Lumbar manipulation and exercise for the treatment of acute low back pain in adolescents: a randomized controlled trial

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Objectives: Low back pain (LBP) is a common condition in adolescents. Although much has been written about the efficacy of lumbar manipulation for adults with LBP, little is known about its effectiveness in adolescents. This study had two primary aims: (1) to assess the efficacy of adding lumbar manipulation to an exercise program in adolescents with acute (<90 days) LBP and (2) to report and assess any adverse reactions associated with lumbar manipulation noted in this study.

Methods: Patients were randomly assigned to receive lumbar manipulation or sham manipulation. All patients performed 4 weeks of physical therapy exercise. Pain, patient-specific functional scale (PSFS), and global rating of change (GROC) scores were measured at evaluation, 1 week, 4 weeks, and 6 months. Relative risk was calculated for adverse reactions noted.

Results: We recruited 35 consecutive patients with acute LBP. One patient was excluded after being diagnosed with a spondylolysis, 34 patients remained for analysis. Both groups experienced significant improvement over time in all measures. There were no differences between groups for pain, PSFS, or GROC scores. No increased risk of adverse reaction from lumbar manipulation was noted.

Discussion: The addition of lumbar manipulation to exercise did not benefit adolescents with acute LBP. There was not an increased risk of an adverse reaction noted in this study from lumbar manipulation performed on adolescents. Further research needs to be done to identify factors that predict positive outcomes following lumbar manipulation in adolescents.

Keywords: Adolescent, Manipulation, Lumbar, Low back pain, Orthopedic manipulative therapy

Introduction

The incidence of low back pain (LBP) in adolescents is increasing, and its impact on adulthood is significant. Burton *et al.*¹ found the lifetime prevalence of LBP at 15 years old to be 50%. More recent studies have found an even higher prevalence, suggesting that LBP is increasing in the adolescent population.² For most, the first incidence of LBP occurs before the age of 20 years. Having an episode of LBP in adolescence is a strong predictor of chronic LBP in adulthood.³ Effectively treating LBP in adolescents could reduce the dramatic impact of LBP when they become adults.

LBP in adolescents has been found to have significant differences than LBP in adults.⁴ The spine is undergoing major anatomical changes during periods of rapid growth and development until the age of 18 years, and spinal growth is mostly complete

by age 24 years.⁵ Adults with LBP demonstrate activity avoidance leading to deconditioning and poor core and lower extremity endurance, while adolescents are more likely to maintain prior levels of sports participation and activity levels. Due to the differences in LBP between adults and adolescents, one should be cautious using adult research to guide the treatment of adolescent LBP.

Lumbar manipulation has been shown to be an effective treatment in adults with LBP when part of a comprehensive treatment program. Current clinical practice guidelines recommend the use of thrust manipulations to reduce pain and disability.⁶ Although much has been written about the efficacy of lumbar manipulation for adults with LBP, little research has been performed assessing its effectiveness in adolescents. A recent systematic review by Vaughn *et al.*⁷ concluded that there is not enough evidence to support or refute the use of manipulative therapy in pediatric patients with spinal pain. Even though adults experience improvement with manipulation, it is not clear if adolescents would experience similar outcomes.

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Authors have expressed concerns about the safety of performing lumbar manipulations on younger patients citing concerns of the vertebral growth plates and hypermobility.^{8,9} Lumbar manipulation is frequently performed on adolescent patients, and moderate adverse events resulting in a temporary increase in symptoms have been reported in the literature.^{10,11} No serious adverse reactions to lumbar manipulation have been reported in the adolescent population, although the occurrence of serious events may be underreported and the true incidence of serious events is unknown.⁸ Analysis of the forces experienced during a manipulation suggests that adolescents can experience greater forces during sports and exercise. The average force imparted during a lumbar manipulation is 328 N.¹² Gymnasts can experience forces through the lumbar spine of 1000N, and blocking in football can be anywhere from 1000N to 8000N.^{13,14} Even common therapy exercises, like resisted side stepping, can reach 700N.¹⁵ The stress to the adolescent spine from lumbar manipulation is likely to be minimal compared to other commonly performed activities.

This study had two primary aims: (1) to assess the efficacy of adding lumbar manipulation to an exercise program in adolescents with acute (<90 days) LBP and (2) to report and assess any adverse reactions associated with lumbar manipulation noted in this study.

The secondary aims of this study were to assess if adding lumbar manipulation to an exercise program changes: (1) patients' perceived improvement, (2) recurrence of symptoms, or (3) additional treatment sought at 6-month follow-up.

Methodology

The design of this study was a blinded randomized controlled trial using a sample of convenience. We considered patients referred to a physical therapy clinic with a primary complaint. These pediatric outpatient orthopedic physical therapy clinics primarily treat adolescent patients. Eligible participants were recruited from May 2012 to April 2014. This study was registered at ClinicalTrials.gov (Identifier number NCT02111278). The institutional review board approved this study prior to recruitment and data collection.

Participants

Inclusion criteria were patients 13–17 years old, with mechanical LBP, and duration of symptoms <90 days. Patients were excluded if they had contraindications to manipulation. These included previous lumbar surgery, signs consistent with nerve root compression (positive straight-leg test of <45°, diminished reflexes, sensation, or lower extremity strength), pregnancy, and those diagnosed with, or suspected of having, a spondylolysis or spondylolisthesis.

Therapists

Patients were evaluated and directed in physical therapy by the 'exercise therapist.' Lumbar manipulation was performed by the 'manual therapist.' Both the exercise therapists and manual therapists were physical therapists who primarily treat adolescent patients with orthopedic injuries. There were a total of five manual therapists performing the lumbar manipulation, all of whom were proficient with the manipulation technique. Four of the five manual therapists were board certified orthopedic clinical specialists, and two were certified in manual therapy.

Interventions

Patients were randomly assigned to 1 of 2 treatment groups: lumbar manipulation + exercise or sham manipulation + exercise. The manipulating therapist performed the manipulation or sham based on group allocation only during the first two treatments. Both groups received 4 weeks of exercise provided by the exercise therapist who was blinded to the manual intervention that the patient received. Exercise consisted of lumbar stabilization, range of motion, postural training, core strengthening, and stretching. As the patient's symptoms improved, high-level functional exercises were added with the goal of returning the patient to all aspects of activity. These exercises were individualized to each patient's needs. The total number of treatment sessions prescribed was eight visits for both groups.

Manipulation group

The manual therapist performed the lumbar manipulation technique described by Flynn *et al.*¹⁶ With the patient supine, the therapist stood opposite the side to be manipulated. The patient was passively sidebent away from the therapist. The therapist passively rotated the thoracic spine and then delivered a quick posterior and inferior thrust through the anterior superior iliac spine. The manipulation was performed on the side, which the patient reported to be more symptomatic. If the patient was unable to identify a more painful side, the side to be manipulated was left to the manual therapist's discretion.

After the manipulation, the manual therapist noted whether a cavitation was heard or felt by the therapist or patient. If a cavitation was experienced, no more manipulations were performed in that session. If no cavitation was produced, the patient was repositioned, and the manipulation was attempted again. If no cavitation was experienced again, the therapist attempted to manipulate the opposite side. A maximum of two attempts per side were attempted.

Sham group

The manual therapist performed the sham lumbar manipulation technique with the patient sidelying. The therapist passively flexed both hips until slight lumbar flexion was noted at the patient's most

painful vertebral level. The therapists took their time palpating the patient's spine taking care to avoid rotating the spine. The therapist then placed both hands on the same lumbar spinous process. An equal and opposite force was then applied to the spinous process with both hands. No physiologic motion was expected with this technique. The therapist then set the patient up for the same sham technique on the opposite side. The sham manipulation technique was performed in an attempt to blind the patient to group allocation. This technique was designed to provide similar hands on treatment time as the manipulation intervention.

History and examination

Prior to randomization, patients completed self-report measures and received a standardized history and physical examination performed by the exercise therapist. The information collected included age, sex, duration and nature of symptoms, spinal mobility, and the Fear-Avoidance Beliefs Questionnaire physical activity subscale (FABQ-PA). We used the FABQ-PA to quantify the patient's fear of pain and beliefs about avoiding activity.¹⁷ Higher FABQ-PA scores have been associated with greater activity limitation in the adolescent population.¹⁸ The FABQ also includes a work subscale component that is scored separately from the FABQ-PA and was not included because many adolescents do not participate in regular work activity and the score would likely not be valid. To assess mobility of the spine, a posterior-anterior spring test was performed at each lumbar level. Mobility was judged as normal, hypomobile, or hypermobile.

Primary outcome measures

The self-report measures used to analyze the primary aims of this study included the patient-specific functional scale (PSFS) and numeric pain-rating scale (NPRS). The PSFS asks the participant to nominate three important activities that they are not able to do, or are having difficulty performing, because of their back pain. Each activity is scored on a numerical-rating scale from 0 (unable to perform) to 10 (able to perform at preinjury level).¹⁹ The PSFS has been shown to be more responsive than other low back outcome measures in adolescents and individuals with minimal activity limitations.^{20,21} The minimal clinical important difference (MCID) of the PSFS has been reported to be ± 6 points over three items.¹⁹ The NPRS is an 11-point pain-rating scale ranging from 0 (no pain) to 10 (worst imaginable pain) to assess current pain intensity as well as the best and worst level of pain during the last 24 hours.²² We used an average of the three ratings. A score of ± 2 represents the MCID.²³ Clinical significance was

defined as meeting or exceeding the MCID on each self-reported measure.

Adverse event reporting

An adverse event is an unfavorable symptom associated with an intervention. We classified adverse events noted in this study as severe, moderate, and mild. A severe adverse event was defined as death, a life-threatening event that requires hospitalization, or a persistent or significant disability.²⁴ We classified patients who experienced a clinically significant decrease in PSFS score (MCID of 6 point decrease) or increase in pain (MCID of 2 point increase) as having a moderate adverse reaction. Patients who reported experiencing pain or discomfort during or following the intervention, but did not have a clinically significant change in pain or function were classified as having a mild reaction. Patients who had an adverse reaction were re-evaluated by the exercise therapist. The patient would be referred back to their physician if he/she demonstrated a significant injury or were deemed inappropriate to continue physical therapy.

Secondary outcome measures

Patients also completed the global rating of change (GROC) scale to assess their perceived improvement. The GROC scale is a 15-point Likert type scale (-7 to $+7$). A score of 0 represents no change from initial injury, $+7$ represents a great deal better, and -7 represents a great deal worse.²⁵ A change in score of ± 3 represents the MCID.²⁶ GROC scores were collected at 1- and 4-week follow-up.

At the 6-month follow-up, patients were contacted by phone and asked if they had chronic symptoms or a recurrence of symptoms. Patients were asked only to consider symptoms significant enough to impair their ability to participate in activity. Patients were also asked if they sought additional treatment for their LBP after the study treatment had ended.

Sample size

Calculations regarding sample size were conducted using the formula recommended by Noordzij *et al.*²⁷ for randomized controlled trials. The PSFS was used for the primary outcome. Sample size calculations were made using a two-tailed test, with $\alpha=0.05$, $\beta=0.20$, an MCID between groups of 6, and a within-group standard deviation (SD) of 5.1. These parameters were based on the findings of previous research.^{19,20} Twelve patients per group were required to adequately power the study for the primary outcome measure.

Blinding and randomization

The manual therapist was aware of treatment allocation, whereas the exercise therapist and patient were blinded to treatment group allocation. We asked each patient to guess which intervention was per-

formed on them following discharge from therapy in order to assess if the patients were successfully blinded to group allocation. Randomization was determined by checking a randomly generated computer list that told the manual therapist the assigned group. An aide not involved in the study generated the computer list by blindly drawing 52 cards that placed an equal number of patients into either the manipulation or sham group.

Data analysis

All analyses were conducted using SPSS 21 software. An intent-to-treat design with the multiple imputation model was used for any missing values. We examined the first aim of the study with a two-way repeated measures multivariate analysis of variance (MANOVA) with treatment group as the between-patient variable and time (baseline, 1 week, 4 weeks, and 6 months) as the within-patient variable. The dependent variables were function (PSFS score) and pain. The relative risk of having an adverse reaction from manipulation was calculated to assess the second aim of this study. A Chi-square analysis was performed to determine if there were any differences between treatment groups for adverse reactions. *Post hoc* repeated measure univariate analyses were performed to assess the individual effect of manipulation on function, pain, and GROC. The alpha level for the univariate analyses were adjusted using the Bonferroni correction for multiple comparisons.

The success of patient blinding was assessed with a Kappa analysis. The patient's guessed group allocation was compared to actual group allocation. Blinding would be considered a success if the reliability of patient ability to guess group allocation is poor ($ICC < 0.50$).²⁸ A Chi-square analysis was performed to determine if there were any differences in treatment groups for recurrence of LBP as well as use of additional treatment after discharge.

Results

Thirty-five patients were enrolled after receiving written consent from the patients and their guardians. One patient was excluded from analysis after being allocated to the manipulation treatment group due to being diagnosed with a bilateral spondylolysis at the L5 vertebra. This patient did not finish all of his physical therapy treatments and was withdrawn from study after diagnosis. Thus, data from 34 patients were available for analysis (Figure 1). All patients received the randomized treatment (manipulation or sham).

Baseline variables were similar between treatment groups (Table 1). Nine patients dropped out of physical therapy before the 4-week follow-up (3 manipulation vs. 6 sham). All patients reported nonstudy related reasons for not continuing with

physical therapy treatment (time and financial constraints). The overall response rate for 6-month follow-up was 91%; we were unable to contact 3 patients for 6-month follow-up. The most common referring diagnosis for patients participating in this study was low back pain (82.4%). Other diagnoses were noted as well: lumbar strain (8.8%), degenerative disk disease (2.9%), low back/sacroiliac joint dysfunction (2.9%), and lumbar facet arthropathy (2.9%). Prior to referral for physical therapy, 94.1% of the patients had imaging of their low back performed by referring physician (Table 2).

The two-way treatment group $\times$ time interaction repeated measures multivariate MANOVA demonstrated no statistically significant between-group differences for function and pain with a mean difference between groups of 0.04 ($P = 0.90$). Within-group differences showed that both groups had statistically and clinically significant improvement at the 6-month follow-up. Repeated measures univariate ANOVA demonstrated no differences between treatment groups for function, pain, or GROC (Table 3).

No differences in the number of patients experiencing a worsening of symptoms were noted between groups (Table 4). At 1 week, 2 of 17 (11.8%) patients in the manipulation group had an adverse reaction to treatment compared with 2 of 17 (11.8%) in the sham group. No patients had adverse reactions at either the 4-week or 6-month follow-up. No patients reported having significant discomfort during or immediately after the manipulation or sham interventions. The relative risk of performing a lumbar manipulation is 1 (95% CI, 0.16–6.30), meaning that there was no additional risk of having an adverse reaction noted in this study.

Twenty of 31 patients, who replied at 6-month follow-up, had at least 1 significant recurrence of LBP symptoms. Thirteen of 31 patients sought additional treatment for LBP symptoms after the 4 weeks of exercise ended. There were no significant differences between treatment groups for recurrence of LBP or additional treatment sought (Table 5).

Twenty-two of 31 (70.9%) patients were correct in guessing group allocation with a kappa score of 0.418 (95% CI, 0.098–0.737), $P < 0.0005$.

Discussion

No other randomized controlled trial has looked at the effectiveness of lumbar manipulation in adolescent patients. Ahlqvist *et al.*²⁹ performed a randomized controlled trial finding that physical therapy is effective for adolescents with LBP. Individualized physical therapy care or self-management was prescribed to 45 patients for 12 weeks. Manipulation was an intervention available to the physical thera-

Figure 1 Flow diagram for patient recruitment and randomization.

Table 1 Baseline demographics and self-reported values

Variable	All patients (n=34)	Manipulation group (n=17)	Sham group (n=17)
Age	14.88 (1.27)	14.76 (1.15)	15.00 (1.41)
Gender (% female)	21 (61.7%)	12 (70.6%)	9 (52.9%)
Duration of symptoms (days)	47.00 (22.61)	43.76 (24.99)	50.24 (20.18)
Traumatic onset of symptoms	12 (35.3%)	7 (41.2%)	5 (29.4%)
FABQ physical activity	13.65 (4.21)	13.12 (3.89)	14.18 (4.56)
Hypomobile	12 (35.3%)	7 (41.2%)	5 (29.4%)
Participates in organized sport	28 (82.4%)	14 (82.4%)	14 (82.4%)
Symptoms distal to knee	1 (2.9%)	1 (5.9%)	0 (0%)
Pain	3.01 (1.44)	2.96 (1.30)	3.02 (1.58)
PSFS	13.52 (4.36)	14.29 (3.89)	12.76 (4.79)

Data are means (SD) or numbers (%).

PSFS: patient-specific functional scale.

Table 2 Imaging

Imaging	X-Ray	Bone scan	MRI
All patients (n=34)	32 (94.1%)	12 (35.3%)	5 (14.7%)

pist, but the number of patients who received manipulation was not reported. The results of that study though, may be biased as the group receiving physical therapy had significantly more attention from the investigators. Exercise has been shown to decrease pain and disability in adolescents with LBP.^{30–33} Our study found no additional benefit of adding lumbar manipulation to an exercise program for adolescents with acute low back pain.

There was no increased risk of experiencing a mild to moderate adverse reaction with adding lumbar manipulation to an exercise program noted in this study. Due to the rarity of a serious adverse event with lumbar manipulation, assessing the risk of a serious adverse event is outside of the scope of this study. The patient who was excluded from analysis after being diagnosed with a spondylolysis reported no adverse reaction during or following lumbar manipulation. After treatment for the spondylolysis, the patient returned to all activity without pain.

The addition of lumbar manipulation to an exercise program did not reduce the recurrence of LBP in adolescents. Disturbingly, 65% of patients in both groups still had LBP or had a recurrence of symptoms at 6-month follow-up. The results of this

study are consistent with other research, finding that adolescents had continued back pain and that symptoms did not resolve in 6 months for most patients even after prescribed rehabilitation.^{21,29} Hestbaek *et al.*³ found that patients having LBP in adolescence were four times more likely to have persistent LBP in adulthood. The results of our study appear to support that the chronicity of LBP seen in adults also occurs in a younger population. Although manipulation did not reduce the recurrence of pain, identifying interventions to successfully reduce long-term LBP in adolescents should be a focus of future research.

The sham manipulation was successful at blinding patients to group allocation. Patients were only slightly better than chance at correctly guessing if the lumbar manipulation or sham technique was performed. Most patients guessed that they were in the lumbar manipulation group suggesting that the sham technique is an effective method for blinding adolescent patients.

In the authors' experience, lumbar manipulation has been beneficial for certain adolescents with LBP for within-session decreases in pain and increases in motion. A subgroup of adolescents who benefit from lumbar manipulation may exist. The results of our study show that lumbar manipulation adds no benefit to exercise when used on a heterogeneous group of adolescents with LBP. Systematic reviews in adults demonstrate only marginal benefits of lumbar manip-

Table 3 Pairwise comparisons of function, pain, and GROC

		Evaluation mean (SD)	Week 1 mean (SD)	Week 4 mean (SD)	6 month follow-up mean (SD)	P Value	Adjusted difference* (95% CI)
Function (PSFS)	Manipulation	14.29 (3.88)	16.53 (5.03)	23.71 (4.63)	26.75 (4.40)	0.143	1.63 (−0.49, 3.75)
	Sham	12.76 (4.79)	14.53 (6.16)	20.91 (5.92)	25.67 (4.97)		
Pain (NPRS)	Manipulation	3.00 (1.33)	2.77 (1.83)	1.02 (1.26)	0.43 (0.76)	.369	−0.21 (0.24, −0.66)
	Sham	3.02 (1.58)	2.87 (1.78)	1.60 (1.35)	0.69 (0.86)		
GROC	Manipulation	0 (0)	1.60 (2.10)	4.93 (2.79)	–	.938	0.06 (−1.51, 1.63)
	Sham	0 (0)	1.80 (2.98)	4.27 (1.68)	–		

*Values calculated for each measure using repeated measure ANOVA.

PSFS: patient-specific functional scale; NPRS: numeric pain-rating scale; GROC: global rating of change.

Table 4 Number of adverse reaction × treatment group

Treatment group	Week 1	Week 4	6 months	Relative risk (95% CI)	P value
Manipulation	2 of 17 (11.8%)	0 of 17 (0 %)	0 of 17 (0 %)	1.00 (0.16, 6.30)	1.00
Sham	2 of 17 (11.8%)	0 of 17 (0 %)	0 of 17 (0 %)	1.00 (0.16, 6.30)	

Chi-square analysis used to calculate P-value.

Table 5 Responses to questions at 6-month follow-up

Questions	Manipulation	Sham	P value
Have you had a significant recurrence of low back pain since physical therapy	9 of 16 (56.3%)	11 of 15 (73.3%)	0.320
Have you sought further treatment for you low back pain	5 of 16 (31.3%)	8 of 15 (53.3%)	0.213

Values calculated using chi-square analysis.

ulation when used on a heterogeneous group of patients with LBP.^{34,35} Subgrouping patients increase the probability of a successful outcome with lumbar manipulation in adults.^{16,36} Lumbar manipulation on adolescents may have some benefit if prediction models similar to ones used in adults can be developed.

Limitations

The main limitation of this study is that the MCID's of the NPRS, PSFS, and GROC have only been established in the adult population. We currently have no information on the MCID of these self-reports measures in the adolescent population. Another limitation is that the use of a single, prescribed manipulation technique does not reflect typical manual therapy practice. Therapists use a variety of techniques guided by clinical experience and patient response to best treat their patients with manual therapy. The methodology chosen for this study does not necessarily reflect standard care.

Conclusion

The addition of lumbar manipulation to exercise did not benefit adolescents with acute LBP. No statistical or clinical differences were noted for pain, function, or GROC between groups. There was not an increased risk of an adverse reaction noted in this study from lumbar manipulation performed on adolescents in comparison to a group receiving a sham manipulation. Adolescents with LBP had a high frequency of chronic or recurrent symptoms at the 6-month follow-up. Future research should be done to try to identify a subgroup of adolescents with LBP who could benefit from lumbar manipulation similar to what has been found in adults.

Disclaimer Statements

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