John C. Licciardone*, DO, MS, MBA

Preventing progression from chronic to widespread pain and its impact on health-related quality of life: a historical cohort study of osteopathic medical care

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Abstract

Context: It is generally acknowledged that osteopathic physicians take a holistic approach to patient care. This style may help prevent the progression of painful musculoskeletal conditions, particularly if combined with osteopathic manipulative treatment (OMT).

Objectives: The study aimed to determine if osteopathic medical care lowers the risk of progression from localized chronic low back pain to widespread pain and lessens the impact of pain on health-related quality of life.

Methods: A historical cohort study was conducted within the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry) using data acquired from April 2016 through March 2021. Registry participants aged 21–79 years with chronic low back pain at the baseline encounter were potentially eligible for inclusion if they had a treating physician, completed all four quarterly follow-up encounters, and did not report physician crossover at the final 12-month encounter. Eligible participants were classified according to the type of physician provider at baseline and thereby into osteopathic or allopathic medical care groups. Participants were also classified according to prior use of OMT at the final encounter. Widespread pain was measured at baseline and each quarterly encounter to determine the period prevalence rate of widespread pain and its severity over 12 months using the Minimum Dataset

for Chronic Low Back Pain recommended by the National Institutes of Health. Participants who reported “not being bothered at all” by widespread pain during each encounter were classified as not having widespread pain, whereas those who were bothered “a little” or “a lot” at any quarterly encounter were classified as having widespread pain. The severity of widespread pain was measured by summing participant responses at each encounter. The Patient-Reported Outcomes Measurement Information System was used at each encounter to measure health-related quality-of-life (HRQOL) scores for physical function, anxiety, depression, fatigue, sleep disturbance, participation in social roles and activities, and pain interference with activities.

Results: A total of 462 participants were studied, including 101 (21.9%) in the osteopathic medical care group and 73 (15.8%) who used OMT. The mean age of participants at baseline was 52.7 ± 13.2 years (range, 22–79 years) and 336 (72.7%) were female. A lower period prevalence rate of widespread pain was observed in the osteopathic medical care group (OR, 0.47; 95% CI, 0.27–0.81; $p=0.006$) and in the OMT group (OR, 0.40; 95% CI, 0.21–0.75; $p=0.004$), although the latter finding did not persist after adjustment for potential confounders. The osteopathic medical care and OMT groups both reported lower widespread pain severity. The osteopathic medical care group also reported better age- and sex-adjusted outcomes for each of the seven HRQOL dimensions throughout the study. The OMT group reported better outcomes in five of the HRQOL dimensions.

Conclusions: This study supports the view that osteopathic physicians practice a holistic approach to medical care that manifests itself through a lower risk of progression from chronic low back pain to widespread pain, lower widespread pain severity, and lesser deficits in HRQOL. Similar findings were generally associated with OMT use.

Keywords: chronic low back pain; fibromyalgia; health-related quality of life; historical cohort study; osteopathic

*Corresponding author: John C. Licciardone, DO, MS, MBA, Regents Professor, Osteopathic Research Center and the Department of Family Medicine, University of North Texas Health Science Center-Texas College of Osteopathic Medicine, 3500 Camp Bowie Boulevard, Fort Worth, TX 76107, USA, E-mail: john.licciardone@unthsc.edu

manipulative treatment; osteopathic medicine; pain research registry; patient-centered care; widespread pain.

Low back pain has been a common reason for patients to visit osteopathic physicians in the United States [1, 2]. The first systematic review and meta-analysis of the effect of osteopathic manipulative treatment (OMT) on low back pain [3] initially led to the only clinical practice guideline issued by the American Osteopathic Association, which recommended that OMT be used in patients with low back pain when somatic dysfunction is the cause of or a contributing factor in its presentation [4]. An updated guideline [5], based on a subsequent systematic review and meta-analysis [6], similarly recommends the use of OMT in patients with low back pain. The OSTEOPATHIC Trial has shown that simple targeting strategies may be used to identify patients with chronic low back pain who are likely to achieve substantial improvement with OMT [7], and that patients may experience a chronic pain recovery with OMT [8].

The dual tenets of a holistic approach to medical care and use of OMT have been widely regarded as potentially supporting the distinctiveness of osteopathic medicine [9]. However, a recent joint statement from the American Medical Association in conjunction with the American Osteopathic Association further bolsters this claim of distinctiveness [10]. This statement emphasized that osteopathic medicine is a distinctive branch of medical practice in the United States that involves a “whole-person” approach to care, including the use of OMT to treat pain in such areas as the low back, neck, shoulders, and knees.

The National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain (RTF) has recommended considering widespread pain a key comorbid condition in patients with chronic low back pain [11]. Given the holistic approach of osteopathic physicians, including potential use of OMT, it is reasonable to hypothesize that they are well positioned to prevent the transition from chronic low back pain to widespread pain and its impact on health-related quality of life (HRQOL). The purpose of this study was to test this hypothesis using data from a pain research registry.

Methods

Study design and participant inclusion criteria

Study participants were recruited through the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation

(PRECISION Pain Research Registry). The registry was established at the University of North Texas Health Science Center in 2016 and transitioned to a digital research platform in 2019, thereby facilitating remote screening and data collection on chronic low back pain management and outcomes from participants throughout the 48 contiguous states and District of Columbia. Potential participants in this historical cohort study must have completed their baseline encounter and all four quarterly follow-up encounters during the period from April 2016 through March 2021. Registry procedures were approved by the North Texas Regional Institutional Review Board (protocol 2015-169) and all enrollees provided written informed consent.

Registry participants must range from 21 to 79 years of age at enrollment and be able to complete case report forms in English, either independently or with assistance from registry staff. This study was limited to registry participants with chronic low back pain according to the RTF diagnostic criteria, which require that participants report having low back pain for at least the past 3–6 months, and with a frequency of at least one-half of the days over the past six months [11]. Participants without a treating physician for low back pain, who had not yet completed the 12-month follow-up encounter, who had missed quarterly encounters, or with physician crossover were excluded. The latter consisted of participants who were treated by an osteopathic physician at enrollment and then by an allopathic physician at 12 months, or vice-versa.

Exposure to osteopathic or allopathic medical care

The type of medical care received was determined by participant response on the baseline encounter item that asked about the type of physician who treats their low back pain (i.e., osteopathic or allopathic physician). The use of OMT was estimated using the medical care group and another case report form item that asked about prior use of spinal manipulation for chronic low back pain at the final encounter. A trichotomous variable was derived from these two elements. Participants who reported never using spinal manipulation were considered to have never used OMT (OMT=0), regardless of their medical care group. Participants who reported prior use of spinal manipulation were considered to have possibly used OMT (OMT=1), if they were in the allopathic medical care group. For example, it is possible that such participants may have received OMT from an osteopathic manipulative medicine specialist during the study period. The latter often restrict their practices to providing OMT as a complement to primary care provided by other physicians. However, other health care professionals, such as chiropractors, may also provide such complementary spinal manipulation. Participants who reported prior use of spinal manipulation were considered to have used OMT (OMT=2) if they were in the osteopathic medical care group.

Outcome measures

Registry participants responded to the widespread pain item included in the Minimum Dataset for Chronic Low Back Pain recommended by the RTF [11] at the baseline encounter and at each of four quarterly follow-up encounters over 12 months. This item, which asked participants about the bothersomeness of widespread pain during the past four weeks, was used to measure the period prevalence rate of

widespread pain. The latter was considered to have occurred if a participant reported being bothered “a little” or “a lot” by widespread pain at any encounter. An ordinal variable was also used to measure widespread pain severity by assigning the following values to each response option at each encounter: “not bothered at all,” 0; “bothered a little,” 1; and “bothered a lot,” 2. Thus, this measure potentially ranged from 0 (no widespread pain) to 10 (most severe widespread pain).

The Patient-Reported Outcomes Measurement Information System with 29 items (PROMIS-29) [12] was used to measure seven dimensions of HRQOL: physical function, anxiety, depression, fatigue, sleep disturbance, participation in social roles and activities, and pain interference with activities. Responses for each dimension were transformed to standardized scores that are normed according to the United States general population, wherein the mean is 50 and SD is 10 on each scale. Higher scores represent worse HRQOL on each scale except physical function and participation in social roles and activities.

Statistical analysis

Sociodemographic characteristics, history of low back pain and comorbid medical conditions, and treatments for low back pain were used to describe the participants, including the mean $\pm$ SD for continuous variables and the number (%) for categorical variables. Contingency table methods were used to compute the crude odds ratio (OR) and 95% confidence interval (CI) for the period prevalence rate of widespread pain over 12 months in the osteopathic medical care group vs. the allopathic medical care group. Multiple logistic regression was used to adjust the OR and 95% CI for age, sex, race, ethnicity, education, cigarette smoking status, history of comorbid conditions (herniated disc, sciatica, osteoarthritis, osteoporosis, hypertension, heart disease, diabetes mellitus, asthma, and depression), and previous low back surgery. Similar analyses were repeated to measure and compare the period prevalence rates of widespread pain in the three OMT use groups. Non-parametric statistics were used to analyze data for the widespread pain severity score because it was not normally distributed. These included the Mann-Whitney test for comparison of the osteopathic and allopathic medical care groups and the Kruskal-Wallis test for comparison of the OMT use groups. Repeated measures analysis of variance was used to compare the medical care and OMT use groups on each of the seven dimensions of HRQOL over 12 months, including adjustment for age and sex. As the clinical importance of significant between-group differences in the HRQOL dimensions may not be intuitively obvious, they were further measured with Cohen's d statistic for effect size [13]. Effect sizes greater than 0.20 were considered clinically important. Data management and statistical analyses were performed with the IBM SPSS Statistics software package (Version 25). Two-sided tests and significance thresholds of $p \leq 0.05$ were used for all statistical analyses.

Results

A total of 462 registry participants met the eligibility criteria, including 101 (21.9%) in the osteopathic medical care group (Figure 1). The mean age of participants at baseline was 52.7 ± 13.2 years (range, 22–79 years) and 336 (72.7%) were

female. The medical care groups were comparable on many sociodemographic and clinical characteristics at the time of registry enrollment (Table 1). Prior use of spinal manipulation was more often reported in the osteopathic medical care group (68.3%) than in the allopathic medical care group (44.0%) ($p < 0.001$). Other less highly significant group differences involved educational level, cigarette smoking status, heart disease, and use of acupuncture. Osteopathic manipulative treatment was used by 73 (15.8%) participants, possibly used by 179 (38.7%) participants, and never used by 210 (45.5%) participants.

The period prevalence rate of widespread pain was 77 (76.2%) for participants in the osteopathic medical care group, as compared with 315 (87.3%) for participants in the allopathic medical care group (OR, 0.47; 95% CI, 0.27–0.81; $p = 0.006$). The lower prevalence of widespread pain in the osteopathic medical care group persisted after adjustment for age, sex, and the other potential confounders (OR, 0.48; 95% CI, 0.26–0.90; $p = 0.02$). The period prevalence rate of widespread pain was 52 (71.2%) for participants who used OMT, 159 (88.8%) for participants who possibly used OMT, and 181 (86.2%) for participants who never used OMT. There was a lower risk of widespread pain in the group that used OMT vs. the group that never used OMT as a control group (OR, 0.40; 95% CI, 0.21–0.75; $p = 0.004$), but not in the group that possibly used OMT (OR, 1.27; 95% CI, 0.69–2.34; $p = 0.43$). The lower prevalence of widespread pain in the group that used OMT did not persist after adjustment for potential confounders (OR, 0.59; 95% CI, 0.27–1.26; $p = 0.17$).

The osteopathic medical care group reported lower widespread pain severity than the allopathic medical care group (median, 2; interquartile range, 0–4 vs. median, 3; interquartile range, 0–5) ($p = 0.008$) (Figure 2). Correspondingly, the group that used OMT reported lower pain severity (median, 2; interquartile range, 0–5.5) than the groups that possibly used OMT (median, 4; interquartile range, 2–7) and never used OMT (median, 4.5; interquartile range, 2–6) ($p = 0.02$).

The osteopathic medical care group reported better age- and sex-adjusted outcomes for each of the seven dimensions of HRQOL throughout the study (Figure 3). The group differences in age- and sex-adjusted main effects were: mean, 3.29; 95% CI, 1.66–4.92 ($p < 0.001$; $d = 0.37$) for physical function; mean, 2.78; 95% CI, 0.50–5.06 ($p = 0.02$; $d = 0.22$) for anxiety; mean, 2.94; 95% CI, 0.74–5.15 ($p = 0.009$; $d = 0.24$) for depression; mean, 2.36; 95% CI, 0.02–4.71 ($p = 0.048$; $d = 0.18$) for fatigue; mean, 2.96; 95% CI, 1.10–4.81 ($p = 0.002$; $d = 0.29$) for sleep disturbance; mean, 3.77; 95% CI, 1.72–5.82 ($p < 0.001$;

Figure 1: Flow of participants through the study.

$d=0.34$) for participation in social roles and activities; and mean, 3.16; 95% CI, 1.36–4.96 ($p=0.001$; $d=0.32$) for pain interference with activities. These group differences were clinically important for all HRQOL dimensions except fatigue.

The use of OMT was associated with better age- and sex-adjusted outcomes for all HRQOL dimensions except fatigue (Figure 4). The group differences in age- and sex-adjusted main effects for participants who used OMT vs. those who never used OMT were: mean, 4.31; 95% CI, 2.48–6.14 ($p<0.001$; $d=0.56$) for physical function; mean, 3.42; 95% CI, 0.86–5.99 ($p=0.009$; $d=0.32$) for anxiety;

mean, 3.05; 95% CI, 0.57–5.53 ($p=0.02$; $d=0.29$) for depression; mean, 1.60; 95% CI, –1.01 to 4.22 ($p=0.23$; $d=0.14$) for fatigue; mean, 2.89; 95% CI, 0.81–4.97 ($p=0.007$; $d=0.33$) for sleep disturbance; mean, 3.90; 95% CI, 1.62–6.19 ($p=0.001$; $d=0.40$) for participation in social roles and activities; and mean, 3.71; 95% CI, 1.69–5.73 ($p<0.001$; $d=0.43$) for pain interference with activities. These group differences were statistically significant and clinically important for all HRQOL dimensions except fatigue. The group that possibly used OMT did not report better age- and sex-adjusted outcomes on any of the HRQOL dimensions.

Table 1: Baseline participant characteristics by medical care group (n=462).

Characteristic	Osteo- pathic medical care		Allopathic medical care		p- Value
	n=101		n=361		
	No.	%	No.	%	
Age, year (mean, SD)	53.5	14.5	52.4	12.8	0.49
Female sex	77	76.2	259	71.7	0.37
Race					0.10
White	86	85.1	264	73.1	
Black	13	12.9	83	23.0	
Asian	1	1.0	5	1.4	
American Indian/Alaska Native	0	0.0	7	1.9	
Native Hawaiian/Pacific Islander	1	1.0	2	0.6	
Hispanic ethnicity	8	7.9	40	11.1	0.36
Educational level					0.01
Less than college degree	50	49.5	230	63.7	
Bachelor or master degree	49	48.5	118	32.7	
Professional or doctoral degree	2	2.0	13	3.6	
Ever lost work for one or more months due to low back pain	32	31.7	153	42.4	0.052
Ever applied for or received disability or workers' compensation benefits due to low back pain	19	18.8	86	23.8	0.29
Ever involved in a legal claim related to low back pain	10	9.9	36	10.0	0.98
Cigarette smoking status					0.03
Never or former smoker	94	93.1	305	84.5	
Current smoker	7	6.9	56	15.5	
BMI, kg/m ² (mean, SD)*	32.3	7.9	33.1	8.5	0.40
Medical conditions ever diagnosed					
Herniated disc	35	34.7	138	38.2	0.51
Sciatica	44	43.6	154	42.7	0.87
Osteoarthritis	38	37.6	145	40.2	0.64
Osteoporosis	15	14.9	40	11.1	0.30
Hypertension	40	39.6	157	43.5	0.49
Heart disease	16	15.8	32	8.9	0.04
Diabetes mellitus	20	19.8	67	18.6	0.78
Asthma	32	31.7	107	29.6	0.69
Depression	55	54.5	174	48.2	0.27
History of low back surgery					0.24
Yes, one surgery	9	8.9	30	8.3	
Yes, more than one surgery	3	3.0	28	7.8	
No	89	88.1	303	83.9	
Ever use of non-pharmacological treatments for low back pain					
Exercise therapy	55	54.5	234	64.8	0.06
Yoga	32	31.7	98	27.1	0.37
Massage therapy	57	56.4	182	50.4	0.28
Spinal manipulation	69	68.3	159	44.0	<0.001
Acupuncture	27	26.7	61	16.9	0.03
Cognitive behavioral therapy	8	7.9	42	11.6	0.29

Table 1: (continued)

Characteristic	Osteo- pathic medical care		Allopathic medical care		p- Value
	n=101		n=361		
	No.	%	No.	%	
Current use of drug therapy for low back pain					
Nonsteroidal anti-inflammatory drugs	62	61.4	238	65.9	0.40
Opioids	26	25.7	130	36.0	0.054

*Body mass index (BMI) was not available for six participants.

Discussion

This study found that the groups who received osteopathic medical care and who used OMT were both less likely to progress from chronic low back pain to widespread pain over the course of 12 months. Accordingly, both of these groups also reported lower widespread pain severity. These findings align with the view that osteopathic physicians provide a more holistic approach to medical care, including use of OMT when indicated for low back pain [9]. In providing medical care for patients with chronic low back pain, osteopathic physicians may assess and treat such patients more comprehensively rather than focusing only on pain within a limited anatomical location, thereby lowering the risk of widespread pain progression and its impact on HRQOL. Indeed, it has been argued that osteopathic tenets and principles for pain management preceded the widely accepted and heuristic biopsychosocial approach [14]. Proponents of the latter approach now recognize the importance of the physician-patient relationship in offering empathy, encouragement, and hope for patients with chronic pain [15].

The study findings also support the American Osteopathic Association guideline for OMT for patients with low back pain [5]. Therein, it is recommended that osteopathic physicians assess patients to determine if somatic dysfunction is the cause or a contributing factor in the presentation of low back pain. If somatic dysfunction is the cause of low back pain, then OMT should be used to address its impact on the body framework system, including any skeletal, arthrodiagonal, and myofascial structures that may be affected, and their related vascular,

Figure 2: Widespread pain severity according to group. Group comparisons involve the medical care group (A) and whether osteopathic manipulative treatment (OMT) was used (B). The severity score represents the sum of participant responses at five quarterly encounters from baseline through the 12-month follow-up. Higher scores represent more severe widespread pain. A score of 0 indicates that widespread pain was not reported during the study.

lymphatic, and neural elements [16]. If somatic dysfunction is only a contributing factor to low back pain, then an examination for the primary cause should be undertaken so that it may be treated accordingly.

The lower risk of widespread pain observed in the groups receiving osteopathic medical care and using OMT over 12 months was associated with benefits in HRQOL. It is noteworthy that these benefits were observed in all seven dimensions of HRQOL except fatigue. These included benefits relating to anxiety, depression, and sleep disturbance, which are not generally assessed in studies of musculoskeletal disorders, including those specifically involving OMT. Previous research has shown that patients treated by osteopathic physicians report greater physician empathy and better interpersonal manner than patients treated by allopathic physicians, as well as better outcomes relating to back-related functioning [17]. The present findings for anxiety, depression, and sleep disturbance further support the view that osteopathic physicians take a holistic approach that transcends merely focusing on the musculoskeletal aspects of chronic low back pain that are more likely to impact such HRQOL dimensions as physical function, participation in social roles and activities, and pain interference with activities.

This study has several strengths that should be noted. It was conducted within a pain research registry involving a digital research platform that enabled remote data acquisition throughout the 48 contiguous states and District of Columbia using a series of validated research instruments relating to chronic low back pain, including several recommended by the RTF [11]. Only 6.7% of registry

participants had missing encounters during the 12 months of follow-up, thereby requiring exclusion from the study. The remaining participants reported complete data, thus obviating the need for imputation of missing data. Participants with physician crossover were excluded to derive more specific estimates of the treatment effects for each of the medical care groups.

The study was limited by using standard case report forms that did not include validated research instruments for widespread pain. The latter may be considered an early or mild stage of fibromyalgia [18]. Clinical criteria for fibromyalgia have been established and modified over the past three decades, including the development of patient self-report instruments for research purposes [19–21]. Such instruments are not deployed in the registry to avoid an onerous participant reporting burden at each encounter. The simple participant self-report item on widespread pain in the Minimum Dataset for Chronic Low Back Pain used herein has shown promise as a sensitive measure of the early manifestations of fibromyalgia [22]; however, it has limited specificity. Consequently, the registry recently began collecting participant data on fibromyalgia as a comorbid condition using a new item on its case report forms. However, there were an insufficient number of participants who completed this new item to perform meaningful analyses in the present study. Similarly, there were too few participants who were entirely free of widespread pain at the baseline encounter to assemble a suitable inception cohort to measure the incidence rate of widespread pain. The period prevalence rate was thus used as an alternative measure of risk.

Figure 3: Health-related quality-of-life outcomes according to medical care group. Group comparisons involve physical function (A), anxiety (B), depression (C), fatigue (D), sleep disturbance (E), participation in social roles and activities (F), and pain interference with activities (G). The scores for these dimensions on the Patient-Reported Outcomes Measurement Information System with 29 items were transformed and standardized using the United States general population, wherein the mean is 50 and standard deviation is 10. Higher scores represent worse outcomes on each dimension except physical function and participation in social roles and activities. Error bars represent 95% confidence intervals.

Figure 4: Health-related quality-of-life outcomes according to osteopathic manipulative treatment (OMT) group. Group comparisons involve physical function (A), anxiety (B), depression (C), fatigue (D), sleep disturbance (E), participation in social roles and activities (F), and pain interference with activities (G). The scores for these dimensions on the Patient-Reported Outcomes Measurement Information System with 29 items were transformed and standardized using the United States general population, wherein the mean is 50 and standard deviation is 10. Higher scores represent worse outcomes on each dimension except physical function and participation in social roles and activities. Error bars represent 95% confidence intervals. Pairwise comparisons of participants who used and never used OMT are further presented in the text.

Conclusions

The study findings reported herein support the claims that osteopathic physicians practice a more holistic approach to medical care. This was demonstrated through a lower risk of progression from chronic low back pain to widespread pain, lower widespread pain severity, and lesser deficits in HRQOL in the groups that received osteopathic medical care and that used OMT.

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Informed consent: All enrollees provided written informed consent.

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