Recovery From Chronic Low Back Pain After Osteopathic Manipulative Treatment: A Randomized Controlled Trial

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Financial Disclosures: Dr Gatchel has served as a consultant for the Productive Rehabilitation Institute of Dallas for Ergonomics in Texas; Palladian Health, LLC, in Buffalo, New York; and West Coast Spine Restoration Center in Riverside, California.

Support: This study was partially funded by the National Institutes of Health (K24-AT002422) and the Osteopathic Heritage Foundations.

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Submitted October 12, 2015; revision received November 24, 2015; accepted December 21, 2015.

Context: Little is known about recovery after spinal manipulation in patients with low back pain (LBP).

Objective: To assess recovery from chronic LBP after a short regimen of osteopathic manipulative treatment (OMT) in a responder analysis of the OSTEOPAThic Health outcomes In Chronic low back pain (OSTEOPATHIC) Trial.

Methods: A randomized double-blind, sham-controlled trial was conducted to determine the efficacy of 6 OMT sessions over 8 weeks. Recovery was assessed at week 12 using a composite measure of pain recovery (10 mm or less on a 100-mm visual analog scale) and functional recovery (2 or less on the Roland-Morris Disability Questionnaire for back-specific functioning). The RRs and numbers-needed-to-treat (NNTs) for recovery with OMT were measured, and corresponding cumulative distribution functions were plotted according to baseline LBP intensity and back-specific functioning. Multiple logistic regression was used to compute the OR for recovery with OMT while simultaneously controlling for potential confounders. Sensitivity analyses were performed to corroborate the primary results.

Results: There were 345 patients who met neither of the recovery criteria at baseline in the primary analyses and 433 patients who met neither or only 1 of these criteria in the sensitivity analyses. There was a large treatment effect for recovery with OMT (RR, 2.36; 95% CI, 1.31-4.24; P=.003), which was associated with a clinically relevant NNT (8.9; 95% CI, 5.4-25.5). This significant finding persisted after adjustment for potential confounders (OR, 2.92; 95% CI, 1.43-5.97; P=.003). There was also a significant interaction effect between OMT and comorbid depression (P=.02), indicating that patients without depression were more likely to recover from chronic LBP with OMT (RR, 3.21; 95% CI, 1.59-6.50; P<.001) (NNT, 6.5; 95% CI, 4.2-14.5). The cumulative distribution functions demonstrated optimal RR and NNT responses in patients with moderate to severe levels of LBP intensity and back-specific dysfunction at baseline. Similar results were observed in the sensitivity analyses.

Conclusions: The OMT regimen was associated with significant and clinically relevant measures for recovery from chronic LBP. A trial of OMT may be useful before progressing to other more costly or invasive interventions in the medical management of patients with chronic LBP. (ClinicalTrials.gov number NCT00315120)

J Am Osteopath Assoc. 2016;116(3):144-155
doi:10.7556/jaoa.2016.031

A video presentation of this study's findings is available online.

Low back pain (LBP) affects an estimated 632 million people worldwide and is the leading cause of disability.[1] Measures of LBP intensity and back-specific functioning are frequently used to assess trajectories of LBP,[2,3] and they are the 2 core outcomes important to researchers, health care professionals, and patients alike.[4] The concept of recovery from LBP varies substantially from person to person, and researchers often disagree on such basic questions as whether to have a common recovery measure for acute and chronic LBP.[5] Nevertheless, empirical data support the use of absolute pain thresholds, below which patients may be considered to be recovered from LBP.[6]

Little is known about recovery after osteopathic manipulative treatment (OMT) despite its common use in patients with LBP.[7] The OSTEOPAThic Health outcomes In Chronic low back pain (OSTEOPATHIC) Trial is the largest single-site efficacy trial of spinal manipulation for chronic LBP, as evidenced by a comparison with 26 trials included in a Cochrane Review.[8] In that trial, 145 patients (63%) who received OMT vs 103 patients (46%) who received sham OMT reported a minimally important change in LBP, and 114 OMT patients (50%) vs 79 sham OMT patients (35%) reported substantial improvement.[9] We report herein the recovery outcomes of patients who received OMT in the OSTEOPATHIC Trial based on a composite measure of LBP intensity and back-specific functioning and present the corresponding cumulative distribution functions as recently recommended by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain.[10]

Methods

Study Design

The methodology and results of the OSTEOPATHIC Trial have been previously reported.[9,11,12] The study was conducted at The Osteopathic Research Center at the University of North Texas Health Science Center Texas College of Osteopathic Medicine in Fort Worth, approved by the institutional review board at the University of North Texas Health Science Center, and overseen by an independent data and safety monitoring board. The trial was registered with ClinicalTrials.gov (NCT00315120).

Patients were randomly allocated by computer-generated pseudorandom numbers to OMT or sham OMT within a 2×2 factorial design. The second factor studied was ultrasound therapy, which was found to be nonefficacious and to not have statistical interaction with OMT. Randomization in blocks of 24 was used to achieve a balanced number of patients in the OMT and sham OMT groups. Patient assignments were conveyed directly to the OMT and sham OMT providers before the first treatment session using consecutively numbered and sealed envelopes. Patients and members of the research staff who enrolled patients or collected data were blinded to treatment assignments. The OMT package[9] was delivered during 15-minute sessions provided by osteopathic physicians, fellows, or residents at weeks 0, 1, 2, 4, 6, and 8, and outcomes were assessed at week 12. Sham OMT involved hand contact, active and passive range of motion, and techniques that simulated OMT but used such maneuvers as light touch, improper patient positioning, purposely misdirected movements, and diminished force by the treatment provider.[9]

Patient-Reported Recovery Measures

Recovery from chronic LBP was determined by a composite measure based on outcomes measured with a 100-mm visual analog scale (VAS) for LBP intensity and the Roland-Morris Disability Questionnaire (RMDQ) for back-specific functioning.[13] The dual criteria for recovery were a VAS score of 10 mm or less and an RMDQ score of 2 or less at week 12. These were selected because of their utility in discriminating between patients who considered themselves recovered or not recovered from LBP.[6] These criteria are also consistent with the finding that few patients require complete pain resolution or restoration of functioning to consider themselves recovered from LBP.[5]

Safety Monitoring

An independent safety officer reviewed and adjudicated all reported adverse events. Serious adverse events were defined as deaths, life-threatening situations, hospitalizations, severe or permanent disability, or other important medical events.

Statistical Analysis

The original trial sample size was conditioned upon analysis of pre- to posttreatment differences between groups on the VAS for LBP intensity. Data were summarized as median (interquartile range [IQR]) for continuous variables, and groups were compared using the Mann-Whitney test. The number (%) were used to summarize categorical variables, and groups were compared using contingency table methods, including RRs and 95% CIs. The clinical relevance of RRs was assessed using guidelines established by the Cochrane Back Review Group[14]: RR<1, negative effect or harm; 1≤RR<1.25, small effect; 1.25≤RR≤2, medium effect; and RR>2, large effect. The numbers-needed-to-treat (NNTs) were computed as the reciprocal of the absolute difference in proportion of patients reporting recovery with OMT relative to sham OMT, and 95% CIs were computed using the Wilson score method.[15] We considered NNTs less than 10 to represent clinically relevant treatment effects based on a systematic review of clinical trials involving oral analgesics.[16]

We estimated and plotted cumulative distribution functions for RRs and NNTs for recovery with OMT. Undefined values of RRs or NNTs attributable to small cell sizes and division by 0 at the lower ends of the cumulative distribution functions were imputed using the first defined data point. Numbers-needed-to-treat in excess of 100 or having negative values were assigned a value of 100 (ie, minimal treatment effect). The cumulative distribution function plots were smoothed by using the moving average of RRs over successive 10-mm intervals of baseline VAS scores and 3-point intervals of baseline RMDQ scores. Such smoothing has the advantage of more effectively displaying general trends in the data rather than simply identifying the maxima and minima for RRs and NNTs, respectively.

We used multiple logistic regression[17] to compute ORs and 95% CIs for recovery with OMT, while controlling for patient demographic and LBP characteristics, general health and comorbid depression at baseline, concurrent medication use for LBP, and adverse events during the trial. Sensitivity analyses were performed to assess the potential impact of excluding 110 randomized patients in the primary analyses because they met at least 1 of the dual recovery criteria at baseline. In the sensitivity analyses, 22 randomized patients who met both of the dual recovery criteria were excluded, thereby leaving a sample of 433 (95%) of the originally randomized patients for analysis. All analyses were based on intention to treat, with missing data imputed using the last observation carried forward. Data were analyzed with SPSS software (version 21; IBM), and Microsoft Excel 2010 (Microsoft Corporation) was used to plot cumulative distribution functions.

Results

Baseline Patient Characteristics and Flow Through the Trial

We assessed 1161 patients for eligibility, and 455 men and women aged 21 to 69 years with nonspecific chronic LBP of at least 3 months duration were enrolled between August 2006 and January 2011 to participate in this double-blind, sham-controlled trial in the Dallas-Fort Worth metroplex. Of the 455 randomized patients, 230 (51%) were assigned to the OMT group and 225 (49%) were assigned to the sham OMT group. The primary analyses conducted herein included 345 of 455 randomized patients (76%) who met neither of the dual recovery criteria at baseline (ie, baseline VAS scores were greater than 10 mm and RMDQ scores were greater than 2). The median age of 345 patients in the primary

analyses was 42 (IQR, 31-52) years and 225 (65%) were women. Median baseline scores were 50 (IQR, 34-64) mm on the VAS for LBP intensity and 6 (IQR, 4-11) on the RMDQ for back-specific functioning. The baseline characteristics of patients in each treatment group were generally comparable (*Table 1*). Overall, 14 patients (4%) discontinued treatment and another 26 (8%) were lost to follow-up. A total of 271 (79%) attended all 6 treatment sessions and the week-12 exit visit. Follow-up and treatment adherence measures were similar for patients in each treatment group (*Figure 1*).

Primary Analyses

The median (IQR) reduction in the VAS score for LBP intensity over 12 weeks was 20 (2-36) mm in the OMT group vs 12 (–5 to 25) mm in the sham OMT group (*P*=.002). The median (IQR) reduction in the RMDQ score for back-specific dysfunction was 2 (0-5) in the OMT group vs 2 (0-4) in the sham OMT group (*P*=.66). A total of 34 patients in the OMT group (19%) met the dual recovery criteria vs 14 in the sham OMT group (8%) (RR, 2.36; 95% CI, 1.31-4.24; *P*=.003). This composite recovery finding was consistent with a large treatment effect with OMT. The maximum RR for recovery with OMT was observed in patients with baseline VAS scores of 41 mm or less (RR, 2.95; 95% CI, 1.36-6.41; *P*=.003). Correspondingly, for back-specific functioning, the maximum RR for recovery was observed in patients with baseline RMDQ scores of 6 or less (RR, 2.57; 95% CI, 1.32-5.01; *P*=.003). However, the cumulative distribution function plots for RRs for recovery with OMT indicate that large treatment effects were observed in 221 patients (64%) with baseline VAS scores of 40 mm or greater and in 170 patients (49%) with RMDQ scores of 6 or greater (*Figure 2*). There was substantially greater variability in RR response with the baseline VAS score than with the RMDQ score.

The overall NNT for recovery with OMT was 8.9 (95% CI, 5.4-25.5). The NNT minima for recovery were observed in the same patient subgroup that generated the RR maxima (ie, those with baseline VAS scores of 41 mm or less and RMDQ scores of 6 or less). The corresponding NNTs for these patients were 4.5 (95% CI, 2.8-12.9) and 5.5 (95% CI, 3.4-16.4), respectively. The cumulative distribution function plots for recovery with OMT show that clinically relevant NNTs were observed in 273 patients (79%) with baseline VAS scores of 30 or greater, and in 245 patients (71%) with RMDQ scores of 4 or greater (*Figure 3*). As with RRs, there was greater variability in NNT response with the baseline VAS score than with the RMDQ score, particularly at the lower end of the cumulative baseline LBP intensity distribution.

Multivariate Analyses

Baseline pain intensity was inversely associated with recovery from chronic LBP in the multiple logistic regression model that simultaneously adjusted for other variables (*Table 2*). The OR for each incremental millimeter on the VAS for LBP intensity was 0.96 (95% CI, 0.94-0.98; *P*<.001). Osteopathic manipulative treatment was the other variable associated with recovery in this multivariate regression model (OR, 2.92; 95% CI, 1.43-5.97; *P*=.003). Neither prescription nor nonprescription medication use for LBP during the trial was associated with recovery. There were also significant OMT×age (*P*=.04) and OMT×comorbid depression (*P*=.02) interaction effects. Further analysis revealed that OMT was most efficacious in effecting a recovery from chronic LBP in the 50- to 69-year-old patient subgroup (RR, 7.50; 95% CI, 1.00-56.47; *P*=.03) (NNT, 6.9; 95% CI, 3.9-39.2) and in patients without comorbid depression (RR, 3.21; 95% CI, 1.59-6.50; *P*<.001) (NNT, 6.5; 95% CI, 4.2-14.5).

Harms

Thirteen patients (7%) in the OMT group and 10 (6%) in the sham OMT group had adverse events (*P*=.56). Correspondingly, there were 5 patients (3%) and 3 patients (2%), respectively, who had serious adverse

Table 1.
Baseline Characteristics of Patients With Chronic Low Back Pain[a]

	Primary Analysis (n=345)		Sensitivity Analysis (n=433)	
Characteristics	**OMT (n=175)**	**Sham OMT (n=170)**	**OMT (n=217)**	**Sham OMT (n=216)**
Age, y, Median (IQR)	43 (31-53)	41 (29-51)	42 (30-51)	41 (29-51)
Women	112 (64)	113 (67)	139 (64)	136 (63)
Employed Full Time	82 (47)	80 (47)	105 (48)	101 (47)
Current Smoker	52 (30)	49 (29)	60 (28)	57 (26)
Duration of LBP >1 Year	94 (54)	89 (52)	111 (51)	107 (50)
Previous Hospitalization or Surgery for LBP	16 (9)	9 (5)	16 (7)	10 (5)
LBP Intensity,[b] Median (IQR)	51 (32-64)	49 (37-61)	47 (28-62)	46 (30-60)
Back-Specific Dysfunction,[c] Median (IQR)	6 (4-11)	6 (4-11)	5 (3-9)	6 (3-10)
General Health,[d] Median (IQR)	67 (52-77)	67 (45-82)	67 (57-82)	72 (52-85)
Comorbid Medical Conditions				
Hypertension	39 (22)	21 (12)	40 (18)	28 (13)
Diabetes mellitus	17 (10)	12 (7)	17 (8)	15 (7)
Osteoarthritis	14 (8)	14 (8)	17 (8)	16 (7)
Depression	40 (23)	40 (24)	44 (20)	45 (21)

[a] Data are given as No. (%) unless otherwise noted. None of the differences between the osteopathic manipulative treatment (OMT) and sham OMT groups was statistically significant except that there was a greater prevalence of hypertension in the OMT group in the primary analysis (*P*=.01).
[b] The visual analog scale (VAS) is 100 mm, with 0 mm indicating no pain and 100 mm indicating worst possible pain.
[c] The Roland-Morris Disability Questionnaire (RMDQ) is a 24-point scale, with 0 indicating no disability and 24 indicating maximum disability.
[d] The Medical Outcomes Study Short Form-36 Health Survey is a 100-point scale, with 0 indicating worst possible health and 100 indicating best possible health.

Abbreviations: LBP, low back pain; IQR, interquartile range.

events (*P*=.72). The latter consisted exclusively of hospitalizations or other important medical events that were not causally related to study interventions. Adverse events were not associated with recovery after adjusting for potential confounders (*Table 2*).

Sensitivity Analyses

The median age of 433 patients in the sensitivity analyses was 41 (IQR, 29-51) years and 275 (64%) were women. Median baseline scores were 46 (IQR, 29-61) mm on the VAS for LBP intensity, and 6 (IQR, 3-10) on the RMDQ for back-specific functioning. The baseline characteristics (*Table 1*) and follow-up and treatment adherence measures (*Figure 1*) were similar for patients in each treatment group. The median (IQR) reduction in the VAS score for LBP intensity over 12 weeks was 20 (2-32) mm in the OMT group vs 10 (–3 to 25) mm in the sham OMT group (*P*=.001). The median (IQR) reduction in the RMDQ score for back-specific dysfunction was 2 (0-4) in the OMT group vs 2 (0-4) in the sham OMT group (*P*=.76). A total of 51 patients (24%) in the OMT group met the dual recovery criteria vs 29 (13%) in the sham OMT group (RR, 1.75; 95% CI, 1.16-2.65; *P*=.007). The RR maxima were observed in patients with baseline VAS scores of 67 mm or less (RR, 1.91; 95% CI, 1.25-2.93; *P*=.002) and with baseline RMDQ scores of 10 or less (RR, 1.79; 1.17-2.73; *P*=.006). The cumulative distribution functions for RRs for recovery with

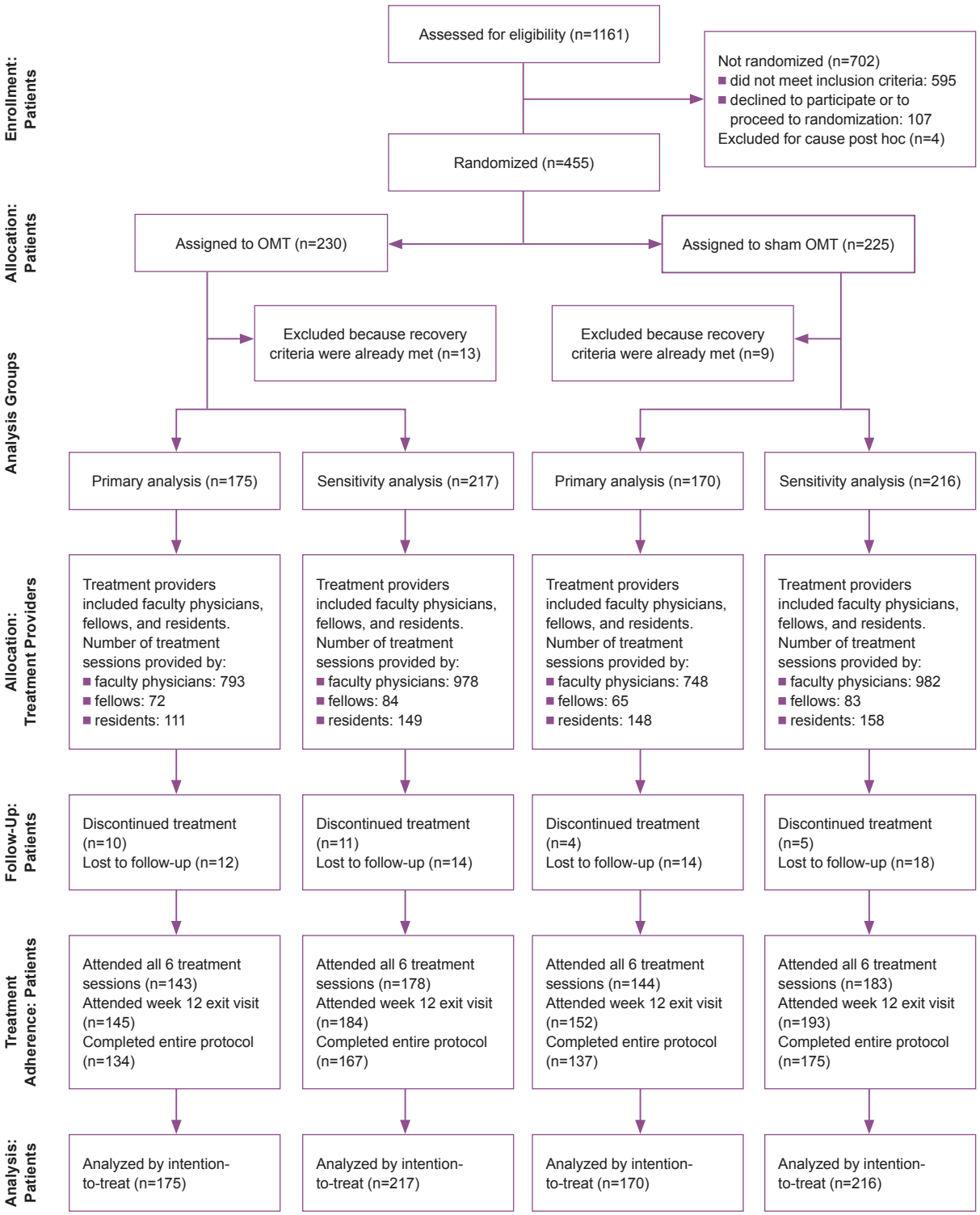

Figure 1.
Flow of patients through the OSTEOPAThic Health outcomes In Chronic low back pain (OSTEOPATHIC) Trial. *Abbreviation:* OMT, osteopathic manipulative treatment.

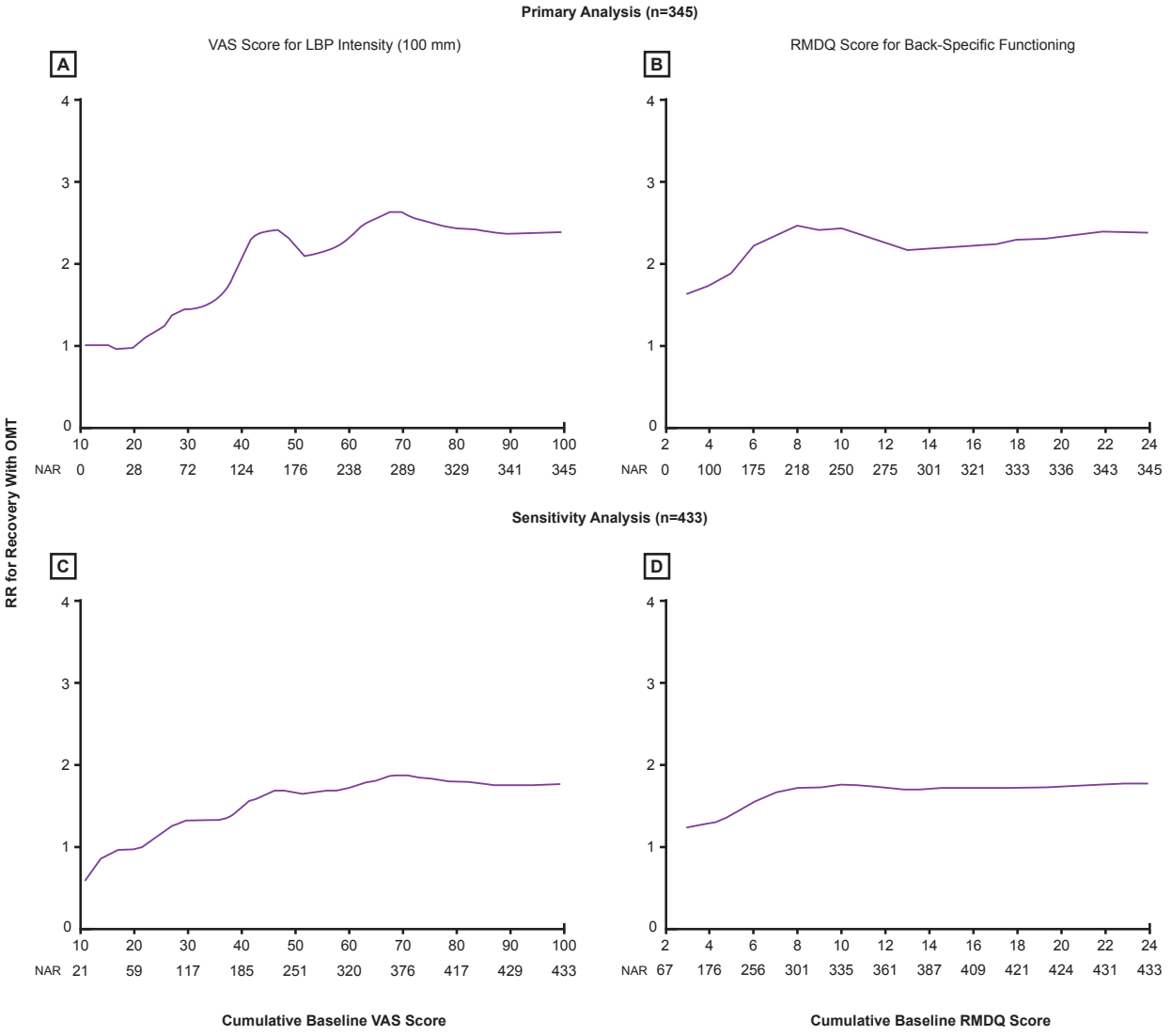

Figure 2.
Cumulative distribution functions for the RR for recovery with osteopathic manipulative treatment (OMT). Data are plotted as the RR for recovery in patients with cumulative baseline scores at or below the indicated level. Plots were smoothed by using the moving average of RRs over successive 10-mm intervals of baseline visual analog scale (VAS) scores and 3-point intervals of Roland-Morris Disability Questionnaire (RMDQ) scores. Primary analyses included patients with baseline VAS scores greater than 10 and RMDQ scores greater than 2. Sensitivity analyses included patients with baseline VAS scores greater than 10 or RMDQ scores greater than 2. The overall RRs (95% CIs) were 2.36 (1.31-4.24) in the primary analyses and 1.75 (1.16-2.65) in the sensitivity analyses. *Abbreviations*: LBP, low back pain; NAR, number at risk.

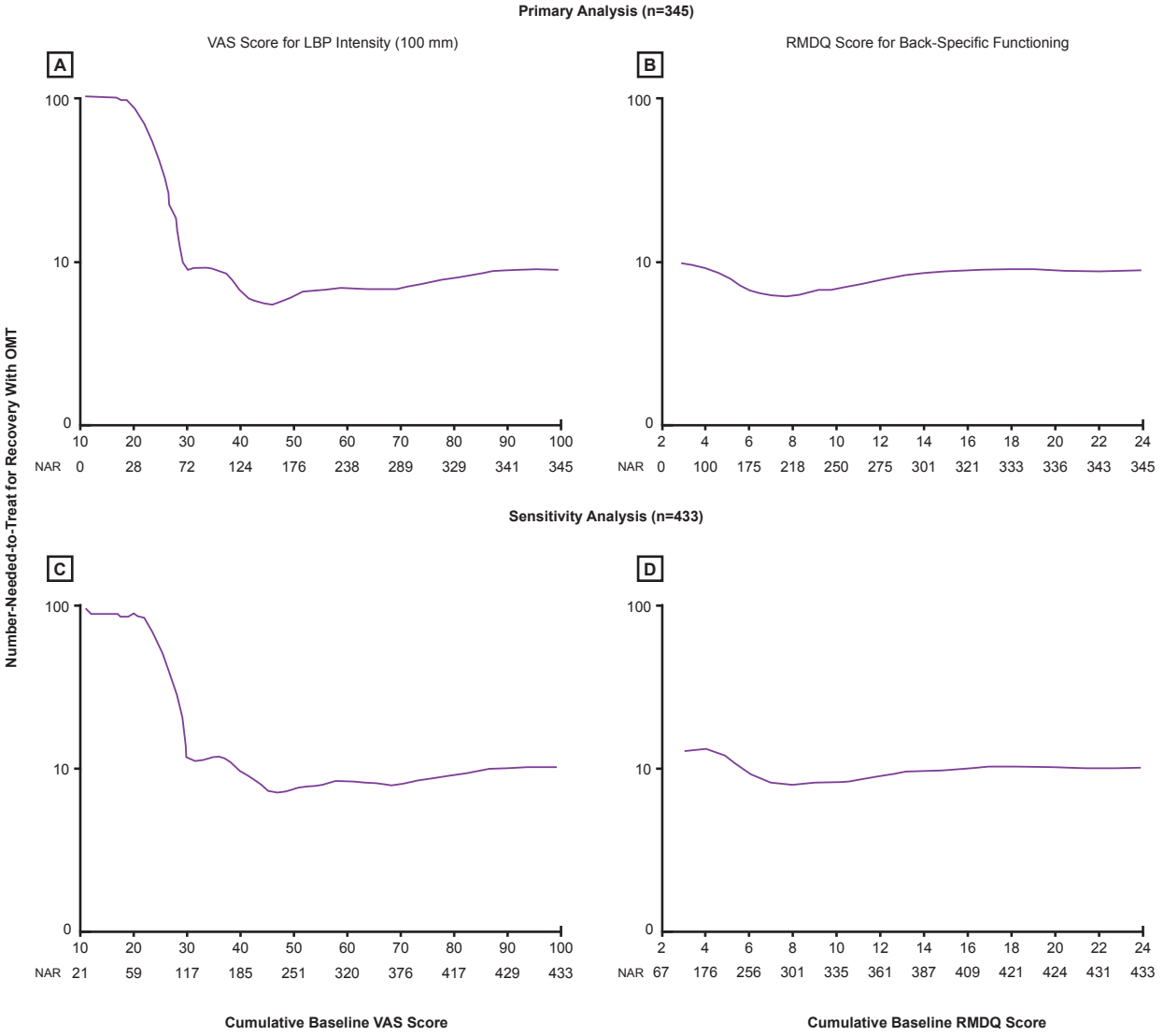

Figure 3.
Cumulative distribution functions for the number-needed-to-treat for recovery with osteopathic manipulative treatment (OMT). Data are plotted as the number-needed-to-treat for recovery in patients with cumulative baseline scores at or below the indicated level. Plots were smoothed by using the moving average of numbers-needed-to-treat over successive 10-mm intervals of baseline visual analog scale (VAS) scores and 3-point intervals of Roland-Morris Disability Questionnaire (RMDQ) scores. Primary analyses included patients with baseline VAS scores greater than 10 and RMDQ scores greater than 2. Sensitivity analyses included patients with baseline VAS scores greater than 10 or RMDQ scores greater than 2. The numbers-needed-to-treat (95% CIs) were 8.9 (5.4-25.5) in the primary analyses and 9.9 (5.8-36.2) in the sensitivity analyses. *Abbreviations*: LBP, low back pain; NAR, number at risk.

Table 2.
Multivariate Risk of Recovery From Chronic Low Back Pain

	Primary Analysis (n=345)			Sensitivity Analysis (n=433)		
Baseline Patient Characteristics[a]	**No. (%)[b]**	**OR[c] (95% CI)**	***P* Value**	**No. (%)[b]**	**OR[c] (95% CI)**	***P* Value**
Age, y						
21-34	21 (19.1)	1	…	37 (24.2)	1	…
35-49	16 (12.3)	0.81 (0.36-1.81)	.60	28 (17.7)	1.16 (0.61-2.20)	.65
50-69	11 (10.5)	0.69 (0.28-1.73)	.43	15 (12.3)	0.90 (0.42-1.94)	.79
Sex						
Men	19 (15.8)	1	…	38 (24.1)	1	…
Women	29 (12.9)	0.91 (0.44-1.89)	.80	42 (15.3)	0.60 (0.34-1.07)	.08
Current Smoker						
No	39 (16.0)	1	…	68 (21.5)	1	…
Yes	9 (8.9)	0.65 (0.28-1.53)	.33	12 (10.3)	0.44 (0.21-0.92)	.03
Duration of LBP >1 Year						
No	26 (16.0)	1	…	48 (22.3)	1	…
Yes	22 (12.0)	0.80 (0.40-1.57)	.51	32 (14.7)	0.73 (0.42-1.27)	.27
Previous Hospitalization or Surgery for LBP						
No	46 (14.4)	1	…	78 (19.2)	1	…
Yes	2 (8.0)	0.71 (0.14-3.71)	.69	2 (7.7)	0.51 (0.10-2.56)	.41
Comorbid Depression						
No	39 (14.7)	1	…	70 (20.3)	1	…
Yes	9 (11.3)	1.52 (0.61-3.75)	.37	10 (11.2)	1.30 (0.57-2.97)	.53
LBP Intensity	…	0.96 (0.94-0.98)	<.001	…	0.97 (0.96-0.99)	<.001
Back-Specific Functioning	…	0.91 (0.82-1.02)	.11	…	0.90 (0.82-0.98)	.01
General Health	…	1.01 (0.99-1.03)	.41	…	1.01 (1.00-1.03)	.17
OMT						
Sham	14 (8.2)	1	…	29 (13.4)	1	…
Active	34 (19.4)	2.92 (1.43-5.97)	.003	51 (23.5)	2.36 (1.35-4.14)	.003
Co-treatments for LBP During Trial						
Prescription medication						
No	43 (15.5)	1	…	74 (20.8)	1	…
Yes	5 (7.5)	0.64 (0.21-1.97)	.44	6 (7.8)	0.61 (0.22-1.66)	.33
Nonprescription medication						
No	28 (15.6)	1	…	52 (22.1)	1	…
Yes	20 (12.0)	0.67 (0.32-1.39)	.28	28 (14.1)	0.62 (0.34-1.11)	.11
Adverse Event Reported During Trial						
No	46 (14.3)	1	…	78 (19.2)	1	…
Yes	2 (8.7)	0.77 (0.15-3.99)	.76	2 (7.7)	0.47 (0.10-2.36)	.36

[a] The median (IQR) baseline values for recovered and nonrecovered patients, respectively, at week 12 in the primary analysis were 35 (22-47) vs 52 (37-65) on the visual analog scale for low back pain (LBP) intensity (*P*<.001); 5 (4-7) vs 7 (4-12) on the Roland Morris Disability Questionnaire (*P*<.001); and 75 (62-82) vs 67 (45-80) on the general health scale of the Medical Outcomes Study Short Form-36 Health Survey (*P*=.02). Similar findings were observed in the sensitivity analysis.

[b] The No. (%) represent those with the given characteristic among the 48 and 80 patients, respectively, who achieved recovery in the primary analysis and sensitivity analysis.

[c] The ORs are adjusted for each variable in the table. The ORs are for each 1-mm increment on the 100-mm visual analog scale and for each 1-unit increment on the Roland Morris Disability Questionnaire and general health scale of the Medical Outcomes Study Short Form-36 Health Survey.

Abbreviation: OMT, osteopathic manipulative treatment.

OMT exhibited less variability according to baseline scores for LBP intensity and back-specific functioning than did the corresponding plots in the primary analyses (*Figure 2*).

The overall NNT for recovery with OMT was 9.9 (95% CI, 5.8-36.2). The NNT minima were observed in patients with baseline VAS scores of 41 or less (NNT, 6.0; 95% CI, 3.4-26.3) and with baseline RMDQ scores of 6 or less (NNT, 7.1; 95% CI, 4.1-29.9). There were virtually no differences between the cumulative distribution function plots for NNTs for recovery with OMT derived from the primary and sensitivity analyses (*Figure 3*). The cumulative distribution function plots for recovery with OMT show that clinically relevant NNTs were observed in 248 patients (57%) with baseline VAS scores of 40 or greater and in 177 patients (41%) with RMDQ scores of 6 or greater.

In the multivariate analyses, the baseline VAS score (OR, 0.97; 95% CI, 0.96-0.99; $P<.001$), the RMDQ score (OR, 0.90; 95% CI, 0.82-0.98; $P=.01$), and cigarette smoking (OR, 0.44; 95% CI, 0.21-0.92; $P=.03$) were each inversely associated with recovery, whereas OMT was directly associated with recovery (OR, 2.36; 95% CI, 1.35-4.14; $P=.003$) (*Table 2*). There was an OMT×comorbid depression interaction effect comparable to that observed in the primary analyses. Harms of treatment were also comparable to those reported in the primary analyses.

Discussion

Our findings indicate that one-fifth to one-fourth of patients receiving OMT may experience improvements in both pain intensity and back-specific functioning consistent with recovery from chronic LBP. These findings represent a large treatment effect as defined by the Cochrane Back Review Group.[14] Multivariate analyses corroborated that OMT was independently associated with recovery after adjusting for potential confounders, thereby suggesting that our findings are relevant to a wide spectrum of patients with chronic LBP regardless of demography, baseline LBP and general health, and concurrent use of prescription and nonprescription medication for LBP. Patients with comorbid depression did not appear to experience a favorable recovery response to OMT in our study. Overall, our findings have important implications because chronic LBP is often refractory to conventional medical treatment, including invasive and costly interventions.[18]

The large and clinically relevant treatment effects for recovery from chronic LBP with OMT observed in the current study may have potentially enormous impact at the population level. Osteopathic manipulative treatment such as that provided by osteopathic physicians in this study is safe, particularly when integrated with the medical management of patients in the context of their history and physical findings.[19] The wisdom of restricting use of efficacious interventions, such as OMT in this study, to osteopathic physicians has been questioned.[20] Allopathic physicians represent an untapped resource in combating the large burden of suffering from LBP in the United States and may potentially integrate basic OMT techniques such as those used in the current study to treat patients with chronic LBP. Other studies[21,22] have described how allopathic family medicine physicians and internists have learned such basic maneuvers during an 18-hour course and subsequently reported greater confidence and skills in managing LBP. Perhaps the transition to a single accreditation system for graduate medical education in the United States affords an opportunity to promote interest and training in OMT among allopathic residents and physicians.[23]

To our knowledge, the current study is the first major trial to implement the recommendation of the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain to report cumulative distribution functions of responses in treatment and control groups.[10] We extended their recommendation by using RRs and NNTs as summary measures according to baseline levels of LBP intensity and

back-specific functioning, and we demonstrated the efficiency of such metrics in explaining recovery from chronic LBP. The simultaneous use of both measures, anchored by established guidelines for interpreting RRs,[14] may help define the clinical relevance of NNT outcomes in future trials. The cumulative distribution functions suggest that patients with baseline VAS scores of about 40 mm or greater on a 100-mm scale for LBP intensity may be targeted for optimal OMT response based on RRs, NNTs, and numbers at risk for recovery from chronic LBP. On the RMDQ, patients with baseline scores of 6 or greater may be targeted.

There are potential limitations to this study. The use of cumulative distribution functions to measure recovery was not specified when the trial was planned over a decade ago because such analytical methods were not used at that time. These analyses were undertaken in response to emerging criteria for recovery[6] and recent recommendations for reporting outcomes relating to chronic LBP.[10] Because we originally randomized patients representing the entire ranges of LBP intensity and back-specific functioning scores at baseline, we subsequently excluded 110 patients who met either recovery criterion at baseline from the primary analyses herein. Consequently, confounding variables may no longer have been distributed at random in the remaining 345 patients.[24] Nevertheless, the efficacy of OMT in effecting a recovery from chronic LBP persisted after adjusting for potential confounders and in the sensitivity analyses, which retained 433 patients. We used the last-observation-carried-forward method to impute missing data. Although more complex methods for data imputation have been previously used in the OSTEOPATHIC Trial, they have not yielded materially different results.[9,25] Finally, the data cannot be extrapolated to determine if the observed recovery rate with OMT would be diminished, maintained, or enhanced over a longer period of follow-up.

Conclusion

The management of LBP is discordant with published clinical practice guidelines.[26] Our OMT regimen of 6 sessions over 8 weeks is consistent with guidelines such as those established by the National Institute for Health and Care Excellence.[27] Our findings indicate that such an OMT regimen is more efficacious in treating and effecting a recovery from chronic LBP than reported in a Cochrane review of spinal manipulation.[8] By comparison, large increases in magnetic resonance imaging, epidural steroidal injections, and spinal surgery for chronic LBP have not improved patient outcomes or disability rates.[18] Thus, a trial of OMT may be useful before progressing to other more costly or invasive interventions in the medical management of patients with chronic LBP, particularly in patients with moderate to severe levels of pain intensity and back-specific dysfunction.

Author contributions

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