Neuromusculoskeletal Medicine (OMT) Original Article

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Osteopathic manipulative treatment of patients with chronic low back pain in the United States: a retrospective cohort study

https://doi.org/10.1515/jom-2022-0212
Received October 20, 2022; accepted January 10, 2023;
published online February 3, 2023

Abstract

Context: The practice of osteopathic manipulative treatment (OMT) varies substantially across nations. Much of this variability may be attributed to disparate international educational, licensing, and regulatory environments that govern the practice of osteopathy by nonphysicians. This is in contrast with the United States, where osteopathic physicians are trained to integrate OMT as part of comprehensive patient management.

Objectives: This study will analyze the factors associated with OMT use and its outcomes when integrated within the overall medical care for chronic low back pain (CLBP) provided by osteopathic physicians in the United States.

Methods: A retrospective cohort study was conducted within the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION) from April 2016 through April 2022 to study the effectiveness of OMT integrated within medical care provided by osteopathic physicians. The outcome measures, which included pain intensity, pain impact, physical function, and health-related quality of life, were assessed with the National Institutes of Health Minimum Dataset, Patient-Reported Outcomes Measurement Information System, and Roland-Morris Disability Questionnaire.

Results: A total of 1,358 adults with CLBP entered the cohort (mean age, 53.2 years; 74.4% female), 913 completed the final quarterly encounter, 348 were in various stages of follow-up, and 97 had withdrawn. Blacks (odds ratio [OR], 0.36; 95% confidence interval [CI], 0.21–0.63; p<0.001), cigarette smokers (OR, 0.56; 95% CI, 0.33–0.93; p=0.02), and nonsteroidal anti-inflammatory drug users (OR, 0.59; 95% CI, 0.43–0.81; p=0.001) were less likely to have utilized OMT in the multivariable analysis. Mean between-group differences among 753 participants with no OMT crossover and complete follow-up favored OMT: 1.02 (95% CI, 0.63–1.42; p<0.001) for pain intensity; 5.12 (95% CI, 3.09–7.16; p<0.001) for pain impact; 3.59 (95% CI, 2.23–4.95; p<0.001) for physical function, and 2.73 (95% CI, 1.19–4.27; p<0.001) for health-related quality of life. Analyses involving propensity-score adjustment and inclusion of participants with missing data yielded similar conclusions. None of 12 prespecified participant characteristics demonstrated an OMT interaction effect.

Conclusions: OMT integrated within medical care provided by osteopathic physicians for CLBP was associated with improved pain and related outcomes. Its use may be facilitated by the growing osteopathic physician workforce in the United States and adherence to relevant clinical practice guidelines.

Keywords: back-related disability; chronic low back pain; health-related quality of life; osteopathic manipulative treatment; pain impact; retrospective cohort study.

The Global Burden of Disease Study identified low back pain as being highly prevalent and the leading cause of years lived with disability [1, 2]. Such disability usually occurs with progression from acute to chronic low back pain (CLBP). The Centers for Disease Control and Prevention (CDC) has disseminated broad guidelines for the treatment of chronic pain that recommend utilizing nonpharmacological treatments and nonopioid therapies as first-line interventions [3]. The American College of Physicians guideline on noninvasive treatments similarly recommends nonpharmacological treatments, including spinal manipulation, and nonsteroidal anti-inflammatory drugs (NSAIDs) prior to considering tramadol, duloxetine, or opioids for patients with CLBP [4]. These recommendations support the clinical practice

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guidelines issued by the American Osteopathic Association, which state that low back pain should be treated with osteopathic manipulative treatment (OMT) if somatic dysfunction is the cause of pain [5, 6].

There are almost 200,000 clinicians delivering osteopathic care worldwide in 46 nations [7], including over 134,000 osteopathic physicians in the United States [8]. In contrast with the United States, where osteopathic physicians integrate OMT within their medical care, "osteopathy" is often practiced internationally by nonphysicians under widely varying educational, licensing, and regulatory environments [9]. Virtually all systematic reviews of OMT trials have been performed by international investigators and include a large representation of studies involving osteopathy [10]. In these reviews, osteopathy is often provided as alternative medicine, or as a complementary treatment that is not integrated within medical care provided by osteopathic physicians. Collectively, these systematic reviews have provided only marginal evidence supporting such OMT, and they are generally limited to pain and functioning outcomes over a few weeks or months among patients with low back pain. An international trial similarly found that OMT for low back pain delivered by nonphysician osteopaths had small treatment effects that were not likely clinically meaningful [11].

Methodological limitations have also hampered clinical trials of OMT for low back pain in the United States. An early trial found no significant effect after 3 weeks when OMT was provided by a "trained manipulator" at the discretion of a different treating physician [12]. Another trial found no significant effects after 3 months when OMT was provided by osteopathic physicians as a complementary treatment for patients who received all other low back pain care from other physicians [13]. A third trial found no significant effects over 6 months, compared with sham manipulation, when OMT was provided by osteopathic medical students [14]. Finally, significant effects pertaining to pain, but not physical function or general health, were observed over 12 weeks when OMT was provided by osteopathic physicians as complementary treatment for patients who received all other low back pain care elsewhere [15]. Thus, no trial to date has studied OMT as part of the overall medical care provided by osteopathic physicians for low back pain.

The purpose of this study was to measure the effectiveness of OMT when osteopathic physicians utilize it as part of a comprehensive approach to CLBP care. To overcome the aforementioned methodological difficulties in performing a rigorous randomized controlled trial in this setting over the past 40 years, we conducted a retrospective cohort study within a national pain research registry with propensity-score adjustment for OMT use upon entry to the cohort. Our hypothesis was that OMT integrated within CLBP care provided by osteopathic physicians would provide significant treatment effects in pain and other outcomes, including health-related quality of life.

Methods

Study design and participants

A retrospective cohort study was utilized to measure the clinical outcomes of OMT over 12 months. Participants were selected from the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION) from April 2016 through April 2022. Registry participants were screened and recruited from the 48 contiguous states and the District of Columbia, primarily through social media. Registry data were self-reported by participants at quarterly encounters utilizing a digital research platform and electronic data capture. Eligible registry participants ranged from 21 to 79 years of age at enrollment, had sufficient English language proficiency to complete case report forms independently or with staff assistance, were not pregnant, and did not reside in institutional facilities. For inclusion, registry participants must have reported CLBP according to criteria established by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain (NIH-RTF) [16]. These criteria require having low back pain for at least the past 3–6 months and with a frequency of at least half of the days in the past 6 months. Participants were also required to have a physician who regularly provided CLBP treatment. This research was approved by the North Texas Regional Institutional Review Board (protocol 2015-169), and all participants provided informed consent prior to contributing data. This study is reported following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [17]. Further information about PRECISION is available at ClinicalTrials.gov [18].

Treatments for low back pain

The use of OMT was determined by participant reporting of their physician type (osteopathic or allopathic) and current or prior use of spinal manipulation to treat low back pain at registry enrollment. Consistent with terminology espoused by the National Center for Complementary and Integrative Health [19], the generic term "spinal manipulation" is utilized by the registry because it is more universally recognized than the term "osteopathic manipulative treatment," or OMT, although the latter includes manual techniques other than spinal manipulation. Because the registry does not collect data on the specific type of spinal manipulation provider, participants who were currently treated by an osteopathic physician and reported utilizing spinal manipulation were classified as OMT users. Participants were classified as OMT nonusers if they were treated by an allopathic physician or by an osteopathic physician without current or prior use of spinal manipulation. Since September 2016, registry participants have been required to have a physician (i.e., osteopathic or allopathic physician) who explicitly treats their low back pain as a condition of enrollment. Thus, the registry does not collect data on the use of chiropractic, as this modality is unlikely to be provided by either osteopathic or allopathic

physicians. The current use of NSAIDs and opioids for low back pain was also measured at registry enrollment.

Outcome measures

The four outcome measures were recommended by the NIH-RTF [16]. A numerical rating scale ranging from 0 to 10 was utilized to measure average low back pain intensity during the 7 days prior to a registry encounter. Pain impact was measured utilizing nine items on the Minimum Dataset recommended by the NIH-RTF, including pain intensity and eight items derived from the Patient-Reported Outcomes Measurement Information System (PROMIS) [20, 21]. These included four items in each of two PROMIS scales involving physical function and pain interference with activities within the 7 days prior to an encounter. Pain impact scores may range from 8 to 50. The Roland-Morris Disability Questionnaire (RMDQ) was utilized as a legacy measure of physical function [16]. It consists of 24 items that measured back-related disability on an encounter date, with scores ranging from 0 to 24 [22]. Health-related quality-of-life measures included four PROMIS scales in the Minimum Dataset (sleep disturbance, pain interference, depression, and low energy/fatigue) and a fifth PROMIS scale to measure anxiety. Collectively, 20 items (four items in each PROMIS scale) comprise the SPADE cluster (sleep disturbance, pain interference, anxiety, depression, and low energy/fatigue) that measures health-related quality-of-life deficits. All SPADE scale scores, except sleep disturbance, are normed according to the general US population and have a mean of 50 and standard deviation (SD) of 10 [20]. The sleep disturbance scale is similarly scored; however, it is normed with a calibration sample enriched for chronic illness. The SPADE cluster score is the mean of its five scales and may range from 38 to 77. Each of the four study outcomes was measured at registry enrollment and at up to four quarterly encounters over 12 months. Higher scores on each measure represent worse outcomes.

Statistical analysis

Descriptive statistics were utilized to characterize participants at registry enrollment. Logistic regression was utilized to compute unadjusted and adjusted odds ratios (ORs) and 95% confidence intervals (CIs) associated with OMT use. The multivariable model included age, gender, race, ethnicity, cigarette smoking status, chronic widespread pain, comorbidities (herniated disc, sciatica, depression), low back surgery, and current medication use for low back pain (NSAIDs, opioids). These variables were largely measured utilizing elements of the Minimum Dataset [16].

Repeated measures analysis of variance (ANOVA) was utilized to assess each of the four outcomes during 12 months of follow-up. Outcomes were measured as between-group differences in means (i.e., in grand means over 12 months) for OMT nonusers minus OMT users. Hence, positive values favored OMT in all analyses. Cohen's d statistic was utilized to assess the clinical relevance of between-group differences, with d values ≥ 0.2 considered clinically important [23]. Participants who withdrew from the registry, reported OMT crossover (i.e., entered the cohort in the OMT group and then switched to a physician who did not provide OMT, or vice versa), or missed any quarterly encounter during 12 months of follow-up were excluded from these analyses. Both unadjusted and propensity-score adjusted analyses were performed. The latter included propensity scores for OMT use upon entry to the cohort, computed with the aforementioned multiple logistic regression model to control for confounding by indication. This is particularly useful in observational studies of treatment effect, wherein randomization is not possible, to control for important factors that may differentiate treatment users and nonusers [24]. In a series of sensitivity analyses, linear mixed models were utilized to study outcomes among participants without OMT crossover, but with either complete or incomplete quarterly encounter data.

A series of subgroup analyses were performed, each including the unadjusted and adjusted analyses described above, to identify OMT interaction effects involving the 12 prespecified variables in the multiple logistic regression model. Data management and analyses were performed with the IBM SPSS Statistics (Version 28) software. Hypotheses were generally tested at the 0.05 level of statistical significance utilizing two-sided tests. However, because the subgroup analyses estimated OMT effects for four outcomes (pain intensity, pain impact, physical function, and health-related quality of life) within 25 subgroups (100 comparisons), a Bonferroni-corrected significance threshold of $p<0.001$ was utilized to interpret the results. Similarly, a Bonferroni-corrected significance threshold of $p=0.001$ was utilized to interpret the OMT interaction effects involving the four outcomes and 12 prespecified subgroup variables (48 comparisons).

Results

Participant characteristics and OMT use

The mean (SD) age of 1,358 participants was 53.2 (13.1) years, and 1,010 (74.4%) were female. There were 187 (13.8%) participants who utilized OMT at registry enrollment. Black race, cigarette smoking, depression, and NSAID use were each inversely associated with OMT use (Table 1). In the multivariable analysis that controlled for potential confounders, participants who were Black (OR, 0.36; 95% CI, 0.21–0.63; $p<0.001$), cigarette smokers (OR, 0.56; 95% CI, 0.33–0.93; $p=0.02$), and current NSAID users (OR, 0.59; 95% CI, 0.43–0.81; $p=0.001$) remained less likely to utilize OMT.

Flow of participants through the study and unadjusted outcomes

Of 1,358 participants who entered the cohort, 913 (67.2%) attended the 12-month encounter, 348 (25.6%) were in various stages of follow-up, and 97 (7.1%) had withdrawn (Figure 1). There were 797 participants without OMT crossover at the 12-month encounter, including the 753 (94.5%) participants with complete follow-up data in the primary analyses. The OMT users reported better outcomes pertaining to pain intensity, pain impact, physical function, and health-related quality of life (Figure 2). The mean between-group differences were: 1.02 (95% CI, 0.63–1.42; $p<0.001$) for pain intensity; 5.12 (95% CI, 3.09–7.16; $p<0.001$) for pain

Table 1: Characteristics of participants with chronic low back pain and a treating physician upon enrollment in the registry according to OMT use.

	No. (%)		Unadjusted			Adjusted[a]		
Characteristic	OMT users (n=187)	OMT nonusers (n=1171)	OR	95% CI	p-Value	OR	95% CI	p-Value
Age (years)								
21–49	63 (33.7)	427 (36.5)	Reference			Reference		
50–64	81 (43.3)	494 (42.2)	1.11	0.78–1.58	0.56	1.15	0.79–1.65	0.47
65–79	43 (23.0)	250 (21.3)	1.17	0.77–1.77	0.47	0.92	0.59–1.43	0.71
Gender								
Male	50 (26.7)	298 (25.4)	Reference			Reference		
Female	137 (73.3)	873 (74.6)	0.94	0.66–1.33	0.71	0.91	0.64–1.31	0.61
Race								
White	167 (89.3)	909 (77.6)	Reference			Reference		
Black	16 (8.6)	223 (19.0)	0.39	0.23–0.67	<0.001	0.36	0.21–0.63	<0.001
Other	4 (2.1)	39 (3.3)	0.56	0.20–1.58	0.27	0.57	0.20–1.64	0.30
Ethnicity								
Non-Hispanic	176 (94.1)	1066 (91.0)	Reference			Reference		
Hispanic	11 (5.9)	105 (9.0)	0.63	0.33–1.20	0.16	0.59	0.31–1.15	0.12
Cigarette smoking status								
Nonsmoker	168 (89.8)	951 (81.2)	Reference			Reference		
Smoker	19 (10.2)	220 (18.8)	0.49	0.30–0.80	0.005	0.56	0.33–0.93	0.02
Chronic widespread pain								
No	147 (78.6)	847 (72.3)	Reference			Reference		
Yes	40 (21.4)	324 (27.7)	0.71	0.49–1.03	0.07	0.79	0.54–1.18	0.25
Herniated disc								
No	118 (63.1)	708 (60.5)	Reference			Reference		
Yes	69 (36.9)	463 (39.5)	0.89	0.65–1.23	0.49	0.95	0.67–1.37	0.80
Sciatica								
No	95 (50.8)	598 (51.1)	Reference			Reference		
Yes	92 (49.2)	573 (48.9)	1.01	0.74–1.38	0.95	0.98	0.70–1.37	0.91
Depression								
No	94 (50.3)	492 (42.0)	Reference			Reference		
Yes	93 (49.7)	679 (58.0)	0.72	0.53–0.98	0.03	0.77	0.56–1.07	0.12
Low back surgery								
No	155 (82.9)	945 (80.7)	Reference			Reference		
Yes	32 (17.1)	226 (19.3)	0.86	0.57–1.30	0.48	0.80	0.51–1.25	0.32
Current NSAID use								
No	82 (43.9)	388 (33.1)	Reference			Reference		
Yes	105 (56.1)	783 (66.9)	0.63	0.46–0.87	0.004	0.59	0.43–0.81	0.001
Current opioid use								
No	133 (71.1)	778 (66.4)	Reference			Reference		
Yes	54 (28.9)	393 (33.6)	0.80	0.57–1.13	0.21	0.88	0.61–1.27	0.50

NSAID, nonsteroidal anti-inflammatory drug; OMT, osteopathic manipulative treatment. [a]Estimates are adjusted for all other variables in the table.

impact; 3.59 (95% CI, 2.23–4.95; p<0.001) for physical function; and 2.73 (95% CI, 1.19–4.27; p<0.001) for health-related quality of life. These results were clinically important, with Cohen's d statistics of 0.60, 0.58, 0.61, and 0.41, respectively.

Propensity-score adjusted outcomes

The use of OMT remained associated with better outcomes after adjusting for propensity scores (Figure 3). The mean between-group differences were: 0.62 (95% CI, 0.24–0.99; p=0.001) for pain intensity; 3.12 (95% CI, 1.16–5.08; p=0.002) for pain impact; 2.24 (95% CI, 0.93–3.56; p<0.001) for physical function; and 1.55 (95% CI, 0.03–3.07; p=0.045) for health-related quality of life. The corresponding Cohen's d statistics were estimated as 0.37, 0.35, 0.38, and 0.24, respectively.

Sensitivity and subgroup analyses

The results of sensitivity analyses that captured available data for 797 participants without OMT crossover, but with

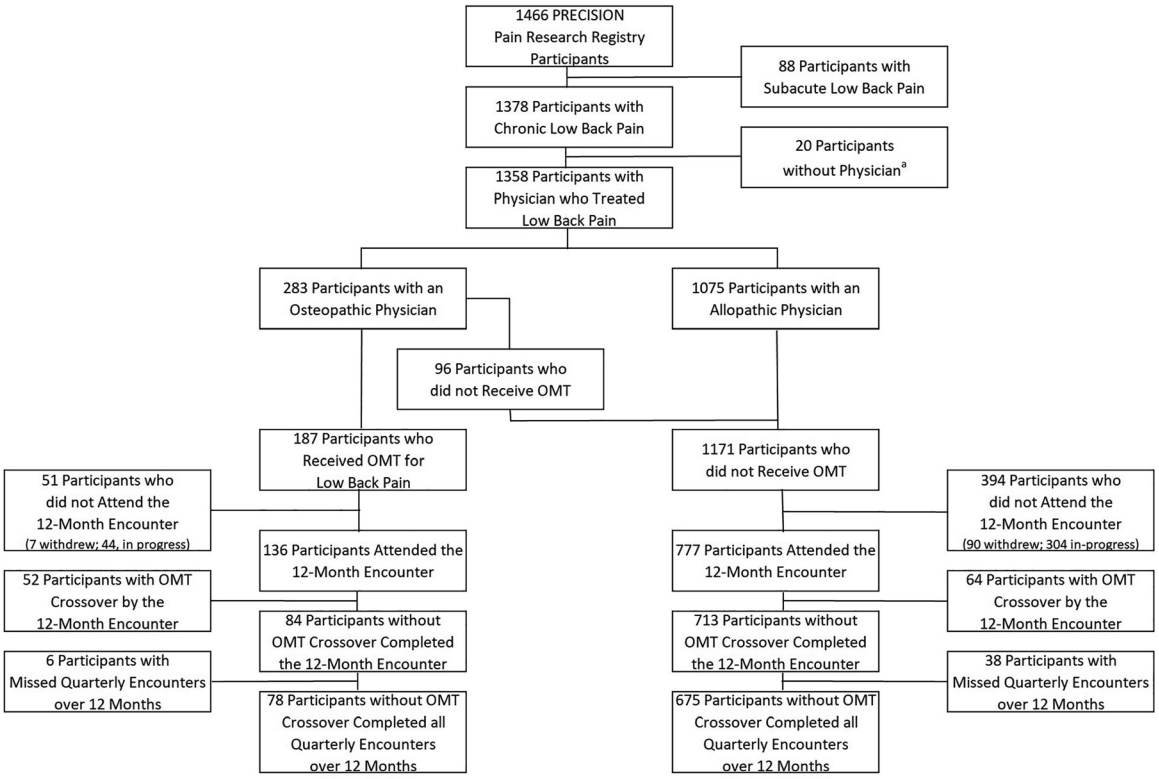

Figure 1: Flow of participants through the study. [a]Registry participants were required to have a physician who treated their low back pain beginning in September 2016.

either complete or incomplete follow-up, were not materially different than the unadjusted and adjusted results reported above (Table 2). The direction of the patient subgroup results favored OMT in 98 of 100 unadjusted analyses and in 97 of 100 adjusted analyses. However, only 43 results in the unadjusted analyses and 10 results in the adjusted analyses met the Bonferroni-corrected significance threshold ($p<0.001$) (Supplemental Table 1). No subgroup comparison demonstrated an OMT interaction effect at the Bonferroni-corrected significance threshold ($p=0.001$).

Discussion

Although OMT use for any condition has generally declined in the United States over time [25], low back pain has been and remains a leading reason to visit osteopathic physicians in the National Ambulatory Medical Care Survey [26, 27]. Approximately one-third of patient visits for CLBP in the United States are provided by osteopathic physicians [28], suggesting that OMT is an important aspect of the osteopathic medical care provided. This is consistent with low back pain being the only indication for which the American Osteopathic Association recommends OMT in its clinical practice guidelines [5, 6]. Findings from the Medical Expenditure Panel Survey further suggest that providing OMT within osteopathic medical care may be cost-effective among patients with back and joint problems [29].

There were some differences among OMT users and nonusers at registry enrollment. Most notably, Black participants were less likely than Whites to utilize OMT. This is consistent with previous studies of utilization of osteopathic physicians for primary care based on the National Ambulatory Medical Care Survey [30, 31]. Cigarette smokers and NSAID users were also less likely to utilize OMT. Conversely, the latter finding supports the view that OMT may have been utilized as an alternative to pharmacological treatments for low back pain [32].

The OMT users reported significantly better results than nonusers in all four outcomes in both the unadjusted and adjusted analyses. The OMT effects were not only clinically important but also additive to the effects attributable to medical care typically provided by allopathic physicians or osteopathic physicians who do not utilize OMT. These results were corroborated by sensitivity analyses that addressed the potential impact of missing follow-up data. To our knowledge, this is the first study to measure OMT outcomes pertaining to CLBP over 12 months, including assessment of pain impact and health-related quality of life. The latter are emerging metrics that capture aspects of the chronic pain experience not addressed by common or legacy measures [16, 33, 34].

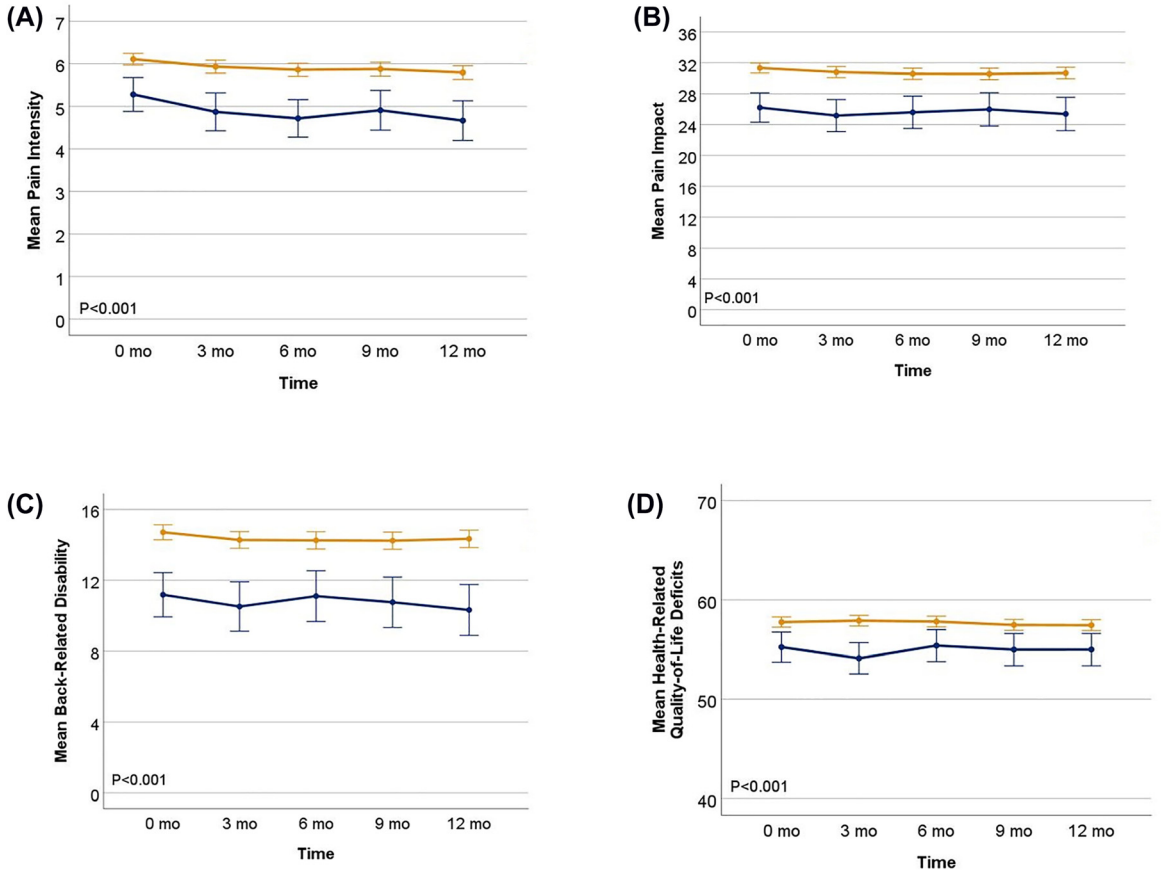

Figure 2: Unadjusted outcomes during 12 months of follow-up. (A) Pain intensity was measured with a numerical rating scale (range, 0–10). (B) Pain impact was measured utilizing pain intensity and the physical function and pain interference scales on the Patient-Reported Outcomes Measurement Information System (PROMIS; range, 8–50). (C) Physical function was measured as back-related disability with the Roland-Morris Disability Questionnaire (RMDQ; range, 0–24). (D) Health-related quality of life was measured utilizing the SPADE cluster (sleep disturbance, pain interference, anxiety, depression, and low energy/fatigue) scales on the PROMIS (range, 38–77). Higher scores reflect worse outcomes on each measure. The means and p values for each outcome are based on 753 participants without OMT crossover and with complete data for all five encounters during 12 months of follow-up. Error bars represent 95% confidence intervals. OMT, osteopathic manipulative treatment.

Not surprisingly, because the direction of the results involving all four outcomes favored OMT in virtually all patient subgroups, there were no OMT interaction effects in the unadjusted or adjusted analyses. Given the overall results, it appears that OMT may be recommended for all adult patients with CLBP regardless of their demographic or clinical characteristics. Nevertheless, the findings pertaining to race are worth noting. Black participants were less likely to utilize OMT, and Black participants who utilized OMT did not report better outcomes than nonusers in any outcome domain. More research is needed to determine if decreased OMT use among Black patients is related to decreased awareness of osteopathic physicians [35], or if there are other race-specific factors involved.

Greater availability and use of OMT may be facilitated by the expanding osteopathic physician workforce. Indeed, the American Medical Association has recognized the remarkable growth of the osteopathic profession over the past decade and acknowledges that OMT may be utilized to treat musculoskeletal disorders, including low back pain, potentially without resorting to opioids or other pharmacological treatments [32]. Extensive training in OMT is required at all colleges of osteopathic medicine throughout the United States. However, maintenance and further development of clinical proficiency in OMT among osteopathic residents may be challenged by the single accreditation system for graduate medical education. In response, curriculum guidelines to meet Accreditation Council for Graduate Medical Education (ACGME) milestones for osteopathically recognized residencies have been developed as a resource for integrating osteopathic evaluation and treatment in all residency types [36].

There were several strengths of this study. It was conducted within a national pain research registry utilizing participants who received OMT in a real-world setting, as

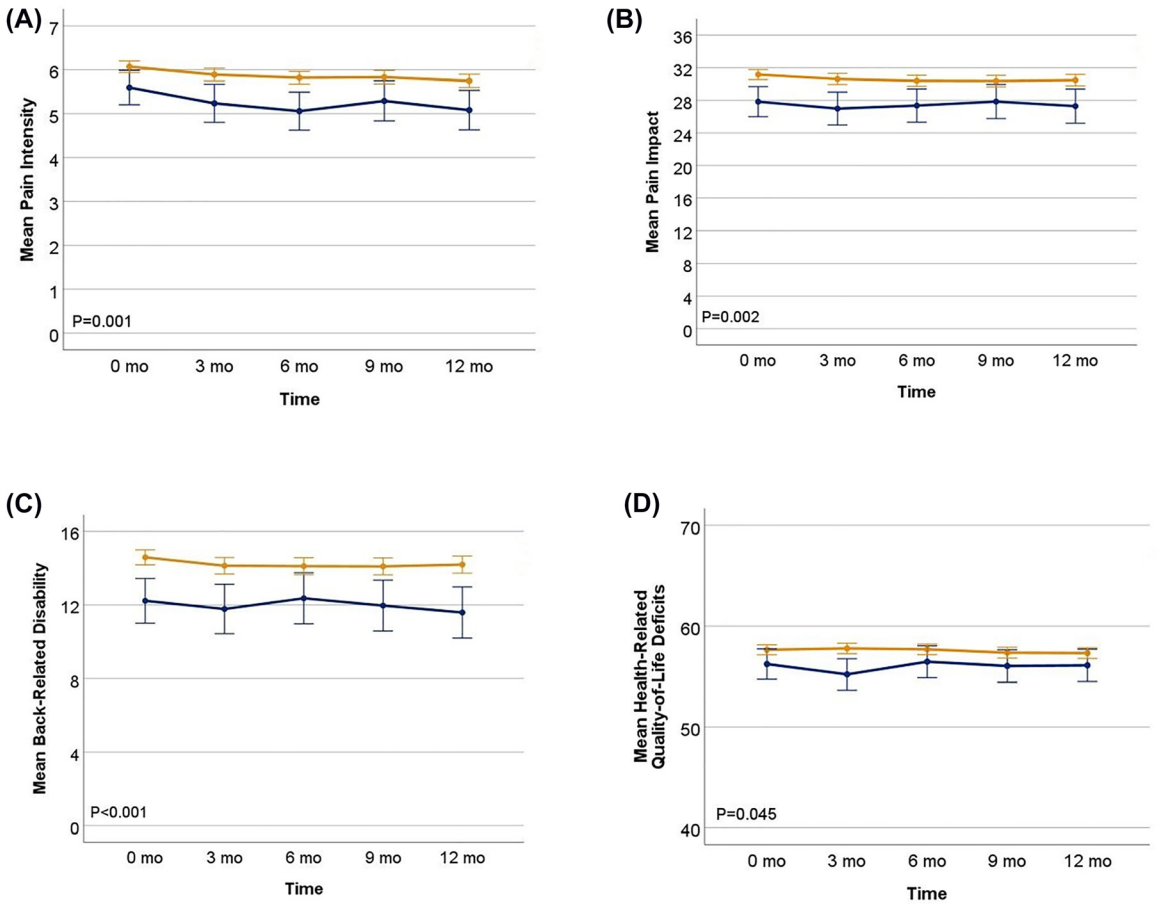

Figure 3: Adjusted outcomes during 12 months of follow-up. (A) Pain intensity was measured with a numerical rating scale (range, 0–10). (B) Pain impact was measured utilizing pain intensity and the physical function and pain interference scales on the Patient-Reported Outcomes Measurement Information System (PROMIS; range, 8–50). (C) Physical function was measured as back-related disability with the RMDQ (range, 0–24). (D) Health-related quality of life was measured utilizing the SPADE cluster (sleep disturbance, pain interference, anxiety, depression, and low energy/fatigue) scales on the PROMIS (range, 38–77). Higher scores reflect worse outcomes on each measure. The means and p values for each outcome are based on 753 participants without OMT crossover and with complete data for all five encounters during 12 months of follow-up and are adjusted for the propensity score for reported OMT use upon entry to the cohort. Error bars represent 95% confidence intervals. OMT, osteopathic manipulative treatment.

integrated within the overall medical care provided by osteopathic physicians. This likely contributed to generalizability of the study findings. Outcomes were studied with measures advocated by the NIH-RTF [16], with relatively low rates of participant withdrawal and missed quarterly encounters. Moreover, the sensitivity analyses that addressed the potential impact of missing follow-up data demonstrated findings that were remarkably consistent with the primary results. Electronic data captured through our digital research platform precluded missing item responses during completed quarterly encounters.

Nevertheless, there were study limitations. First, participants were not randomized to initiate OMT at enrollment, as would have occurred in a clinical trial. The effects of prior OMT may have been already evident at enrollment and maintained thereafter. Moreover, although OMT users and nonusers were comparable on many demographic and clinical characteristics, OMT users were less likely to be Black, cigarette smokers, or NSAID users. To help mitigate such differences, we utilized propensity scores for OMT use upon entry to the cohort to minimize confounding by indication. The statistical significance of the findings for all four outcomes remained unchanged after this adjustment. Moreover, although attenuated, OMT effects remained clinically important for all outcomes. Second, one of every eight participants who attended the 12-month encounter reported OMT crossover and were excluded from the primary analyses. In clinical trials involving experimental drugs, such participants would have been included in an intention-to-treat analysis to address potential safety signals or other reasons for crossover. However, OMT has a record of safety in treating low back pain, and its use is supported by clinical practice guidelines [3–6]. In our study, OMT crossover was more likely related to extraneous factors such as the mobility of the population. An unplanned post-hoc

Table 2: Outcomes of OMT according to method of analysis.

	Unadjusted				Adjusted[a]			
Outcome/method of analysis	**Δ[b]**	**95% CI**	***p*-Value**	***d***	**Δ**	**95% CI**	***p*-Value**	***d***
Pain intensity								
Repeated measures ANOVA (n=753)[c]	1.02	0.63–1.42	<0.001	0.60	0.62	0.24–0.99	0.001	0.37
Linear mixed methods (n=797)[d]	1.03	0.64–1.41	<0.001	0.50	0.57	0.21–0.94	0.002	0.28
Pain impact								
Repeated measures ANOVA (n=753)	5.12	3.09–7.16	<0.001	0.58	3.12	1.16–5.08	0.002	0.35
Linear mixed methods (n=797)	5.44	3.47–7.41	<0.001	0.57	3.19	1.29–5.09	0.001	0.33
Physical function								
Repeated measures ANOVA (n=753)	3.59	2.23–4.95	<0.001	0.61	2.24	0.93–3.56	<0.001	0.38
Linear mixed methods (n=797)	3.78	2.47–5.10	<0.001	0.59	2.30	1.02–3.57	<0.001	0.36
Health-related quality of life								
Repeated measures ANOVA (n=753)	2.73	1.19–4.27	<0.001	0.41	1.55	0.03–3.07	0.045	0.24
Linear mixed methods (n=797)	2.93	1.44–4.42	<0.001	0.41	1.62	0.15–3.09	0.03	0.22

ANOVA, analysis of variance; CI, confidence interval; OMT, osteopathic manipulative treatment. [a]Estimates are adjusted utilizing propensity scores for reported OMT use upon entry to the cohort based on age, gender, race, ethnicity, cigarette smoking status, chronic widespread pain, comorbidities (herniated disc, sciatica, depression), low back surgery, and current medication use for low back pain (nonsteroidal anti-inflammatory drugs, opioids). [b]Represents the mean difference between OMT users and nonusers. Positive values favor OMT. [c]Includes participants without OMT crossover and with complete data during 12 months of follow-up. [d]Includes participants without OMT crossover and with either complete or missing data during 12 months of follow-up.

analysis found that almost one-third of participants with OMT crossover changed their residential address during follow-up. Other potential reasons for OMT crossover may have involved changes in healthcare coverage or access to physician networks over time, or physician relocation or retirement. Because our study reflected real-life clinical practice and measured actual OMT use, the primary analyses (analogous to a per-protocol approach) were less likely to yield biased results owing to OMT exposure misclassification than an intention-to-treat approach [37]. Finally, OMT use was based on participant-reported physician type and use of spinal manipulation rather than on medical records. Participants may not have accurately recalled this information or may have received other forms of spinal manipulation from providers other than osteopathic physicians. Data on the use of chiropractic or other specific forms of spinal manipulation were not collected by the registry.

Conclusions

This study indicates that OMT, as classified herein, is effective when integrated within the overall medical care provided by osteopathic physicians for patients with CLBP. Greater availability and use of OMT may be facilitated by the growing osteopathic physician workforce in the United States and by adherence to clinical practice guidelines that promote spinal manipulation as a first-line CLBP treatment.

Research funding: This work was supported by the Osteopathic Heritage Foundation (grant number 2021-25).

Author contributions: All authors provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; all authors drafted the article or revised it critically for important intellectual content; all authors contributed to the analysis and interpretation of data; all authors gave final approval of the version of the article to be published; and all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Competing interests: None reported.

Ethical approval: This study was approved by the North Texas Institutional Review Board (protocol 2015-169); ClinicalTrials registry number: NCT04853732.

Informed consent: All participants in this study provided informed consent prior to entering the study.

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Supplementary Material: This article contains supplementary material (https://doi.org/10.1515/jom-2022-0212).