Preliminary Findings on the Use of Osteopathic Manipulative Treatment: Outcomes During the Formation of the Practice-Based Research Network, DO-Touch.NET

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Context: Few studies have assessed the use of osteopathic manipulative treatment (OMT) and subsequent patient-reported outcomes.

Objective: To assess the current use of OMT and associated patient-reported outcomes.

Design: A retrospective medical record review and a prospective observational study.

Setting: Two university-based sites and their clinics associated with the practice-based research network DO-Touch.NET.

Participants: Patients aged 18 years or older who received OMT.

Main Outcome Measures: Medical records from 2007 were retrospectively reviewed to identify conditions being managed with OMT. From 2008 to 2010, patients were recruited before seeing their physicians. Questionnaires were distributed to patients and physicians, and information including demographics, chief complaints, symptom severity, current and past treatments, interference of symptoms with quality of life, physical examination findings, diagnoses, OMT performed, and immediate patient response to OMT was collected. A subset of patients provided data on symptom severity and frequency and other treatments daily for the 7 days after OMT. On day 7, symptom interference with quality of life was reassessed.

Results: Retrospective data were collected from 2569 office visits, and prospective data were collected from 299 office visits (patient age range, 18-93 years). In the medical record review, 17 of the top 25 diagnoses (68%) were related to musculoskeletal conditions. In the prospective study, 18 of the top 24 medical diagnoses (75%) were related to musculoskeletal conditions. Immediately after OMT, patients at 271 of 296 office visits (92%) felt better or much better; those at 5 (<2%) felt worse. After 7 days, patients at 126 of 175 office visits (72%) felt better or much better, and those at 10 (6%) felt worse. Average and worst symptom severity decreased until post-OMT days 4 and 5, respectively, when severity leveled off. There was decreased interference of symptoms with quality of life from before OMT to 7 days after OMT in usual/general activities, sleep, mood, and relationships (all $P \leq .05$).

Conclusion: These preliminary results suggest that for adults, OMT is predominantly used for managing musculoskeletal pain conditions and is effective for short-term symptom relief. Continued surveillance of DO-Touch.NET member practice outcomes may help identify priorities for osteopathic research and define evidence-based standards for OMT practice and training.

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The aim of medicine is to provide safe, effective, efficient, timely, patient-centered, and equitable care.[1] An important aspect of advancing the practice of medicine is improving physician knowledge of the long-term course of common diseases and the impact of various treatments on those diseases.[2-6] Although the osteopathic medical profession has consistently promoted these aims, it has had limited success in systematically documenting its members' impact on such diseases. Osteopathic manipulative treatment (OMT) is a unique aspect of medical care provided by osteopathic physicians, but, to our knowledge, the most recent studies on the use of OMT within the adult population were conducted in the late 1990s.[7-10] Johnson and Kurtz[7] surveyed physicians evaluating, in part, the conditions that they manage using OMT. In that study, more than half of the 950 physicians surveyed indicated that they used OMT in 5% or less of their patients. When OMT was used, it was used for musculoskeletal conditions in more than 50% of the patients.[7] A retrospective study[10] of 1331 patient encounters in family practice training programs demonstrated that somatic dysfunction was diagnosed in approximately 31% of patient encounters, and OMT was performed in 25% of encounters. However, because the estimates of the provision of OMT from these studies are based on data obtained approximately 15 years ago and are based on self-reported general impressions of OMT from physicians, these estimates do not necessarily reflect the current provision of OMT.

Surveys have also been conducted to evaluate the overall impressions of OMT. Licciardone and Herron[9] conducted a national phone survey regarding patient satisfaction with health care and public perceptions of osteopathic medicine, including OMT. The survey evaluated general perceptions and did not focus on any specific patient encounters. In another survey, patients in an osteopathic manipulative medicine (OMM) specialty clinic were asked about their quality of life.[11] However, that survey did not specifically examine the impact of OMT on the patient's quality of life.

Extensive anecdotal reporting and some preliminary research indicate that OMT has a therapeutic benefit.[3,12-34] Examples of conditions positively influenced by OMT are low back pain, otitis media, postsurgical ileus, pneumonia, vertigo, chronic obstructive pulmonary disease, preterm labor, irritable bowel disease, ulcerative colitis, depression, fever, migraine headaches, chronic prostatitis, cough, tinnitus, and asthma.[14,17,19,20,25,26,28,29,31,35-39] For people with low back pain, an expanding body of evidence indicates that OMT has a therapeutic benefit.[36-39] A study[38] published in 2013 reported convincing evidence that OMT has at least moderate effectiveness for those with low back pain. Yet for conditions other than low back pain, studies have been infrequent and underpowered, and many have had weak methodologies.

In a survey of 459 patients seen at an OMM specialty clinic, Licciardone et al[22] reported that OMT had a positive impact on pain and mobility. This survey focused on OMT in general and not on any specific condition, and the evidence for the therapeutic benefit of OMT was based on patient recall. Patients were asked to compare their pain and mobility from previous clinic visits before and after OMT. Further, this study had limited generalizability because the data were collected from a single OMM specialty clinic and the selection criteria for the study limited participants to patients who had visited the clinic at least 3 times. Because of the limitations of previous studies investigating the therapeutic benefit of OMT, it is currently impossible to perform a systematic, scientific assessment of the effectiveness of OMT on any condition other than low back pain.

The randomized controlled trial (RCT) has been the gold standard in research to improve knowledge and advance medicine. In many cases, applying this design in human clinical studies is problematic. For instance, the cost to recruit and retain participants tends to be high. Although designed to yield clear and important outcomes that are internally valid, generalizing outcomes is often limited. Further, interventions based on RCTs are often less efficacious than expected[40-45] because the controlled

settings of RCTs are unrealistic in "real-world" practices and can create interventions that may be too complex or costly to integrate with existing activities.[40,42,43,46]

With the goal of improving clinical care, consortia of practitioners first established practice-based research networks (PBRNs) in the late 1960s.[2,4-6,47-57] These practices affiliated with one another to investigate questions related to improving the care they provided and improving their discipline. These networks tend to be patient centered and primary-care centered, so they are well suited for conducting research within practices that maintain traditional principles of osteopathic medicine. To date, OMT research has not been able to produce the level of outcomes required to expand knowledge and to meet the profession's needs in an age of evidence-based medicine. Because PBRNs have the potential to generate large data sets quickly and with relative ease, an OMT-focused PBRN would be able to produce much-needed evidence to determine the current value of OMT. For more than a century, the use of OMT in clinical practice has been based primarily on anecdotal evidence, so it is important to first observe the current use, characteristics, and outcomes of OMT to help generate more detailed and probing research studies. In 2007, we initiated preliminary work for establishing a PBRN, and in 2009, we established DO-Touch.NET (Doctors of Osteopathy Treating with OMM: determining its Usefulness in Current Healthcare), a PBRN with a mission to evaluate and advance the practice of OMM. Additional background information regarding the network can be found on its website at http://www.DO-Touch.NET.

In the present article, we report the preliminary findings of the DO-Touch.NET study, which was started before the formal formation of the PBRN. The objectives of the study, which is an ongoing prospective observational study on the current practice of OMT, are to determine the scope of conditions being managed with OMT and the characteristics of patients currently receiving OMT and to evaluate the patient-reported outcomes of treatment. We hypothesized that OMT would primarily be used in the management of musculoskeletal pain disorders and that patients receiving OMT would report fewer and less severe symptoms and improved quality of life.

Methods

The current study comprised 2 parts: a 1-year retrospective review to identify the scope of conditions being managed with OMT and a prospective observational study to identify characteristics of current OMT practice and patient perceptions of treatment. The retrospective study included medical records from office visits that took place in 2007 at 2 university-based sites (A.T. Still University-Kirksville College of Osteopathic Medicine [ATSU-KCOM] and the Penn State Milton S. Hershey Medical Center [MSHMC]). The prospective observational study was conducted from 2008 to 2010 at 4 clinics; 2 were associated with the MSHMC and participated in the development of the tools needed to support DO-Touch.NET, and 2 were the first member sites of the network. All data were incorporated into an online data collection system that was tested and refined to ensure convenience in data collection and quality of data. The A.T. Still University-Kirksville and Penn State Hershey institutional review boards approved both the retrospective and prospective parts of the current study.

Retrospective Review

The International Classification of Diseases, 9th edition (ICD-9)[58] code for the primary diagnosis of patients receiving OMT was extracted from the billing records for 2007 at the 2 participating universities. At the MSHMC, the electronic billing system was queried to identify all office visits for which OMT was billed. At ATSU-KCOM, the electronic billing system generated a summary of each individual office visit, which required manual sorting and identification of the desired information. The summary report for ATSU-KCOM was reviewed 3 times to ensure accurate extraction of diagnosis data.

Prospective Observational Study

Pilot Data

During 2008, in conjunction with the retrospective review, we collected pilot data at clinic sites affiliated with ATSU-KCOM and the MSHMC about the characteristics of current OMT practice. These pilot data were combined with patient- and physician-reported data collected during 2009 and 2010 as part of DO-Touch.NET's first prospective observational study.

Participants

Patients aged 18 years or older who received OMT from a participating physician were recruited from 2008 to 2010 to participate in the study. Patients with dementia, psychological conditions, or difficulties communicating in English were excluded from participation. Patient recruitment occurred at the clinics when the patients arrived for their appointments. A research assistant (C.H.) reviewed the study with each patient and answered any questions, and each patient signed an approved informed consent form before participation.

Patient-Reported Data

Throughout the study, data regarding the office visits were collected from the patients and physicians. In 2009, the follow-up questionnaires were added and the office visit questionnaire was fine-tuned. Institutional review board approval was obtained before these changes were implemented.

In 2009 and 2010, the patients completed the Patient Office Visit Questionnaire immediately before seeing their physician. This questionnaire requested information about demographic data, chief complaints, current medications for symptoms, and symptom interference with quality of life. The baseline data included a qualitative assessment of the chief complaint(s) associated with the visit and a quantitative evaluation of the average (ie, overall) and worst severity of symptoms associated with the chief complaint(s) that occurred during the week before the office visit. Severity of symptoms was evaluated using standardized 0- to 10-point scales, with 0 indicating no problem and 10 indicating worst imaginable. The frequency and duration of symptoms were also recorded. Qualitative assessment of the chief complaint(s) in 2008 was obtained from the physician's report of the patient's chief complaint(s). Quality of life scales were constructed based on the Brief Pain Inventory[59-61] and assessed symptom interference with usual/general activities, work, sleep, mood, relationships with other people, and enjoyment of life. Scores were measured on a scale of 0 to 10, with 0 indicating none and 10 indicating worst.

From 2008 to 2010, the Patient Posttreatment Questionnaire was completed by the patient immediately after treatment. Questionnaires were given to the patients after the physician had left the room to promote unbiased reporting. This questionnaire assessed the patient's perception of his or her symptoms after treatment (ie, much better, better, same, or worse).

In 2009 and 2010, 2 additional follow-up questionnaires were completed by the patients. For 6 days after treatment, patients completed the Daily Follow-up Questionnaire. This questionnaire assessed the severity, frequency, and duration of symptoms over the previous 24 hours for each chief complaint identified at the office visit, as well as medication used and other activities performed on those days such as stretching and physical therapy. On day 7, patients completed the One-Week Follow-up Questionnaire, which evaluated the patient's symptom levels associated with the chief complaint(s) over the past 24 hours, as well as quality of life, any new symptoms and adverse effects that occurred during the week after treatment, and overall satisfaction with and perception of the effect of the OMT intervention. Most of these questions on the One-Week Follow-up Questionnaire were identical to the questions in the Patient Office Visit Questionnaire, the Patient Posttreatment Questionnaire, and the Daily Follow-up Questionnaire to maximize fidelity in the analysis of patient responses. Patients had the option to complete the Daily and One-Week

Follow-up Questionnaires online or on paper. Patients who elected to complete the questionnaires on paper received a stamped, addressed envelope for return of the questionnaires to the central coordinating center. A toll-free telephone number was available to all patients if assistance was needed to complete the questionnaires. If patients had given their consent during enrollment, they were given 1 or 2 reminders by e-mail or telephone during the week after treatment to complete the questionnaires.

Physician-Reported Data

Physicians completed the Physical Examination and Treatment Form for each office visit. This questionnaire was completed during or immediately after the office visit by the physician or a research assistant. When the form was completed by a research assistant, the treating physician confirmed the accuracy of the data.

On the form, physicians provided information about the patient's medical history, physical examination, diagnosis, treatment, and home instructions. The medical history was based on the physician's interview with the patient. Data were also collected on the chief complaint(s), the history of the chief complaint(s), and the review of systems. Physical examination findings were documented, including but not limited to the musculoskeletal (structural) examination findings, the regions evaluated, the types of palpatory tests used to identify somatic dysfunction, and the severity of positive findings (data not presented). Additional data were collected on which body regions were treated, the types of techniques used in treating the somatic dysfunction, and the physician's assessment of the patient's response to the treatment. Data collected for the physician's assessment included medical and related somatic dysfunction diagnoses using ICD-9 codes.[58] In 2009 and 2010, any medications, physical therapy, or other treatments prescribed, such as recommendations for physical activity, nutrition, or other guidance, were documented.

Participating physicians also completed a background questionnaire, which included questions about medical school, residency, specialty, years in practice, ongoing training in OMT techniques, and techniques currently used in daily practice.

Statistical Analyses

Basic descriptive statistics and 95% confidence intervals (CIs) were used to assess the scope of conditions being managed with OMT in both the retrospective and prospective analyses. For data from the prospective study, descriptive statistics were used to assess the characteristics of patients who received OMT. For data from the prospective part of the study in 2009 and 2010, a linear mixed model was used to test for changes in the severity level of symptoms associated with the chief complaint(s) from before OMT through the 7 days after treatment. A random effect was included in the model to account for repeated office visits by some patients, and the residual variances were estimated separately for each clinic to account for clustering within clinics. A similar linear mixed model was used to test for change in the interference of symptoms with quality of life from before treatment to 7 days after treatment. Clinically meaningful change in symptom severity levels was defined as a 30% or greater change from before treatment to post-OMT day 7.[62] The percentage of patients who experienced clinically meaningful improvement or worsening was calculated. Effect sizes were estimated using Cohen *d*, with *d* less than 0.5 indicating a small effect, *d* greater than or equal to 0.5 but less than 0.8 indicating a medium effect, and *d* greater than or equal to 0.8 indicating a large effect.[63]

Sensitivity analyses were performed on the 2009-2010 data to determine whether the results were affected by patients who did not complete the full 7 days of questionnaires after treatment. These sensitivity analyses included the following: (1) Mann-Whitney test comparing data from those who completed the perceived response to OMT questions both immediately and 7 days after OMT (perceived response completers) with data from noncompleters regarding the patient percep-

tion of the effect of the treatment immediately after OMT, (2) linear mixed models comparing pretreatment symptom severity levels of those who completed at least 5 of the 7 follow-up questionnaires (follow-up questionnaire completers) with levels of those who completed 4 or less of the follow-up questionnaires, (3) linear mixed models testing for change in symptom severity level from before treatment through the 7 days after treatment using data only from patients who completed all 7 follow-up questionnaires, and (4) linear mixed models comparing data from those who completed the quality of life measures before treatment and 7 days after OMT (quality of life completers) with data from noncompleters regarding pretreatment interference of symptoms with quality of life.

Perceived response subgroups were formed based on the patient perceptions of response to OMT from the Patient Posttreatment Questionnaire and the One-Week Follow-up Questionnaire. To evaluate the consistency of patient perceptions of their response to treatment with their response to treatment as quantified using symptom severity levels, a linear mixed model was used to compare the perceived response subgroups on average symptom severity level from before treatment through the 7 days after treatment. Analyses were conducted using SAS statistical software, version 9.3 (SAS Institute Inc). Because some patients skipped some questions when completing the questionnaires, the sample sizes varied between analyses. All available data were used in the analyses and no missing data were imputed. *P* values less than or equal to .05 were considered statistically significant.

Results

Retrospective Review

For the 1-year retrospective review using billing data from 2 university-based sites, diagnosis data were collected from 2569 office visits. The incidence of the top 25 most frequently reported diagnoses is summarized in *Figure 1*. Of these, 17 diagnoses (68%) were musculoskeletal pain conditions.

Prospective Observational Study

For the prospective observational study, data were collected from 299 visits by 259 patients treated during office visits from 2008 to 2010, with demographic and follow-up data obtained from the 172 patients (133 women [77%] and 39 men [23%]) treated during 212 office visits in 2009 and 2010. The mean (standard deviation) age was 54 (17) years (range, 18-93 years). Of those 172 patients treated in 2009 and 2010, most (167 [97%]) were Caucasian, non-Hispanic, or had no ethnicity specified; 63 (37%) had at least a college education; and 62 (37%) were employed full-time, 15 (9%) were employed part-time, 17 (10%) were unemployed, and 60 (36%) were retired. The median reported annual income was between $35,000 and $49,999.

Twelve physicians from 4 clinics participated in the prospective study; 6 specialized in neuromusculoskeletal medicine, 3 specialized in family medicine, 2 specialized in both neuromusculoskeletal medicine and family medicine, and 1 reported postgraduate training in sports medicine in addition to family medicine. The mean (standard deviation) years in practice was 19 (12) years (range, 3-40 years). Three physicians had completed an OMM undergraduate fellowship. Regarding current OMT technique use, all 12 physicians reported that they use articulatory; high-velocity, low-amplitude; muscle energy; and myofascial release techniques. In addition, 11 physicians reported using counterstrain/facilitated positional and soft tissue techniques; 10, balanced ligamentous tension/ligamentous articular strain technique; 9, cranial and indirect/functional techniques; and 5, visceral techniques.

The most common patient-reported symptoms associated with chief complaint were primarily related to musculoskeletal pain (*Figure 2*). The most frequently reported medical diagnoses of these patients were primarily musculoskeletal pain conditions (18 of 24 diagnoses [75%]) (*Figure 3*) and were consistent with the

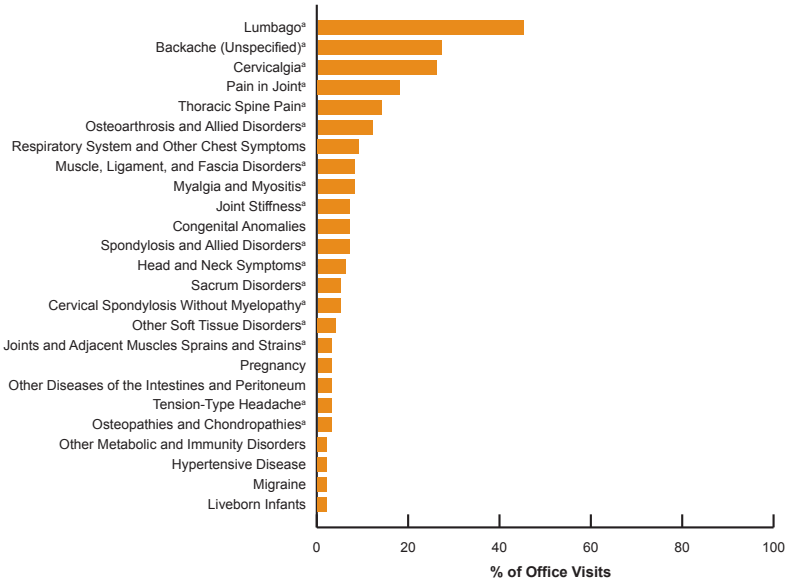

Figure 1.
Most frequently reported medical diagnoses managed with osteopathic manipulative treatment according to billing data of 2569 office visits that took place in 2007 at 2 university-based sites.
[a]Musculoskeletal pain condition.

findings from the retrospective review (*Figure 1*). Of 256 office visits for which medical diagnoses were reported, 175 (68%) were solely for musculoskeletal conditions, and an additional 54 (21%) were for both musculoskeletal and nonmusculoskeletal conditions. Of 221 patients, 152 (69%) were seen solely for musculoskeletal conditions and an additional 51 (23%) were seen for both musculoskeletal and nonmusculoskeletal conditions.

Immediately after OMT, patients at 296 of 299 office visits (99%) completed the perceived response to OMT question on the Patient Posttreatment Questionnaire; patients reported that they felt better or much better at 271 of those office visits (92%), the same at 20 visits (7%), and worse at 5 visits (<2%). For 2009-2010 data, of the patients who completed the perceived response to OMT question on the One-Week Follow-up Questionnaire (175 office visits [83%]), those at 126 office visits (72%) felt better or much better 7 days after OMT, those at 39 visits (22%) felt the same, and those at 10 visits (6%) felt worse. Those at 173 of 212 office visits (82%) completed the perceived response to OMT questions both immediately and 7 days after OMT (perceived response completers), those at 39 visits (18%) responded only immediately after OMT, and those at 2 visits (<1%) responded only 7 days after OMT. Responses immediately after OMT from perceived response completers were not significantly different from those of noncompleters (158 of 173 completers [91%] vs 32 of 37 noncompleters [86%] felt better or much better, $P=.41$).

Regarding the average and worst symptom severity questions on the Patient Office Visit Questionnaire, the Daily Follow-up Questionnaires, and the One-Week Follow-up Questionnaire, there was a significant decrease (both $P<.001$) in the average and worst severity of symptoms associated with the chief complaint(s) over the week after treatment from the level before OMT (*Figure 4*). Symptom severity demonstrated the largest decrease from before treatment to post-OMT day 1 and continued to decrease slightly until post-OMT day 4 for average severity and post-OMT day 5 for worst severity, when severity scores leveled off. Of the 174 office visits where patients completed at least 5 of the 7 follow-up questionnaires (follow-up questionnaire completers), 121 (70%) experienced a clinically meaningful improvement (ie, decrease of ≥30%) in their average symptom severity levels from before treatment to post-OMT day 7, 45 (26%) experienced no meaningful change (ie, change of <30%), and 8 (5%) experienced a clinically meaningful worsening (ie, increase of ≥30%). The effect size of OMT on average symptom severity levels over 1 week was large ($d=1.2$).

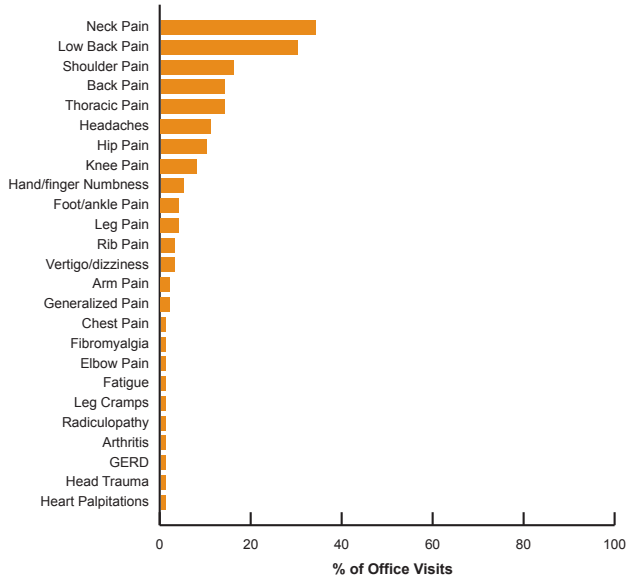

Figure 2.
Most common chief complaints managed with osteopathic manipulative treatment during a prospective observational study of 299 office visits that took place from 2008 to 2010 at participating clinics. *Abbreviation*: GERD, gastroesophageal reflux disease.

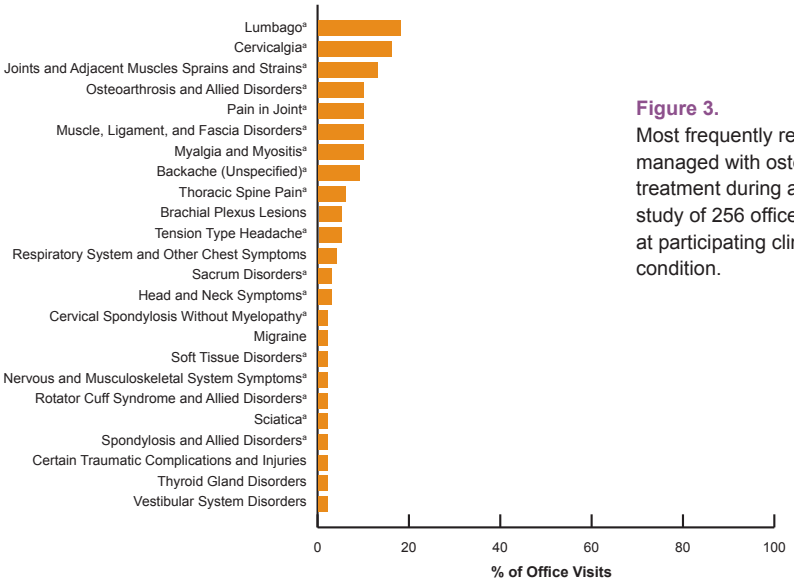

Figure 3.
Most frequently reported medical diagnoses managed with osteopathic manipulative treatment during a prospective observational study of 256 office visits from 2008 to 2010 at participating clinics. [a]Musculoskeletal pain condition.

Of the patients who provided pretreatment symptom severity data, 1 sensitivity analysis indicated there was no significant difference between follow-up questionnaire completers (174 of 209 [83%]) and noncompleters (35 of 209 [17%]) on pretreatment mean symptom severity ($P=.25$ and .72 for average and worst severity, respectively). Results from a second sensitivity analysis testing for change in symptom severity level using data only from the 131 patients who completed all 7 follow-up questionnaires were consistent with results using data from all patients (both $P<.001$), with severity leveling off at post-OMT day 4.

The follow-up questionnaire completers were divided into 5 subgroups based on their perceived response to

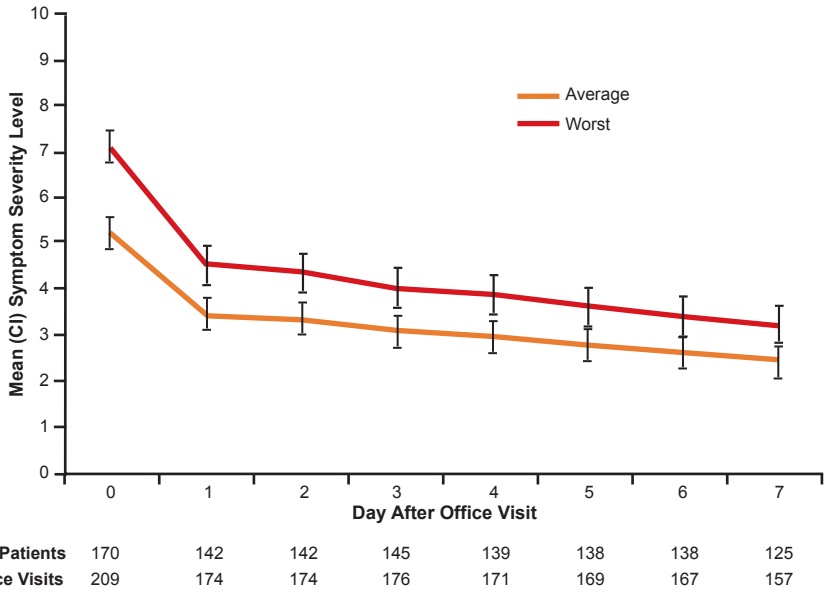

Figure 4.
Patient-reported average and worst severity of symptoms associated with the chief complaints during the 7 days after osteopathic manipulative treatment. Symptom severity was measured on a 0- to 10-point scale, with 0 indicating no problem and 10 indicating worst imaginable. Patient data were obtained during a prospective observational study of 209 office visits by 170 patients that took place from 2008 to 2010 at participating clinics. *Abbreviation:* CI, confidence interval.

treatment taken from the Patient Posttreatment Questionnaire and the One-Week Follow-up Questionnaire. Of 173 follow-up questionnaire completers, the largest subgroup consisted of those who reported feeling better or much better both immediately and 7 days after OMT (115 [66%]), followed by the subgroup of those who reported feeling better or much better immediately after OMT but feeling the same 7 days after treatment as they did before OMT (33 [19%]). Smaller subgroups included those who reported feeling better immediately but feeling worse 7 days after OMT (10 [6%]), feeling the same or worse immediately but feeling better or much better 7 days after OMT (10 [6%]), and feeling the same or worse both immediately and 7 days after OMT (5 [3%]).

Overall, the 5 perceived response subgroups were significantly different on average symptom severity levels ($P<.001$) (*Figure 5*). Specifically, comparisons of the subgroups for each day showed the subgroups were not different on pretreatment severity levels but did differ on severity levels after 7 days, with the 2 subgroups with patients who reported feeling better or much better 7 days after OMT having lower severity than the 3 subgroups with patients who reported feeling the same or worse 7 days after OMT. Symptom severity levels in the largest subgroup, with those who felt better or much better at both times, improved from pretreatment levels until post-OMT day 4, when severity leveled off. The mean (95% CI) decrease in symptom severity from before treatment to 7 days after OMT was 3.1 (2.5 to 3.6) points. Clinically meaningful improvement (ie, increase of ⩾30%) in symptom severity was seen in 85 of 107 patients (79%) in this subgroup with a large effect size ($d=1.6$). In the subgroup with patients who felt better or much better immediately but felt the same as before treatment 7 days after OMT, symptom severity levels were improved at post-OMT day 1 but leveled off for the following days. The mean (95% CI) decrease in symptom severity from before treatment to 7 days after OMT was 1.7 (0.7 to 2.7) points. Clinically meaningful improvement was seen in 18 of 32 patients (56%) in this

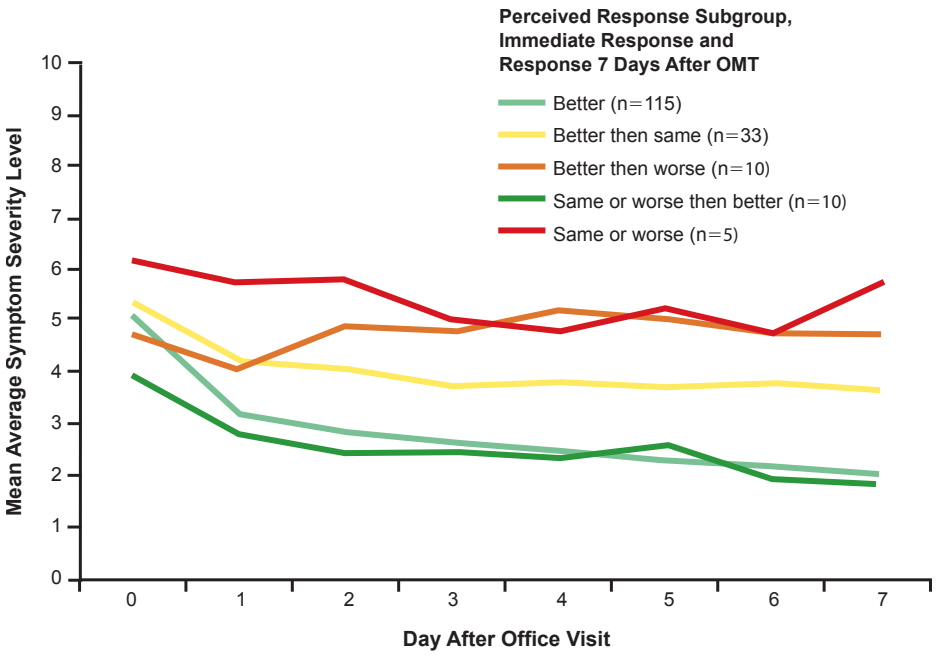

Figure 5.
Patient-reported average severity of symptoms by perceived response subgroup for average severity of symptoms associated with chief complaints during the 7 days after osteopathic manipulative treatment (OMT). Symptom severity was measured on a 0- to 10-point scale, with 0 indicating no problem and 10 indicating worst imaginable. Perceived response subgroups were formed based on the patient's perceptions of response to OMT from the Patient Posttreatment Questionnaire and the One-Week Follow-up Questionnaire. Patient data were obtained during a prospective observational study of 173 office visits by 142 patients that took place from 2009 to 2010 at participating clinics.

subgroup with a large effect size (d=1.2). For the 10 patients in the subgroup who felt the same or worse immediately but better or much better 7 days after OMT, symptom severity levels were unchanged, but the data suggest symptom severity levels improved (mean [95% CI] decrease from before treatment to 7 days after OMT, 2.1 [0.1 to 4.1] points). Clinically meaningful improvement was seen in 7 of 9 patients in this subgroup with a large effect size (d=1.1). For the other 2 subgroups (better then worse and same or worse at both times), symptom severity levels were unchanged, with a mean (95% CI) change in severity of 0.0 (-1.7 to 1.8) points and 0.4 (-2.3 to 3.0) points, clinically meaningful improvement in 2 of 10 and 2 of 5 patients, and small effect sizes (d=0.1 and 0.3), respectively.

Interference of symptoms with quality of life before OMT and at 7 days after OMT were compared (*Table*). There was significant improvement (ie, decrease in interference from chief complaints) of at least 1 point with usual/general activities, sleep, mood, and relationships with other people (all $P \leq .05$). Of the office visits where patients completed pretreatment quality of life questions, sensitivity analysis indicated there was no significant difference between those office visits where patients completed the quality of life measures before and 7 days after OMT (quality of life completers) (172 of 212 [81%]) and noncompleters (40 of 212 [19%]) on any of the pretreatment quality of life measures (all $P \geq .47$).

Comment

Results from both the retrospective and prospective components of the current study indicate that OMT is primarily used for musculoskeletal conditions, either solely or concurrently with nonmusculoskeletal conditions. Yet, there was a long list of less commonly identified diagnoses reported in our study (ie, those recorded less than 5% of the time), suggesting a broader use for OMT. This finding is consistent with the range of medical conditions historically reported to be managed with OMT. Examples

Table.
Patient-Reported Change in Interference of Symptoms Associated With Chief Complaints With Quality of Life From Before OMT to 7 Days After OMT[a]

Interference with...	Before OMT, Mean (95% CI)	7 Days After OMT, Mean (95% CI)	Change Mean (95% CI), Range	*P* Value[b]
Usual/general activities	4.7 (4.2 to 5.2)	3.2 (2.7 to 3.6)	-1.6 (-2.2 to -0.9), -8 to 5	.01
Work	3.6 (3.2 to 4.1)	2.9 (2.4 to 3.4)	-0.7 (-1.4 to 0.0), -8 to 7	.35
Sleep	4.4 (3.9 to 4.8)	3.0 (2.5 to 3.5)	-1.4 (-2.0 to -0.7), -8 to 6	.05
Mood	4.2 (3.8 to 4.6)	2.6 (2.2 to 3.0)	-1.6 (-2.2 to -1.0), -9 to 6	.005
Relationships	2.6 (2.2 to 3.0)	1.6 (1.2 to 2.0)	-1.0 (-1.6 to -0.4), -10 to 8	.04
Enjoyment of life	4.3 (3.9 to 4.7)	3.0 (2.6 to 3.5)	-1.3 (-1.9 to -0.6), -9 to 6	.08

[a] Data for 207 office visits by 172 patients.
[b] Mixed linear model testing whether interference of symptoms with quality of life changed from before osteopathic manipulative treatment (OMT) to 7 days after treatment. The model accounted for repeated office visits by participants and clustering of participants within sites.

Abbreviation: CI, confidence interval.

of these conditions are arrhythmias, asthma, bronchitis, chronic obstructive pulmonary disease, constipation, cough, migraine, otitis media, pregnancy, sinusitis, syncope, and tremor. Our findings indicate that capturing a modern assessment of OMT's efficacy for managing these conditions requires a substantial expansion of the data warehouse generated by DO-Touch.NET so that a meaningful cohort of observations for these conditions can be evaluated.

In Johnson and Kurtz's 1998 survey,[7] which collected data on conditions managed with OMT, a larger and more diverse population of osteopathic physicians participated than in our study. Although the categorization of diagnoses was not identical between the current study and the study by Johnson and Kurtz,[7] the general trend that OMT is used for conditions of the musculoskeletal system appears to be consistent.

The data collected in the current study were limited to the adult population. A 2010 retrospective study by Lund and Carreiro[64] reported characteristics of pediatric patients who received OMT. In that study, diagnoses managed with OMT in children were of nonmusculoskeletal origin in 43.5% of patient visits. In the 1- to 4-year age group, 64.0% of the OMT visits were used to manage nonmusculoskeletal conditions, most commonly otitis media, upper respiratory infection, and behavioral problems. In the 5- to 12-year age group, OMT was used to manage nonmusculoskeletal conditions in 48.8% of the visits, most commonly headache, otitis media, and behavioral problems. Interestingly, in children older than 12 years, 82.3% of the conditions managed with OMT were for musculoskeletal conditions, demonstrating a major shift in OMT practice characteristics and foreshadowing practice characteristics in the adult population. These results raise numerous interesting questions that should be investigated. Broadening the DO-Touch.NET study design to include age-appropriate data collection tools so that systematic prospective observations of the pediatric population can be performed would be an impor-

tant step in understanding the efficacy of OMT and its current practice characteristics.

In the current study, a large majority (92%) of patients reported a positive response to OMT immediately after treatment, whereas 72% reported that they still felt better 7 days after OMT. Immediate and short-term improvement in the severity level of symptoms associated with the chief complaint(s) was evident when compared with the symptom severity level from the week before OMT; a majority of patients (69%) reported a clinically meaningful reduction in average symptom severity level. The large effect size ($d=1.2$) suggests that OMT is highly effective in reducing symptom severity, especially as it is currently used in clinical settings. The daily average and worst severity of symptoms decreased throughout most of the week after OMT, but the primary reduction in symptom severity occurred in the first 24 hours after treatment. The underlying mechanism for this reduction in symptom severity 1 day after OMT is unknown, yet neural and humoral mechanisms have been implicated. For example, current evidence indicates that changes in neural activities from manual treatments are sustained for less than 1 minute and often less than 1 second,[65-74] but somatohumeral changes persist from hours to up to 1 day, particularly β-endorphin,[75,76] substance P,[77] tumor-necrosis factor α,[77] interleukin 1β[78] and 2,[79] and the endocannabinoid-like substance palmitylethanolamide.[75,80] Consequently, somatohumeral changes may be responsible for the response noted in the current study.

From the Patient Posttreatment Questionnaire and the One-Week Follow-up Questionnaire, patient reports of the perception of response to OMT were used to create subgroups. These subgroups were compared with respect to their symptom severity levels during the week after OMT to examine the consistency between these 2 outcome measures. The effect sizes for both subgroups with patients who reported feeling better 7 days after OMT were large ($d\geq1.1$), whereas the effect sizes for the subgroups with patients who felt better immediately then felt worse 7 days after OMT and who felt the same or worse both immediately and 7 days after OMT were small ($d\leq0.3$). These results suggest consistency between these 2 patient-reported measures of the effect of OMT for these 4 subgroups. However, the large effect size ($d=1.2$) for the symptom severity data seen in the subgroup with patients who reported feeling better immediately then feeling unchanged 7 days after OMT was not consistent with the small effect size that would be expected in this subgroup and may be a result of recall bias in the patients' reported perception of the effect of OMT. This inconsistency may indicate that other issues are influencing perceptions of pain for patients of this subgroup, which would be consistent with the current view that chronic pain is influenced by numerous biopsychosocial factors.[81]

Decreases in the interference of symptoms with usual/general activities, sleep, mood, and relationships with other people indicated that OMT had a positive impact on many biopsychosocial factors that have been shown to be influenced by pain.[81,82] A larger data set from a nationwide study with diverse patient and physician populations is needed to determine the robustness of the effect of OMT on quality of life as seen in the current study. From a larger data set, subgroup analysis comparing quality of life measures with daily severity scores and patient perceptions of their response to OMT will be important to better understand key determinants that would predict a positive or negative response to OMT.

Overall, the current study provides a more rigorously and comprehensively collected data set compared with those of previously published studies[7-9,11,22] because our data were prospectively collected from patients and physicians at the time of the office visit that included OMT. This study design allows for corroboration between patient- and physician-reported data and between several pain and quality of life patient-reported measures. Previous studies considered general impressions of only patients or only physicians about osteopathic care.[7-9,11,22]

There were several limitations in the current study. First, in the retrospective review, the data that could be

collected from the billing systems were limited. With the increased use of electronic medical records, future retrospective assessments on the use of OMT will be much more robust. Second, the diagnostic categories used by the physicians may have had substantial overlap; for example, the same patient could have been accurately diagnosed with any of 4 ICD-9 diagnoses (lumbago, backache, osteoarthroses of the spine, or sacrum disorders). Methods are being developed to ensure that the most specific diagnoses are consistently used by the physicians within DO-Touch.NET. Third, the generalizability of the results from the prospective observational study is limited by characteristics of the sample. Demographics were not available for the pilot data collected in 2008, and the demographics from the 2009-2010 data do not reflect the general US population, particularly in terms of race, ethnicity, and employment status. This limitation is related to the number of data collection sites within the current prospective observational study being too small to capture the diversity of the population of patients who receive OMT.

In addition, our study was unable to determine if the improvement in patient-reported symptom severity and reduction in interference of symptoms with quality of life were a direct result of the OMT. In OMM, OMT is just 1 component of the interaction between the patient and physician. Other components of OMM, such as the way the physician interacts with the patient, spends time with the patient, asks the patient questions, listens to the patient, and touches the patient, may have been associated with the improvement noted in our study. Perhaps touch alone triggered the placebo response instead of the specific techniques used, causing a direct mechanical response. In this type of study, there is no control for these components of OMM, so we have reported the association between the most obvious and tangible aspect of the office visit, OMT, and the patient-reported outcomes. Future studies are needed to separate out these factors to evaluate the therapeutic nature of OMM vs OMT.

Another limitation is that there was a group of patients who did not complete all the follow-up questionnaires, so the reported data may not completely represent current practices and patient outcomes. Several sensitivity analyses were performed on the data set to determine if signs of bias could be identified in the results because of differences between those who were completers and those who were noncompleters. None of the sensitivity analyses indicated the presence of bias, particularly because there was no relationship between the severity of symptoms and whether the patient completed all the follow-up questionnaires.

Lastly, this prospective observational study examining current practice patterns did not allow for randomization of patients to a control group or for blinding of patients and physicians to the treatment provided, both of which are essential components of a traditional RCT. However, RCTs in which the patient and physician are blinded to treatment assignment are not appropriate for evaluating current practice characteristics and outcomes in the clinical setting, especially when the treatment involves direct physical contact between the physician and the patient, as with OMT. In the future, collaboration with other PBRNs with sites where OMT is not provided should be prioritized to conduct comparative effectiveness studies. Such a design may provide a more realistic and meaningful assessment of the role of OMT in current and future health care.

The ongoing prospective utilization study currently being conducted within DO-Touch.NET has been refined based on the experience gleaned from the current study, and many of the identified limitations of the study reported here have been addressed in the ongoing study. The long-term objectives of the ongoing study remain consistent with those outlined in the current study. However, before these objectives can be achieved, a methodology needs to be established that will determine what outcome measures best indicate a positive or negative response to OMT within the general population. In the published literature, response to OMT is usually determined from either the physician's or the patient's

perspective using broad, nonspecific, subjective parameters. In the current study, numerous parameters were systematically collected from both the patient's and the physician's perspectives. This type of data collection allows for evaluation of responsiveness for specific symptoms within a biopsychosocial context. With the larger data set being collected in the ongoing study, an evidence-based methodology for determining responsiveness will be determined. With this methodology, fertile areas for OMT research can be identified from the data being collected within DO-Touch.NET, more rigorous research looking at underlying mechanisms of action for OMT can be pursued, and comparative effectiveness and cost-effectiveness studies can be conducted. As a result, new knowledge can be obtained on the impact of various treatments on the long-term course of common diseases. Clinical practice guidelines can be developed, positively impacting the current practice of OMT and the training of future osteopathic physicians. Although study outcomes will help guide future physicians in determining which patients will respond best to OMT, evaluating, recording, and quantifying the techniques of those physicians who demonstrate consistent positive responses in their patients will also help shape how future osteopathic physicians learn to perform those techniques.

Conclusion

For the adult population, OMT is predominately used for managing musculoskeletal pain conditions and, based on several methods of assessing patient-reported outcomes, demonstrates short-term effectiveness. Expansion of the number of participating physicians and patients and the long-term assessment of the effect of OMT compared with that of other forms of treatment are needed to achieve a more comprehensive understanding of this diagnostic and treatment model, particularly in visceral and systemic conditions less commonly managed with OMT.

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