartz et al5 suggest that the “driving force for [new lymphatic vessel development] is the need for organized interstitial fluid flow.” Considering this, postmastectomy lymphangiogenesis may be a repair mechanism that restores the optimal interstitial fluid flow. If this mechanism does occur, it may be subject to dysfunction in patients with postmastectomy lymphedema. Therefore, treatments aimed at facilitating optimal lymphatic system functioning may be of benefit in this population.

Various treatment modalities have been studied for postmastectomy lymphedema. Some investigators conclude that surgery is effective,6,7 while others have found that physiotherapeutic techniques, such as lymphatic drainage, significantly reduce the severity of postmastectomy lymphedema.8,9 Considering the effectiveness of physiotherapeutic management8,9 and the invasiveness of surgery, it behooves the osteopathic physician to consider osteopathic manipulative treatment (OMT), specifically, lymphatic pump techniques, for this patient population. Some clinicians may question whether these techniques would be indicated for this condition due to the risk of metastasis. Of course, such osteopathic manipulative techniques should be used with sound medical judgment in these patients.10 It may be best to confirm that there is no residual cancer prior to initiating OMT. Furthermore, other
contraindications for lymphatic pump techniques (ie, congestive heart failure) should be kept in mind during patient evaluation.

Although it is suggested that lymphatic pump techniques can be used in patients with postmastectomy lymphedema, there are currently no studies regarding the effect of specific OMT modalities on postmastectomy lymphedema. It is crucial for the osteopathic medical community to have evidence-based clinical data to refer to when considering the appropriate OMT regimen for patients with postmastectomy lymphedema. As such, osteopathic clinicians and researchers may want to implement a study design specific to this topic to not only provide such clinical data to fellows physicians, but also to heighten the awareness of this relatively prevalent pathologic condition.

Manipulation of the lymphatic system is an important component of osteopathic medicine. Thus, as agents of the osteopathic medical profession, we must strive to be at the forefront of research concerning treatments for lymphatic impairment. As Andrew Taylor Still, MD, DO, so eloquently wrote, the lymphatic system is that “which supplies the water of life.”

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References

Avoiding Antiretroviral-Associated Cytopenias

To the Editor:

There are two main challenges in the management of patients with diseases caused by the human immunodeficiency virus (HIV). These challenges are (1) to choose the most appropriate therapeutic regimen for each patient and (2) to minimize toxicities related to highly active antiretroviral therapy (HAART). Successfully meeting these challenges would lead to enhanced therapeutic efficacy and improved quality of life for the patient.

Among the various types of toxicities associated with HAART, cytopenias—including anemia, leucopenia, neutropenia, and thrombocytopenia—are of greatest concern. Anemia is the most commonly diagnosed form of cytopenia. Cytopenias are not often encountered in the Western world, because close clinical monitoring and acute interventions result in low rates of hematologic complications. However, cytopenias remain problematic in many other regions of the world.

When treatment with HAART leads to insufficient hematopoiesis, patients are often diagnosed with cytopenia. Among the nucleoside reverse transcriptase inhibitors used as part of the HAART regimen, AZT (zidovudine/azidothymidine) is associated with the most severe cytopenic effects. The incidence of clinically severe cytopenia can be minimized by using certain combinations of antiretroviral medications. These combinations would retain therapeutic efficacy while being less hematotoxic to patients than individual drugs.

Cytopenia is also a common adverse effect of other chemotherapeutic agents used to treat patients with HIV-associated opportunistic infections, including such agents as amphotericin B, ganciclovir, pentamidine, and trimethoprim/sulfamethoxazole. These medications may be used for either treatment or prophylactic purposes. In addition, opportunistic infections and HIV-associated malignancies can cause cytopenias. Furthermore, coexisting or preexisting medical conditions in HIV-infected individuals may exacerbate cytopenic conditions.

During HAART, it is likely that certain patients may be diagnosed with cytopenia at varying levels of severity. Thus, the diagnosis of cytopenia and its underlying mechanisms during antiretroviral therapy would ensure optimal management of patients with HIV disease. Treatment of such patients should be aimed toward specific causes. Hematopoietic growth factors, including erythropoietin and granulocyte-colony stimulating factors (G-CSFs), have been shown to provide significant clinical benefits in patients with HIV disease.

For providers of care to patients with HIV disease, it is important to
have thorough pharmacologic knowledge of individual antiretroviral agents—especially the profiles of these agents' adverse effects—in order to avoid such serious hematologic complications as cytopenia.

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References

Solving Clinical Problems Osteopathically

To the Editor:

The paper is great, not only in its scientific and clinical value, but also because it approaches a clinical problem osteopathically. The approach used by Goldstein et al gives osteopathic clinicians more tools in what Michael L. Kuchera, DO, has termed our “armamentarium” of skills.

The May 2005 letter to the editor by Robert A. Cain, DO, Program Director at Grandview Hospital in Dayton, Ohio (“Promoting active engagement with osteopathic principles and practice in interns and residents.” J Am Osteopath Assoc. 2005;105:236–237), underscored how important it is for residents to think osteopathically, but I believe that Dr Goldstein’s article demonstrates how osteopathic skills are applicable in all medical specialties.

I have forwarded Dr Goldstein’s article to one of my colleagues who is beginning her anesthesiology residency training in Milan, Italy.

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Recurring Limitations in OMT Research

To the Editor:
I’m writing in response to the original contribution by Frederick J. Goldstein, PhD, et al, that appeared in the June issue of JAOA—The Journal of the American Osteopathic Association (“Preoperative intravenous morphine sulfate with postoperative osteopathic manipulative treatment reduces patient analgesic use after total abdominal hysterectomy.” 2005;105:273–279). As a supporter of research on osteopathic manipulative treatment (OMT) and evidence-based medicine, I continually seek evidence on the effectiveness of OMT within my own practice and the osteopathic medical profession. Unfortunately, it appears that we, as a profession, continue to produce nothing more than large numbers of pilot studies on the effectiveness of OMT.

In their study of women undergoing elective total abdominal hysterectomy, Goldstein et al report that the study group receiving preoperative morphine and postoperative OMT (Group 4) used less morphine postoperatively compared with patients who received preoperative morphine and postoperative sham manipulative treatment (Group 3). However, patients’ subjective pain scores—an important patient-oriented outcome—were no different between these groups.

In addition, the total postoperative dose of morphine sulfate for patients in Group 4 was no better than for those patients receiving preoperative saline and postoperative sham manipulative treatment (Group 1). These two features (ie, no change in subjective pain scores and no difference in outcomes among the two study groups) are the most revealing findings of the study.

The study had only 39 participants dispersed among four study groups, creating small group numbers: three groups had 10 participants, one group had 9. No discussion on the study’s power or sample size calculations was provided for readers, like myself, to make accurate conclusions about the study results. I do not believe merely stating that the study is a pilot experiment is sufficient.

The authors did reference studies using preoperative morphine in similar patient cohorts, giving a basis for some type of sample size estimate, however.1-3

In addition, though the authors noted a statistically significant finding between Groups 3 and 4 with regard to reduced morphine use in the first 24 hours after elective total abdominal hysterectomy (P=.02), overlapping confidence intervals cast some doubt on the stability of the data and whether these findings were truly beyond chance alone.

Finally, there were no groups that received saline or morphine alone (ie, without OMT or sham manipulative
treatment), and, according to extensive discussions at the Sixth Annual American Association of Colleges of Osteopathic Medicine Osteopathic Collaborative Clinical Trials Initiatives Conference, this remains a controversial methodology issue for OMT research.4

It is important for our profession to produce valid OMT research of high quality. However, we should be wary of falling prey to the lures of publication bias; that is, only submitting and publishing findings that show that OMT “works.” It is just as important to find areas in clinical practice where the use of OMT as a treatment modality is not justified—just as antibiotics are not justified for viral upper respiratory infections.6

It seems to me that among the largest concerns for today’s OMT researchers is the profession’s seeming inability to produce large blinded studies conducive to reproducibility and generalizability.

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References

Response

As always, we appreciate comments by others on our clinical research. In response to those points raised by Roberto Cardarelli, DO, MPH, regarding our June 2005 original contribution (2005;105:273–279), we offer the following.

Although we are in basic agreement with Dr Cardarelli that “we, as a profession, continue to produce...large numbers of pilot studies on the effectiveness of OMT (osteopathic manipulative treatment),” our June 2005 study rendered statistically significant results in spite of the small number of patients. Furthermore, as clinicians and researchers, we chose not to enroll more subjects than necessary.

On the topic of sample size, Dr Cardarelli also noted that our study had 39 participants placed in four study groups, adding that “No discussion on the study’s power or sample size calculations was provided for readers...to make accurate conclusions about the study results.”

Accurate conclusions are typically not derived from proof-of-concept research that is appropriately classified as a “pilot.” In addition, power analyses are typically performed if the planning estimates fail to hold and a nonsignificant difference of the primary end point is observed. In our case, power is not an issue given that a significant difference ($P=0.02$) was detected relative to the dose of morphine sulfate.

As noted in our original contribution, our study protocol was approved by the institutional review boards of the City Avenue Hospital (Philadelphia, Pa), which reviewed our sample size estimates and carefully weighed all biethical issues ascribed to this study, as well as the American Osteopathic Association's Bureau of Research (now the Council on Research), which conducted a similar review and subsequently provided financial support for our clinical investigation.

As previously mentioned, we felt it was not appropriate to randomize a greater number of patients in our study without the opportunity of gathering more data than we were already able to produce with 39 subjects. We did consider an adaptive study design that used Bayesian monitoring. However, in the end, we agreed that the clarity yielded with the design described was the most efficient option to address this research question.

Regarding the significance of our statistical findings, Dr Cardarelli wrote: “In addition, though the authors noted a statistically significant finding between Groups 3 and 4 with regard to reduced morphine use in the first 24 hours after elective total abdominal hysterectomy ($P=0.02$), overlapping confidence intervals cast some doubt on the stability of the data and whether these findings were truly beyond chance alone.”

It is our hope that readers understand that the objective of this level of research (ie, a pilot study) is to derive a signal from the randomized treatment groups. It is important to remember that probability values are only intended to provide insight relative to the likelihood of finding a difference of a certain magnitude. In this particular case, the probability that a difference of this magnitude would occur by chance is approximately 2%, which is an impressive finding.

As Dr Cardarelli indicated, subjective pain scores are certainly important for treating patients in general. However, subjective measures are not necessarily useful parameters for a scientifically based clinical investigation on pain management. In fact, we clearly stated in our paper that similar findings were also reported by Miaskowski et al1 and Adams et al.2 In addition, differences in pain scores were not necessarily expected knowing that morphine doses were patient controlled, ensuring an adequate level of analgesia. Thus, our study design was sanctioned, in part, by a methodology that was able to assume that all patients would receive
the full complement of medication required for appropriate pain control.

Finally, Dr Cardarelli noted that our study did not include groups that received “saline or morphine alone (ie, without OMT or sham manipulative treatment).” He added, “according to extensive discussions at the Sixth Annual American Association of Colleges of Osteopathic Medicine Osteopathic Collaborative Clinical Trials Initiatives Conference, this remains a controversial methodology issue for OMT research.” Although it was, admittedly, not clearly noted in our June 2005 JAOA article, our research was completed more than a year before the April 2005 conference to which Dr Cardarelli referred. Therefore, we feel it is not entirely appropriate to attempt to draw a connection between this conference and our study. Even if we grant Dr Cardarelli’s point momentarily for the sake of argument, however, we would like to note that he does not state that there were definitive conclusions regarding this study methodology at this conference, only “discussions,” which though certainly deleterious to all conferences do somewhat temper his “connective” comment.

In any research involving OMT, there will always be a question of whether or not human touch alone will bring about beneficial changes in patients. It is clear that such benefits can, and do, occur.3–5 Therefore, our study design intentionally sought to separate “touch” from actual osteopathic manipulation. We wanted to—and succeeded in—developing a clinical research model that demonstrated that touching alone will not “do it”; osteopathic manipulation must occur for patients to receive clinical benefits. The objective of our study was, as stated, to determine whether there was a clinical effect of adding postoperative OMT to preemptive morphine sulfate in patients undergoing elective total abdominal hysterectomy. Adding study groups who received only preemptive saline or only morphine would address a different research question from the one we sought to answer with our study design.

Dr Still practiced allopathic medicine for some 30 years before he concluded that “known drugs have been a failure and the patient dies just as quickly with them, and often more quickly, than without them.”1 Dr Still not only believed the conventional system of medicine failed to heal patients, he also believed it was morally corrupting to them.2

Dr Still was a Christian minister with a strong sense of morality. His moral vision often conflicted with the prevailing values of the allopathic medical system, which he said, “was no science, and the system of drugs was only a trade, followed by the doctor for the money that could be obtained by it from the ignorant sick.”2 He saw the allopathic medical system as corrupted with greed that built “temples to the god who purged, puked, perspired, opiated, drank whiskey and other stimulants; destroyed its thousands, ruined nations, established whiskey saloons, opium dens....”2 In contrast to the widespread belief that drugs were the solution for patients, he believed that drugs were the root of patients’ problems.

All diseases resulted from deviations from the body’s perfect structure, according to Dr Still. Such deviations created physiological imbalances in function. Dr Still wrote, “The Osteopath seeks first physiological perfection of form, by normally adjusting the osseous frame work, so that all arteries may deliver blood to nourish and construct all parts.”2 After the perfect form has been corrected with osteopathic manipulative treatment (OMT), Dr Still believed that God and nature would heal the disease. He, thus, pioneered the holistic approach to medicine, arguing that “[finding] health should be the object of the doctor. Anyone can find disease.”2

Osteopathic medicine was more compassionate than conventional medicine, believed Dr Still. He encouraged his followers to improve upon past theories of disease and treatment to

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create a better medical system. Shortly after founding the American School of Osteopathy, he wrote that osteopathic medical students should “use any means that are better than any known method of the past, as used in surgery, as used in obstetrics, and in the treatment of diseases generally.”2 Thus, Dr Still created osteopathic medicine as a separate and radical new philosophy that improved upon allopathic medicine on many fronts, especially on the fronts of morality, humanity, and efficacy.

Today, more than 100 years after Dr Still first raised the banner of osteopathic medicine, osteopathic physicians walk on a precarious tight rope with their allopathic brothers and sisters. Since Dr Still’s time, osteopathic physicians have successfully fought for “separate but equal rights,” and they now practice side by side with their allopathic counterparts. Osteopathic physicians are fully licensed in all 50 states, and more than 50% of osteopathic medical school graduates now attend residency programs accredited by the allopathic Accreditation Council for Graduate Medical Education.3

In a 2001 survey of osteopathic physicians by Johnson et al,4 more than 50% of the respondents said they used OMT on less than 5% of their patients. The survey was the latest indication that osteopathic physicians have become more like allopathic physicians in all respects—fewer perform OMT, more prescribe drugs, and many perform surgery as a first option.

What has happened since the 1890s to make so many osteopathic physicians move so close to the allopathic medical system? Many osteopathic physicians are struggling for the answer to this question. Meanwhile, the leadership of the osteopathic medical profession has yet to clearly define the profession’s uniqueness in modern medicine. A 2002 survey of osteopathic physicians by Johnson et al5 found that “not a single philosophic concept or resultant practice behavior had concurrency from more than a third of the respondents as distinguishing osteopathic from allopathic medicine.” Johnson et al6 concluded that many osteopathic physicians, especially those who are recent graduates, no longer use OMT for a variety of reasons, including institutional barriers, negative professional attitudes, and lack of postgraduate training.

I believe that such surveys, while insightful in certain areas, overlook the most important and critical reason for the failure of osteopathic physicians to use OMT—a lack of randomized controlled studies to support the efficacy of OMT. A paradox has developed: training in osteopathic medical schools emphasizes evidence-based medicine, but graduates of these schools do not apply the same level of scientific scrutiny to OMT research.6

I found this problem highlighted when I conducted an electronic search of recent literature in regard to low back pain. Using the National Library of Medicine’s PubMed and Ovid MEDLINE databases, as well as the OSTMED database, I searched for literature dated from January 1990 through December 2005 containing the terms osteopathic manipulative treatment and low back pain. This search yielded only a small number of randomized controlled studies specific to low back pain, and the conclusions of these studies varied considerably.

The study that was most favorable to manipulation, by Andersson et al,7 found that OMT may be as efficacious as conventional medical therapy. A study of moderate favorability, by Licciardone et al,8 indicated that the efficacy of OMT is no better than that of sham manipulation. The least favorable study, by Assendelft et al,9 concluded that, “Spinal manipulative therapy had no statistically or clinically significant advantage over general practitioner care, analgesics, physical therapy, exercises, or back school.”

As the old saying goes, “There are lies, damn lies, and statistics.” Yet, if OMT in its most favorable study is only as efficacious as conventional medical care for patients with somatic dysfunction, what does this say about the other conditions that OMT is used for? Perhaps more time and research will help resolve the paradox of osteopathic medicine. However, the osteopathic medical profession has been waiting 100 years for research to firmly support the efficacy of OMT. Many osteopathic physicians simply refuse to wait any longer.

Dr Still believed that osteopathic medicine was more compassionate, efficacious, and moral than the medical system of the 19th century. His writings illustrate his compassion and conviction when he challenged his followers to improve upon existing theories of disease and treatment.1,2 Considering the primitive nature of medications and surgical practices during the 1890s, OMT was arguably an improvement upon many contemporary medical practices. Since then, however, modern medicine has made substantial progress in pharmacology, imaging, surgery, and many other diagnostic and therapeutic modalities. This progress has made the conventional medicine of the 21st century much more compassionate and efficacious than it was during the 19th century.

In the face of the many improvements in conventional medicine since 1892—and with the lack of research substantiating the efficacy of OMT—would Dr Still maintain today that OMT represents an improvement upon conventional medical practices? Or would he seek to begin a new chapter in osteopathic medicine—one that focuses on the other positive factors that make osteopathic medicine distinctive? Dr Still highlighted one such distinction when he stated, “We are here to call a horse a horse, to demonstrate what we assert, and leave the results to be accepted or rejected by men and women who can and will think in the words of our own blessed language.”1

Osteopathic medicine is unique because patients have embraced osteo-
Osteopathic physicians for their pragmatism and communication skills. Osteopathic medicine owes its success to those patients who see beyond OMT. It is time for the leadership of the osteopathic medical profession to also look beyond OMT, or the real uniqueness of this profession will become lost.

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References