Need for objective measures to prove clinical outcome

To the Editor:
This letter is in response to the original contribution by John Licciardone, DO, MBA; Russell Gamber, DO; and Kathryn Cardarelli, MPH, “Patient satisfaction and clinical outcomes associated with osteopathic manipulative treatment” (JAOA 2002;102:13-20).

This study wonderfully points out a correlation of patient satisfaction and osteopathic manipulative treatment, but it failed to prove any true clinical outcome. The subjective outcome measures for pain relief and mobility used in this study are possibly just different measures of patient satisfaction. Without objective measures, such as joint range of motion or a change in two points on a visual analog pain scale, the researcher cannot know whether the improved mobility or decreased pain is secondary to the actual therapy or whether it is placebo effect. One can argue that at least one third of the patients who subjectively reported less pain or increased mobility

was simply the result of a placebo effect. They recommend using a visual analogue scale (VAS) or joint range-of-motion test in future studies to control for the placebo effect.

It is interesting to note that many observers refuse to accept patient self-reports as objective clinical outcomes, despite the fact that the Medical Outcomes Study 36-Item Short Form (SF-36), an entirely self-reported instrument, has achieved prominence as a clinical outcomes measure. This instrument provides valid and reliable measures in eight scales, all of which are germane to OMT and to the treatment of musculoskeletal disorders: physical functioning, role limitations because of physical problems, bodily pain, general health, vitality, social functioning, role limitations because of emotional problems, and mental health.

A recent systematic review of clinical trials that compared placebo with no treatment generally found little evidence that placebos had powerful clinical effects. In 27 trials involving the treatment of pain, placebo had a small beneficial effect, as indicated by a reduction in the intensity of pain of 6.5 mm on a 100 mm VAS. This represents a standardized effect size of –0.27 (95% confidence interval, –0.40 to –0.15). In comparison, a reanalysis of our study data on pre-OMT and post-OMT measures for pain yielded a standardized effect size of –2.00 (95% confidence interval, –2.17 to –1.83). The magnitude of this reduction in pain, in comparison with the reported placebo effect noted above, suggests that OMT benefits in our study cannot simply be attributed to the placebo effect. This is also corroborated by the magnitude of the paired t-statistic that was originally reported for the pain outcome (t = 33.3). Parenthetically, contrary to the suggestion of Oleski and Kim, this systematic review considered a VAS to be a subjective, not objective, measure of outcome.

As suggested in the last sentence of our article, the real challenge for osteopathic researchers is to undertake studies that compare the outcomes of OMT with those achieved by other types of treatment. This type of study may involve a randomized controlled trial in which all subjects receive standard care while one trial arm also receives OMT as a co-treatment. For example, a recent trial4 found that subjects who received OMT as a co-treatment for low back pain required less medication (analgesics, anti-inflammatory agents, and muscle relaxants) and used less physical therapy than subjects who did not receive OMT.

Response

To the Editor:
The comments provided by Sheryl Oleski, MS-V, and Michael Kim, DO, in response to our study on patient satisfaction and clinical outcomes associated with osteopathic manipulative treatment (OMT)1 provide a useful framework for addressing some common osteopathic research issues, particularly concerning the placebo effect. Their main point appears to be that our study revealed high levels of patient satisfaction with OMT but that it failed to demonstrate the effectiveness of OMT in decreasing pain or improving mobility. Further, Oleski and Kim imply that patients’ self-reported ratings of pain and mobility are not objective outcome measures and, therefore, any observed benefit of OMT in our study may have been simply the result of a placebo effect. They recommend using a visual analogue scale (VAS) or joint range-of-motion test in future studies to control for the placebo effect.

It is interesting to note that many observers refuse to accept patient self-reports as objective clinical outcomes, despite the fact that the Medical Outcomes Study 36-Item Short Form (SF-36), an entirely self-reported instrument, has achieved prominence as a clinical outcomes measure. This instrument provides valid and reliable measures in eight scales, all of which are germane to OMT and to the treatment of musculoskeletal disorders: physical functioning, role limitations because of physical problems, bodily pain, general health, vitality, social functioning, role limitations because of emotional problems, and mental health.

A recent systematic review of clinical trials that compared placebo with no treatment generally found little evidence that placebos had powerful clinical effects. In 27 trials involving the treatment of pain, placebo had a small beneficial effect, as indicated by a reduction in the intensity of pain of 6.5 mm on a 100 mm VAS. This represents a standardized effect size of –0.27 (95% confidence interval, –0.40 to –0.15). In comparison, a reanalysis of our study data on pre-OMT and post-OMT measures for pain yielded a standardized effect size of –2.00 (95% confidence interval, –2.17 to –1.83). The magnitude of this reduction in pain, in comparison with the reported placebo effect noted above, suggests that OMT benefits in our study cannot simply be attributed to the placebo effect. This is also corroborated by the magnitude of the paired t-statistic that was originally reported for the pain outcome (t = 33.3). Parenthetically, contrary to the suggestion of Oleski and Kim, this systematic review considered a VAS to be a subjective, not objective, measure of outcome.

As suggested in the last sentence of our article, the real challenge for osteopathic researchers is to undertake studies that compare the outcomes of OMT with those achieved by other types of treatment. This type of study may involve a randomized controlled trial in which all subjects receive standard care while one trial arm also receives OMT as a co-treatment. For example, a recent trial4 found that subjects who received OMT as a co-treatment for low back pain required less medication (analgesics, anti-inflammatory agents, and muscle relaxants) and used less physical therapy than subjects who did not receive OMT.

Sheryl Lynn Oleski, MS-V
Philadelphia, Pennsylvania

Michael D. S. Kim, DO
Philadelphia, Pennsylvania

References
Methodologically, however, the lack of a placebo control group (ie, a group that received some placebo intervention in addition to standard care for low back pain) and the lack of subject blinding were important weaknesses of this trial.

To control for the placebo effect, we performed a clinical trial in rehabilitation inpatients following knee or hip arthroplasty that included OMT and “sham manipulation” arms (ie, all subjects received standard care in addition to their assigned intervention) (J.C.L., unpublished data, 2001). Clinical outcomes were no better in the OMT group than in the sham manipulation group. Thus, to address more thoroughly the issue of potential placebo effects attributable to OMT in a subsequent trial involving subjects with chronic low back pain, we used OMT, sham manipulation, and “no-intervention control” arms (all subjects received standard care for back pain in addition to their assigned intervention). The results of this trial, which should shed more light on the actual therapeutic effects of OMT as compared with any placebo effects, are forthcoming (J.C.L., unpublished data, 2002). Nevertheless, additional evidence-based research on OMT efficacy is much needed.

J. C. Licciardone, DO, MBA
Department of Family Medicine
Texas College of Osteopathic Medicine
University of North Texas Health Science Center
Fort Worth, Texas

References

The place to start incorporating philosophy into osteopathic medical education is in the first 2 years of medical school. The osteopathic philosophy needs to be integrated into the entire curriculum, right from the beginning. We should be teaching our students to think osteopathically; then and only then will they go on to incorporate OMT as a useful tool in their practices.

Like Mr. Acunto, I was frustrated in my attempts to learn the osteopathic philosophy as a medical student. Many times a basic science or systems course instructor was asked how his or her lesson could be viewed osteopathically and, most often, the instructor’s response was “that is not applicable to this situation.” Such response points up the need for the science faculty to incorporate the osteopathic philosophy into their courses. The OMT instructors had to spend their time undoing what had been done by the “real teachers.” They had to teach us that there are applications of osteopathic philosophy in all clinical situations. Sadly, for most students, it was too late. The resistance to the osteopathic philosophy that many students develop in the first 2 years of medical school tends to be reinforced in their clinical rotations. Those of us who had chosen osteopathic medical school in order to learn this philosophy felt we had to beg to be taught its clinical application.

When the osteopathic philosophy is taught as the foundation of medicine, students will already understand how to incorporate osteopathic principles and the use of OMT into their clinical practices—challenging the clinical attending physicians to revisit what and how they teach.

Lynn Beals-Becker, DO
Ann Arbor, Michigan