

Somatic Dysfunction and Its Association With Chronic Low Back Pain, Back-Specific Functioning, and General Health: Results From the OSTEOPATHIC Trial

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Context: Somatic dysfunction is diagnosed by the presence of any of 4 TART criteria: tissue texture abnormality, asymmetry, restriction of motion, or tenderness.

Objective: To measure the prevalence of somatic dysfunction in patients with chronic low back pain (LBP) and to study the associations of somatic dysfunction with LBP severity, back-specific functioning, and general health.

Design: Cross-sectional study nested within a randomized controlled trial.

Setting: University-based study in Dallas-Fort Worth, Texas.

Patients: A total of 455 adult research patients with non-specific chronic LBP.

Main Study Measures: Somatic dysfunction in the lumbar, sacrum/pelvis, and pelvis/innominate regions, including key lesions representing severe somatic dysfunction. A 10-cm visual analog scale (VAS), the Roland-Morris Disability Questionnaire (RMDQ), and the Medical Outcomes Study Short Form-36 Health Survey (SF-36) were used to measure LBP severity, back-specific functioning, and general health, respectively.

Results: Severe somatic dysfunction was most prevalent in the lumbar (225 [49%]), sacrum/pelvis (129 [28%]), and pelvis/innominate (48 [11%]) regions. Only 30 patients (7%) had no somatic dysfunction in the lumbar, sacrum/pelvis, or pelvis/innominate regions. There were 4 statistically significant pairwise correlations for severe somatic dysfunction: thoracic (T) 10-12 with ribs; T10-12 with lumbar; lumbar with sacrum/pelvis; and sacrum/pelvis with pelvis/innominate. Having a key lesion in the lumbar region ($\rho=0.80$) or sacrum/pelvis region ($\rho=0.71$) was strongly correlated with the overall number of key lesions. There were no consistent demographic or clinical predictors of somatic dysfunction. The presence (vs absence) of severe somatic dysfunction in the lumbar region was associated with greater LBP severity (median VAS score, 4.7 vs 3.8, respectively; $P=.003$) and greater back-specific disability (median RMDQ score, 6 vs 4, respectively; $P=.01$). The presence (vs absence) of severe somatic dysfunction in the sacrum/pelvis region was associated with greater back-specific disability (median RMDQ score, 6 vs 5, respectively; $P=.02$) and poorer general health (median SF-36 score, 62 vs 72, respectively; $P=.002$). An increasing number of key lesions was associated with back-specific disability ($P=.009$) and poorer general health ($P=.02$).

Conclusion: The present study demonstrates that somatic dysfunction, particularly in the lumbar and sacrum/pelvis regions, is common in patients with chronic LBP. Forthcoming extensions of the OSTEOPATHIC Trial will assess the efficacy of OMT according to baseline levels of somatic dysfunction.

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Somatic dysfunction is a uniquely osteopathic concept that is defined as "impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodiagonal, and myofascial structures, and related vascular, lymphatic, and neural elements."¹ The diagnostic criteria for somatic dysfunction include tissue texture abnormality, asymmetry, restriction of motion, and tenderness (TART)—any of which must be present for the diagnosis. The biomechanical model of osteopathic med-

icine posits that manual techniques may be used to alleviate somatic dysfunction, thereby restoring normal motion and function throughout the body.² This model also accepts that patient education, medications, or surgery may be used, as appropriate.

Many osteopathic manual treatment (OMT) techniques are available to treat patients with somatic dysfunction. Although these various techniques may be classified across several dimensions, the “manipulation” vs “mobilization” dichotomy reflects how these techniques are most often viewed and classified by manual therapy practitioners outside the osteopathic medical profession. This dichotomy was also observed in a survey of American Osteopathic Association members, which found that the 3 most frequently used OMT techniques were soft tissue; high-velocity, low-amplitude thrust; and muscle energy.³

It has been noted that “OMT is not used to treat back pain; OMT is used to treat somatic dysfunction that may be the cause of back pain.”⁴ Regrettably, there is little research that correlates somatic dysfunction with patient symptoms or conventional medical diagnoses and, by extension, that facilitates studying the efficacy of OMT in managing such symptoms or medical conditions. Two major trials of OMT in patients with low back pain (LBP) excluded unknown numbers of patients because they were “not treatable by manipulation of the lumbosacral area”⁵ or because they had “no lesion that could be manipulated.”⁶ Although this restrictive approach to study inclusion has intuitive appeal, it unnecessarily increases screening workload and may reduce sample size and statistical power in clinical trials, while also limiting the generalizability of results beyond the osteopathic medical profession. Interestingly, despite these restrictive inclusion criteria, neither trial found that OMT reduced LBP to statistically significant levels at its endpoint.^{5,6} The North Texas Clinical Trial of OMT for Chronic Low Back Pain, which did not use such exclusion criteria, demonstrated that OMT reduced LBP to statistically significant levels compared with the no-treatment study arm, but not compared with the sham manipulation study arm.⁷

The OSTEOPATHic Health outcomes In Chronic low back pain (OSTEOPATHIC) Trial⁸ was conducted as an extension of the North Texas Clinical Trial of OMT for Chronic Low Back Pain. Major enhancements in the OSTEOPATHIC Trial included methodologic features intended to achieve “low risk of bias,” as well as increased sample size to ensure adequate statistical power in testing research hypotheses. Regarding the latter, the OSTEOPATHIC Trial is the largest clinical trial involving OMT. As with the North Texas Clinical Trial, the OSTEOPATHIC Trial did not institute inclusion criteria relating to the presence of a “manipulatable lesion.” However, baseline assessment of somatic dysfunction was performed using the TART criteria. The purpose of the present article is to

describe results from the OSTEOPATHIC Trial—specifically baseline levels of somatic dysfunction in research patients with chronic LBP and the association of somatic dysfunction with LBP severity, back-specific functioning, and general health at baseline.

Methods

The OSTEOPATHIC Trial was approved by the Institutional Review Board of the University of North Texas Health Science Center. The study was registered with ClinicalTrials.gov (NCT00315120) before enrollment of research patients. Methodologic aspects of the trial have been reported in detail elsewhere.⁸ We used a randomized, double-blind, sham-controlled, 2×2 factorial design to study the efficacy of OMT and ultrasound therapy in patients with nonspecific chronic LBP.

Inclusion and Exclusion Criteria

Patients were included if they were between 21 and 69 years of age, and reported having LBP constantly or on most days over the past 3 months. Patients were excluded for any of the following reasons: presence of a “red flag” condition; low back surgery in the past year; receipt of worker’s compensation benefits in the past 3 months; ongoing litigation involving back problems; medical conditions that might impede OMT or ultrasound protocol implementation; corticosteroid use in the past month; or clinical evidence of lumbar radiculopathy (as determined by testing for ankle dorsiflexion weakness; great toe extensor weakness; impaired ankle reflexes; loss of light touch sensation in the medial, dorsal, and lateral aspects of the foot; ipsilateral straight leg raising; and crossed straight leg raising).⁹

Diagnosis of Somatic Dysfunction

Each patient received an osteopathic structural examination before randomization. The musculoskeletal table of the Outpatient Osteopathic SOAP Note Form¹⁰ was completed as part of this assessment. This form has been validated as an objective tool for measuring and recording the diagnosis and treatment of somatic dysfunction during patient encounters.¹¹ The musculoskeletal table was used to record the severity of somatic dysfunction in each of 14 anatomic regions on the basis of TART criteria. The severity scale consisted of 4 levels: none (no somatic dysfunction or background level); mild (more than background level; minor TART elements); moderate (obvious TART elements; restriction of motion or tissue texture abnormality, with or without symptoms); and severe (key lesion present; significant, symptomatic; restriction of motion or tissue texture abnormality stands out with minimum search or provocation).¹⁰ We focused on the severity of somatic dysfunction in the following anatomic regions: thoracic (T) 10-12, ribs, lumbar, sacrum/pelvis, and pelvis/innominate. Fifteen osteopathic

ORIGINAL CONTRIBUTION

physicians, residents, and fellows performed these structural examinations over the 5 years of the study.

Baseline Measures

The primary outcome of interest in the OSTEOPATHIC Trial was LBP severity, as measured by a 10-cm visual analog scale (VAS, 0-10 cm, with higher scores indicating more pain).¹² In addition, the Roland-Morris Disability Questionnaire (RMDQ, 0-24 points, with higher scores indicating greater disability)¹³ and the Medical Outcomes Study Short Form-36 Health Survey (SF-36, 0-100 points, with higher scores indicating better health)¹⁴ were administered to assess back-specific functioning and general health, respectively. Each measure was performed before treatment, thereby facilitating evaluation of the measure's association with somatic dysfunction in patients with chronic LBP.

Statistical Analysis

Descriptive statistics were used to characterize the trial participants. We subsequently explored the underlying distributions of somatic dysfunction according to anatomic region, and of LBP severity, back-specific functioning, and general health. Because none of these distributions met statistical criteria for normality, we relied predominantly on nonparametric methods for analysis of the study data. We then dichotomized the severity of somatic dysfunction by combining the 3 lowest levels (none, mild, and moderate) and contrasting these with the highest level (severe). The severe level represents clinically significant, key lesions, which are important because they maintain a dysfunctional pattern that includes secondary dysfunctions.¹

The Spearman rank correlation coefficient (ρ) was used to assess severe somatic dysfunction in each of the 10 pairwise combinations of anatomic regions. We also computed the correlation coefficient for severe somatic dysfunction in each anatomic region and the overall number of key lesions (potentially ranging from 0 to 5, as determined by the presence of severe somatic dysfunction in each anatomic region). Multiple logistic regression analysis was used to compute adjusted odds ratios (ORs) and 95% confidence intervals (CIs) for the presence of severe somatic dysfunction in each anatomic region on the basis of age, sex, cigarette smoking history, and current diagnosis of 3 common, chronic medical conditions (ie, hypertension, diabetes mellitus, and osteoarthritis).

The Mann-Whitney test was used to compare LBP severity, back-specific functioning, and general health of patients with and without severe somatic dysfunction in each anatomic region. The Kruskal-Wallis 1-way analysis of variance by ranks was used to further assess the relationships between the number of key lesions and LBP severity, back-specific functioning, and general health. Database management and analyses were performed with

the IBM SPSS Statistics Version 20 software package (IBM Corporation, Armonk, New York). Hypothesis testing was conducted at the .05 level of statistical significance.

Results

A total of 455 adult research patients with nonspecific chronic LBP were included in the present study. The baseline characteristics of these patients are presented in *Table 1*. The median age of the patients was 41 years, and 284 patients (62%) were women. The median LBP chronicity was 1 year. Relatively few patients had been hospitalized or had surgery for their LBP. A total of 222 patients (49%) had used nonprescription drugs for LBP in the previous 4 weeks. However, only 59 patients (13%) used prescription drugs for LBP during this period.

The distributions of somatic dysfunction according to anatomic region are presented in *Figure 1*. These distributions vary substantially from 1 anatomic region to another. Severe somatic dysfunction was most prevalent in the

Table 1.
Baseline Characteristics of Patients
With Nonspecific Chronic Low Back Pain (N=455)

Characteristic	Results ^a
Median Age, y (IQR)	41 (22)
Women	284 (62)
Completed College Education	200 (44)
Employed Full-Time	215 (47)
Medically Uninsured	163 (36)
Current Smokers	119 (26)
Comorbid Conditions	
Hypertension	71 (16)
Diabetes mellitus	34 (7)
Osteoarthritis	33 (7)
Depression	90 (20)
Chronic LBP Duration > 1 y	228 (50)
Previously Hospitalized for LBP	21 (5)
Previous Surgery for LBP	10 (2)
Used Drugs for LBP in Previous 4 wk	
Nonprescription	222 (49)
Prescription	59 (13)
LBP-Related Findings, median score (IQR)	
VAS ^b	4.4 (3.4)
RMDQ ^c	5 (6)
SF-36 ^d	72 (30)

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

^b A visual analog scale (VAS; 0 to 10 cm) was used to measure low back pain (LBP). Higher scores indicate more pain.

^c The Roland-Morris Disability Questionnaire (RMDQ; 0 to 24 points) was used to measure back-specific functioning. Higher scores indicate greater disability.

^d The Medical Outcomes Study Short Form-36 Health Survey (SF-36; 0 to 100 points) was used to measure general health. Higher scores indicate better health.

Abbreviation: IQR, interquartile range.

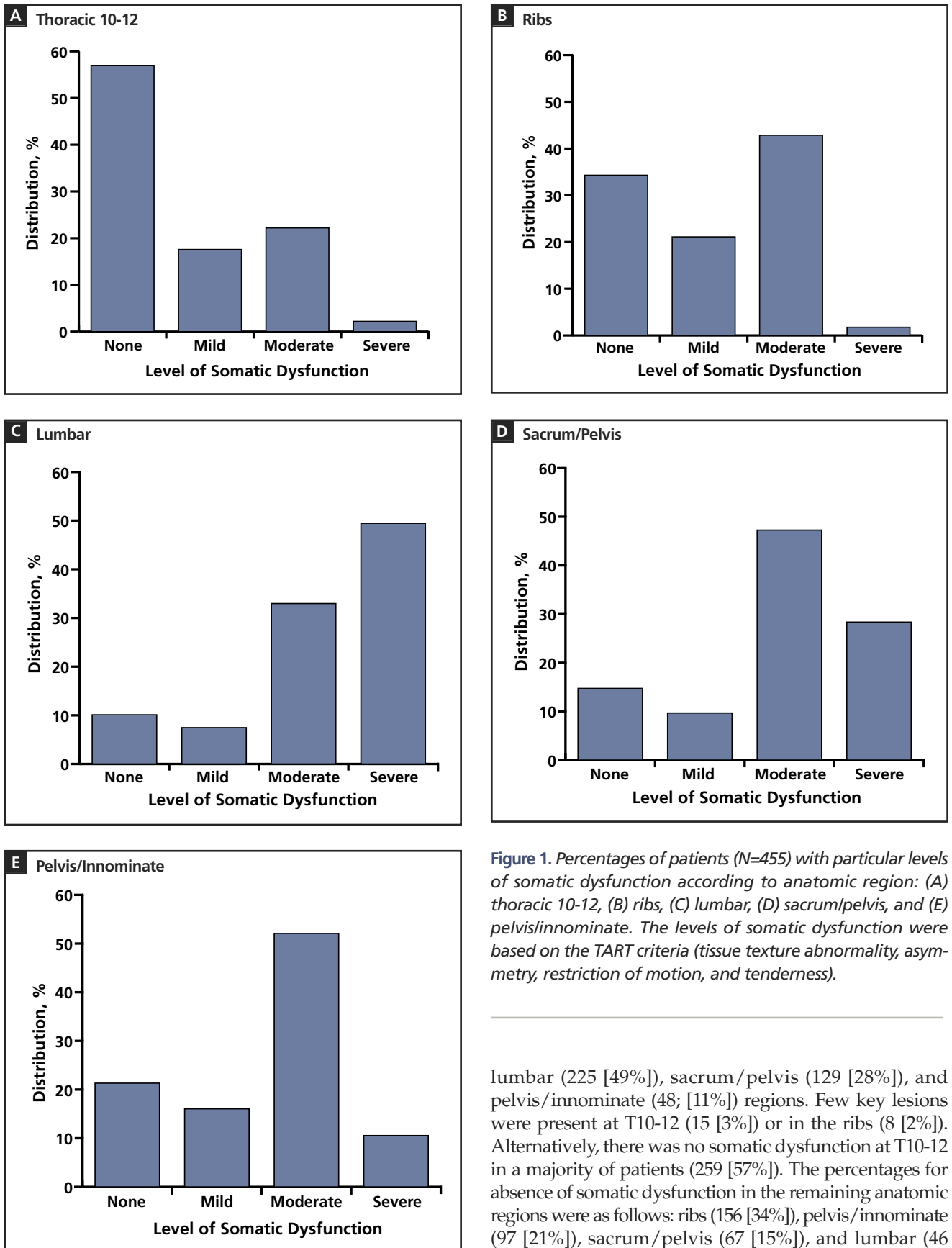


Figure 1. Percentages of patients ($N=455$) with particular levels of somatic dysfunction according to anatomic region: (A) thoracic 10-12, (B) ribs, (C) lumbar, (D) sacrum/pelvis, and (E) pelvis/innominate. The levels of somatic dysfunction were based on the TART criteria (tissue texture abnormality, asymmetry, restriction of motion, and tenderness).

lumbar (225 [49%]), sacrum/pelvis (129 [28%]), and pelvis/innominate (48 [11%]) regions. Few key lesions were present at T10-12 (15 [3%]) or in the ribs (8 [2%]). Alternatively, there was no somatic dysfunction at T10-12 in a majority of patients (259 [57%]). The percentages for absence of somatic dysfunction in the remaining anatomic regions were as follows: ribs (156 [34%]), pelvis/innominate (97 [21%]), sacrum/pelvis (67 [15%]), and lumbar (46

Table 2.
Correlations for Severe Somatic Dysfunction (Key Lesion) by Anatomic Region

Region With Key Lesion	Region With Key Lesion ^a					Key Lesions, No.
	Thoracic 10-12	Ribs	Lumbar	Sacrum/Pelvis	Pelvis/Innominate	
Thoracic 10-12	...	0.26 (<.001)	0.14 (.003)	-0.01 (.88)	-0.02 (.62)	0.24 (<.001)
Ribs	0.07 (.15)	-0.01 (.83)	0.06 (.18)	0.18 (<.001)
Lumbar	0.30 (<.001)	0.09 (.06)	0.80 (<.001)
Sacrum/Pelvis	0.23 (<.001)	0.71 (<.001)
Pelvis/Innominate	0.43 (<.001)
Key Lesions, No.

^a Correlations are reported as Spearman rank correlation coefficient (P value) for each table entry.

[10%]). Only 30 patients (7%) had no somatic dysfunction at all in the lumbar, sacrum/pelvis, or pelvis/innominate regions.

The distribution of number of key lesions was as follows: none (185 [41%]), 1 (141 [31%]), 2 (105 [23%]), 3 (23 [5%]), 4 (0), and 5 (1 [0.2%]). The correlations for severe somatic dysfunction in each anatomic region are presented in Table 2. There were 4 statistically significant pairwise correlations for severe somatic dysfunction: T10-12 with ribs, T10-12 with lumbar, lumbar with sacrum/pelvis, and

sacrum/pelvis with pelvis/innominate. Having severe somatic dysfunction in any anatomic region was correlated with the overall number of key lesions (P<.001 for each correlation). However, having severe somatic dysfunction in the lumbar region (ρ=0.80) or sacrum/pelvis region (ρ=0.71) correlated much more strongly with the overall number of key lesions.

We performed multiple logistic regression analyses for factors associated with severe somatic dysfunction in the lumbar, sacrum/pelvis, and pelvis/innominate regions

Table 3.
Factors Associated With Severe Somatic Dysfunction According to Anatomic Region^a

Characteristic	Anatomic Region								
	Lumbar			Sacrum/Pelvis			Pelvis/Innominate		
	OR	95% CI	P Value	OR	95% CI	P Value	OR	95% CI	P Value
Age, y									
21-34	1.00	1.00	1.00
35-49	1.00	0.64-1.56	.99	1.39	0.81-2.36	.23	0.99	0.47-2.08	.98
50-69	0.87	0.52-1.46	.59	1.83	1.02-3.27	.04	0.92	0.39-2.16	.85
Sex									
Women	1.00	1.00	1.00
Men	0.93	0.63-1.37	.71	0.84	0.53-1.31	.44	0.83	0.43-1.58	.56
Cigarette Smoking									
Status									
Nonsmoker	1.00	1.00	1.00
Smoker	1.09	0.71-1.68	.69	1.31	0.82-2.12	.26	1.41	0.72-2.75	.32
Hypertension									
Not diagnosed	1.00	1.00	1.00
Diagnosed	1.31	0.74-2.29	.35	1.10	0.61-2.01	.75	1.03	0.42-2.51	.95
Diabetes Mellitus									
Not diagnosed	1.00	1.00	1.00
Diagnosed	1.59	0.74-3.43	.24	2.02	0.93-4.35	.07	1.06	0.32-3.44	.93
Osteoarthritis									
Not diagnosed	1.00	1.00	1.00
Diagnosed	1.19	0.57-2.52	.64	2.19	1.03-4.65	.04	2.09	0.76-5.71	.15

^a Data based on multiple logistic regression analysis, with odds ratio (OR) adjusted for each characteristic.

Abbreviation: CI, confidence interval.

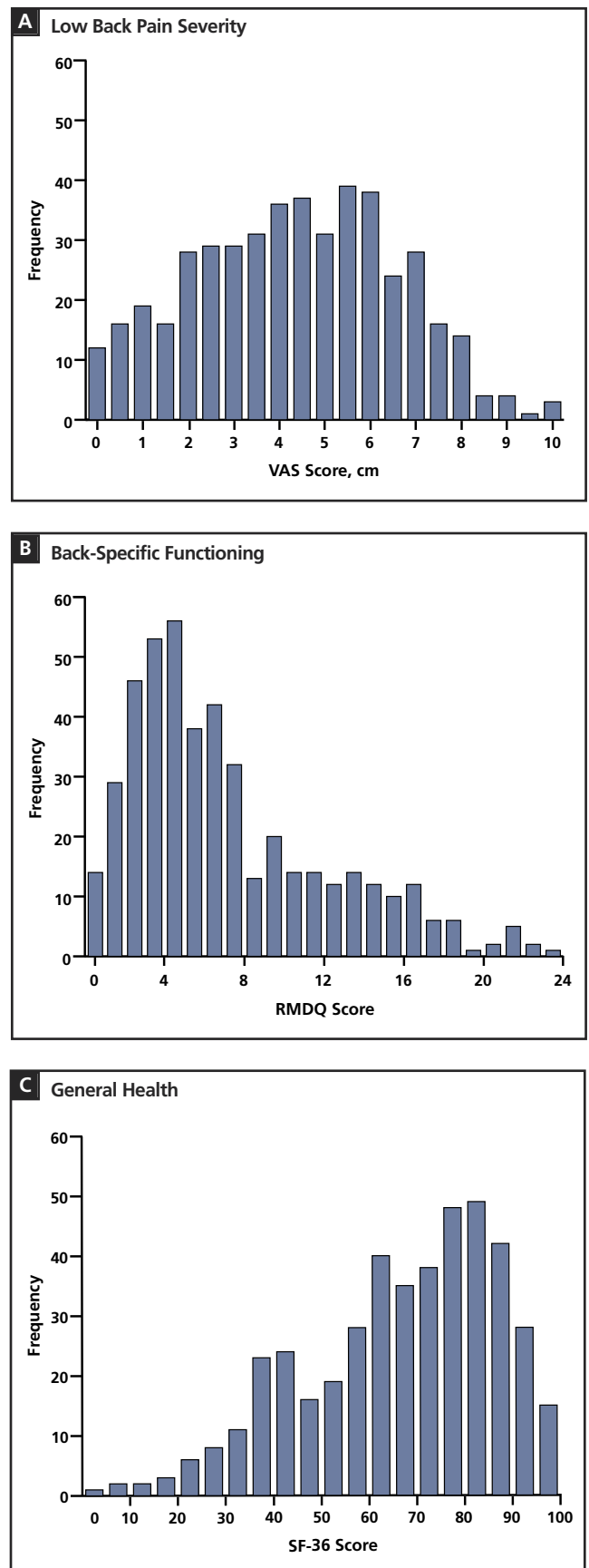
(Table 3). There were too few key lesions for meaningful analyses in the remaining anatomic regions. There were only 2 marginal associations between patient characteristics and the presence of severe somatic dysfunction, both involving the sacrum/pelvis region. Patients between 50 and 69 years of age were more likely to have severe somatic dysfunction than those between 21 and 34 years of age (OR, 1.83; 95% CI, 1.02-3.27; $P=.04$). Patients diagnosed as having osteoarthritis were also more likely to have severe somatic dysfunction than those without osteoarthritis (OR, 2.19; 95% CI, 1.03-4.65; $P=.04$).

The frequency distributions of LBP severity, back-specific functioning, and general health, as measured by VAS pain, RMDQ, and SF-36 scores, respectively, are presented in Figure 2. The hypothesis of normality was rejected for each distribution (Shapiro-Wilk test, $P<.001$ for each variable). Figure 3 presents median scores on the VAS for pain, RMDQ, and SF-36 for patients with and without severe somatic dysfunction in each anatomic region. The presence (vs absence) of severe somatic dysfunction in the lumbar region was associated with greater LBP severity (median VAS score, 4.7 vs 3.8, respectively; $P=.003$) and greater back-specific disability (median RMDQ score, 6 vs 4, respectively; $P=.01$). The presence (vs absence) of severe somatic dysfunction in the sacrum/pelvis region was associated with greater back-specific disability (median RMDQ score, 6 vs 5, respectively; $P=.02$) and poorer general health (median SF-36 score, 62 vs 72, respectively; $P=.002$). Figure 4 presents median scores on the VAS for pain, RMDQ, and SF-36 general health scale for patients according to the number of key lesions. An increasing number of key lesions was associated with back-specific disability ($P=.009$) and poorer general health ($P=.02$).

Comment

To our knowledge, this is the first study of somatic dysfunction nested within a clinical trial of OMT for patients with LBP. Severe somatic dysfunction in the lumbar region was present in about half of the patients in the OSTEO-

Figure 2. Frequency distributions of scores of patients ($N=455$) for (A) low back pain severity, (B) back-specific functioning, and (C) general health. The hypothesis of normality was rejected for each distribution (Shapiro-Wilk test, $P<.001$ for each variable). Low back pain was scored on a 10-cm visual analog scale (VAS, 0-10 cm, with higher scores indicating more pain), back-specific functioning on the Roland-Morris Disability Questionnaire (RMDQ, 0-24 points, with higher scores indicating greater disability), and general health on the Medical Outcomes Study Short Form-36 Health Survey (SF-36, 0-100 points, with higher scores indicating better health).



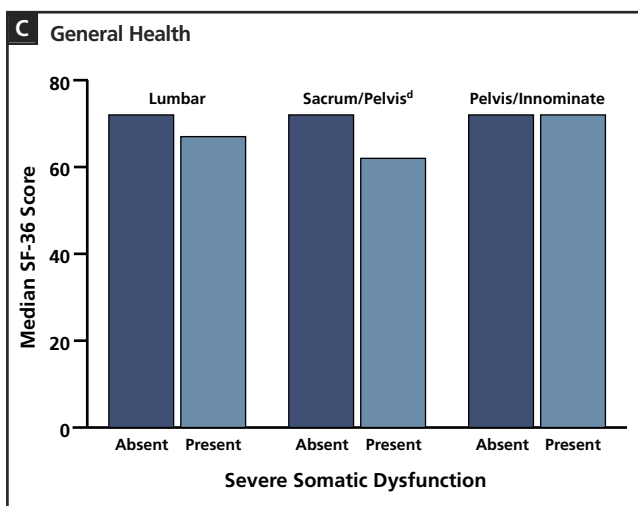
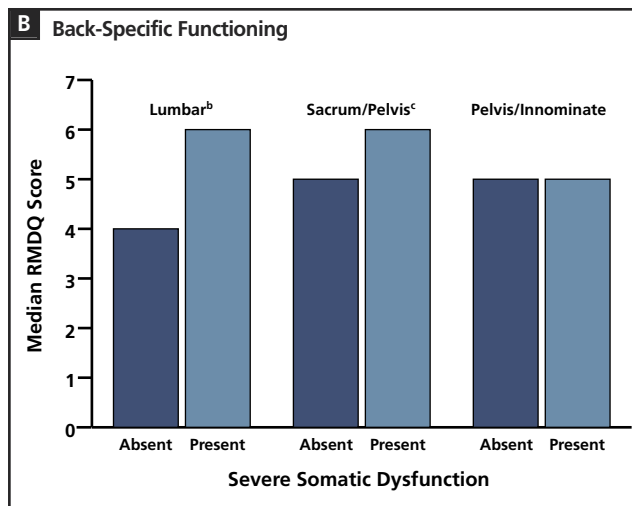
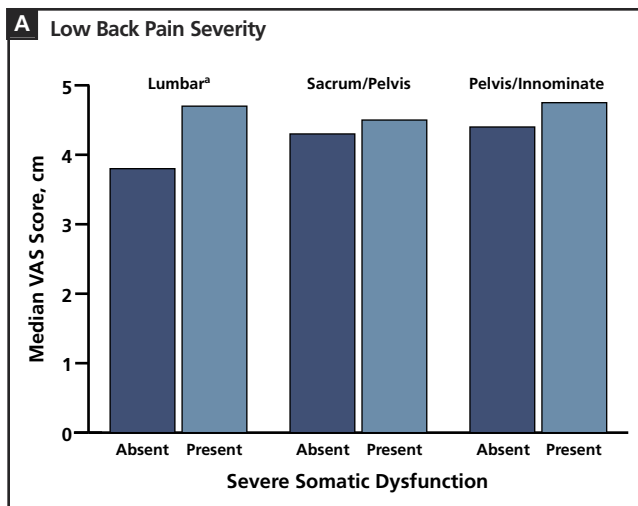


Figure 3. Associations between severe somatic dysfunction and median scores for (A) low back pain severity, (B) back-specific functioning, and (C) general health, according to anatomic region of patients (N=455). The Mann-Whitney test was used for these analyses because the underlying data were not normally distributed. Low back pain was scored on a 10-cm visual analog scale (VAS, 0-10 cm, with higher scores indicating more pain), back-specific functioning on the Roland-Morris Disability Questionnaire (RMDQ, 0-24 points, with higher scores indicating greater disability), and general health on the Medical Outcomes Study Short Form-36 Health Survey (SF-36, 0-100 points, with higher scores indicating better health). ^aP=.003. ^bP=.01. ^cP=.02. ^dP=.002.

PATHIC Trial. Conversely, only a few patients had no somatic dysfunction in the lumbar, sacrum/pelvis, or pelvis/innominate regions during the baseline structural examination. The latter finding brings into question the need for criteria to exclude patients without somatic dysfunction in clinical trials of OMT. Given the chronicity of LBP, it remains unclear if the few patients without somatic dysfunction at baseline would remain without somatic dysfunction during the entire course of a clinical trial.

There were no consistent statistically significant associations of age, sex, cigarette smoking, or chronic medical conditions with severe somatic dysfunction in the lumbar, sacrum/pelvis, or pelvis/innominate regions. However, these analyses should be considered exploratory in nature because they were limited in 2 ways. First, although 455 patients provided adequate statistical power to test the primary OSTEOPATHIC Trial hypothesis relating to OMT efficacy in reducing LBP, that number of patients was not sufficient to adequately assess all aspects of somatic dys-

function and its relationship to other variables in the present study. This lack of statistical power was demonstrated by the relatively wide 95% CIs in our multiple logistic regression analyses. Second, the cross-sectional nature of the present study precluded a definitive evaluation of the temporal relationships between certain explanatory factors (ie, cigarette smoking, hypertension, diabetes mellitus, osteoarthritis) and severe somatic dysfunction. It might be intuitively appealing to speculate that such chronic diseases precipitate severe somatic dysfunction, as suggested by some of the study findings. However, larger prospective studies of incident, rather than prevalent, somatic dysfunction are necessary to adequately address such issues.^{15,16}

We found statistically significant associations between severe somatic dysfunction in the lumbar and sacrum/pelvis regions and outcomes that are relevant to patients with chronic LBP, including LBP severity, back-specific functioning, and general health. Furthermore, as the number of key lesions increased, both back-specific func-

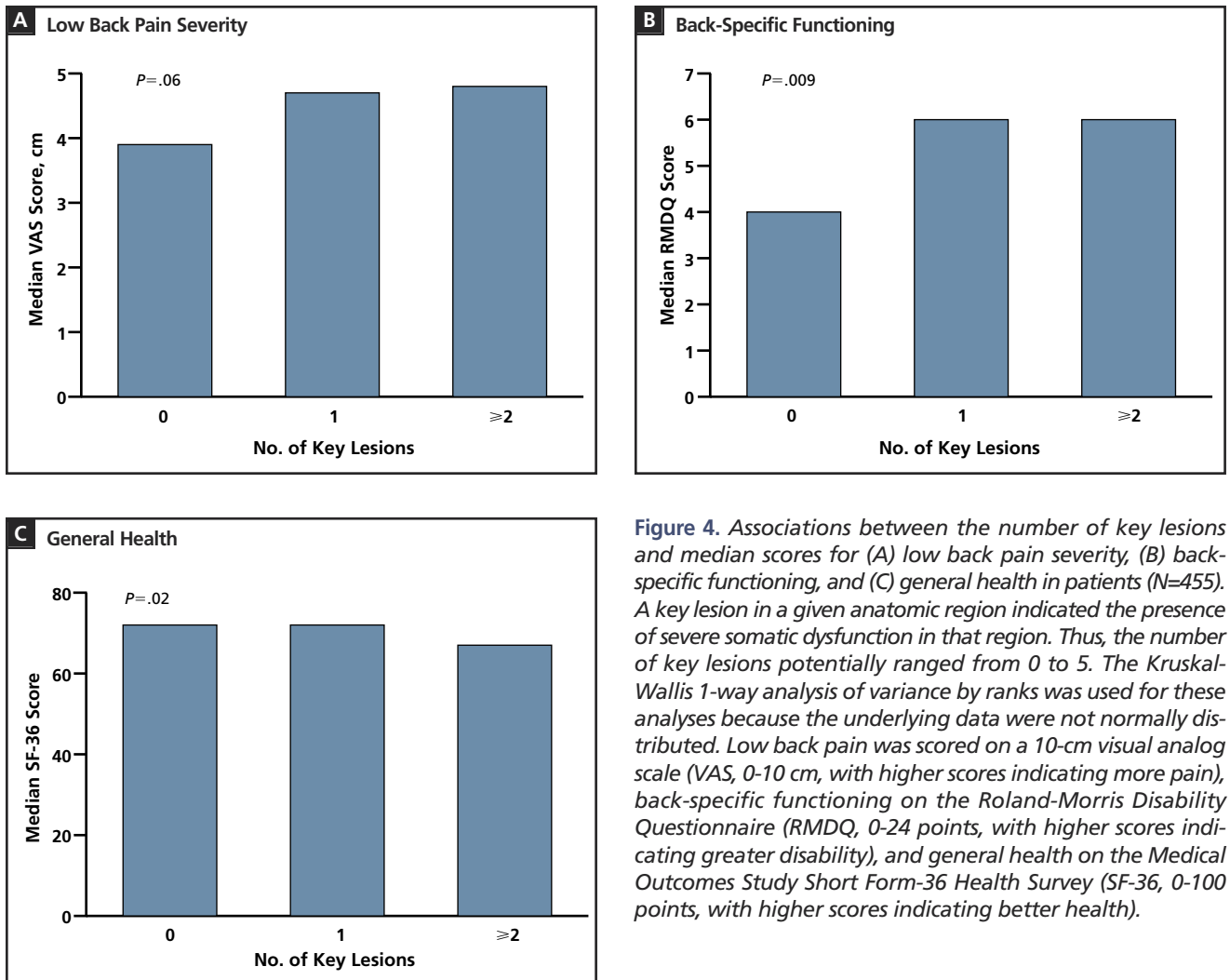


Figure 4. Associations between the number of key lesions and median scores for (A) low back pain severity, (B) back-specific functioning, and (C) general health in patients (N=455). A key lesion in a given anatomic region indicated the presence of severe somatic dysfunction in that region. Thus, the number of key lesions potentially ranged from 0 to 5. The Kruskal-Wallis 1-way analysis of variance by ranks was used for these analyses because the underlying data were not normally distributed. Low back pain was scored on a 10-cm visual analog scale (VAS, 0-10 cm, with higher scores indicating more pain), back-specific functioning on the Roland-Morris Disability Questionnaire (RMDQ, 0-24 points, with higher scores indicating greater disability), and general health on the Medical Outcomes Study Short Form-36 Health Survey (SF-36, 0-100 points, with higher scores indicating better health).

tioning and general health deteriorated in patients. There was also a statistical trend toward greater LBP severity with increasing numbers of key lesions. All of these associations were likely attenuated by the non-normality of VAS pain, RMDQ, and SF-36 scores. These non-normal data necessitated using nonparametric statistical methods, which generally do not make optimal use of the information in a data set.

A remaining potential limitation of the present study involves the possibility of interexaminer variability in diagnosing somatic dysfunction by using the musculoskeletal table of the Outpatient Osteopathic SOAP Note Form.¹⁰ The descriptors for severity on this form create the potential for overlap in scoring. For example, it may be difficult to differentiate between “background levels” of somatic dysfunction (ie, severity defined as “none”) and “minor” TART elements (ie, severity defined as “mild”). Similarly, distinguishing between “obvious” TART elements (ie, severity defined as “moderate”) and key lesions that “stand

out” (ie, severity defined as “severe”) may be difficult. Although we provided fidelity training for OMT providers during our study,¹⁷ we did not formally assess provider performance or interexaminer reliability.

Conclusion

The present study demonstrates that somatic dysfunction, particularly in the lumbar and sacrum/pelvis regions, is common in patients with chronic LBP. Severe somatic dysfunction in the lumbar region is directly associated with LBP severity and back-specific disability. Severe somatic dysfunction in the sacrum/pelvis region is directly associated with back-specific disability and is inversely associated with general health. An increasing number of key lesions was associated with greater back-specific disability and poorer general health. Forthcoming extensions of the OSTEOPATHIC Trial will assess the efficacy of OMT according to baseline levels of somatic dysfunction.

(continued)

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Editor's Note: In this article, the authors use the term *osteopathic manual treatment* to describe the techniques used to treat patients with somatic dysfunction. The style guidelines of JAOA—*The Journal of the American Osteopathic Association* and AOA policy prefer the term *osteopathic manipulative treatment*. Given the context of this article, the authors believe that the term *osteopathic manual treatment* is more appropriate because it is more encompassing than *osteopathic manipulative treatment*.