

Osteopathic Medical Care With and Without Osteopathic Manipulative Treatment in Patients With Chronic Low Back Pain: A Pain Registry–Based Study

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Context: The OSTEOPATHIC Trial demonstrated substantial improvement in pain intensity, decreased need for rescue medication for pain, and greater likelihood of recovery in patients with chronic low back pain who received 6 osteopathic manipulative treatment (OMT) sessions over 3 months.

Objective: To assess osteopathic medical care and the effectiveness of OMT for chronic low back pain in a real-world setting without the constraints of a rigid research protocol.

Methods: An observational study of 445 adults with chronic low back pain who had an established osteopathic physician (ie, DO) or allopathic physician (ie, MD) was conducted within the PRECISION Pain Research Registry from April 2016 through February 2019. Primary outcome measures included a numerical rating scale for low back pain intensity, the Roland-Morris Disability Questionnaire for back-related functioning, and use of nonsteroidal anti-inflammatory drugs or opioids for low back pain.

Results: A total of 79, 48, and 318 patients, respectively, were treated by DOs who used OMT, DOs who did not use OMT, or MDs. Patients treated by DOs who used OMT reported significantly lesser low back pain intensity (mean numerical rating score, 5.6; 95% CI, 5.1-6.1 vs 6.1; 95% CI, 5.9-6.3; $P=.04$) and back-related disability (mean Roland-Morris Disability score, 12.4; 95% CI, 11.1-13.8 vs 14.4; 95% CI, 13.7-15.0; $P=.009$) than patients treated by MDs. Patients treated by DOs who used OMT also reported less frequent use of nonsteroidal anti-inflammatory drugs (multivariate odds ratio, 0.41; 95% CI, 0.24-0.70; $P=.001$) or opioids (multivariate odds ratio, 0.52; 95% CI, 0.28-0.98; $P=.04$). There were no significant differences in primary outcomes between DOs who did not use OMT and MDs.

Conclusion: This study of community-based patients in a pain research registry supports the effectiveness of OMT as an integral component of osteopathic medical care for chronic low back pain. Patients treated by DOs who did not use OMT did not experience better results than patients treated by MDs in any primary outcome measure. Further research is needed to more specifically compare the effects of OMT with other treatment effects that may be attributed to patient-DO interactions during medical encounters.

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Randomized controlled trials,¹⁻³ systematic reviews and meta-analyses,^{4,5} and national health care surveys^{6,7} in the United States provide varying levels of support for the view that osteopathic medical care, including osteopathic manipulative treatment (OMT), is a particularly effective intervention for low back pain. Based largely on findings from the first systematic review and meta-analysis conducted to assess this research question,⁴ the only clinical practice guideline developed by the American Osteopathic Association recommends using OMT in patients wherein somatic dysfunction is a cause of, or contributing factor to, low back pain.⁸

Specifically, with regard to chronic low back pain, the OSTEOPATHIC Trial has provided the most compelling evidence to date that supports the efficacy of OMT.^{3,9} The OSTEOPATHIC Trial demonstrated substantial improvement in pain intensity, decreased need for rescue medication for pain, and greater likelihood of recovery in patients with chronic low back pain who received 6 OMT sessions during a 3-month period.^{3,9} Nevertheless, the extent to which such findings are generalizable to other patients with chronic low back pain remains unclear. The National Ambulatory Medical Care Survey (NAMCS) has been used in efforts to address this question. Therein, from 2003 to 2004 it was shown that osteopathic physicians (ie, DOs) provided a disproportionately large proportion of medical care visits for chronic low back pain.⁷ Osteopathic physicians also prescribed pharmacologic therapy less often and maintained greater continuity of care than allopathic physicians (ie, MDs) in another NAMCS study⁶ of patients with low back pain from 2002 to 2006. However, the latter findings were not specific to chronic low back pain. Additionally, osteopathic research using NAMCS is limited in that it does not provide specific data on the use of OMT within patient visits. The purpose of the present study was to address such limitations and voids in the current osteopathic literature pertaining to the use of OMT for chronic low back pain in real-world settings by using data collected from a community-based pain research registry.

Methods

Patient Recruitment, Screening, and Enrollment

Patients with chronic low back pain were recruited from the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry) within the Osteopathic Research Center at the University of North Texas Health Science Center Texas College of Osteopathic Medicine during the period of April 2016 through February 2019. The registry procedures and protocol for collecting patient-reported data within the Dallas-Fort Worth metroplex have been reported elsewhere.¹⁰ Registry staff screened patients for eligibility at multiple venues, including the group practice plan at the University of North Texas Health Science Center, local community events, and health fairs. Recruitment flyers were distributed at local hospitals, clinics, and physician offices to direct patients to the online screening questionnaire. Conference presentations, print advertising, emails, and letters were used to seek physician referrals for patient screening. Direct-to-patient advertising through the registry's website and social media were also used to screen patients. The research protocol was approved by the North Texas Regional Institutional Review Board (#2015-169). All eligible patients provided written informed consent prior to enrolling in the registry and participating in this study.

Inclusion and Exclusion Criteria

The inclusion criteria involved having chronic low back pain according to the case definition established by the National Institutes of Health (NIH) Task Force on Research Standards for Chronic Low Back Pain.¹¹ This criterion requires that patients self-report having low back pain for at least 3 to 6 months with a frequency of pain of at least half of the days during the past 6 months. Other inclusion criteria for this study were being 21 to 79 years of age; being able to respond to data collection instruments in English; and having a physician who had provided medical care for low back pain. Exclusion criteria were being pregnant (based on self-report) or being institutionalized. Patients received monetary compensation

for their time and travel expenses to complete the baseline registry visit that included data for this study.

Registry Data Collection

The PRECISION Pain Research Registry routinely collects data to characterize patients and their clinical status upon enrollment. The relevant measures for this study are described in the following paragraphs.

NIH Minimum Dataset for Low Back Pain

This instrument is recommended by the NIH Task Force on Research Standards for Chronic Low Back Pain to describe patients participating in research studies.¹¹ It consists of 40 patient-reported items, including sociodemographic characteristics, medical history, symptoms, functioning, and interventions for low back pain.

SPADE Cluster for Quality of Life Deficits

The 29-item Patient-Reported Outcomes Measurement Information System (PROMIS-29) is a quality of life measure that includes items derived from the PROMIS pain behavior item bank that assesses how low back pain interferes with normal activities and assesses levels of anxiety, depression, fatigue, and sleep disturbance.¹² The SPADE cluster (sleep disturbance, pain interference with activities, anxiety, depression, and low energy/fatigue scales) was used as a composite measure of quality of life, with higher scores representing greater quality of life deficits.

History of Medical Conditions Inventory

This inventory consists of a series of back-related or general medical conditions with which patients may report having ever been diagnosed. This study focused on herniated disc, sciatica, and depression, which are comorbidities commonly reported by patients with chronic low back pain.

History of Nonpharmacologic Treatments for Low Back Pain Inventory

This inventory was derived from a series of nonpharmacologic treatments evaluated in a systematic

review¹³ for the American College of Physicians Clinical Practice Guideline for low back pain.¹⁴ The present study focused on spinal manipulation as a non-pharmacologic treatment. The reported use of spinal manipulation for low back pain by patients currently treated by DOs was assumed to represent OMT.

Primary Outcome Measures

The primary outcome measures in this study included low back pain intensity, back-related functioning, and use of nonsteroidal anti-inflammatory drugs (NSAIDs) or opioids for low back pain. The numerical rating scale (NRS) for pain intensity and the Roland-Morris Disability Questionnaire (RMDQ) for back-related functioning are commonly used outcome measures for low back pain. The NRS is included in the NIH Minimum Dataset, and the NIH Task Force on Research Standards for Chronic Low Back Pain recommends the RMDQ as a legacy measure of back-related functioning.¹¹ These 2 measures may also be combined to serve as a composite measure of recovery from chronic low back pain.¹⁵

Guidelines from the Centers for Disease Control and Prevention¹⁶ and the American College of Physicians¹⁴ both emphasize the need to initially select nonpharmacologic treatments for patients with chronic low back pain. Both guidelines recommend opioid therapy only if non-pharmacologic and first-line pharmacologic treatments such as NSAIDs fail to provide an adequate response and if the anticipated benefits of opioid therapy for a given patient outweigh the potential risks.^{14,16} Thus, the reported use of NSAIDs or opioids by patients with chronic low back pain may be taken as surrogate measures of physician adherence to recommended treatment guidelines.

NRS for Low Back Pain Intensity

The NRS used in this study measured low back pain “on average over the past 7 days” with an 11-point scale ranging from 0 (“no pain”) to 10 (“worst pain”).

Roland-Morris Disability Questionnaire

The RMDQ consists of 24 items that assess back-related functioning by measuring how much low back

pain adversely affects patient functioning and activities.¹⁷ Each item was scored as either 1 (“agree” that low back pain has an adverse impact) or 0 (“disagree” that low back pain has an adverse impact). The RMDQ is scored as the sum of responses to each item, thereby potentially ranging from 0 to 24. The composite outcome of 1 or less on the NRS for low back pain intensity and 2 or less on the RMDQ may be taken to indicate recovery from chronic low back pain.

Use of NSAIDs or Opioids for Low Back Pain

The use of NSAIDs or opioids for low back pain was primarily assessed with an item from the NIH Minimum Dataset (for opioids) and an analogous item developed for reporting NSAID use. Such self-reported medication use has generally shown good agreement with pharmacy records.¹⁸

Data Management and Statistical Analysis

Patients completed the data collection instruments using a computer or mobile device provided by project personnel and the Qualtrics Survey Software. Research coordinators assisted patients if they had difficulty reading or understanding the questions. The electronic data collection system permitted patients to take breaks while answering questions if needed; however, it required completion of all items on the research instruments. Qualtrics survey data were exported to the SPSS version 23 software (IBM), which was subsequently used for data management and analysis. Descriptive statistics were computed using numbers and percentages for nominal and dichotomous variables and mean (SD) for continuous variables. Statistical comparisons of patients treated by physicians within each of the 3 categories (DOs who used OMT, DOs who did not use OMT, or MDs) were performed using contingency table methods for categorical variables or analysis of variance with the Fisher least significant difference test for post hoc comparisons for continuous variables. Additionally, analysis of covariance was performed to adjust the low back pain intensity and back-related functioning outcomes for patient age and sex. Simple logistic regression models

were initially used to compute odds ratios (ORs) and 95% CIs for patient-reported use of NSAIDs or opioids according to the type of treating physician, with MDs used as the reference category. Multiple logistic regression was subsequently used to adjust for potential confounders. Therein, the age, the NRS score for low back pain intensity, and the Roland-Morris Disability score were entered as covariates, and the ORs and 95% CIs for use of the relevant drug category (NSAIDs or opioids) were adjusted for current use of the alternative drug category (opioids or NSAIDs). Hypotheses were tested at the .05 level of statistical significance.

Results

Sociodemographic and Clinical Characteristics of Patients

There were 518 registry patients screened for study participation, and 445 (85.9%) met the eligibility criteria (**Figure 1**). Patients ranged from 21 to 79 years of age, with a mean (SD) age of 54.0 (12.0) years. There were 308 (69.2%) female patients. The mean (SD) low back pain intensity reported by patients was 6.1 (2.0) and the mean (SD) Roland-Morris Disability score was 14.1 (5.9). No patient met the composite pain and functioning criteria for recovery from chronic low back pain. A total of 288 patients (64.7%) reported currently using NSAIDs for low back pain, 164 (36.9%) reported using opioids, and 91 (20.4%) reported using both NSAIDs and opioids. Osteopathic physicians treated 127 patients (28.5%), including 79 (17.8%) who reported receiving OMT for low back pain. There were no significant differences among patients at the time of registry enrollment by type of treating physician, with the exception that current smokers were less likely to be treated by DOs who used OMT (**Table 1**).

Low Back Pain Intensity and Back-Related Disability

There were significant differences in low back pain intensity reported by patients according to the type of treating physician ($P=.02$) (**Figure 2**). Significant post

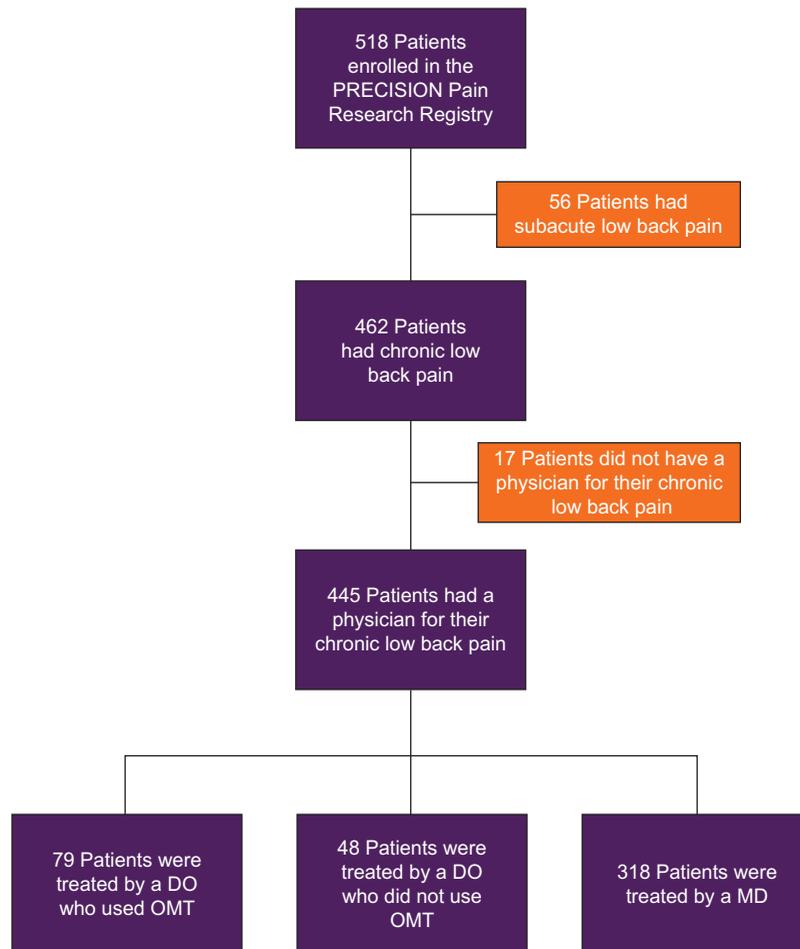


Figure 1.

Flowchart showing reasons for exclusion at each stage of the study and the distribution of patients according to type of physician. *Abbreviations:* DO, osteopathic physician; MD, allopathic physician; OMT, osteopathic manipulative treatment; PRECISION, Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation.

hoc comparisons were observed for patients treated by DOs who used OMT vs patients treated by DOs who did not use OMT ($P=.008$) and for patients treated by DOs who used OMT vs patients treated by MDs ($P=.04$). Similarly, there were significant differences in back-related disability reported by patients according to the type of treating physician ($P=.02$) (Figure 3). Significant post hoc comparisons were observed for patients treated by DOs who used OMT vs patients treated by DOs who did not use OMT ($P=.03$) and for patients treated by DOs who used OMT vs patients treated by MDs ($P=.009$).

Use of NSAIDs or Opioids for Low Back Pain

Nonsteroidal anti-inflammatory drugs were reportedly used for low back pain by 41 (51.9%), 30 (62.5%), and 217 (68.2%) patients treated by DOs who used OMT, DOs who did not use OMT, or MDs, respectively. The corresponding summary measures for NSAID use in comparison with patients treated by MDs were as follows: OR, 0.50; 95% CI, 0.30-0.83; $P=.007$ for patients treated by DOs who used OMT; and OR, 0.78; 95% CI, 0.41-1.46; $P=.43$ for patients treated by DOs who did not use OMT. Patients treated by DOs who used OMT also less frequently reported

Table 1.
Sociodemographic and Clinical Characteristics of Patients With Chronic Low Back Pain by Type of Treating Physician (N=445)^a

Characteristic	DO Who Used OMT	DO Who Did Not Use OMT	MD	P Value
Total, n	79	48	318	
Age, y, mean (SD)	53.0 (14.7)	56.8 (10.6)	53.8 (11.5)	.20
Female	57 (72.2)	38 (79.2)	213 (67)	.19
Current cigarette smoker	7 (8.9)	12 (25.0)	71 (22.3)	.02
SPADE quality of life score, ^b mean (SD)	10.4 (3.2)	11.1 (3.2)	10.9 (3.1)	.37
Presence of widespread pain	18 (22.8)	14 (29.2)	85 (26.7)	.69
Diagnosis of herniated disc	29 (36.7)	12 (25.0)	115 (36.2)	.30
Diagnosis of sciatica	31 (39.2)	14 (29.2)	104 (32.7)	.44
Diagnosis of depression	34 (43.0)	23 (47.9)	153 (48.1)	.72
Previous low back surgery	13 (16.5)	8 (16.7)	46 (14.5)	.86
Ever unemployed or unable to do usual work for ≥ 1 month due to low back pain	27 (34.2)	14 (29.2)	133 (41.8)	.15
Ever received disability or workers' compensation benefits because of inability to work due to low back pain	16 (20.3)	11 (22.9)	82 (25.8)	.57
Ever involved in a lawsuit or legal claim related to low back pain	9 (11.4)	1 (2.1)	40 (12.6)	.10
Had current treating physician for low back pain for 5 years or longer	16 (20.3)	14 (29.2)	88 (27.7)	.37

^a Data are given as No. (%) unless otherwise indicated.

^b Higher scores on the SPADE cluster represent poorer quality of life.

Abbreviations: DO, osteopathic physician; MD, allopathic physician; NSAID, nonsteroidal anti-inflammatory drug; OMT, osteopathic manipulative treatment; SPADE, sleep disturbance, pain interference with activities, anxiety, depression, low energy/fatigue.

using NSAIDs in the multivariate analysis that controlled for potential confounders (OR, 0.41; 95% CI, 0.24-0.70; $P=.001$) (Table 2). Increasing age, being a male patient, having a diagnosis of a herniated disc, and currently using opioids were other patient factors significantly associated with reporting less frequent use of NSAIDs for low back pain.

Opioids were reportedly used for low back pain by 20 (25.3%), 17 (35.4%), and 127 (39.9%) patients treated by DOs who used OMT, DOs who did not use OMT, or MDs, respectively. The corresponding summary measures for opioid use in comparison with patients treated by MDs were as follows: OR, 0.51;

95% CI, 0.29-0.89; $P=.02$ for patients treated by DOs who used OMT; and OR, 0.82; 95% CI, 0.44-1.55 $P=.55$ for patients treated by DOs who did not use OMT. Patients treated by DOs who used OMT also less frequently reported using opioids in the multivariate analysis (OR, 0.52; 95% CI, 0.28-0.98; $P=.04$). Current cigarette smoking, presence of widespread pain, having a diagnosis of a herniated disc, and increasing levels of back-related disability were patient factors significantly associated with reporting more frequent use of opioids for low back pain, whereas reported current use of NSAIDs was associated with less frequent use of opioids.

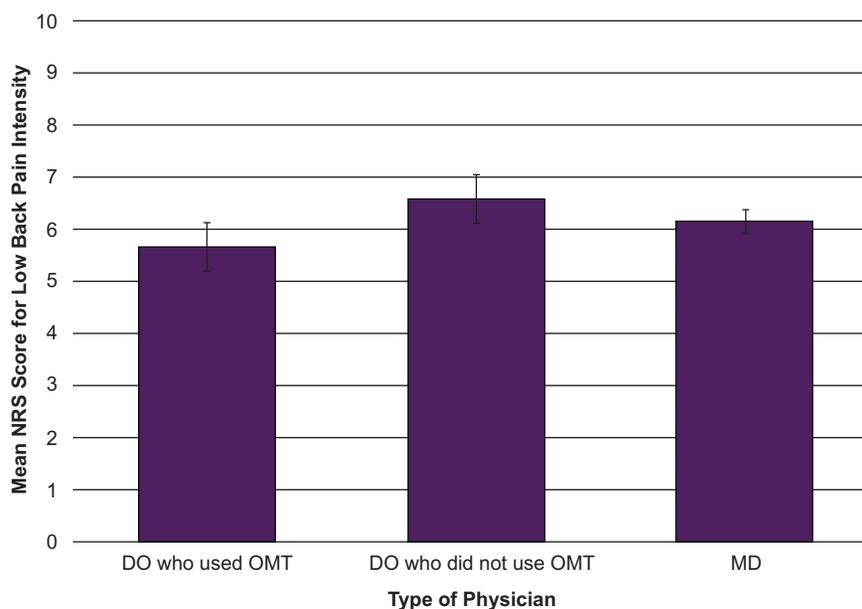


Figure 2.

Patient-reported measures of low back pain intensity at the time of enrollment in the PRECISION Pain Research Registry by type of physician ($P=.02$). Low back pain intensity was measured with a numerical rating scale (NRS). The error bars represent 95% CIs. Significant post hoc comparisons were observed for osteopathic physicians (DOs) who used osteopathic manipulative treatment (OMT) vs DOs who did not use OMT ($P=.008$) and for DOs who used OMT vs allopathic physicians (MDs) ($P=.04$).

Discussion

This study involving a community-based pain research registry supports the effectiveness of OMT as an integral component of osteopathic medical care for chronic low back pain. The study findings further suggest that a standardized algorithmic approach to OMT, which is desirable in explanatory clinical trials, does not need to be used to achieve clinically relevant outcomes in real-world settings. Previous research in the OSTEOPATHIC Trial has shown that well-defined subgroups of patients with chronic low back pain may be identified and targeted for OMT based on their low back pain intensity and back-related functioning.¹⁹ The present findings now show that OMT may be effectively individualized or “tailored” for a wide variety of patients with chronic low back pain. Clinical practice guidelines from the Centers for Disease Control and Prevention¹⁶ and the American College of Physicians¹⁴ emphasize the importance of initiating management for chronic low back pain with nonpharmacologic treatments and avoiding opioid therapy unless

the benefits outweigh the risks for a given patient. The present study indicates that patients treated by DOs who used OMT as a nonpharmacologic treatment were less likely to use NSAIDs or opioids for their low back pain. Patients treated by DOs who did not use OMT did not experience better results than patients treated by MDs in any primary outcome measure. Thus, it appears that using OMT as a component of osteopathic medical care for chronic low back pain facilitates the successful implementation of current clinical practice guidelines.

Of the 127 patients treated by DOs, 79 (62.2%) reported having received OMT. It is unclear why more than one-third of patients treated by DOs never received OMT. Two possible explanations are that some patients did not wish to receive OMT or that their physicians did not provide OMT for various reasons. One reason may have been that patients did not have somatic dysfunction that was the cause of, or a contributing factor to, their chronic low back pain.⁸ Other reasons may have included

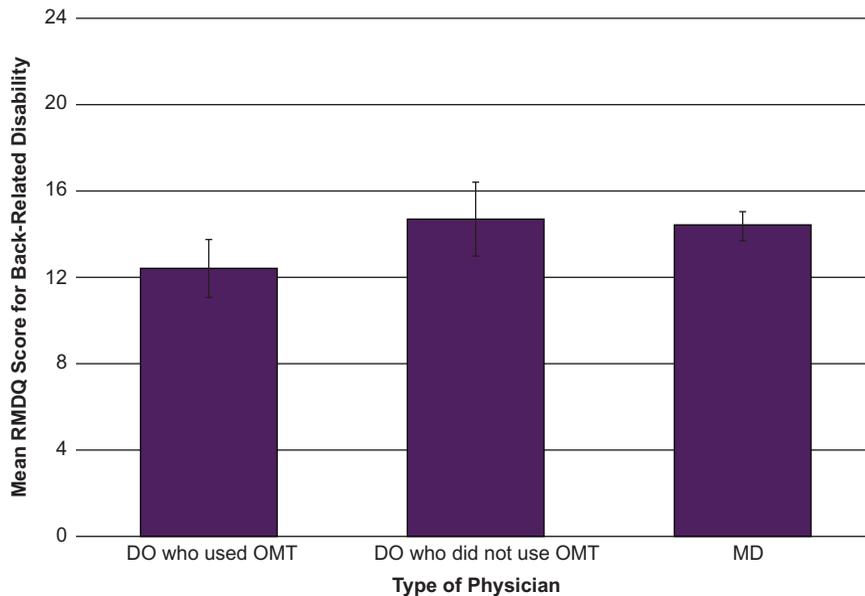


Figure 3.

Patient-reported measures of back-related disability at the time of registry enrollment by type of physician ($P=.02$). Back-related disability was measured with the Roland-Morris Disability Questionnaire (RMDQ). The error bars represent 95% CIs. Significant post hoc comparisons were observed for osteopathic physicians (DOs) who used osteopathic manipulative treatment (OMT) vs DOs who did not use OMT ($P=.03$), and for DOs who used OMT vs allopathic physicians (MDs) ($P=.009$).

insufficient time within the medical encounter to provide OMT, limited insurance coverage or inadequate reimbursement for OMT, or lack of physician comfort or confidence in providing OMT. There were no apparent patient sociodemographic or clinical characteristics that adequately explained the lack of OMT among 48 patients treated by DOs (Table 1).

There were several strengths of our study. Patients were recruited from a community-based pain research registry, thereby enabling us to study osteopathic medical care and use of OMT in a representative sample of patients with chronic low back pain. Recommendations of the NIH Task Force on Research Standards for Chronic Low Back Pain were adopted in conducting our study, including use of the case definition for chronic low back pain, recommended primary outcome measures pertaining to low back pain intensity and back-related functioning, and use of opioid therapy for low back pain.¹¹ The greatest limitation of the study was its lack of randomization. However, this limitation did not appear to be an import-

ant source of bias, as patients within each of the 3 study groups were not significantly different from one another on any sociodemographic or clinical characteristic, except cigarette smoking status (Table 1). Moreover, multivariate analyses that adjusted the primary outcomes for potential confounders did not materially affect the interpretation of the initially observed results.

Further research is needed to more specifically compare the OMT effects within osteopathic medical care for chronic low back pain with other effects that may be attributed to patient-physician interactions during medical encounters. Such factors as physician interpersonal manner, empathy, and communication style have been hypothesized to represent characteristics of DOs that may yield more favorable clinical outcomes among their patients, independent of the use of OMT. A formal mediation analysis that simultaneously considers the role of such patient-physician interactions and use of OMT is an important next step in elucidating the effects of osteopathic medical care for chronic low back pain.

Table 2.
Multiple Logistic Regression for Factors Associated With Current Use of Nonsteroidal Anti-Inflammatory Drugs or Opioids for Chronic Low Back Pain (N=445)^a

Characteristic	Current User			
	NSAIDs		Opioids	
	OR (95% CI)	P Value	OR (95% CI)	P Value
Type of Physician				
MD	1.00	...	1.00	...
DO who used OMT	0.41 (0.24-0.70)	.001	0.52 (0.28-0.98)	.04
DO who did not use OMT	0.70 (0.36-1.36)	.30	0.79 (0.38-1.63)	.52
Age	0.98 (0.96-1.00)	.047	1.01 (0.99-1.03)	.24
Sex				
Female	1.00	...	1.00	...
Male	0.62 (0.40-0.97)	.04	0.90 (0.55-1.48)	.69
Cigarette Smoking Status				
Never or Former Smoker	1.00	...	1.00	...
Current Smoker	0.91 (0.52-1.57)	.72	2.13 (1.21-3.75)	.009
Presence of Widespread Pain				
No	1.00	...	1.00	...
Yes	0.87 (0.53-1.44)	.60	1.81 (1.09-3.00)	.02
Diagnosis of a Herniated Disc				
No	1.00	...	1.00	...
Yes	0.55 (0.35-0.87)	.01	2.45 (1.54-3.91)	<.001
Diagnosis of Sciatica				
No	1.00	...	1.00	...
Yes	1.43 (0.91-2.24)	.12	1.41 (0.88-2.24)	.15
Diagnosis of Depression				
No	1.00	...	1.00	...
Yes	1.18 (0.76-1.83)	.46	1.20 (0.76-1.90)	.44
Low Back Pain Intensity	0.97 (0.86-1.08)	.56	0.95 (0.84-1.08)	.41
Back-Related Disability	1.01 (0.97-1.06)	.56	1.10 (1.05-1.15)	<.001
Currently Uses NSAID				
No	1.00	...
Yes	0.55 (0.34-0.87)	.01
Currently Uses Opioids				
No	1.00
Yes	0.55 (0.35-0.87)	.01

^a Odds ratios (ORs) and 95% CIs were computed using multiple logistic regression for current use of nonsteroidal anti-inflammatory drugs (NSAIDs) or opioids. Age, low back pain intensity, and back-related disability were entered as covariates in these models, with the ORs and 95% CIs for these variables representing each unit increase in age (y), numerical rating scale score, and Roland-Morris Disability score, respectively.

Abbreviations: DO, osteopathic physician; MD, allopathic physician; OMT, osteopathic manipulative treatment.

Conclusion

This study of community-based patients in a pain research registry supports the effectiveness of OMT as an integral component of osteopathic medical care for chronic low back pain. Patients treated by DOs who used OMT experienced superior clinical outcomes pertaining to low back pain intensity and back-related functioning, while less frequently using NSAIDs or opioids, than patients treated by MDs. Patients treated by DOs who did not use OMT did not experience such outcomes. Further research is needed to more specifically compare the effects of OMT with the other effects of osteopathic medical care that may be attributed to patient-physician interactions during medical encounters.

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Author Contributions

Both authors provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; both authors drafted the article or revised it critically for important intellectual content; both authors gave final approval of the version of the article to be published; and both 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.

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