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Original article

Changes in biomechanical dysfunction and low back pain reduction with osteopathic manual treatment: Results from the OSTEOPATHIC Trial

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ABSTRACT

The purpose of this study was to measure changes in biomechanical dysfunction following osteopathic manual treatment (OMT) and to assess how such changes predict subsequent low back pain (LBP) outcomes. Secondary analyses were performed with data collected during the OSTEOPATHIC Trial wherein a randomized, double-blind, sham-controlled, 2 × 2 factorial design was used to study OMT for chronic LBP. At baseline, prevalence rates of non-neutral lumbar dysfunction, pubic shear, innominate shear, restricted sacral nutation, and psoas syndrome were determined in 230 patients who received OMT. Five OMT sessions were provided at weeks 0, 1, 2, 4, and 6, and the prevalence of each biomechanical dysfunction was again measured at week 8 immediately before the final OMT session. Moderate pain improvement (≥30% reduction on a 100-mm visual analogue scale) at week 12 defined a successful LBP response to treatment. Prevalence rates at baseline were: non-neutral lumbar dysfunction, 124 (54%); pubic shear, 191 (83%); innominate shear, 69 (30%); restricted sacral nutation, 87 (38%), and psoas syndrome, 117 (51%). Significant improvements in each biomechanical dysfunction were observed with OMT; however, only psoas syndrome remission occurred more frequently in LBP responders than non-responders (P for interaction = 0.002). Remission of psoas syndrome was the only change in biomechanical dysfunction that predicted subsequent LBP response after controlling for the other biomechanical dysfunctions and potential confounders (odds ratio, 5.11; 95% confidence interval, 1.54–16.96). These findings suggest that remission of psoas syndrome may be an important and previously unrecognized mechanism explaining clinical improvement in patients with chronic LBP following OMT.

1. Introduction

An estimated 632 million persons worldwide are reported to suffer from low back pain (LBP), making it the leading cause of years lived with disability (Vos et al., 2013). Patients with LBP frequently consult manual therapy practitioners in the United States, including osteopathic physicians and chiropractors (Barnes et al., 2008). Although established practice guidelines recommend manual therapies for chronic or persistent LBP (Chou et al., 2007; National Institute for Health and Clinical Excellence, 2009), questions remain about the mechanisms by which they exert their effects. Previous mechanistic research has focused on biomechanical effects of high-velocity, low-amplitude techniques, or "thrusts" (Triano, 2001; Evans, 2002; Maigne and Vautravers, 2003; Evans and Breen, 2006). Nevertheless, the *Biology of Manual Therapies* conference hosted by the National Institutes of Health raised key questions about the underlying foundational biomechanics of manual therapies and how such therapies impact body biomechanics (Khalsa et al., 2006). Research suggests that the underlying mechanisms of manual therapy may be multifactorial, including such elements as decreased spinal stiffness and improved lumbar multifidus muscle recruitment (Fritz et al., 2011).

Osteopathic medicine has integrated manual therapy techniques, collectively known as osteopathic manual treatment (OMT), into its system of health care (Mein et al., 2001). Osteopathic physicians are an important source of medical care for chronic LBP in the United States, providing one-third of medical visits for this condition (Licciardone, 2008). The results of the OSTEOPATHIC Trial

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recently demonstrated statistically significant and clinically relevant improvements in patients with chronic LBP following a short-term, multimodal OMT regimen (Licciardone et al., 2013b, 2013c). The purpose of the present study was to perform secondary analyses of the OSTEOPATHIC Trial data to measure changes in biomechanical dysfunction following OMT and to assess how such changes predict subsequent chronic LBP outcomes.

2. Methods

2.1. Study overview

The methodology and outcomes of the OSTEOPATHIC Trial have been reported elsewhere (Licciardone et al., 2008; Licciardone and Kearns, 2012; Licciardone et al., 2012a, 2012b, 2013a, 2013b, 2013c). The trial featured a randomized, double-blind, sham-controlled, 2×2 factorial design to study OMT and ultrasound therapy over 12 weeks in patients with nonspecific chronic LBP. Patients were recruited within Dallas-Fort Worth from August 2006 to September 2010 through newspaper advertisements, community agencies, and medical clinics.

Patients 21–69 years of age were eligible to participate if they reported having LBP most days in the past three months. Patients were excluded if they reported "red flags" suggesting serious underlying conditions as the cause of LBP (Bigos et al., 1994). These included history of any of the following: cancer; unexplained weight loss; immunosuppression; urinary infection; intravenous drug use; prolonged use of corticosteroids; spinal fracture or significant trauma; urinary retention or overflow incontinence; loss of anal sphincter tone or fecal incontinence; saddle anesthesia; or global or progressive motor weakness in the lower extremities. Patients were also excluded if they reported history of any of the following: recent low back surgery; receipt of worker's compensation benefits or ongoing litigation involving back problems; medical conditions that might impede OMT (or ultrasound therapy) protocol implementation; corticosteroid use in the past month; or use of manual therapy in the past three months or more than three times in the past year. Patients were excluded if any of the following signs of lumbar radiculopathy was observed during clinical screening: 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 (Bigos et al., 1994).

Patients were randomly allocated to treatment and these assignments were conveyed to treatment providers via opaque sealed envelopes. Neither patients nor outcome assessors were informed of treatment group assignments. Study procedures were approved by the Institutional Review Board at the University of North Texas Health Science Center and the trial was registered with ClinicalTrials.gov (NCT00315120) prior to implementation.

The 230 patients in the OSTEOPATHIC Trial who were assigned to receive active OMT were the focus of this study because data on biomechanical dysfunction were systematically recorded throughout the trial only in these patients. This cohort consisted of 115 patients who received active OMT and active ultrasound therapy, and another 115 patients who received active OMT and sham ultrasound therapy. Active ultrasound therapy was not efficacious when compared with sham ultrasound therapy in providing improvements in LBP or secondary outcomes (Licciardone et al., 2013c).

2.2. Structural examination for biomechanical dysfunction

During each treatment session patients were examined for five biomechanical dysfunctions that are often present with persistent LBP (Greenman, 1996; Kuchera, 2007). Non-neutral lumbar dysfunction was diagnosed by finding either restricted extension or flexion upon assessing the lumbar transverse processes with the patient in the seated or prone positions. Pubic shear dysfunction was diagnosed by finding the superior aspect of the pubic tubercle higher on one side than the other in the horizontal plane with the patient in the supine position. Innominate shear dysfunction was diagnosed by finding the inferior aspect of the ischial tuberosity lower on one side than the other or a dramatically inferior and slightly posterior inferolateral sacral angle on the side of the deep sacral sulcus with the patient in the prone position. Restricted sacral nutation was diagnosed by finding inability of either sacral base to nod forward across a transverse axis between the innominates with the patient in the prone position. Psoas syndrome was diagnosed by finding a psoas muscle tender point upon palpation in conjunction with suspected imbalance of the psoas muscles as determined by restriction during a sweeping motion of the hip capsule. These examinations were performed by each patient's designated provider to give equal attention to all patients and to help maintain blinding throughout the study; however, the findings were used primarily to guide OMT delivery. Consequently, the presence or absence of these biomechanical dysfunctions was systematically recorded only for those 230 patients assigned to receive OMT.

2.3. Osteopathic manual treatment

Osteopathic manual treatment targeted the lumbosacral, iliac, and pubic regions and consisted primarily of high-velocity, low-amplitude thrusts; moderate-velocity, moderate amplitude thrusts; soft tissue stretching, kneading, and pressure; myofascial stretching and release; positional treatment of myofascial tender points (counterstrain); and muscle energy techniques. These techniques were delivered by 15 osteopathic physicians, fellows, or residents during 15-min treatment sessions at weeks 0, 1, 2, 4, 6, and 8. Treatment fidelity methods (Bellg et al., 2004) were used to train providers to perform the structural examination for biomechanical dysfunction and to deliver OMT. These methods included standardized provider training using structured practice and role playing with pilot participants and regular booster sessions to minimize drift in provider skills over time. Patients were allowed to receive their usual LBP care and other co-treatments during the study except for non-assigned manual therapies.

2.4. Low back pain response

Low back pain was measured at baseline, prior to each subsequent treatment session, and at week 12 using a 100-mm visual analogue scale (VAS), which was anchored by "no pain" at 0 mm and "worst possible pain" at 100 mm. Moderate pain improvement, defined by $\geq$ 30% reduction from baseline through week 12, was the minimal threshold for detecting a successful LBP response. This relative criterion, based on the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) consensus statement recommendations (Dworkin et al., 2008), was used rather than an absolute criterion to minimize floor effects in assessing OMT efficacy. This criterion is highly sensitive and specific in predicting global impression of change in chronic pain patients (Emshoff et al., 2011) and provides readily interpretable evidence for clinical applications and recommendations (Farrar et al., 2000).

2.5. Statistical analysis

Descriptive statistics were used to summarize the baseline characteristics of patients and to compare the characteristics of LBP

responders and non-responders. Complete data were available for LBP scores at baseline; however, missing pain data at subsequent visits were imputed using the last observation carried forward. Measures of biomechanical dysfunction at baseline were not recorded for 11 (5%) patients. Multiple imputation modeling was used to estimate these missing data based on the presence or absence of key somatic dysfunction within each of three anatomical regions (lumbar, sacrum/pelvis, and pelvis/innominate). The presence or absence of such findings, assessed only at baseline, was determined using the osteopathic concept of "somatic dysfunction." The latter is defined as "impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodial, and myofascial structures, and related vascular, lymphatic, and neural elements" (American Association of Colleges of Osteopathic Medicine, 2009). Key somatic dysfunction is intuitively appealing as a surrogate measure of biomechanical dysfunction because it is present only with severe (grade 3) findings that help maintain other secondary dysfunctions (American Association of Colleges of Osteopathic Medicine, 2009). Key somatic dysfunction was associated with baseline deficits in back-specific functioning and general health in OSTEOPATHIC Trial patients (Licciardone and Kearns, 2012). Similarly, we used multiple imputation modeling with key somatic dysfunction and achievement of moderate LBP improvement to impute missing biomechanical dysfunction data for 52 (23%) patients at week 8. The Spearman rank correlation coefficient was used to measure associations among the five biomechanical dysfunctions at baseline.

We initially assessed how changes in each biomechanical dysfunction between weeks 0 and 8 predicted subsequent LBP response. This was summarized using odds ratios (ORs) and 95% confidence interval (CIs) for LBP response in patients with remission (i.e., biomechanical dysfunction present at baseline and absent at week 8) relative to those with progression (biomechanical dysfunction absent at baseline and present at week 8). Patients with stable biomechanical dysfunction were not included in this analysis. A *P*-value for interaction (Altman and Bland, 2003) was computed to determine the statistical significance of differences between LBP responder and non-responder subgroups. We subsequently used logistic regression to more extensively study the relationships among changes in biomechanical dysfunction and LBP response while simultaneously controlling for changes in each of the other biomechanical dysfunctions (partially adjusted model) and for other potential confounders (fully adjusted model). The latter included age, sex, and educational level; baseline measures of employment status, co-morbid osteoarthritis, LBP duration, and use of prescription and non-prescription medication for LBP; and co-treatment with either active or sham ultrasound therapy. In these models, the ORs and 95% CIs for LBP response were computed for patients with remission or stability of biomechanical dysfunction relative to those with progression.

Hypothesis testing was by intention-to-treat with a two-sided $\alpha = 0.05$. Rothman's *T* statistic (Hogan et al., 1978) was initially used to test for statistical interaction between OMT and ultrasound therapy before assessing subsequent LBP improvement outcomes. Three sensitivity analyses were performed to assess the internal validity of our results: using only patients who completed the study per protocol (i.e., attended all treatment sessions and provided complete data); using substantial LBP improvement (≥50% pain reduction) as the criterion for LBP response; and comparing the subgroups who received co-treatment with active or sham

Table 1
Baseline patient characteristics.[a]

Characteristic	Low back pain response status			
	Overall ($n = 230$)	Responders ($n = 145$)	Non-responders ($n = 85$)	*P*
Median age (yrs) (IQR)	41 (22)	41 (22)	41 (23)	0.65
No. (%) of women	144 (63)	90 (62)	54 (64)	0.83
No. (%) completed college education	107 (47)	81 (56)	26 (31)	<0.001
No. (%) employed full-time	110 (48)	72 (50)	38 (45)	0.47
No. (%) medically uninsured	86 (37)	49 (34)	37 (44)	0.14
No. (%) current smoker	61 (27)	34 (23)	27 (32)	0.17
No. (%) with co-morbid conditions				
Hypertension	42 (18)	27 (19)	15 (18)	0.85
Diabetes mellitus	19 (8)	11 (8)	8 (9)	0.63
Osteoarthritis	17 (7)	12 (8)	5 (6)	0.50
Depression	44 (19)	23 (16)	21 (25)	0.10
No. (%) with duration of chronic LBP greater than 1 year	118 (51)	72 (50)	46 (54)	0.51
No. (%) previously hospitalized for LBP	13 (6)	5 (3)	8 (9)	0.08[e]
No. (%) previously had surgery for LBP	5 (2)	2 (1)	3 (4)	0.36[e]
Median VAS score for LBP (mm) (IQR)[b]	44 (36)	47 (34)	38 (37)	0.08
Median Roland-Morris disability score (IQR)[c]	5 (6)	5 (6)	5 (5)	0.87
Median SF-36 general health score (IQR)[d]	67 (25)	72 (25)	67 (22)	0.10
No. (%) received ultrasound therapy co-treatment	115 (50)	72 (50)	43 (51)	0.89
No (%) with biomechanical dysfunction				
Non-neutral lumbar dysfunction	124 (54)	73 (50)	51 (60)	0.16
Pubic shear	191 (83)	122 (84)	69 (81)	0.57
Innominate shear	69 (30)	41 (28)	28 (33)	0.45
Restricted sacral nutation	87 (38)	59 (41)	28 (33)	0.24
Psoas syndrome	117 (51)	79 (54)	38 (45)	0.15
No. (%) used medication for LBP during past four weeks				
Non-prescription	115 (50)	74 (51)	41 (48)	0.68
Prescription	27 (12)	16 (11)	11 (13)	0.66

IQR = interquartile range; LBP = low back pain; SF-36 = Medical Outcomes Study Short Form-36 Health Survey; VAS = visual analogue scale.
[a] Low back pain response was defined as ≥30% pain reduction from baseline to week 12.
[b] A VAS (0–100 mm) was used to measure LBP, with higher scores indicating more pain.
[c] The Roland-Morris Disability Questionnaire (0–24 points) was used to measure back-specific functioning, with higher scores indicating greater disability.
[d] The SF-36 general health scale (0–100 points) was used to measure generic health, with higher scores indicating better health.
[e] Based on Fisher's exact test.

Table 2
Correlations among each of the baseline biomechanical dysfunctions.[a]

	Non-neutral lumbar dysfunction	Pubic shear	Innominate shear	Restricted sacral nutation	Psoas syndrome
Non-neutral lumbar dysfunction	…	0.02 (0.74)	0.07 (0.31)	0.37 (<0.001)	0.20 (0.002)
Pubic shear		…	0.06 (0.41)	−0.03 (0.67)	−0.08 (0.24)
Innominate shear			…	0.25 (<0.001)	0.07 (0.30)
Restricted sacral nutation				…	0.37 (<0.001)
Psoas syndrome					…

[a] Table entries are Spearman rank correlation coefficient (*P*-value). $n = 230$.

ultrasound therapy. Data management and statistical analyses were performed with the SPSS Statistics version 20 software (IBM Corporation, Armonk, NY).

3. Results

3.1. Patient characteristics and flow

The median age of patients at baseline was 41 years, and 144 (63%) were women (Table 1). The median VAS score was 44 mm. There was no statistical interaction between OMT and ultrasound therapy in assessing moderate pain improvement (*T*, −0.04; 95% CI, −0.22 to 0.14). There were 145 (63%) LBP responders and 85 (37%) non-responders at week 12. The only significant subgroup difference at baseline was that LBP responders were more likely than non-responders to have completed college education ($P < 0.001$). A total of 191 (83%), 197 (86%), and 180 (78%), respectively, attended all six treatment sessions, the week 12 exit visit, and completed the trial per protocol. The subgroups of patients who received co-treatment with active or sham ultrasound

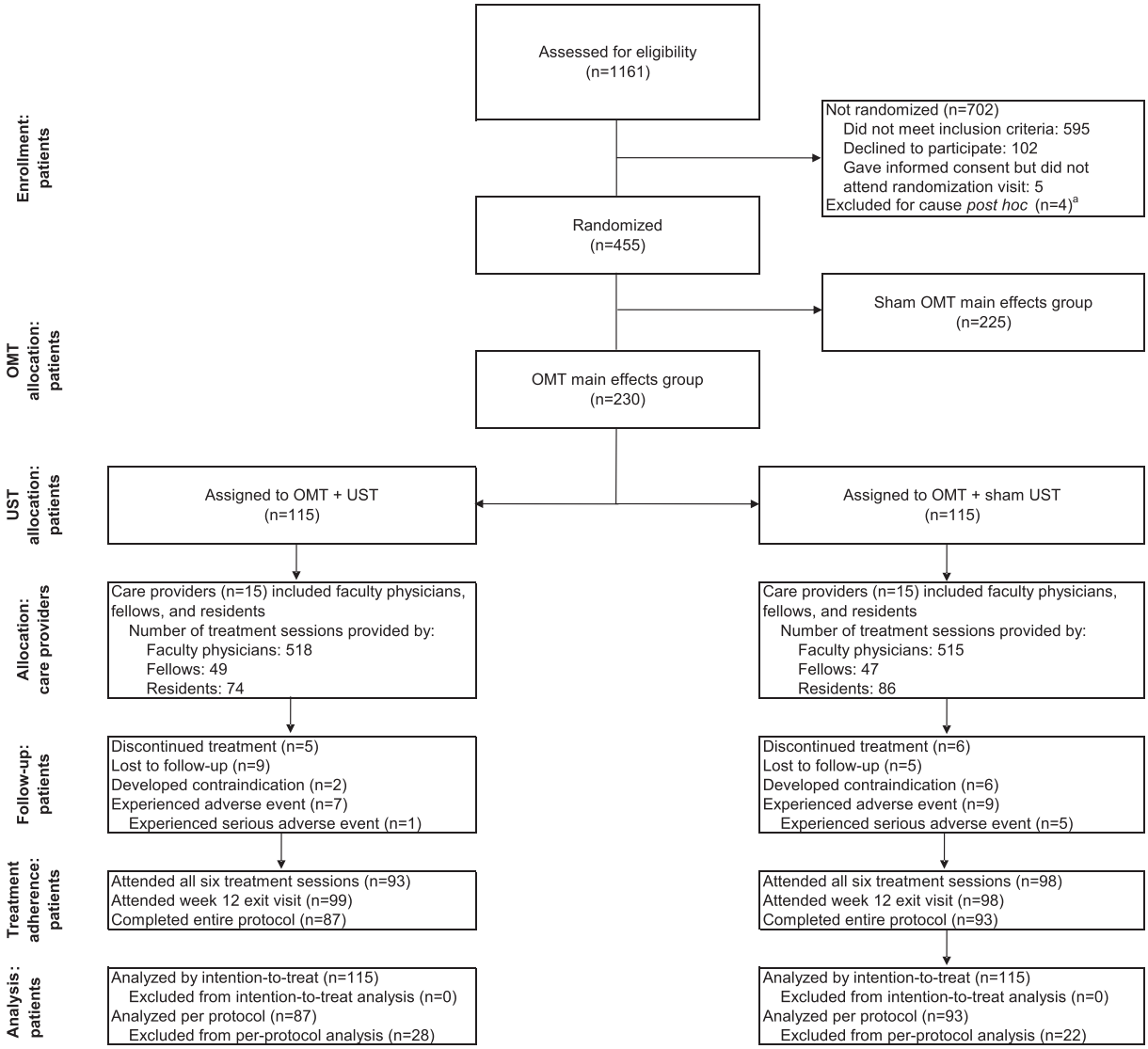

Fig. 1. Flow of patients through the OSTEOPATHIC Trial. OMT = osteopathic manual treatment; UST = ultrasound therapy. [a]Four patients were excluded for cause *post hoc* because it was subsequently discovered that they did not meet the inclusion criteria. Two of these patients provided false information to initially qualify for the study.

therapy were comparable with respect to distribution of types of care providers, levels of follow-up and adherence, and safety profiles (Fig. 1).

3.2. Baseline biomechanical dysfunction

The baseline prevalence rates of each biomechanical dysfunction were: non-neutral lumbar dysfunction, 124 (54%); pubic shear, 191 (83%); innominate shear, 69 (30%); restricted sacral nutation, 87 (38%), and psoas syndrome, 117 (51%). There was no significant difference between LBP responders and non-responders in the prevalence of any biomechanical dysfunction at baseline. Eight of the 10 correlations among biomechanical dysfunctions at baseline were positive (Table 2). However, only four correlations were statistically significant, with Spearman rank correlation coefficients ranging from 0.20 to 0.37. Restricted sacral nutation was most strongly correlated with other biomechanical dysfunctions. Although pubic shear was the most prevalent biomechanical dysfunction, it was not significantly correlated with any other biomechanical dysfunction.

3.3. Changes in biomechanical dysfunction

There were significant improvements in each biomechanical dysfunction with OMT (Table 3). The odds of remission of biomechanical dysfunction were generally on the order of two- to threefold greater than progression. However, the only significant subgroup difference was that psoas syndrome was more likely to remit in LBP responders (OR, 3.07; 95% CI, 1.68–5.61) than in non-responders (OR, 0.72; 95% CI, 0.35–1.47) (P for interaction = 0.002).

3.4. Multivariate factors associated with low back pain response

Remission of psoas syndrome persisted as a significant predictor of LBP response to OMT when assessing all patients and simultaneously controlling for each biomechanical dysfunction and other potential confounders (Table 4). Remission of psoas syndrome most strongly predicted LBP response in the fully adjusted model, (OR, 5.11; 95% CI, 1.54–16.96). Completion of college education was the only other factor significantly associated with LBP response in this fully adjusted model (OR, 3.26; 95% CI, 1.72–6.16).

3.5. Sensitivity analyses

The results of our three sensitivity analyses were congruent with those reported herein. We have reported only the intention-to-treat results for moderate pain improvement because these incorporated a larger number of patients and thereby represented more precise measures of treatment effect.

4. Discussion

Patients who received OMT in the OSTEOPATHIC Trial experienced significant improvements in non-neutral lumbar dysfunction, pubic shear, innominate shear, restricted sacral nutation, and psoas syndrome over eight weeks. However, remission of psoas syndrome with OMT was the only improvement that occurred significantly more often in LBP responders than non-responders. This finding was further corroborated in multivariate analyses that demonstrated the preeminence of psoas syndrome remission with OMT in predicting subsequent LBP response after simultaneously controlling for changes in other biomechanical dysfunctions and for potential confounders.

A previous study measured the prevalence rates of biomechanical dysfunction in 183 patients with disabling LBP (mean duration, 31 months), including 33 (18%) patients who had failed previous surgical intervention (Greenman, 1996). Therein, the prevalence rate of psoas syndrome and related muscle imbalances exceeded 90% (Greenman, 1996). The lower prevalence of psoas syndrome (51%) in our patients with chronic LBP, coupled with its common remission following OMT, suggests an opportunity to intervene with OMT at an earlier stage before psoas syndrome becomes chronic. Such intervention may decrease the need for surgery and prevent subsequent back-related disability.

Psoas syndrome is not included within the common classification schemes that primary care clinicians use for subgrouping

Table 3
Changes in biomechanical dysfunction from baseline to week 8.[a]

Biomechanical dysfunction	Stable (present)	Remission	Progression	Stable (absent)	OR	95% CI	P for interaction
	No. (%)	No. (%)	No. (%)	No. (%)			
Non-neutral lumbar dysfunction							
Overall (n = 230)	55 (24)	69 (30)	23 (10)	83 (36)	3.00	1.87–4.81	…
Responders (n = 145)	35 (24)	38 (26)	17 (12)	55 (38)	2.24	1.26–3.96	0.12
Non-responders (n = 85)	20 (24)	31 (36)	6 (7)	28 (33)	5.17	2.16–12.38	
Pubic shear							
Overall (n = 230)	144 (63)	47 (20)	18 (8)	21 (9)	2.61	1.52–4.50	…
Responders (n = 145)	87 (60)	35 (24)	11 (8)	12 (8)	3.18	1.62–6.26	0.29
Non-responders (n = 85)	57 (67)	12 (14)	7 (8)	9 (11)	1.71	0.67–4.35	
Innominate shear							
Overall (n = 230)	23 (10)	46 (20)	23 (10)	138 (60)	2.00	1.21–3.30	…
Responders (n = 145)	13 (9)	28 (19)	14 (10)	90 (62)	2.00	1.05–3.80	>0.99
Non-responders (n = 85)	10 (12)	18 (21)	9 (11)	48 (56)	2.00	0.90–4.45	
Restricted sacral nutation							
Overall (n = 230)	45 (20)	42 (18)	20 (9)	123 (53)	2.10	1.23–3.58	…
Responders (n = 145)	32 (22)	27 (19)	13 (9)	73 (50)	2.08	1.07–4.03	0.96
Non-responders (n = 85)	13 (15)	15 (18)	7 (8)	50 (59)	2.14	0.87–5.26	
Psoas syndrome							
Overall (n = 230)	61 (27)	56 (24)	32 (14)	81 (35)	1.75	1.13–2.70	…
Responders (n = 145)	36 (25)	43 (30)	14 (10)	52 (36)	3.07	1.68–5.61	0.002
Non-responders (n = 85)	25 (29)	13 (15)	18 (21)	29 (34)	0.72	0.35–1.47	

CI = confidence interval; OR = odds ratio.

[a] Low back pain response was defined as ≥30% pain reduction from baseline to week 12. The 230 overall patients included 145 responders and 85 non-responders. Percentages may not total 100 because of rounding. The ORs are for remission relative to progression of each biomechanical dysfunction.

Table 4
Factors associated with low back pain response at week 12.[a]

	Responders	Non responders	Unadjusted		Partially adjusted[b]		Fully adjusted[c]	
	No. (%)	No. (%)	OR	95% CI	OR	95% CI	OR	95% CI
Change in non-neutral lumbar dysfunction								
Progression	17 (12)	6 (7)	1.00	…	1.00	…	1.00	…
Stable	90 (62)	48 (56)	0.66	0.24–1.79	0.57	0.15–2.12	0.55	0.13–2.24
Remission	38 (26)	31 (36)	0.43	0.15–1.23	0.34	0.09–1.30	0.31	0.07–1.30
Change in pubic shear								
Progression	11 (8)	7 (8)	1.00	…	1.00	…	1.00	…
Stable	99 (68)	66 (78)	0.95	0.35–2.59	0.93	0.30–2.90	0.70	0.21–2.34
Remission	35 (24)	12 (14)	1.86	0.59–5.88	1.55	0.40–5.97	1.20	0.29–5.02
Change in innominate shear								
Progression	14 (10)	9 (11)	1.00	…	1.00	…	1.00	…
Stable	103 (71)	58 (68)	1.14	0.47–2.80	1.15	0.35–3.74	1.52	0.43–5.39
Remission	28 (19)	18 (21)	1.00	0.36–2.79	1.05	0.29–3.89	1.50	0.37–6.10
Change in restricted sacral nutation								
Progression	13 (9)	7 (8)	1.00	…	1.00	…	1.00	…
Stable	105 (72)	63 (74)	0.90	0.34–2.37	0.93	0.28–3.06	0.86	0.25–2,99
Remission	27 (19)	15 (18)	0.97	0.32–2.95	0.91	0.24–3.42	0.77	0.19–3.07
Change in psoas syndrome								
Progression	14 (10)	18 (21)	1.00	…	1.00	…	1.00	…
Stable[d]	88 (61)	54 (64)	2.10	0.96–4.55	2.38	0.94–6.04	2.45	0.88–6.83
Remission[e]	43 (30)	13 (15)	4.25	1.67–10.82	4.70	1.52–14.58	5.11	1.54–16.96

[a] Low back pain response was defined as ≥30% pain reduction from baseline to week 12. The 230 patients included 145 responders and 85 non-responders. Changes in biomechanical dysfunction were assessed at week 8 in comparison with baseline. Percentages may not total 100 because of rounding.
[b] The partially adjusted model simultaneously controlled for changes in each of the other biomechanical dysfunctions.
[c] The fully adjusted model simultaneously controlled for changes in each of the other biomechanical dysfunctions; age, sex, and educational level; baseline measures of work status, co-morbid osteoarthritis, low back pain duration, and use of prescription and non-prescription medication for low back pain; and co-treatment with either active or sham ultrasound therapy. The only unreported factor that achieved statistical significance in this model was completion of college education (OR, 3.26; 95% CI, 1.72–6.16).
[d] Statistical trend ($P < 0.10$) for each OR (95% CI).
[e] $P < 0.01$ for each OR (95% CI).

patients with nonspecific LBP (Kent and Keating, 2005). Thus, psoas syndrome may be a frequently missed diagnosis in patients initially presenting with a variety of clinical scenarios involving LBP (Tufo et al., 2012). Gradual forceful stretching of the psoas muscle, which can induce relaxation and produce marked muscle elongation, has been suggested as an alternative mechanism to explain the effects of manual therapy in the absence of convincing evidence on treatment of "manipulable" lesions (Maigne and Vautravers, 2003). Muscle functional magnetic resonance imaging has been used to measure transverse relaxation time (T2) asymmetry of lumbar muscles in patients with nonspecific acute LBP, and to measure changes in T2 asymmetry and in LBP severity following a single OMT session that included one or more manual therapy techniques comparable to those used in our study (Clark et al., 2009). There was a relatively large difference between patients with LBP and controls in T2 asymmetry of the psoas muscle, and a significant reduction in T2 asymmetry and corresponding LBP improvement was observed only in the psoas muscle immediately following OMT (Clark et al., 2009).

A recent imaging study has provided additional insight on the psoas muscle in patients with chronic LBP. These patients were found to have larger cross-sectional areas of the psoas muscle relative to the corresponding intervertebral disc at the levels of L3/L4 and L4/L5 than controls, presumably because of increased activity during the healing processes following mild degenerative changes of the lumbar spine (Arbanas et al., 2013). However, in the presence of marked degenerative disease or Modic changes, the relative cross-sectional area of the psoas muscle was diminished (Arbanas et al., 2013). Muscular imbalance, particularly involving the psoas muscle, can promote poor biomechanics and chronic LBP (Greenman, 1996; Kuchera, 2007). A novel treatment of botulinum toxin A injected under ultrasound guidance to treat psoas muscle imbalance demonstrated promising results in a series of three patients with chronic LBP (Finkelstein et al., 2008).

The overarching strengths and limitations of the OSTEOPATHIC Trial have been described (Licciardone et al., 2008, 2013c). To our knowledge, the OSTEOPATHIC Trial is the largest OMT trial to date. Other strengths included allocation concealment, blinding of outcome assessors, high levels of treatment adherence and outcomes reporting, and intention-to-treat analysis; however, it is possible that some degree of patient unblinding may have occurred during the trial. We pragmatically assessed OMT, using a multimodal regimen as practiced in clinical settings to complement usual care and self-care for chronic LBP. Several techniques included in our protocol were accepted for LBP treatment by professional associations representing chiropractors and physiotherapists (Harvey et al., 2003).

Limitations specific to the present study include: systematic lack of data on biomechanical dysfunction for, and consequent exclusion of, 225 patients who received sham OMT; need for imputed data on biomechanical dysfunction in 5% and 23% of patients at baseline and week 8, respectively; that the moderate pain improvement threshold of ≥30% reduction classified patients with less beneficial pain outcomes as LBP non-responders; and that one-half of patients each received co-treatment with active or sham ultrasound therapy. Nevertheless, the congruence between reported findings and those observed in our sensitivity analyses tends to mitigate concerns relating to missing biomechanical dysfunction data, differing LBP response thresholds, and ultrasound co-treatments. Finally, it is possible that subgroup comparisons of LBP responders and non-responders may have been biased by unknown confounders that were no longer distributed at random within these subgroups (Hennekens and Demets, 2009). Low back pain responders were more likely than non-responders to have completed college education; nevertheless, we were able to control for this factor in our multivariate analysis. It is unclear, however, if other unknown and uncontrolled factors may have distorted the relationships between changes in biomechanical dysfunction with OMT and subsequent LBP response.

5. Conclusions

A short course of OMT commonly led to remission of biomechanical dysfunction of the lumbar spine, sacrum, and pelvis. However, only remission of psoas syndrome with OMT emerged as a significant predictor of subsequent LBP response. Additional research is warranted to corroborate these findings using an appropriate control treatment arm and other types of manual therapy.

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