Depression, Somatization, and Somatic Dysfunction in Patients With Nonspecific Chronic Low Back Pain: Results From the OSTEOPATHIC Trial

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Context: Depression and somatization are often present in patients with chronic low back pain (LBP).

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Objectives: To measure the presence of depression and somatization in patients with chronic LBP and to study the associations of depression and somatization with somatic dysfunction, LBP severity, back-specific functioning, and general health.

Design: Cross-sectional study using baseline measures collected within a randomized controlled trial.

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

Patients: A total of 202 adult research participants with nonspecific chronic LBP.

Main Study Measures: Depression was self-reported and also measured with the Modified Zung Depression Index (MZDI). Somatization was measured with the Modified Somatic Perception Questionnaire (MSPQ). The MZDI and

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MSPQ scores were used to classify patients as "normal," "at risk," or "distressed" using the Distress and Risk Assessment Method. Somatic dysfunction was assessed using the Outpatient Osteopathic SOAP Note Form. A 100-mm 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: There were 53 patients (26%) and 44 patients (22%) who were classified as having depression on the basis of self-reports and the MZDI cut point, respectively. A total of 38 patients (19%) were classified as having somatization on the basis of the MSPQ cut point. There were significant correlations among self-reported depression and the MZDI and MSPQ scores (P<.001 for each pairwise correlation). Similarly, the MZDI and MSPQ scores were both correlated with LBP severity and back-specific disability, and they were inversely correlated with general health (P < .001 for each pairwise correlation). Depression and the number of key osteopathic lesions were also each correlated with back-specific disability and inversely correlated with general health (P < .001 for each pairwise correlation). The MZDI (P=.006) and MSPQ (P=.004) scores were also correlated with the number of key osteopathic lesions.

Conclusions: The associations among depression, somatization, and LBP in this study are consistent with the findings of previous studies. These associations, coupled with the findings that MZDI and MSPQ scores are correlated with somatic dysfunction, may have important implications for the use of osteopathic manual treatment in patients with chronic LBP.

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Chronic low back pain (LBP) frequently involves a multifactorial etiology and requires ongoing medical management. As depicted in *Figure 1*, the biopsychosocial model has been widely used to reflect the complexity of factors that may be associated with chronic medical conditions.¹ Therein, disease is defined as an objective bio-

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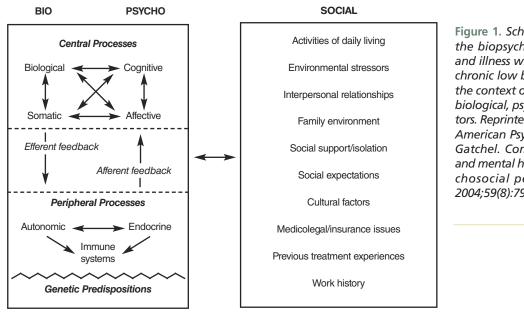


Figure 1. Schematic representation of the biopsychosocial model of disease and illness wherein a condition such as chronic low back pain is viewed within the context of a complex interaction of biological, psychological, and social factors. Reprinted with permission from the American Psychological Association (RJ Gatchel. Comorbidity of chronic pain and mental health disorders: the biopsychosocial perspective. Am Psychol. 2004;59(8):795-805).¹

logical event involving the disruption of specific body structures or organ systems by means of anatomical, pathological, or physiological changes. In contrast, illness generally refers to a subjective experience or self-attribution that a disease is present. Thus, with regard to chronic LBP, the biopsychosocial model views it as a complex interaction of biological, psychological, and social factors, with each individual having unique interactions that affect processing of nociceptive input to derive a global perception of pain.

Correspondingly, the osteopathic approach to the treatment of patients with chronic LBP includes consideration of body unity, homeostasis, and structure-function relationships.² Cardinal manifestations within each of these 3 domains include depression, dysregulation of the autonomic nervous system, and somatic dysfunction, respectively. A better understanding of the interrelationships among these factors is crucial in developing better treatment options for patients with chronic LBP, including osteopathic manual treatment (OMT). The purpose of the present study was to explore these interrelationships and their associations with LBP severity, back-specific functioning, and general health using baseline data from the OSTEOPATHic Health outcomes In Chronic low back pain (OSTEOPATHIC) Trial.³

Methods

The OSTEOPATHIC Trial was approved by the Institutional Review Board at the University of North Texas Health Science Center and registered with ClinicalTrials.gov (NCT00315120). Methodological aspects of the trial have been reported in detail elsewhere.³ We used a randomized, double-blind, sham-controlled, 2×2 factorial design to

study the efficacy of OMT and ultrasound therapy (UST) in patients with nonspecific chronic LBP between August 2006 and January 2011. Essentially, patients were 21 to 69 years of age without any of the following: "red flag" conditions; history of recent low back surgery, receipt of worker's compensation benefits, or ongoing litigation involving back problems; medical conditions that might impede OMT or UST protocol implementation; corticosteroid use in the past month; or clinical evidence of lumbar radiculopathy, as determined by the presence of 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, or shooting posterior leg pain or foot pain upon ipsilateral or contralateral straight leg raising.⁴ The present study, which focuses on depression, somatization, and somatic dysfunction, was facilitated by implementation of the Distress and Risk Assessment Method (DRAM),⁵ consisting of the Modified Zung Depression Index (MZDI) and the Modified Somatic Perception Questionnaire (MSPQ). These instruments were completed at baseline by patients entering the study after January 2009.

Self-Reported Depression

Patients were queried about a diagnosis of clinical depression using a standard checklist of medical conditions prior to randomization. Generally, unless deemed critical to determining trial eligibility, no further attempt was made to confirm these self-reported patient responses through medical records. Specifically, patients were asked whether they currently suffered from depression, or if they had been diagnosed with depression at any point within 3 months prior to screening for trial eligibility.

The Modified Zung Depression Index

The MZDI was administered prior to randomization and consists of 23 items, presented as a series of positive or negative statements.⁵ There are 4 possible responses for each item based on the frequency of recent occurrence reported by each patient (rarely or none of the time, some or little of the time, a moderate amount of the time, or most of the time). Each item based on a negative statement (ie, reflecting depression) is scored on a 4-point scale, with 3 points assigned to "most of the time" responses and no points assigned to "rarely or none of the time." Reversed scoring is used for items based on positive statements not associated with depression. Thus, MZDI scores may range from 0 to 69, with higher scores indicating a greater risk of depression. The cut point for depression is an MZDI score of 34 or higher.

The Modified Somatic Perception Questionnaire

The MSPQ was administered prior to randomization and consists of 13 items reflecting heightened autonomic or somatic awareness.⁵ Such dysregulation may also be termed "somatic anxiety" or "somatization." There are 4 possible responses for each item based on the frequency of occurrence during the past week reported by each patient (not at all; a little, slightly; a great deal, quite a bit; or extremely, could not have been worse). Each item is scored on a 4-point scale with 3 points assigned to "extremely, could not have been worse" responses, and no points assigned to "not at all." Thus, MSPQ scores may range from 0 to 39, with higher scores indicating a greater risk of somatization. The cut point for somatization is an MSPQ score of 12 or higher.

The Distress and Risk Assessment Method

The DRAM was administered prior to randomization and is recommended as a screening procedure to predict treatment outcome, particularly in patients with LBP of nonspecific etiology.⁵ Four group classifications emerged from cluster analysis based on early use and validation of the DRAM⁵: (1) "normal," MZDI score less than 17; (2) "at risk," MZDI score ranging from 17 to 33 and MSPQ score less than 12; (3) "distressed—somatic," MZDI score ranging from 17 to 33 and MSPQ score of 12 or higher; and (4) "distressed-depressed," MZDI score of 34 or higher. In this classification scheme, the MSPQ is only used to stratify patients into either the at-risk group or the distressedsomatic subgroup. Nevertheless, a clear clinical differentiation of the distressed subgroups was not apparent, and they are often combined to achieve greater statistical power in analytic studies.

Somatic Dysfunction

The methodology for the osteopathic structural examination that was performed prior to randomization has been pre-

viously described.6 The musculoskeletal table of the Outpatient Osteopathic SOAP Note Form7 was used to record the severity of somatic dysfunction based on TART criteria (ie, tissue texture abnormality, asymmetry, restriction of motion, and tenderness). The severity scale consisted of 4 levels, including the following descriptors: none (no somatic dysfunction or background level); mild (more than background level; minor TART elements); moderate (obvious TART elements; in particular, restriction of motion and/or tissue texture abnormality, with or without symptoms); and severe (key lesion present; significant; symptomatic; restriction of motion and/or tissue texture abnormality stands out with minimum search or provocation).7 We focused on the severity of somatic dysfunction in the following anatomical regions: thoracic (T) 10-12; ribs; lumbar; sacrum/pelvis; and pelvis/innominate.

Measures of Low Back Pain, Back-Specific Functioning, and General Health

The OSTEOPATHIC Trial measured LBP severity at baseline and throughout the study with a 100-mm visual analog scale (VAS).⁸ Additionally, the Roland-Morris Disability Questionnaire (RMDQ)⁹ and the Medical Outcomes Study Short Form-36 Health Survey (SF-36)¹⁰ were administered to assess back-specific functioning and general health, respectively. The RMDQ includes 24 dichotomous items, with each scored as 0 or 1. Higher scores on the RMDQ indicate greater disability. The SF-36 includes 36 survey items that are scored according to established algorithms to provide scores ranging from 0 (worst) to 100 (best) for each of 8 health-related scales. The general health scale, which is based on a subset of these survey items, was used as a generic measure of health.

Statistical Analysis

The baseline characteristics of patients were summarized using descriptive statistics. None of the variables relating to depression, somatization, somatic dysfunction, LBP severity, back-specific functioning, or general health was normally distributed. Consequently, we relied on nonparametric methods for analysis of the study data. We dichotomized the severity of somatic dysfunction by combining the 3 lowest levels (none, mild, and obvious) in contrast with the highest level (severe), which represented the presence of a clinically significant, key lesion. These key lesions are important because they maintain a dysfunctional pattern that includes other secondary dysfunctions.¹¹ The Spearman rank correlation coefficient (ρ) was initially used to assess correlations among the variables of interest. We subsequently used χ^2 analyses to further study the relationships of self-reported depression, the trichotomized MZDI score (<17, 17 to 33, and \geq 34), the dichotomized MSPQ score (<12, ≥12), and the tri-

chotomized DRAM classification (normal, at risk, distressed) with the severity of somatic dysfunction, as indicated by the number of key osteopathic lesions found in the 5 anatomical regions of interest (trichotomized as 0, 1, or \geq 2). Finally, we studied the relationships of MZDI and MSPQ scores with LBP severity, back-specific functioning, and general health using scatter plots, with linear regression best-fit lines and corresponding R^2 values. Database management and analyses were performed with the SPSS Statistics version 20 software package (IBM Corporation, Armonk, New York). Hypothesis testing was conducted at the .05 level of statistical significance.

Results

Baseline Patient Characteristics

The baseline characteristics of the 202 patients are presented in *Table 1*. The median age was 38 years, and 120 patients (59%) were women. A total of 97 patients (48%) reported having LBP for more than 1 year. Relatively few patients had been hospitalized or had surgery for LBP. Depression was self-reported by 53 patients (26%). A total of 44 patients (22%) were classified as having depression and 38 patients (19%) were classified as having somatization on the basis of the MZDI and MSPQ cut points, respectively. About one-third of patients were each classified as normal, at risk, or distressed using the DRAM. Key osteopathic lesions were present in 159 patients (79%).

Correlations Among Study Factors

The correlations among relevant study factors are presented in *Table 2*. There were highly significant correlations among self-reported depression and the MZDI and MSPQ scores (P<.001 for each of these 3 pairwise correlations). Similarly, the MZDI and MSPQ scores were both strongly correlated with LBP severity and back-specific disability, and they were inversely correlated with general health (P<.001 for each of these 6 pairwise correlations). Self-reported depression and the number of key osteopathic lesions were also both strongly correlated with back-specific disability and inversely correlated with general health (P<.001 for each of these 4 pairwise correlations). The MZDI (P=.006) and MSPQ (P=.004) scores were also correlated with the number of key osteopathic lesions. The duration of chronic LBP was least strongly correlated with the other factors.

Associations of Psychological Factors With Somatic Dysfunction

The associations between psychological factors (self-reported depression, trichotomized MZDI and dichotomized MSPQ scores, and DRAM classification) and somatic dysfunction are presented in *Figure 2*. Both the trichotomized MZDI scores (P=.002) and DRAM classifications (P=.002) were significantly associated with the number of key osteo-

Table 1. Baseline Patient Characteristics						
Characteristic, No. (%)ª	Total (n=202)					
Age, median (IQR), y	38 (22)					
Women	120 (59)					
Completed College Education	84 (42)					
Employed Full Time	79 (39)					
Medically Uninsured	76 (38)					
Current Smokers	53 (26)					
Duration of Chronic LBP >1 y	97 (48)					
Previously Hospitalized for LBP	12 (6)					
Previously Had Surgical Procedure for LBP	2 (1)					
Comorbid Depression	53 (26)					
Modified Zung Depression Index Score, median (IQR) ^b	21 (20)					
Modified Somatic Perception Questionnaire Score, median (IQR) ^c	5 (8)					
DRAM Classification						
Normal	74 (37)					
At risk	68 (34)					
Distressed	60 (30)					
Key Osteopathic Lesions						
0	43 (21)					
1	84 (42)					
≥2	75 (37)					
VAS Score for LBP, median (IQR), mm ^d	48 (32)					
Roland-Morris Disability Score, median (IQR) ^e	5 (7)					
SF-36 General Health Score, median (IQR) ^f	72 (26)					

^a Data presented as No. (%) unless otherwise noted.

^b The Modified Zung Depression Index score (0 to 69 points) was used to screen for depression, with higher scores more strongly associated with depression.

- ^c The Modified Somatic Perception Questionnaire score was used to screen for somatization, with higher scores more strongly associated with somatization.
- ^d A visual analog scale (VAS) (0 to 100 mm) was used to measure low back pain (LBP), with higher scores indicating greater pain severity.
- ^e The Roland-Morris Disability Questionnaire (0 to 24 points) was used to measure back-specific functioning, with higher scores indicating greater disability.
- ^f The Medical Outcomes Study Short Form-36 Health Survey (SF-36) general health scale (0 to 100 points) was used to measure general health, with higher scores indicating better health.

Abbreviations: DRAM, Distress and Risk Assessment Method; IQR, interquartile range.

pathic lesions. Contingency subtable analyses revealed that the MZDI findings were attributable to significant differences between patients having MZDI scores lower than 17 and patients having MZDI scores of 17 to 33 (P<.001). Similarly, the DRAM findings were attributable to significant differences between patients classified as "normal" and patients classified as "at risk" (P<.001). Neither self-reported depression nor the dichotomized MSPQ scores

Table 2. Correlations Among Depression, Somatization, Somatic Dysfunction, and Clinical Measures at Baseline ^a									
Variable	Self-Reported Depression	MZDI Score ^b	MSPQ Score ^c	No. of Key Osteopathic Lesions	Duration of Chronic LBP	VAS Score for LBP ^d	RMDQ Score ^e	SF-36 General Health Scale Score ^f	
Self-reported depression	(0.31 (<.001)	0.32 (<.001)	0.09 (.18)	0.17 (.02)	0.21 (.003)	0.39 (<.001)	-0.27 (<.001)	
MZDI score			0.52 (<.001)	0.19 (.006)	0.16 (.02)	0.25 (<.001)	0.45 (<.001)	-0.52 (<.001)	
MSPQ score				0.20 (.004)	0.18 (.01)	0.29 (<.001)	0.52 (<.001)	-0.50 (<.001)	
No. of key osteopathic lesions					0.22 (.002)	0.20 (.004)	0.32 (<.001)	-0.23 (.001)	
Duration of chronic LBP						0.16 (.02)	0.18 (.01)	-0.05 (.47)	
VAS score for LBP							0.46 (<.001)	-0.26 (<.001)	
RMDQ score								-0.51 (<.001)	
SF-36 general health scale score									

^a Table entries represent the Spearman rank correlation coefficient (P value).

^b Higher scores on the Modified Zung Depression Index (MZDI) indicate greater risk of depression.

^c Higher scores on the Modified Somatic Perception Questionnaire (MSPQ) indicate greater risk of somatization.

^d Higher scores on the visual analog scale (VAS) indicate greater LBP severity.

^e Higher scores on the Roland-Morris Disability Questionnaire (RMDQ) indicate greater back-specific disability.

^f Higher scores on the Medical Outcomes Study Short Form-36 Health Survey (SF-36) general health scale indicate better health.

Abbreviation: LBP, low back pain.

were significantly associated with the number of key osteopathic lesions.

Association of MZDI Scores With Low Back Pain Severity, Back-Specific Functioning, and General Health

Scores on the MZDI were significantly associated with the VAS pain, RMDQ, and SF-36 general health scale scores (P<.001 for each association). Overall, as shown in *Figure 3*, LBP severity increased, and back-specific functioning and general health deteriorated, with increasing MZDI scores. The MZDI scores best explained the variance in general health (R^2 , 0.25). However, among patients in the distressed classification, the MZDI scores explained very little of the variance in LBP severity (R^2 , 0.00), back-specific functioning (R^2 , 0.00), or general health (R^2 , 0.00).

Association of MSPQ Scores With Low Back Pain Severity, Back-Specific Functioning, and General Health

As with the MZDI, scores on the MSPQ were statistically associated with the VAS pain, RMDQ, and SF-36 general health scale scores (P<.001 for each association). Similarly, as shown in *Figure 4*, LBP severity increased and backspecific functioning and general health deteriorated with increasing MSPQ scores. However, the MSPQ scores best explained the variance in back-specific functioning (R^2 , 0.31). Also, among patients in the distressed classification, the MSPQ scores were a better explanatory factor than the MZDI scores for the variance in LBP severity (R^2 , 0.13), back-specific functioning (R^2 , 0.38), and general health (R^2 , 0.12).

Comment

Depression and somatization have been implicated in the transition from acute to chronic LBP,¹² and also appear to be influential in the development of disability in patients with LBP.¹³ The occurrence of depression and somatization in our patients was similar to that previously observed in patients with chronic LBP,¹⁴⁻¹⁶ and greater than that of general population controls.^{14,15} The correlations among depression, somatization, and pain duration and ratings in our study were also similar to those previously reported in chronic LBP patients.¹⁶

Patients with pain or depression frequently exhibit common clinical features, suggesting that they may share some aspects of pathophysiology represented by common pathways and neurotransmitters.¹⁷ Three cytokines—interleukin (IL)-1 β , IL-6, and tumor necrosis factor (TNF)- α — have been characterized as typical pro-inflammatory cytokines that are central to clinical manifestations of the "sickness response."¹⁸ The latter subsumes both pain and depression. It is hypothesized that the normal, adaptive mechanisms of the sickness response are altered over time

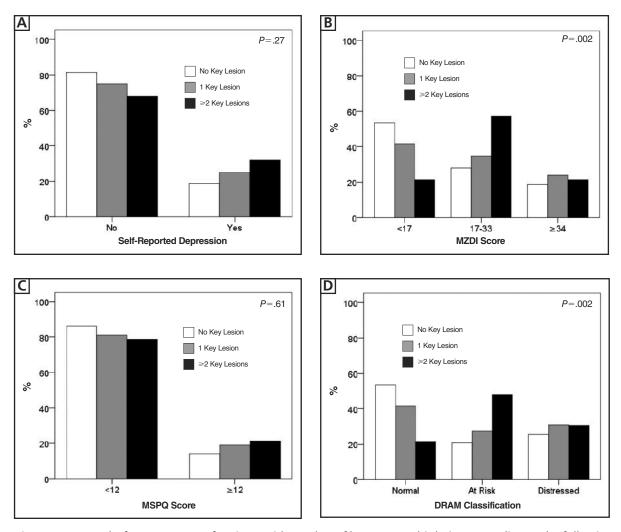
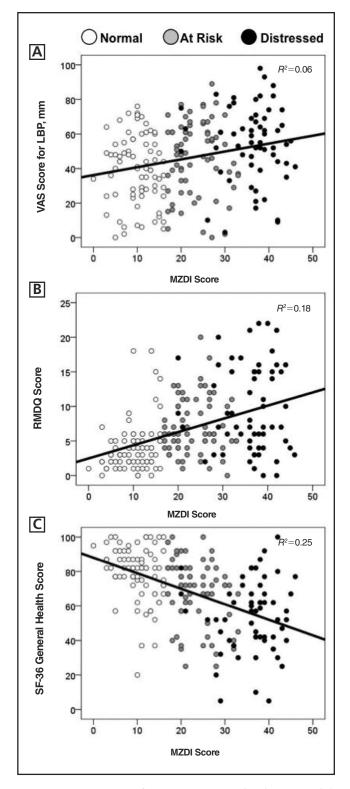


Figure 2. Bar graphs for percentage of patients with number of key osteopathic lesions according to the following psychological factors: self-reported depression (A), Modified Zung Depression Index (MZDI) score (B), Modified Somatic Perception Questionnaire (MSPQ) score (C), and Distress and Risk Assessment Method (DRAM) classification (D). For each graph, n=202.

in chronic conditions, such that signaling is no longer providing contextually appropriate information. Interventions that attenuate this cascade of cellular events initiated by pro-inflammatory cytokines may prove helpful in preventing or managing pathological depression and chronic pain.¹⁸ A recent study found no differences in TNF- α serum concentrations between chronic LBP patients with and without depression, although both groups of patients had significantly higher TNF- α concentrations than healthy controls.¹⁷ On the basis of these and previous results, the study authors concluded that TNF- α acts as a mediator, by similar mechanisms, in both chronic LBP and depression. These findings may have potentially important clinical implications, as TNF- α concentrations decreased significantly after 12 weeks in patients with chronic LBP in response to a 6-session regimen of OMT.¹⁹

Recently, there has been a greater recognition of the role that "central sensitization" plays in patients with musculoskeletal pain.²⁰ As distinct from nociceptive or peripheral neuropathic pain, central sensitization refers specifically to neurophysiological processes occurring at a cellular level throughout a widely distributed central nervous system.²¹ Aside from altered processing in the brain, there are also "bottom-up" mechanisms involved in the pathophysiology of central sensitization. For example, peripheral injury and other forms of stressors may trigger the release of pro-inflammatory cytokines, thereby activating spinal cord glia with cyclooxygenase-2 and prostaglandin E2



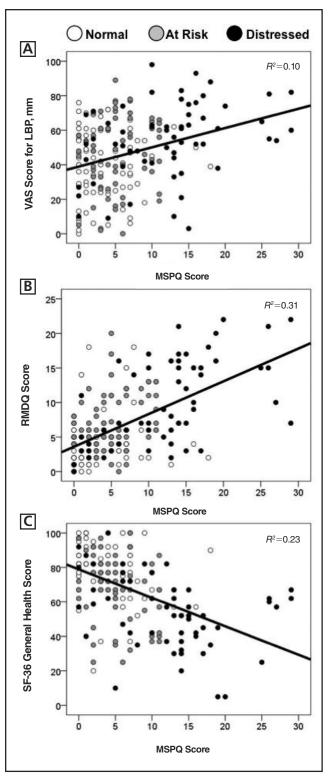


Figure 3. Scatter plots for low back pain (LBP) severity (A), back-specific functioning (B), and general health (C) vs the Modified Zung Depression Index (MZDI) score. For each plot, n=202 and P<.001. Abbreviations: RMDQ, Roland-Morris Disability Questionnaire; SF-36, Medical Outcomes Study Short Form-36 Health Survey; VAS, visual analog scale.

Figure 4. Scatter plots for low back pain (LBP) severity (A), back-specific functioning (B), and general health (C) vs the Modified Somatic Perception Questionnaire (MSPQ) score. For each plot, n=202 and P<.001. Abbreviations: RMDQ, Roland-Morris Disability Questionnaire; SF-36, Medical Outcomes Study Short Form-36 Health Survey; VAS, visual analog scale.

expression in the central nervous system.²⁰ Interestingly, we have also found statistical associations between IL-1β and IL-6 serum concentrations and the severity of somatic dysfunction, as manifested by the number of key osteopathic lesions, in patients with chronic LBP.¹⁹ Nevertheless, on the basis of self-reported LBP severity, disability, health status, depression, and anxiety, central sensitization has been classified as the mechanism for LBP in less than one-fourth of patients, as compared with nociception in more than one-half of patients.²² Similarly, using the same discriminant validity classification scheme,²² the baseline scores for VAS pain, RMDQ, SF-36 general health, work status, and LBP chronicity of our patients were consistent with a predominant nociceptive mechanism of pain.

To our knowledge, the present study is the first to find empirical evidence suggesting a statistical correlation between depression and somatization, as measured by MZDI and MSPQ scores, and the severity of somatic dysfunction as determined by the number of key osteopathic lesions in the T10-12, ribs, lumbar, sacrum/pelvis, and pelvis/innominate anatomical regions. Further analyses of these results, using cut points based on the DRAM classification system, found the strongest association with number of key osteopathic lesions among patients having MZDI scores from 17 to 33 and among those classified by the DRAM as "at risk." There was no significant association with the number of key osteopathic lesions in patients with self-reported depression, nor in the subgroups of patients with high MZDI scores (≥34), high MPSQ scores (≥ 12) , or a classification of "distressed" on the DRAM. Future analyses of these baseline measures, coupled with longitudinal assessments of depression and somatization and the OSTEOPATHIC Trial outcomes, may provide more insight on the utility of OMT in the treatment of patients with chronic LBP.

There are potential limitations of our study. First, as indicated above, self-reported depression generally was not subjected to corroboration by medical records. Thus, there may have been some misclassification of depression on the basis of self-reports of patients. Nevertheless, the self-reporting of depression in our study was comparable to that reported in other studies of patients with chronic LBP, and we also observed a significant correlation between self-reported depression and MZDI scores in our study. Second, it is possible that some significant findings may represent type I errors because of multiple comparisons, particularly in our correlational analyses. However, because this was an exploratory study, we elected not to adjust for multiple comparisons. Third, there may have been interexaminer variability in diagnosing somatic dysfunction using the musculoskeletal table of the Outpatient Osteopathic SOAP Note Form,7 particularly in distinguishing between "obvious" TART elements (severity defined as "moderate"

and not considered key lesions) and key lesions that "stand out" (severity defined as "severe"). Although we provided fidelity training for OMT providers during the study,²³ we did not formally assess provider performance or interexaminer reliability.

Conclusion

The associations among depression, somatization, and LBP in this study are consistent with the findings of previous studies. We also found that MZDI and MSPQ scores are correlated with somatic dysfunction as determined by the number of key osteopathic lesions. Together, these findings may have important implications for the management of chronic LBP with OMT. Future analyses based on the OSTEOPATHIC Trial outcomes may provide more insight on the utility of OMT in patients with chronic LBP.

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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.

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