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Comparison of the Effectiveness of Three Manual Physical Therapy Techniques in a Subgroup of Patients With Low Back Pain Who Satisfy a Clinical Prediction Rule

A Randomized Clinical Trial

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Study Design. Randomized clinical trial.

Objective. The purpose of this randomized clinical trial was to examine the generalizability of 3 different manual therapy techniques in a patient population with low back pain that satisfy a clinical prediction rule (CPR).

Summary of Background Data. Recently a CPR that identifies patients with LBP who are likely to respond rapidly and dramatically to thrust manipulation has been developed and validated. The generalizability of the CPR requires further investigation.

Methods. A total of 112 patients were enrolled in the trial and provided demographic information and completed a number of self-report questionnaires including the Oswestry Disability Questionnaire (ODQ) and the Numerical Pain Rating Scale (NPRS) at baseline, 1-week, 4-weeks, and 6-months. Patients were randomly assigned to receive 1 of the 3 manual therapy techniques for 2 consecutive treatment sessions followed by exercise regimen for an additional 3 sessions. We examined the primary aim using a linear mixed model for repeated measures, using the ODQ and NPRS as dependent variables. The hypothesis of interest was the group by time interaction, which was further explored with pair-wise comparisons of the estimated marginal means.

Results. There was a significant group x time interaction for the ODQ ($P < 0.001$) and NPRS scores ($P = 0.001$). Pair-wise comparisons revealed no differences between the supine thrust manipulation and side-lying thrust manipulation at any follow-up period. Significant differences in the ODQ and NPRS existed at each follow-up between the thrust manipulation and the nonthrust manipulation groups at 1-week and 4-weeks. There was also a significant difference in ODQ scores at 6-months in favor of the thrust groups.

Conclusion. The results of the study support the generalizability of the CPR to another thrust manipulation technique, but not to the nonthrust manipulation technique that was used in this study. In general, our results also provided support that the CPR can be generalized to different settings from which it was derived and validated. However, additional research is needed to examine this issue.

Key words: clinical prediction rule, low back pain, thrust manipulation. **Spine 2009;34:2720–2729**

Low back pain (LBP) is a common and costly condition. Healthcare expenditures for patients with LBP in the United States have continued to increase at a rate higher than healthcare expenditures in general.[1] Although rates of surgical procedures for patients with LBP are rising in the United States,[2] the majority of individuals with LBP continue to be managed nonsurgically with a variety of treatment strategies, accounting for the majority of the costs associated with LBP.[3] Various forms of manual therapy are used by several professional groups in the management of LBP.[4,5] Manual therapy is a general term referring to a broad category of procedures designed to impact musculoskeletal structures for the purpose of reducing pain and improving function.[6,7] The most commonly used forms of manual therapy for individuals with LBP are high velocity thrust and low velocity nonthrust manipulation directed towards the joints of the lumbar spine. Thrust and nonthrust manipulation procedures are distinguished on a biomechanical basis, with thrust manipulation techniques employing a high-velocity, low amplitude force, whereas nonthrust techniques are delivered with a low-velocity force.[8] There is often a lack of precision surrounding manual therapy terminology in clinical research. Some studies use the term "manipulation" to refer strictly to thrust procedures,[9,10] whereas other studies have used the term "manipulation" when only nonthrust procedures were used.[11] Other clinical

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studies have applied the term "manipulation" to refer to treatments employing a combination of thrust and nonthrust procedures.[12–15] and some studies use the label "manipulation" to refer to an even broader array of techniques including thrust and nonthrust manipulation along with soft tissue massage and other hands-on treatment procedures.[16,17] Other clinical studies label a treatment group "manual therapy" with little explanation of the particular techniques used.[18–20]

Inconsistent terminology related to manual therapy and manipulation may be partially attributable to the perception that thrust and nonthrust procedures are of equivalent clinical effectiveness (or ineffectiveness). This perception may arise from the theories that have been promoted to describe the mechanisms by which manipulation exerts a clinical effect. Traditional theories explaining the underlying mechanisms of manipulation procedures have focused on changing the structural alignment of the spine and reducing stiffness.[21–24] These theories have focused attention on delivering manipulation procedures to specific spinal motion segments in precise directions as key determinants of a successful manipulation,[25] with less focus on the velocity or amplitude of the manipulation. Recent research suggests the mechanisms underlying the clinical effects of manipulation may be more related to the neurophysiologic effects of mechanoreceptor stimulation and subsequent impact on motor neuron excitability than the traditional theories focused on alignment and stiffness.[26,27] If these theories are accurate, then the key determinants of a successful procedure may be related to factors that dictate mechanoreceptor response, including velocity and amplitude of the force.[28] Clinical outcomes may therefore be dictated more by the type of manipulation performed (thrust or nonthrust), than the particular technique that is used. Few studies have directly compared the clinical outcomes of thrust *versus* nonthrust manipulation, but those that have suggest their effectiveness may differ.[29] These findings indicate a need for additional research before thrust and nonthrust manipulation should be considered equivalent or interchangeable treatments.

Lack of clarity in distinguishing among types of manipulation may contribute to the mixed results reported in randomized trials and reflected in systematic reviews and practice guidelines examining the effectiveness of "manipulation" or "manual therapy" for individuals with LBP.[30,31] In addition, if thrust and nonthrust manipulation procedures should not be considered interchangeable, imprecision in distinguishing between these types of manipulation may make it more difficult to identify parameters that would allow clinicians to identify the subgroups of patients with LBP likely to respond to either intervention. The inability to identify relevant subgroups of patients with LBP likely to respond to particular treatments has also been offered as part of the explanation for negative or equivocal results of randomized clinical trials examining those treatments.[32] We previously derived[33] and validated[10] a clinical prediction rule (CPR) defining a set of clinical parameters that could accurately identify a subgroup of patients with LBP likely to respond with rapid and prolonged reductions in pain and disability following thrust manipulation. The CPR was developed using 1 specific thrust manipulation technique. It is not known if the results obtained using the CPR would generalize to different thrust manipulation techniques, or to nonthrust manipulation procedures. It is also important to examine the generalizability of a CPR to different clinicians and practice settings.[34] The purpose of this multicenter randomized clinical trial was to examine the generalizability of the spinal manipulation CPR to different thrust and nonthrust manipulation techniques by comparing the outcomes of 3 different manipulation techniques in patients with LBP who fit the CPR. We also sought to explore the generalizability of the CPR by examining the outcomes in different practice settings.

■ Materials and Methods

Patients over a 28-month period (June 2005–September 2007) attending physical therapy at an outpatient clinic in 1 of 4 settings with a report of LBP (with or without symptoms in the lower extremity) were screened for eligibility criteria. The settings were the United States Military Health System, and outpatient physical therapy clinics affiliated with Concord Hospital, Concord, NH; Intermountain Healthcare, Salt Lake City, UT; and the University of Southern California, Los Angeles, CA. For patients to be eligible, they had to have a modified Oswestry Disability Questionnaire (ODQ) score of >25%, be between 18 and 60 years of age, and to be positive for the spinal manipulation CPR, which required the presence of at least 4 of the 5 findings listed in Table 1. Exclusion criteria included the presence of any red flags (*i.e.*, tumor, metabolic diseases, RA, osteoporosis, prolonged history of steroid use, *etc.*), signs consistent with nerve root compression (reproduction of low back or leg pain with straight leg raise at less than 45°, muscle weakness involving a major muscle group of the lower extremity, diminished lower extremity muscle stretch reflex, or diminished or absent sensation to pinprick in any lower extremity dermatome). Other exclusion criteria included prior surgery to the lumbar spine and current pregnancy. This study was approved by the Institutional Review Boards at Andrews Air Force base, San Antonio, TX; Concord Hospital, Concord, NH; Intermountain Healthcare, Salt Lake City, UT; and the

Table 1. Five Criteria in the Spinal Manipulation Clinical Prediction Rule

Criterion	Definition of Positive
Duration of current episode of low back pain	<16 days
Extent of distal symptoms	No symptoms distal to the knee
FABQW subscale score	<19 points
Segmental mobility testing	≥1 hypomobile segment in the lumbar spine
Hip internal rotation range of motion	≥At least 1 hip with >35° of internal rotation range of motion

FABQW indicates fear-avoidance beliefs questionnaire work subscale.

University of Southern California, Los Angeles, CA. All patients provided informed consent before their enrollment in the study. This trial was registered with ClinicalTrials.gov (NCT00257998).

Examination Procedures

All patients provided demographic information and completed a number of self-report questionnaires, followed by a standardized history and physical examination at baseline (which included items in the CPR). A physical therapist blind to group assignment performed all evaluation procedures.

The following self-report questionnaires were completed at baseline as well as each follow-up period:

The Numerical Pain Rating Scale (NPRS)[35] was used to capture the patient's level of pain. Patients were asked to indicate the intensity of current, best, and worst levels of pain over the past 24 hours, using an 11-point scale ranging from 0 "no pain" to 10 "worst pain imaginable." The average of the 3 ratings was used to represent the patient's level of pain over the previous 24 hours. The minimum clinically important difference (MCID) for the NPRS has been reported to be 2 points.[36]

The ODQ[37] was used to measure disability and consists of 10 questions, each scored from 0 to 5, with higher scores indicating greater disability. Scores were then converted to a percentage score. The MCID for the modified ODQ has been reported as 6% in a sample of patients with acute LBP undergoing physical therapy.[37] We used the ODQ as our primary outcome.

The Fear-Avoidance Beliefs Questionnaire[38] (FABQ) was used to quantify the patient's fear of pain and beliefs about avoiding activity. Each FABQ item is scored from 0 to 6 with higher numbers indicating greater fear-avoidance beliefs. The FABQ has 2 subscales; a 7-item work subscale (FABQW), and a 4-item physical activity subscale (FABQPA). Fear avoidance beliefs have been associated with current and future disability and work loss in patients with acute[39] and chronic[40] LBP. The FABQW is one of the CPR criteria (Table 1).

Randomization

Following the baseline examination, patients were randomly assigned to receive 1 of the 3 manual therapy techniques for 2 consecutive treatment sessions, after which all patients received the same exercise regimen for an additional 3 sessions. Concealed allocation was performed by using a computer-generated randomized table of numbers created for each participating site before the beginning of the study. Individual, sequentially numbered index cards with the random assignment where prepared. The index cards were folded and placed in sealed opaque envelopes. The examining therapist remained blind to the patient's treatment group assignment at all times. Patients were instructed not to discuss the particular manual therapy technique received with the examining therapist. All patients received their first treatment within 3 days of the initial examination.

Treating Therapists

Seventeen physical therapists with a mean of 9.1 year (SD: 5.9, range, 1.5–21) of clinical experience participated in the treatment of all patients in this study. All therapists underwent a standardized training regimen, which included studying a manual of standard procedures with the operational definitions of each examination and treatment procedure. Participating therapists underwent 4 hour training session provided by one of the investigators. During this training session, therapists were required to demonstrate the examination and treatment techniques to ensure that all study procedures were performed in a standardized fashion.

Treatment

Treatment for the 3 groups differed only during the first 2 sessions that were received within the first week after randomization. During these sessions patients received the manual therapy technique to which they were randomized, and a spinal range of motion (ROM) exercise that was common to all groups. Following the first 2 sessions all patients received the same standardized exercise regimen for 3 additional sessions (once weekly for 3 weeks) for a total of 5 treatment sessions over a 4-week period.

Manual Therapy Technique for Sessions 1 and 2

Supine Thrust Manipulation Group. This treatment group received the manipulation technique that was used in the development and validation of the CPR.[10,33] The technique is performed with the patient supine. The therapist stands on the side opposite of that to be manipulated. The patient was passively moved into side-bending towards the side to be manipulated. The patient interlocks the fingers behind his or her head. The therapist passively rotates the patient, then delivers a high-velocity, low amplitude thrust to the anterior superior iliac spine in a posterior and inferior direction (Figure 1). Therapists were instructed to use the decision-making employed in validation of the CPR.[10] The side to be manipulated was the more symptomatic side based on the patient's self-report. If the patient could not identify a more symptomatic side, the therapist selected a side for manipulation. After the manipulation was performed, the therapist noted whether or not a cavitation (*i.e.*, a "pop") was either heard or felt by the therapist or patient. If a pop was experienced, the procedure was complete for that session. If no cavitation was produced, the patient was repositioned and the manipulation was attempted again. If no cavitation was experienced, the therapist attempted to manipulate the opposite side. A maximum of 2 attempts per side was permitted.

Side-Lying Thrust Manipulation Group. This treatment group received an alternative thrust manipulation technique performed with the patient side-lying. The patient was side-lying with the more painful side up. The therapist flexed the top leg

Figure 1. Supine thrust manipulation technique used in this study.

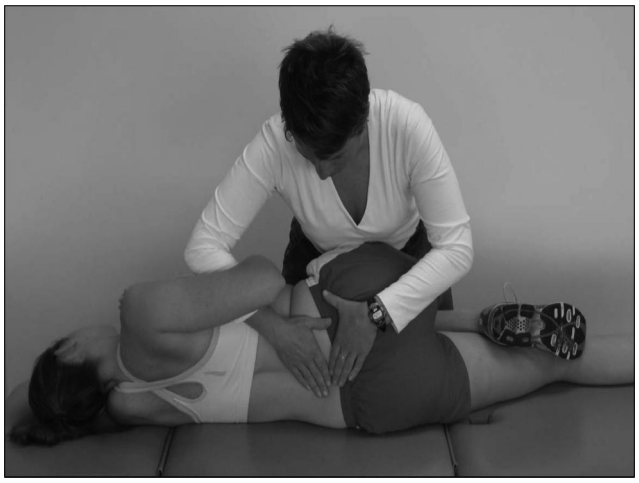

Figure 2. Side-lying thrust manipulation technique used in this study.

Figure 3. Non-thrust manipulation technique used in this study.

until movement was palpated at the selected segment interspace. The therapist then grasped the patient's bottom shoulder and arm and introduced sidebending and rotation until motion was felt at the selected interspace. Setup was maintained while the patient was rolled toward the therapist. Finally the therapist applied a high-velocity, low amplitude thrust of the pelvis in an anterior direction (Figure 2). Similar decision-making was used to guide the therapist. The more painful side was nominated by the patient unless he or she was unable, in which case the therapist chose the side. Production of a cavitation was used to determine when the procedure was completed during a session, with a maximum of 2 attempts allowed per side. The therapist could choose the level of the lower lumbar spine (*i.e.*, L4–L5) towards which to direct the manipulation. This was done because prior research has suggested manipulation procedures may be more effective when directed towards the lower lumbar region,[41] however, the techniques are not likely specific to one particular lumbar spinal level.[25]

Non-Thrust Manipulation Technique Group. This treatment group received central lumbar posterior-anterior nonthrust manipulation procedures directed at L4 and L5. The therapist placed the hypothenar eminence of 1 hand over the spinous process of L4. With the elbows remaining extended, the therapist delivered a low-velocity, high amplitude oscillatory force (at approximately 2 Hz) directed at L4 for a total 60 seconds[23] (Figure 3). Following a 30-second rest the therapist performed a similar set of oscillations directed at L5. A second set of oscillations was then performed in a similar manner at L4 and L5. The procedure was completed during a session after 2 sets of 60 seconds of nonthrust oscillatory manipulations were performed over L4 and L5. We selected to target L4–L5 for the mobilization technique as it has been demonstrated that nonthrust manipulation directed at the lower lumbar levels results in greater analgesia than when directed at the upper lumbar spine.[9]

Procedures Common to All Groups

During the first 2 treatment sessions, patients in all treatment groups were instructed in a spinal ROM exercise after completion of the manual therapy procedure. The ROM exercise required patients to lie supine and move the pelvis in an anterior and posterior direction to promote extension and flexion of the lumbar spine, respectively. Patients were instructed to perform the exercise in a pain-free range. Patients were instructed to perform a set of 10 repetitions in the clinic during the first and second sessions after the manipulation procedure, and were instructed to perform 10 repetitions of the exercise 3 to 4 times daily until the beginning of the third treatment session.

Beginning on the third treatment session, all patients were treated with the same strengthening and stabilization exercise program as used in the validation of the CPR.[10] The exercise program was designed to target trunk musculature that has been identified as important stabilizers of the spine including abdominal hollowing for the transversus abdominus, bridging and quadruped arm and leg extensions for the multifidus/erector spinae, and side-support exercises for the oblique abdominals.[42–45] Patients were also asked to complete the strengthening program once daily on the days they did not attend physical therapy.

Follow-up

Follow-up assessments were performed after 1 week (third visit), 4 weeks (fifth visit) and 6 months. At each follow-up, patients completed the ODQ and NPRS. Additionally, at the 1-week follow-up patients completed a questionnaire regarding any side effects they may have experienced since the initial treatment session. The questionnaire was modified from that used by Cagnie *et al*[46] and included questions regarding commonly described side effects associated with the use of spinal manipulation techniques such as stiffness, muscle spasm, fatigue, or radiating discomfort. Patients could also mark "other" and then identify any other less common side effects they had experienced since the first treatment. If the patient indicated they had experienced any side effects, they were asked to report the time of onset relative to their last treatment session (categorized as ≤24 hours or greater than 24 hours), duration of the side effect symptoms (categorized as ≤24 hours or >24 hours) and severity of symptoms (scored on a 1–4 scale where 1 = light to 4 = severe).

Sample Size Determination

Sample size and power calculations were performed using Sample Power statistical software version 12.1 (SPSS Inc., Chicago, IL). Original calculations were based on the ability to detect differences between the treatment groups and between the 4 practice settings, assuming a 9% difference in ODQ scores after 1 week with a within-group standard deviation of 10 points. Difficulties in recruitment in some settings led us to focus on

detecting differences between treatment groups. A total of 110 patients provided 92% power under these assumptions with an alpha level of 0.05.

Data Analysis

Baseline demographics were compared across treatment groups, using one-way ANOVA or Kruskal-Wallis tests with *post hoc* comparisons for continuous data, and χ^2 for categorical data. We examined the primary aim, using a linear mixed model for repeated measures to account for the nesting of patients within practice settings. Time and treatment group were modeled as fixed effects with the ODQ score as the dependent variable. The hypothesis of interest was the group by time interaction, which was further explored with pair-wise comparisons of the estimated marginal means. A separate linear model was constructed with NPRS as the dependent variable. We used intention-to-treat analysis with all patients analyzed in the group to which they were randomized using the last value forward method.

We also examined the results by comparing the percentage of patients in each manipulation group achieving a successful outcome at each follow-up, using χ^2 tests. Consistent with previous studies examining this CPR, a criterion of at least 50% improvement on the ODQ from baseline was used to define success.[10,33,47] An improvement of 30% on the ODQ has been identified as the threshold for identifying minimal clinical improvement[48]; therefore a 50% threshold provides an estimate of "success" beyond a minimally important change.

Differences between practice settings were explored by examining patients receiving the same manipulation technique using a linear model with repeated measures. The ODQ served as the dependent variable, with setting modeled as a fixed effect. The hypothesis of interest was the time by setting interaction which would indicate a differential response over time in different settings for patients receiving the same manipulation technique. Separate analyses were planned for each manipulation technique and using the NPRS as the dependent variable.

The proportion of individuals reporting side effects in each group, and differences in the onset and duration of reported side effects were analyzed using χ^2 tests. An alpha value of 0.05 was used for all comparisons. Data analysis was performed using the SPSS Version 15.0 statistical software package (SPSS Inc., Chicago, IL).

■ Results

A total of 112 patients, (mean age: 40.4 [SD = 11.5] [49% female]), satisfied the eligibility criteria, agreed to participate, and were randomized into the supine thrust manipulation (n = 37), side-lying thrust manipulation (n = 38), or the nonthrust manipulation group (n = 37). Sixty-one patients were recruited from New Hampshire, 33 from Utah, 16 from Los Angeles, and 2 from the Military Health Care System. Baseline characteristics between the groups were similar for most variables ($P > 0.05$). The supine thrust manipulation group had a higher BMI than the side-lying thrust manipulation group ($P = 0.02$) (Table 2). There was no difference ($P > 0.05$) between any of the groups for the mean duration of symptoms which was 46.9 (SD: 31.2) for the supine thrust manipulation group, 51.7 (SD: 36.4) for the side-lying thrust manipulation group, and 51.2 (SD: 37.4) for the nonthrust manipulation group. A flow diagram of patient recruitment and retention can be found in Figure 4. Ninety-eight patients (87.5%) returned the 6-month follow-up packets. Response rates did not differ between groups ($P = 0.75$).

Repeated measures analyses revealed significant group × time interactions for the ODQ ($P < 0.001$) and NPRS scores ($P = 0.001$). Estimated marginal means for the ODQ and NPRS by group at each time period are pictured in Figure 5 and 6 respectively. Pair-wise comparisons of ODQ scores by group revealed no differences between the supine thrust manipulation and side-lying

Table 2. Baseline Demographics and Self-Reported Variables for Both Treatment Groups (Data Represent Mean [Standard Deviation] Unless Otherwise Indicated)

Variable	All Patients (n = 112)	Supine Thrust Manipulation Group (n = 37)	Side-Lying Thrust Manipulation Group (n = 38)	Nonthrust Manipulation Group (n = 37)
Age	40.3 (11.5)	43.7 (10.4)	37.1 (11.5)	40.1 (12.0)
Gender (% female)	52%	46%	56%	51%
Symptom duration (median days, interquartile range)	45 (27, 60)	44 (27.5, 59)	45 (27, 67.8)	48 (23.5, 60)
Body mass index	27.2 (4.6)	29.0 (4.6)	26.0 (4.4)	26.5 (3.9)
Pain rating	5.2 (1.2)	5.4 (1.3)	5.2 (1.0)	5.1 (1.3)
ODQ	35.5 (7.7)	36.8 (8.7)	35.4 (6.7)	34.4 (7.6)
FABQPA	12.9 (4.7)	13.4 (4.3)	13.7 (4.8)	11.5 (4.7)
FABQW	12.2 (7.7)	11.8 (7.7)	11.7 (5.8)	13.1 (9.3)
Current medication usage for low back pain	73%	78%	68%	73%
Prior history of low back pain	47%	47%	53%	41%
Has missed work in past 6 wk due to low back pain	39%	46%	30%	40%
Currently unable to work due to low back pain	6%	9%	3%	6%
Current smoker	11%	8%	13%	11%
Believe manipulation would improve symptoms	59%	64%	61%	53%

ODQ indicates Oswestry Disability Questionnaire; FABQPA, Fear-Avoidance Beliefs Questionnaire Physical Activity Subscale; FABQW, Fear-Avoidance Beliefs Questionnaire Work Subscale.

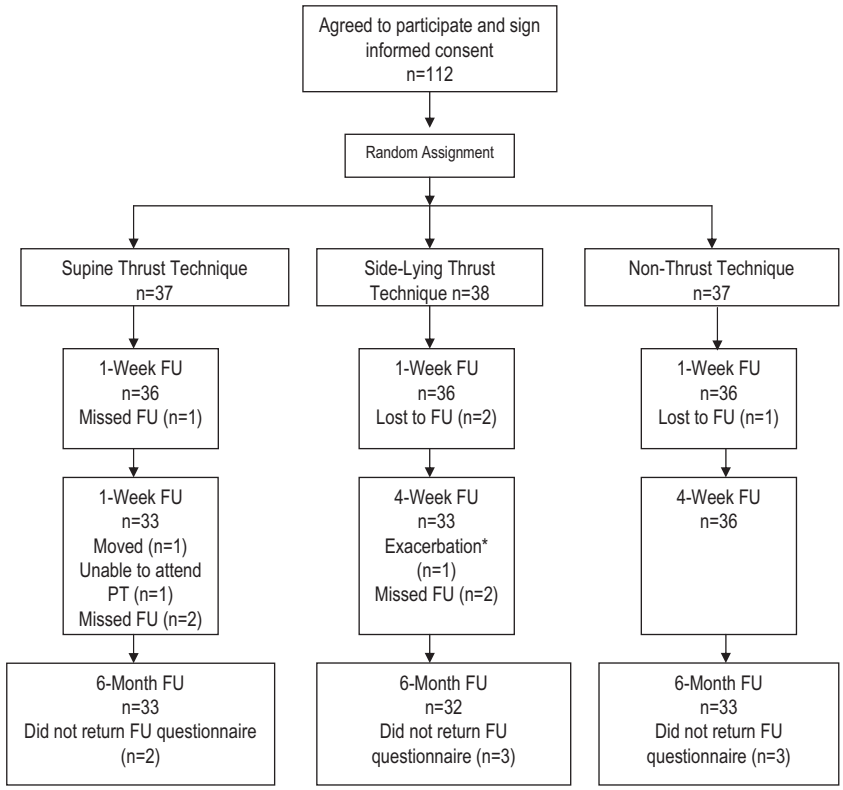

Figure 4. Flow diagram of subject retention. *Patient experienced exacerbation that was unrelated to the study and was withdrawn by the treating therapist.

thrust manipulation at any follow-up period (Table 3). Significant differences existed at each follow-up between the supine thrust manipulation and the nonthrust manipulation groups, and between the side-lying thrust manipulation and the nonthrust manipulation groups (Table 3). Pair-wise comparisons of NPRS scores also showed no differences between the 2 thrust manipulation groups at any follow-up. Significant differences existed between the supine thrust manipulation and nonthrust manipulation, and between the side-lying thrust manipulation and nonthrust manipulation at the 1-week and 4-week follow-ups, but not at 6-months (Table 3).

At each follow-up period significantly more patients achieved a successful outcome (at least 50% reduction in ODQ score) in the supine thrust and side-lying thrust manipulation groups then the nonthrust group (Figure 7). After 1 week success rates were 54.1%, 52.6%, and 8.1% for the supine thrust, side-lying thrust and nonthrust manipulation groups, respectively ($P < 0.001$). At the 4-week follow-up the success rates were 86.5%, 81.6%, and 18.9% ($P < 0.001$), while after 6 months the rates were 91.9%, 89.5%, and 67.6% ($P = 0.009$), respectively.

Due to the unbalanced recruitment, we compared only the New Hampshire, UT, and Los Angeles sites to explore differences in outcomes based on setting. Because there were no differences in outcome at any time point between the supine and side-lying thrust manipulation groups, we compared all patients receiving thrust

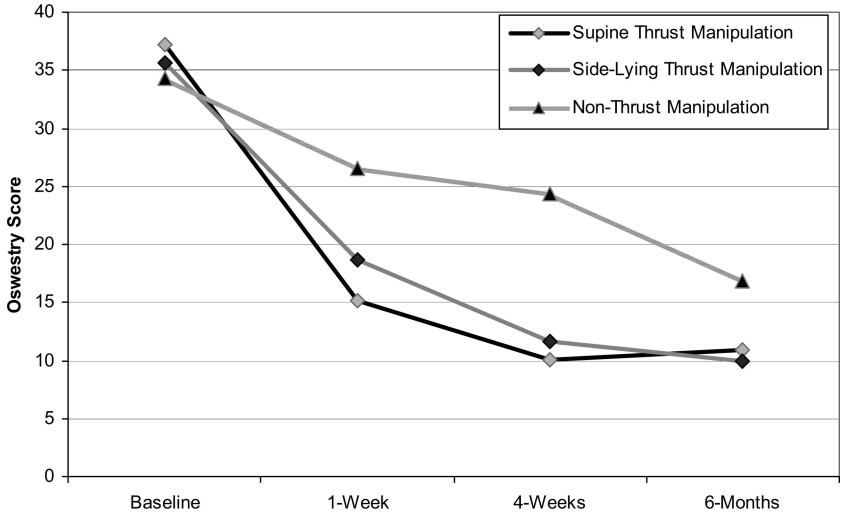

Figure 5. Estimated marginal means for the Oswestry Disability Scores at each data collection period.

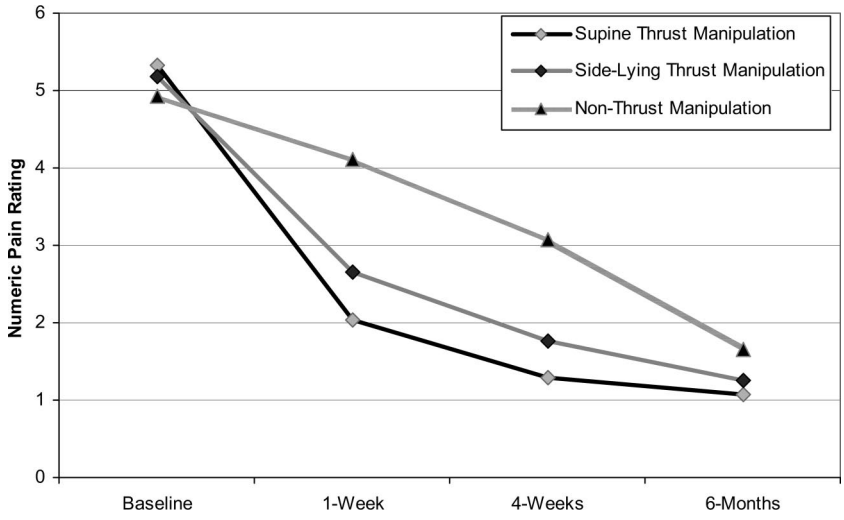

Figure 6. Estimated marginal means for numeric pain scores at each data collection period.

manipulation at 1 of these 3 settings, which included a total of 73 patients (41 from New Hampshire, 19 from Utah, 13 from Los Angeles). Comparison of baseline characteristics by setting revealed that patients from Los Angeles were younger, with a lower BMI than patients from either Utah or New Hampshire. Patients from Los Angeles also had higher FABQPA scores and a shorter duration of symptoms than patients from New Hampshire. These variables were therefore modeled as covariates in the analyses. There was no time by clinic interaction present for ODQ ($P = 0.14$) (Figure 8) or NPRS ($P = 0.41$) scores. Further exploration of the pair-wise differences did reveal a difference in ODQ scores at the one-week follow-up between patients treated with thrust manipulation in the Los Angeles and Utah settings (mean difference = 7.5, 95% CI: 1.1, 13.9) (Figure 8).

Overall, 28 patients (25%) reported at least 1 side effect. The percentage did not differ between treatment groups (Table 4). The most common side effect reported for all groups was aggravation of symptoms, followed by stiffness. All reported side effects began within 4 hours of treatment and were resolved within 48 hours of onset. No serious complications were reported by any patients.

Table 3. Pair-Wise Comparisons of the Estimated Marginal Means at Each Time Period

Variable	Supine Thrust *vs.* Side-Lying Thrust*	Supine Thrust *vs.* Nonthrust*	Side-Lying Thrust *vs.* Nonthrust*
Oswestry score			
1 wk	3.51 (−2.02, 9.04) $P = 0.21$	11.45 (5.29, 17.60) $P < 0.001$	7.94 (2.67, 13.20) $P = 0.003$
4 wk	1.50 (−4.08, 7.08) $P = 0.60$	14.23 (8.02, 20.43) $P < 0.001$	12.73 (7.47, 17.99) $P < 0.001$
6 mo	−0.85 (−5.52, 3.83) $P = 0.72$	5.97 (0.69, 11.25) $P = 0.027$	6.81 (2.28, 11.35) $P = 0.004$
Numeric pain rating scores			
1 wk	0.61 (−0.16, 1.38) $P = 0.12$	2.07 (1.22, 2.91) $P < 0.001$	1.46 (0.77, 2.15) $P < 0.001$
4 wk	0.47 (−0.57, 1.50) $P = 0.37$	1.79 (0.67, 2.90) $P = 0.002$	1.32 (0.47, 2.16) $P = 0.002$
6 mo	0.19 (−0.57, 0.96) $P = 0.62$	0.58 (−0.27, 1.43) $P = 0.18$	0.39 (−0.33, 1.10) $P = 0.29$

*Mean difference with 95% confidence interval.

■ Discussion

The primary goal of this study was to examine the generalizability of the CPR developed to identify patients with LBP likely to benefit from one thrust manipulation technique to another thrust manipulation technique and to a nonthrust manipulation technique. We also sought to examine the generalizability of the CPR to different settings. The results of the study support the generalizability of the CPR to an additional thrust manipulation technique, but not to a nonthrust manipulation technique. This result appears to be consistent with recent research that has re-examined the traditional theories that have been used to explain the mechanisms underlying the clinical benefit that some patients with LBP appear to derive from manipulation interventions. Traditional theories, although varied, have tended to focus on mechanical aspects of manipulation as central to their clinical impact including the disruption of "adhesions" or release of trapped intra-articular material in spinal joints, and the realigning of spinal structures.[27,49] If reducing restrictions to motion and structural realignment are the goals of manipulation, the velocity and amplitude of the manipulation may be less important consideration than the specificity and direction of the technique used because of the importance of specifically directing the force to the involved spinal segment in the required direction.[50] More recent explanations, however, suggest that the mechanism of effect for manipulation may be related to the unique sensory input of a high-velocity, low amplitude thrust on afferent discharge, and the subsequent effects on motoneuronal activity and central motor excitability.[51,52] Afferent response has been shown to vary based on the velocity and amplitude of the force applied.[53,54] If the mechanisms underlying the clinical effects of manipulation are related to these neurophysio-

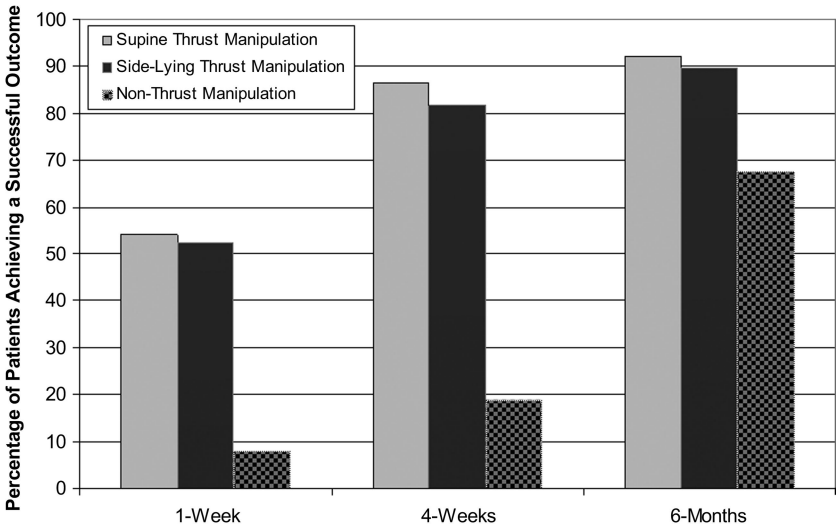

Figure 7. The percentage of patients in each treatment group achieving a successful outcome based on at least 50% reduction in Oswestry Scores.

logic responses, which are determined by the velocity and amplitude of the force, distinguishing between thrust and nonthrust techniques is likely to be critical.

The generalizability of the CPR to other thrust manipulation techniques, but not to nonthrust manipulation techniques, has been supported in previous clinical studies as well. Cleland *et al*[47] reported on a series of 11 patients with LBP who satisfied the CPR. The patients were treated with the side-lying thrust manipulation technique instead of the supine thrust manipulation used in the development of the CPR. Of the 11 patients, 10 demonstrated a successful outcome (>50% reduction in disability) after 1 week, supporting the generalizability of the CPR to alternative thrust manipulation techniques. Recently, Hancock *et al*[55] examined the results of a randomized trial[14] involving 239 patients with LBP randomized to receive either active or placebo manipulation. Nonthrust manipulation techniques were used for 97% of patients in the active manipulation group.[14] The authors reported that the patients' status on the CPR was not predictive of the clinical outcomes between the treatment groups.[55] These results, along with the results of the present study, indicate that the CPR is not generalizable to treatment protocols that substitute nonthrust manipulation techniques for thrust manipulation techniques.

The ability to examine the generalizability of the CPR to different settings was compromised by the unbalanced recruitment across settings in this study. In general our results supported the generalizability of the CPR to different settings from which patients were recruited in this study, however, additional research is needed to examine this issue. We believe that standardizing the clinical decision-making to use thrust manipulation with the CPR, and standardizing the treatment protocol and dosage will make the results achieved by using the CPR generalizable to different settings. Our previous research has supported this belief by finding comparable clinical outcomes for different individual physical therapists with varying levels of experience and expertise applying management for patients with LBP based on the CPR.[56]

Several shortcomings of the present study should be considered. We were not able to track the number of patients screened for eligibility in the study from each of the settings. Our previous research suggests that approx-

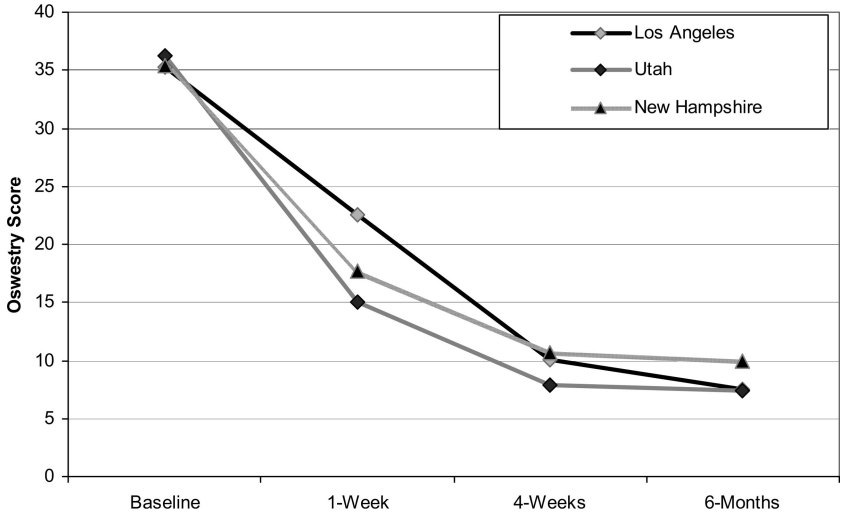

Figure 8. Comparison of outcomes by setting for patients receiving thrust manipulation.

Table 4. Frequency of Side Effects Reported in Each Group

	Supine Thrust Manipulation Group	Side-Lying Thrust Manipulation Group	Nonthrust Manipulation Group
No. subjects reporting side effects (%)	9 (24.3%)	9 (23.7%)	10 (27.0%)
Type of side effect reported			
Aggravation of symptoms	60%	44%	75%
Stiffness	27%	33%	17%
Spasm	13%	33%	0%
Radiating pain	0%	0%	8%

imately 25% to 40% of patients with LBP referred to physical therapy will be positive on the CPR.[10,33,47,57] We are not able to determine if this study fits with these previous estimates. Our study design did not include a control group, therefore we are unable to determine if the use of thrust manipulation for patients who are positive on the CPR would produce superior outcomes when compared to no treatment. Spontaneous recovery within the first few days or weeks is believed to occur frequently in individuals with an acute episode of LBP,[58] however, most patients in this trial had symptoms for a sufficient duration to make spontaneous symptom resolution unlikely. Only 14% of patients satisfied the <16 days criteria, and the mean duration of symptoms was 50 days. There was no difference in symptom duration among the treatment groups, therefore spontaneous resolution would not explain the different recovery rates between groups. We also did not use a placebo manipulation technique, therefore we are unable to determine the influence of placebo effects on the outcomes of the study. Because all patients received "hands-on" treatment and a standardized treatment schedule we believe that the placebo effect would be equally represented in all treatment groups.

■ Key Points

- There exists a lack of clarity in the literature distinguishing among types of manual therapy which may contribute to the mixed results reported in randomized trials and reflected in systematic reviews.
- Previously a clinical prediction rule (CPR) that could accurately identify a subgroup of patients with LBP likely to respond with rapid and prolonged reductions in pain and disability following thrust manipulation has been developed and validated. However, the CPR required further analysis to determine its generalizability to other thrust and nonthrust techniques and different practice settings.
- The results of the current study support the hypothesis that the CPR is generalizable to additional thrust manipulation techniques, but not to nonthrust manipulation techniques.
- In general our results also provided support that the CPR can be generalized to different settings from which it was derived and validated. However, additional research is needed to examine this issue.

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