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Similar Effects of Thrust and Non-Thrust Spinal Manipulation Found in Adults With Subacute and Chronic Low Back Pain – A Controlled Trial with Adaptive Allocation

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Abstract

Study Design—A three-arm controlled trial with adaptive allocation.

Objectives—The aim of this study was to compare short-term effects of a side-lying, thrust spinal manipulation (SM) procedure and a non-thrust, flexion-distraction SM procedure in adults with subacute or chronic low back pain (LBP) over 2 weeks.

Summary of Background Data—SM has been recommended in recently published clinical guidelines for LBP management. Previous studies suggest that thrust and non-thrust SM procedures, though distinctly different in joint loading characteristics, have similar effects on patients with LBP.

Methods—Participants were eligible if they were 21–54 years old, had LBP for at least 4 weeks, scored 6 or above on the Roland-Morris disability questionnaire, and met the diagnostic classification of 1, 2, or 3 according to the Quebec Task Force Classification for Spinal Disorders. Participants were allocated in a 3:3:2 ratio to 4 sessions of thrust or non-thrust SM procedures directed at the lower lumbar and pelvic regions, or to a 2-week wait list control. The primary outcome was LBP-related disability using Roland-Morris disability questionnaire and the secondary outcomes were LBP intensity using visual analog scale, Fear-Avoidance Beliefs Questionnaire, and the 36-Item Short Form Health Survey. The study was conducted at the Palmer Center for Chiropractic Research with care provided by experienced doctors of chiropractic. Clinicians and patients were not blinded to treatment group.

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Results—Of 192 participants enrolled, the mean age was 40 years and 54% were male. Improvement in disability, LBP intensity, Fear-Avoidance Beliefs Questionnaire – work subscale, and 36-Item Short Form Health Survey – physical health summary measure for the two SM groups were significantly greater than the control group. No difference in any outcomes was observed between the two SM groups.

Conclusions—Thrust and non-thrust SM procedures with distinctly different joint loading characteristics demonstrated similar effects in short-term LBP improvement and both were superior to a wait list control.

Keywords

controlled trial; adaptive allocation; subacute low back pain; chronic low back pain; thrust spinal manipulation; non-thrust spinal manipulation; Roland-Morris Disability Questionnaire; pain intensity; Fear-Avoidance Belief Questionnaire; 36-Item Short Form Health Survey; short-term effect

Introduction

Low back pain (LBP) has long been recognized as a major health concern due to its high prevalence and associated socioeconomic costs.¹⁻⁴ Spinal manipulation (SM), a form of manual therapy commonly used in the US,^{5,6} has been recommended by clinical guidelines for LBP management.^{7,8} Recommendations are based on evidence that SM demonstrates mild to moderate effectiveness, comparable to other non-invasive LBP treatment methods.⁹ While many aspects of underlying therapeutic mechanisms are unknown, evidence suggests that SM exerts a beneficial effect via multiple mechanisms including biomechanical, neurophysiological, cellular, and/or psychosocial components.¹⁰⁻¹³

SM procedures can be broadly divided into two types: thrust and non-thrust.¹⁴⁻¹⁷ Thrust SM is a high-velocity low-amplitude procedure characterized by a single, short duration thrust (ranging from 100 to 500 ms) directed at a target joint that often results in an audible sound, or cavitation.¹⁸⁻²¹ Non-thrust SM employs low-velocity and often repeated joint movements of varying amplitude.²²⁻²⁴ Though the application of thrust and non-thrust SM procedures vary from each other in terms of biomechanical characteristics, both types target primarily joints, whereas many other manual therapy techniques target muscles, fascia, or other soft tissues not necessarily associated directly with joint structures.²⁵

Previous studies evaluating thrust and non-thrust SM procedures for individuals with LBP have reported either an advantage for thrust SM procedures²⁶ or similar effects between thrust and non-thrust SM.²⁷⁻²⁹ The objective of this study was to determine if 2 biomechanically distinct types of chiropractic SM procedures resulted in different short-term outcomes in patients with subacute or chronic LBP. We chose to focus on adults between 21-54 years old, assuming they would have fewer comorbidities that could potentially confound treatment response.

Materials and methods

Participants were recruited primarily through direct mail and local media services that is further described in Hondras et al.³⁰ Individuals were eligible for this study if they (1) were 21-54 years old, (2) presented with LBP of at least 4 weeks duration; (3) scored 6 or above on the Roland Morris disability questionnaire (RMDQ), and (4) had musculoskeletal LBP without radiation, or with radiation to either the proximal or distal extremity, consistent with the Quebec Task Force (QTF) Classification for Spinal Disorders categories 1-3.³¹

Individuals were excluded if they (1) had LBP associated with confirmed nerve root compression, neurological signs, lumbar spine stenosis, history of back surgery, chronic pain syndrome, LBP from fracture, infection, or visceral disease; (2) had comorbid conditions that could complicate the prognosis of LBP, including pregnancy, or clear evidence of narcotic or other drug abuse; (3) had major clinical depression defined as scores greater than 29 on the Beck Depression Inventory—Second Edition;³² (4) had pathology that contraindicated SM of the lumbar spine and pelvis such as cauda equina syndrome; (5) had inflammatory arthropathies involving the spine, bleeding disorders, and significant osteoporosis; (6) were involved with current or pending litigation related to this LBP episode; (7) were receiving disability for any health-related condition; (8) had received SM for any reason within the past month; (9) were unwilling to postpone the use of manual therapies for LBP for the duration of the study period; or (10) were unable to read or verbally comprehend English.

Study design

This was a prospective controlled trial with three arms: 1) thrust SM in a side-lying posture; 2) non-thrust SM in a prone posture; and 3) wait list control. The wait list group was included to account for the natural history of LBP. Those interested in participating in the study underwent a brief telephone screen. Those still eligible and interested completed a baseline visit that included the informed consent process, completion of self-reported outcomes and eligibility screening. Eligible participants were scheduled for their first treatment visit at which they were allocated to one of the 3 treatment groups. Participants assigned to the SM groups had 2 treatment visits per week for 2 weeks (4 treatment visits in total), while those in the wait list control group had no treatment visits. Participants completed the self-reported outcomes during their final study visit at week 3. Study coordinators administered the outcome assessments without coaching or otherwise influencing participants' responses. All study activities were conducted at the Research Clinic, Palmer Center for Chiropractic Research in Davenport, IA, United States.

Allocation—Because the primary purpose of the study was to compare outcomes between the thrust and non-thrust SM procedures, participants were allocated to the three groups in a 3:3:2 ratio: thrust SM, non-thrust SM and wait list. A study coordinator allocated participants to a treatment group through a Web interface to the adaptive computer-generated allocation algorithm. All future assignments were concealed. The algorithm balanced patient characteristics between groups by minimizing on gender, age and baseline level of RMDQ (<11 vs. 11), and variables that had been shown to be prognostic: duration of the current

LBP episode (>12 vs. 12 months) and baseline level of Fear-Avoidance Beliefs Questionnaire (FABQ) for work (<19 vs. 19).³³

Blinding—Clinicians were not blinded to group assignment, but were blinded to the participants' outcome measures. Study investigators and biostatisticians were blinded to group assignment. Participants knew that they were allocated to the 2-week wait list group or one of 2 standard SM interventions but did not receive further detailed information regarding the interventions they did not receive.

Clinical interventions

Treatment was directed at one or two joints at the fourth or fifth lumbar vertebra or sacroiliac joints during each visit.³⁴ Within these specific treatment areas, the clinicians were given freedom to decide the side and the specific spinal level of treatment application. Four doctors of chiropractic delivered the SM interventions, all with more than 6 years of practice experience. Treatment was delivered to either L4, L5, or S-I joint as determined by the clinicians using anatomical landmarks and methods typically employed among doctors of chiropractor.³⁵ To address treatment fidelity, the clinic director held weekly meetings with the study clinicians to review all study participant charts, review study protocols to ensure compliance, and trouble-shoot any issues that may have arisen.

Side-lying, thrust spinal manipulation procedure—Thrust SM intervention was performed with the participant in a side-lying position with the superior or free hip and knee flexed and adducted across the midline.³⁶ The clinician contacted the participant's flexed free lower extremity with his/her own thigh to stabilize the lower body. One of the clinician's hands held the participant's superior shoulder/upper arm to stabilize the upper body. The thrust was applied through the clinician's remaining hand, specifically through the lateral palmar surface in the region of the pisiform bone. The thrust was delivered toward the target joint complex by a quick, short, controlled movement of the hand, often combined with a slight body drop (to generate the necessary force). Typically, this maneuver results in local joint gapping, or cavitation.³⁷

Non-thrust, flexion-distraction spinal manipulation procedure—Non-thrust SM used in this study is sometimes referred to as “flexion-distraction” or Cox technique.^{22,36} Participants receiving non-thrust SM were positioned prone on a treatment table designed to allow free and controlled motion of the lower extremities by the clinician. Movement of the distal section of the table was controlled manually by the clinician. During treatment, a specific vertebra was manually stabilized (held) by the clinician who applied anterior and cephalad pressure to the spinous process. The distal table section was capable of maneuvering the lower extremities in flexion, lateral flexion, and circumduction motion while maintaining a traction force on the lumbar spine. A single non-thrust SM session typically included the application of up to 15 slowly applied traction cycles, each lasting approximately 1-3 seconds. Participant tolerance to the procedure was constantly assessed by the clinician and helped determine the number of cycles and motions applied. Non-thrust SM of the sacroiliac joint was performed by stabilizing the lumbar spine at the L5 segment, while laterally flexing the caudal section of the table away from the target sacroiliac joint. To

further focus traction forces through the sacroiliac joint, the thoracic section was tilted up on the side of the involved sacroiliac joint while the caudal section was tilted down, theoretically placing a shearing load on the joint.

Wait List Control—Participants assigned to the wait list control group were assessed at baseline and the two week follow-up period but did not receive SM.

Primary outcome measure

LBP-related disability was assessed using the 24-item RMDQ. The one-page RMDQ is among the most commonly used instruments in LBP research and has been validated extensively for reliability and validity.³⁸⁻⁴⁰ It is more responsive to change over time than other disability measures for LBP.⁴¹⁻⁴³ The recommended minimal clinically important difference (MCID) for RMDQ is 2-3 points.⁴⁴

Secondary outcome measures—The visual analog scale (VAS), a 100 mm line that is anchored at the ends of the line with 0 mm as “no pain” and 100 mm as “worst pain ever felt,” was used to measure LBP intensity. The scale has excellent metric properties, is easy to administer and score, and is commonly used in LBP research.^{45,46} The recommended MCID for the VAS is 15 mm.⁴⁷ In this study, LBP intensity was defined as average pain during past week.⁴³ The FABQ measures patients’ fear of pain and consequent avoidance of physical activity because of their fear.⁴⁸ The Short Form-36 (SF-36) is a multi-purpose, short-form survey of health status yielding both a physical and a mental health summary measure.⁴⁹

Sample size

An overall statistical significance at the 0.05 level for pairwise comparisons among the 3 groups was controlled for with the Bonferroni method. A sample size of 72 in each of the SM groups, assuming a standard deviation of 4.0, provided 81% power to detect a difference of 2.2 points between the thrust and non-thrust SM groups for the RMDQ. The 3:3:2 allocation ratio resulted in a sample size of 48 in the wait list control group; this provided 71% power to detect differences of 2.2 between this group and each of the SM groups.

Statistical analysis

Data analyses were performed using SAS System for Windows (Release 9.3; SAS Institute Inc., Cary, NC). The descriptive statistics of the changes from baseline to week 3 were calculated for outcome variables. We used an intention-to-treat approach with non-missing data in which participants were analyzed according to their treatment allocation. An analysis of covariance (ANCOVA) model was performed for each outcome variable at week 3 with terms in the model for the variables in the minimization algorithm, the respective outcome variable at baseline and treatment group. The adjusted mean estimate at week 3 for each group and between-group pairwise differences with 95% confidence intervals were obtained from the models.

Results

One hundred ninety-two participants were enrolled and followed up from July 2004 to April 2006 (Figure 1). Of the 1940 potential participants who were screened by phone, 881 were ineligible mainly due to duration of LBP less than 4 weeks (31%), receiving SM in the last month (26%), no current LBP (19%), or seeking/receiving worker's compensation (15%). Of those who had a baseline visit, 485 were ineligible mainly due to RMDQ score less than 6 (53%), QTF classification not 1, 2, or 3 (12%), duration of LBP less than 4 weeks (9%), or depression score greater than 29 (6%). Of the 192 allocated, 171 completed the study.

Of the 192 participants, 54% were male and the mean (SD) age was 40 (9.4) (Table 1). A mean RMDQ score of 9.7 (3.2) and a moderate level of pain intensity of 55.7 (20.9) mm were reported at baseline. The majority of the participants (90%) reported chronic LBP with the current episode lasting for more than three months and 62% had LBP lasting for more than 1 year.

The mean (SD) decrease in RMDQ was 4.0 (4.2) for the thrust SM group, 3.8 (4.1) for the non-thrust SM group, and 1.0 (3.0) for the wait list group. The mean (SD) decrease in LBP intensity was 23.5 mm (28.3) for the thrust SM group, 17.8 mm (25.8) for the non-thrust SM group, and 6.1 mm (19.6) for the wait list group.

Adjusted mean RMDQ and pain intensity at week 3 was not different between the two SM groups, but both SM groups had significantly lower scores than the wait list group (Table 2). The FABQ and the SF-36 measures showed similar patterns, but there was no significant difference between the SM groups and the wait list group on the FABQ physical activity subscale or SF-36 mental health summary.

There were no serious adverse events reported in this study.

Discussion

The objective of the current study was to determine if 2 biomechanically distinct types of chiropractic SM procedures resulted in different short-term outcomes in patients with subacute or chronic LBP. Both SM procedures generated short-term reductions in disability and pain intensity that were statistically and clinically significantly better than a wait list control.^{44,47} However, there were no differences between the 2 active SM treatments.

The short-term effects of thrust and non-thrust on LBP have been reported previously in the literature. Hadler et al. (1987) examined the effects of one session of side-lying thrust SM and one session of side-lying, non-thrust SM on relatively young (18 – 40 years), acute LBP patients.²⁷ Patients (n = 54) were stratified to those with LBP ≤ 2 weeks and those > 2 weeks, randomly allocated to either treatment, and followed up for 2 weeks. The authors found that while patients who had LBP > 2 weeks responded better to thrust SM initially, there was no difference in RMDQ between thrust and non-thrust SM after 2 weeks.

Hondras et al. (2009) examined the effects of thrust and non-thrust SM on older adults (55 years or older, n = 240) with subacute or chronic LBP when compared to minimal

conservative medical care.²⁸ The authors found no significant differences between the 2 SM procedures at weeks 3 (interim endpoint following 6 sessions of treatment) and 6 (primary endpoint following a total of 12 sessions), for RMDQ, pain intensity, FABQ – physical activity subscale, and the SF-36 physical health summary measure. The current study and the study by Hondras et al. (2009) were conducted simultaneously at the same research clinic. Compared to the current study, which restricted SM treatment to L4, L5, and sacroiliac joints, Hondras et al. (2009) also included L1 to L3 segments as possible manipulation sites.

Cleland et al. (2009) examined the effects of supine thrust SM, side-lying thrust SM, and posterior-to-anterior, non-thrust SM on patients (18 – 60 years) with acute or subacute LBP.²⁶ Patients (n = 112) were randomly allocated to receive 2 sessions of SM. The authors found that patients receiving either the supine or side-lying thrust SM had significantly lower Oswestry Disability Index (ODI) scores and pain intensity than those receiving non-thrust SM at both 1 and 4 weeks after allocation. No difference was found between the two thrust SM groups in either outcome at these two follow-up time points.

Cook et al. (2013) examined the effects of thrust SM and posterior-to-anterior, non-thrust SM on patients (18 years or older) with mechanical LBP.²⁹ Patients (n = 154) were randomized to receive two sessions of either SM in addition to standardized home exercise program. The authors found that there was no significant between group difference in ODI score or NRS pain between the thrust and non-thrust SM following 2 sessions of SM and at discharge. Using the same data collected in the study by Cook et al. (2013),²⁹ Learman et al. (2013) further examined the effects of thrust and non-thrust SM on those who were 55 years or older.⁵⁰ Of this particular subset of patients (n = 49), similar observations were made compared to the original study.

It is noteworthy that there are substantial variations among these studies in terms of specific thrust and non-thrust techniques used, the use of other interventions, treatment frequency and duration, patient populations, and outcome measures. As a result, care needs to be taken when interpreting the findings. Nevertheless, the overall observation suggests that the short-term effects of the two biomechanically distinct SM treatments (thrust and non-thrust) are similar in patients with LBP.

One limitation of the current study is that the outcomes were only measured after 4 sessions of SM treatment. The most recent literature recommends 12 sessions of SM treatment.⁵¹ Additionally the wait list group was used to control for time and thus natural history progression or improvement, but did not control for attention, touch, or other non-specific effects.¹¹ Thus, it is possible that improvements observed in the active treatment groups were completely or partially due to non-specific effects. Generalizability in this study is limited to those who were suffering from subacute or chronic LBP with a minimum disability of 6 in RMDQ. Finally the outcomes may be different on other patient populations such as those who are older or suffer from radiculopathy.²³

In summary, short-term improvement in LBP-related disability, pain intensity, fear avoidance of work and physical health outcomes were similar between biomechanically

distinct thrust and non-thrust SM procedures in patients with subacute or chronic LBP, and both were superior to a wait list control. More studies are needed to identify the biomechanical characteristics of SM that contribute to LBP improvement.

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Figure 1.
The study flow CONSORT diagram.

Table 1

Baseline description of participants by treatment group

	Thrust SM (n=72)		Non-Thrust SM (n=72)		Wait List Control (n=48)	
	n	%	n	%	n	%
Demographics						
Male	38	53	39	54	26	54
Age (years), mean (SD)	40.5	(10.0)	39.3	(8.8)	40.3	(9.5)
White	63	88	63	88	43	90
Hispanic or Latino	7	10	5	7	1	2
At least some college	49	68	46	64	38	79
Married or living with partner	43	60	44	61	23	48
Employed	60	83	60	83	39	81
Health insurance	46	64	46	64	28	58
Currently smoke cigarettes	30	42	27	38	24	50
Obese (BMI>30)	38	53	25	35	24	50
LBP History						
QTF Diagnostic classification						
1: Pain without radiation	50	69	44	61	28	58
2: Pain + radiation to proximal extremity	14	19	19	26	12	25
3: Pain + radiation to distal extremity	8	11	9	13	8	17
Duration of LBP episode						
4 weeks<3 months	7	10	1	1	3	6
3-12 months	16	22	14	20	13	27
>12 months	49	68	57	79	32	67
History of previous LBP episodes	52	72	57	79	40	83
History of previous spinal manipulation	56	78	62	86	38	79
Baseline Outcomes						
Roland Morris Disability Questionnaire, mean (SD)	9.8	(3.6)	9.5	(3.0)	9.7	(3.0)
Average LBP during past week (VAS, mm), mean (SD)	56.5	(22.5)	54.5	(20.3)	56.1	(19.6)
Fear-Avoidance Beliefs Questionnaires						
Physical Activity Subscale, mean (SD)	15.4	(4.8)	15.1	(4.8)	17.3	(4.5)

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	Thrust SM (n=72)		Non-Thrust SM (n=72)		Wait List Control (n=48)	
	n	%	n	%	n	%
Work Subscale, mean (SD)	13.1	(9.7)	13.5	(9.2)	13.9	(10.9)
Short Form-36 Health Survey						
Physical Health Summary Measure, mean (SD)	35.2	(7.7)	36.6	(7.9)	36.5	(7.1)
Mental Health Summary Measure, mean (SD)	45.4	(10.7)	47.4	(10.1)	45.6	(10.2)

BMI – body mass index; QTF – Quebec Task Force Classification for Spinal Disorders; LBP – low back pain; VAS – visual analog scale.

Adjusted mean estimates and 95% confidence intervals by group and for differences between-group^{**} at week 3

Table 2

	Adjusted mean estimates at week 3 (95% CI) [*]			Adjusted mean between-group difference (95% CI) ^{**}		
	Thrust SM (n=63)	Non-thrust SM (n=66)	Wait List Control (n=42)	Thrust SM vs. Non-thrust SM	Thrust SM vs. Wait List Control	Non-thrust SM vs. Wait List Control
Roland Morris Disability Questionnaire	5.8 (4.8 to 6.8)	5.8 (4.8 to 6.7)	8.9 (7.7 to 10.0)	0 (-1.4, 1.5)	-3.0 (-4.7 to -1.4)	-3.1 (-4.8 to -1.4)
Average LBP intensity during past week (VAS, mm)	31.0 (25.2 to 36.7)	35.2 (29.5 to 40.9)	48.0 (41.2 to 54.8)	-4.2 (-13.5 to 5.0)	-17.1 (-27.5 to -6.7)	-12.8 (-23.1 to -2.6)
Fear-Avoidance Beliefs Questionnaires						
Physical Activity Subscale	12.9 (11.7 to 14.1)	14.3 (13.1 to 15.5)	14.4 (12.9 to 16.0)	-1.5 (-3.4 to 0.5)	-1.6 (-3.8 to 0.7)	-0.1 (-2.4 to 2.2)
Work Subscale	12.1 (10.3 to 13.8)	11.6 (9.8 to 13.3)	15.2 (13.1 to 17.3)	0.5 (-2.2 to 3.3)	-3.1 (-6.2 to 0)	-3.6 (-6.7 to -0.5)
Short Form-36 Health Survey						
Physical Health Summary Measure	39.6 (37.9 to 41.3)	39.9 (38.3 to 41.6)	34.8 (32.8 to 36.9)	-0.4 (-3.1 to 2.3)	4.7 (1.6 to 7.8)	5.1 (2.0 to 8.1)
Mental Health Summary Measure	49.2 (47.4 to 51.0)	51.1 (49.3 to 52.9)	49.8 (47.6 to 52.0)	-1.9 (-4.8 to 1.1)	-0.6 (-3.9 to 2.7)	1.3 (-2.0 to 4.6)

SM – spinal manipulation; CI – confidence interval; VAS – visual analog scale.

^{*} Adjusted for sex, age, duration of current LBP episode, level of baseline Roland Morris score, level of baseline Fear-Avoidance Belief score for work, and the respective baseline outcome variable^{**} Controlled for pairwise comparisons with the Bonferroni method