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Immediate and Short-term Effects of Thoracic Spine Manipulation in Patients With Cervical Radiculopathy: A Randomized Controlled Trial

ecent evidence supports the use of high-velocity, low-amplitude thrust manipulation to the thoracic spine in patients with neck pain. ^{3,6,8,11,20,42,43} Immediate and short-term improvements in pain and cervical spine range of motion (ROM) have been

- BACKGROUND: Thoracic spine thrust manipulation has been shown to improve patient-rated outcomes for individuals with neck pain. However, there is limited evidence of its effectiveness in patients with cervical radiculopathy.
- OBJECTIVES: To compare the immediate and short-term effects of thoracic manipulation to those of a sham thoracic manipulation in patients with cervical radiculopathy.
- METHODS: In this multicenter randomized controlled trial, participants with cervical radiculopathy were randomized to receive either manipulation (n = 22) or sham manipulation (n = 21) of the thoracic spine. Outcomes were measured at baseline, immediately after treatment, and at a follow-up 48 to 72 hours after manipulation. A repeated-measures analysis of variance was used to analyze neck and upper extremity pain (numeric pain-rating scale), disability (Neck Disability Index), cervical range of motion (ROM), and endurance (deep neck flexor endurance test). The chi-square test was used to analyze changes in neck and upper extremity pain, centralization of symptoms, and beliefs about receiving the active manipulation treatment using a global rating of change scale.
- RESULTS: Neck and upper extremity pain, cervical ROM, disability, and deep neck flexor endurance all showed significant interactions between group and time (P<.01). Immediately after treatment and at the</p>

- 48-to-72-hour follow-up, the manipulation group had lower neck pain (P<.01), better cervical ROM (P<.01), lower disability (P<.01), and better deep neck flexor endurance (P = .02) compared to the sham manipulation group. The manipulation group had moderate to large effect-size changes over time. No betweengroup differences for upper extremity pain were found immediately following the intervention (P = .34) and at 48 to 72 hours after the intervention (P = .18). At 48 to 72 hours after treatment, a greater proportion of participants in the manipulation group reported improvement (global rating of change scale score of 4 or greater) in neck and upper extremity symptoms (P<.01), centralization of symptoms (P<.01), and beliefs about receiving an active manipulation (P = .01) compared to the sham manipulation group.
- CONCLUSION: One session of thoracic manipulation resulted in improvements in pain, disability, cervical ROM, and deep neck flexor endurance in patients with cervical radiculopathy. Patients treated with manipulation were more likely to report at least moderate change in their neck and upper extremity symptoms up to 48 to 72 hours following treatment.
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- **KEY WORDS:** clinical trial, neck pain, radiculopathy, thoracic spine, thrust manipulation

reported following manipulation of the thoracic spine.11 Moreover, thoracic manipulation has demonstrated better outcomes compared to mobilization (nonthrust) in patients with neck pain.8,32 Current evidence supports the use of thoracic manipulation in patients with neck pain, but there is a paucity of evidence for its use in patients with neck and arm pain related to cervical radiculopathy. A single case report has suggested that thoracic manipulation may be useful in the treatment of cervical radiculopathy, noting a decrease in upper extremity radicular symptoms following a single dose of thoracic manipulation.12 Thoracic manipulation may be a viable treatment option in the early phases of treatment, when cervical manual interventions may not be tolerated well by patients with cervical radiculopathy.12

Cervical radiculopathy is most commonly associated with a cervical disc derangement or other space-occupying lesion, resulting in nerve root inflammation, impingement, or both.³⁰ Patients can present with or without neck pain and with a multitude of upper extremity symptoms. Physical therapy management of cervical radiculopathy includes manual therapy, exercise, and cervical traction.^{3,7,9,30,39,42} Manual therapy may

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consist of mobilization/manipulation to the cervical and thoracic spine, neurodynamic techniques, and soft tissue mobilization. 12,27,42 Exercise involves strengthening the deep neck flexor muscles and scapular-thoracic region.9,42 Traction includes manual, mechanical, and home traction options.4,17,42 Studies indicate that a multimodal approach using these interventions has resulted in improved outcomes4,8,9,31,42 and can be predictive of a successful outcome in this patient population. The use of a standardized multimodal treatment of manual therapy and exercise has resulted in improvements in pain and disability.⁴²

Unfortunately, multimodal treatment studies are unable to establish the isolated intervention effects of thoracic manipulation on symptoms, impairments, and function. Moreover, a 2016 systematic review³⁵ reported a lack of evidence for the effectiveness of thoracic manipulation as a single-mode intervention in patients with cervical radiculopathy. This same systematic review³⁵ suggests a need for more evidence to support the use of thoracic manipulation as a treatment option in this patient population. Further research is needed to justify the use of thoracic manipulation and to understand its short-term effects on related impairments and outcomes in patients with cervical radiculopathy.

The primary purpose of this study was to assess the immediate and short-term effects of 1 session of thoracic manipulation in patients with cervical radiculopathy, compared to those of a sham thoracic manipulation, on the primary outcomes of neck and upper extremity pain and patient-perceived changes in neck and upper extremity symptoms. Secondary outcomes included neck disability, active cervical spine motion, deep neck flexor muscle endurance, upper extremity numbness and tingling, and symptom distribution. We hypothesized that participants randomized to receive thoracic manipulation would have greater improvements in pain, disability, cervical ROM, and deep neck flexor muscle endurance compared to those receiving sham manipulation. Further, we hypothesized that a greater proportion of participants in the manipulation group would report at least moderate improvement in neck and upper extremity symptoms, as well as centralization of symptoms, compared to those in the sham manipulation group.

METHODS

Participants

ONSECUTIVE PATIENTS WITH UNIlateral upper extremity pain, paresthesia, or numbness, with or without neck pain, were recruited for this multicenter randomized controlled trial at 6 orthopaedic physical therapy clinics in Georgia, Virginia, and California between September 2011 and July 2014. Inclusion criteria were being 18 to 65 years of age, having a Neck Disability Index (NDI) score of 10/50 points or greater, and having a clinical diagnosis of cervical radiculopathy, as defined by Wainner and Gill³⁸ (positive scores on 3 of 4 clinical tests: Spurling's test, upperlimb neurodynamic test/median nerve bias, cervical distraction test, and cervical rotation toward the symptomatic side of less than 60°). When 3 of these 4 tests are positive, the diagnostic accuracy has a specificity of 0.94 (95% confidence interval [CI]: 0.88, 1.00) and a positive likelihood ratio of 6.1 (95% CI: 2.0, 18.6).38 The inclusion criterion of an NDI score of 10 points or greater was selected to capture a meaningful clinical change of at least 8.5 points.41 Exclusion criteria included history of previous cervical or thoracic spine surgery, bilateral upper extremity symptoms, signs or symptoms of upper motor neuron disorder, medical red flags (eg, tumor, fracture, rheumatoid arthritis, osteoporosis, prolonged steroid use), and cervical steroidal injection or medication within the past 2 weeks. Patients who satisfied the eligibility criteria were invited to participate in the study. Participants were queried about prior thoracic or cervical thrust manipulation for their current condition, and none reported having received these manipulations for their current episode of cervical radiculopathy.

Procedures

Before participating in the study, all participants signed an informed-consent form, and the rights of participants were protected. The study protocol was approved by the Institutional Review Board at Virginia Commonwealth University Office of Research (HM13804). The protocol was registered on ClinicalTrials.gov (NCT01495728). Each participant underwent standardized data collection, which included patient-reported outcomes and impairment measures. The data-collection procedures were performed at baseline, immediately after treatment, and 48 to 72 hours after treatment. The evaluating physical therapist collected baseline outcomes and performed the manipulation and sham manipulation, while another clinician blinded to group allocation collected all follow-up outcomes. Randomization Following the baseline examination, participants were randomly assigned to receive manipulation or sham manipulation to the upper and mid thoracic spine. Numbered, sequential, sealed opaque envelopes containing group allocation for each clinic were opened by the evaluating physical therapist after the baseline examination. To decrease the potential effect of the clinic on treatment outcomes, randomization was stratified in blocks of 2 and 4 by clinic. Participants were blinded to group assignment. Blinding was assessed at the second follow-up time point (48-72 hours) by asking participants to indicate which group they believed they were assigned to (active or placebo look-alike treatment).

Intervention

Six physical therapists, 1 at each of the 6 outpatient clinics, recruited participants and performed the intervention. The physical therapists were 83% men (n = 5) and had an average of 8 years (range, 2-15 years) of orthopaedic physical ther-

apy experience. All clinicians were given on-site training and were provided with a standardized instruction manual for all examination, treatment, blinding, and data-collection procedures.

Manipulation Group Participants in the manipulation group received a supine high-velocity, low-amplitude thrust manipulation technique directed bilaterally to the upper thoracic (C7-T3) and midthoracic (T4-T9) spine (FIGURE 1; APPENDIX A, available at www.jospt.org). This specific technique has been described and used in clinical trials as a component for successful treatment of mechanical neck pain and cervicogenic headaches.14,15 If there was no audible cavitation, a second attempt was performed. An audible cavitation was expected for each manipulation to be considered a success. Audible cavitations were recorded for each group.

Sham Manipulation Group Participants in the sham manipulation group were placed in a position identical to that used in the manipulation group, except that the hand over the inferior vertebrae of the motion segment was open (fingers extended). Participants were then asked to inhale and then exhale, but no thrust manipulation was delivered during exhala-



FIGURE 1. Upper thoracic manipulation.

tion. This open-hand sham manipulation procedure has been described in detail in a previous clinical trial (APPENDIX A).⁶

Immediately after treatment and at the 48-to-72-hour follow-up, the physical therapist assessed for any adverse effects of manipulation, including an increase in neck, shoulder, arm, and/or hand symptoms. Participants in both groups were instructed to resume normal daily activities until the next scheduled visit, with no home exercise or advice. Participants were instructed to contact the investigator if they experienced any soreness lasting more than 3 hours.

Outcomes

The primary outcomes included selfreported pain of the neck and upper extremity on a numeric pain-rating scale (NPRS)22 and changes in perceived improvement on the global rating of change scale (GROC).21 The primary outcomes were selected to assess the immediate and short-term effects of thoracic manipulation on perceived benefits and common symptoms in participants with cervical radiculopathy. The secondary outcomes were disability on the NDI,36 cervical ROM,5 deep neck flexor muscle endurance,19 and numbness, tingling, and distribution of symptoms, which were used to assess the effects of thoracic manipulation on disability, cervical spine impairments, and centralization of the distal symptoms. The NPRS, cervical ROM, and deep neck flexor muscle endurance data were collected at baseline, immediately following the manipulation procedure, and at 48 to 72 hours after the procedure. The GROC was collected at both follow-up time points, and the NDI at baseline and 48 to 72 hours after the intervention.

The NPRS²² was administered by asking patients to rate the intensity of their current pain level on an 11-point scale ranging from 0 (no pain) to 10 (worst pain imaginable). Neck pain and upper extremity pain were separately assessed on the NPRS. Use of the NPRS for neck pain has been found to be reliable in pa-

tients with cervical radiculopathy,⁴¹ with a minimal clinically important difference (MCID) of 2.2 points.⁴¹ Clinically meaningful score cutoffs for the NPRS for pain in the upper extremity have not been established for patients with cervical radiculopathy. The MCID is 1.1 points in patients with shoulder-related pain.²⁵

The GROC is a 15-point scale²¹ on which respondents rate their perception of change after treatment. The scale ranges from –7 (a very great deal worse) to 0 (about the same) to +7 (a very great deal better). A score of +4 has been used to indicate moderate positive improvement in patient status.²¹ Participants rated their neck symptoms and upper extremity symptoms separately on the GROC.

The NDI³⁶ is a 10-item questionnaire that measures the impact of neck symptoms on functional activities. Each item is scored from 0 to 5, with a total score that ranges from 0 to 50 points and higher scores representing higher disability. The NDI has acceptable reliability in the assessment of self-perceived disability and an MCID of 8.5 points in patients with cervical radiculopathy.⁴¹

Active cervical ROM (flexion, extension, rotation, sidebending) was assessed using a goniometer, as described by Cleland et al.⁵ Rotation and sidebending were assessed on both the symptomatic and asymptomatic sides. The reliability of active cervical ROM measurements has been established in patients with mechanical neck pain.⁵ The minimal detectable change (MDC) of cervical ROM ranges from 9.6° to 18.8° for flexion, 7.0° to 13.0° for extension, 5.9° to 10.0° for right sidebending, 9.1° to 19.0° for left sidebending, 7.6° to 13.9° for right rotation, and 6.4° to 6.7° for left rotation.^{5,16}

The deep neck flexor muscle endurance test was performed as described by Harris et al.¹⁹ This test has been found to have moderate reliability, with an MDC of 16.2 seconds in patients with neck pain.¹⁹

The distribution of tingling, numbness, and symptoms associated with cervical radiculopathy was assessed before and after

treatment. Prior to treatment, patients were educated about their symptoms and centralization using a body diagram and written instructions (APPENDIX B, available at www.jospt.org)^{13,40} and confirmed that they understood the centralization phenomenon. A change in symptoms related to centralization was recorded as "yes" or "no" during both follow-up time points by the clinician blinded to group allocation.

Sample-Size Calculation

Currently employed, n (%)

Onset, n (%)

<1 mo

1-3 mo

3-6 mo

>6 mo

Unknown

*Values are mean \pm SD.

Fear of movement (yes), n (%)

Effect sizes (0.62-0.66) for changes in neck pain treated with a multimodal approach and thoracic manipulation in patients with chronic neck pain have been estimated in prior randomized trials.^{6,8,29} To generate a conservative sample-size estimate, we used an effect size of 0.40, alpha of .05, and power of 80%. A sample size of 22 participants per treatment

group was indicated to detect a groupby-time interaction. Anticipating a 15% loss to follow-up, we aimed to recruit 25 participants per group, for a total of 50. Recruitment was stopped before achieving the recruitment goal for 2 reasons: (1) a very low dropout rate, and (2) an interim analysis showing that the effect size for neck pain (0.80) exceeded both the conservative estimate (0.40) and the estimates from previous trials (0.62-0.66).^{6,8,29}

Data Analysis

All analyses were performed using SPSS Version 22 (IBM Corporation, Armonk, NY). Descriptive statistics were reported for the demographic characteristics of each group (TABLE 1). To determine whether covariates should be used in the analysis, baseline data for all outcome

15 (71.4)

17 (81.0)

3 (14.3)

4 (19.0)

2 (9.5)

11 (52.4)

1 (4.8)

variables were inspected. No betweengroup differences greater than the MDC for each outcome variable were identified; therefore, the analyses did not include baseline variables as covariates.

The primary analysis included separate 2-by-3, repeated-measures analysis of variance (ANOVA) models to assess the effect of thoracic manipulation on neck and upper extremity pain as measured by the NPRS. Given a significant interaction, independent t tests (1-tailed) were used to determine whether the manipulation group had lower scores on the NPRS at the 2 follow-up time points compared to the sham manipulation group.

For each group, the average changes in NPRS score (both neck and upper extremity pain) from baseline to immediately after treatment and from baseline to 48 to 72 hours after treatment were calculated. The average between-group differences for the changes in NPRS score from baseline to immediate follow-up and from baseline to follow-up after 48 to 72 hours were also calculated. The 95% CI and effect size (Cohen *d*) for all variables were calculated.

The GROC score was dichotomized for the analysis. Participants who reported a GROC score of at least +4 (moderately better) were classified as having a moderate to large change in neck and/ or upper extremity symptoms.21 The proportion of participants with a +4 GROC score or greater was compared between groups using a chi-square test at both follow-up time points. We calculated the odds ratio and 95% CI for those who scored at least +4 on the GROCs for both neck and upper extremity symptoms at the immediate and 48-to-72-hour followups. The number needed to treat and 95% CI to achieve a score of at least +4 on the GROCs for both neck and upper extremity symptoms were calculated at the 48-to-72-hour follow-up.

Independent 2-by-3, repeatedmeasures ANOVAs were used to assess between-group differences at each time point for each cervical ROM variable

TABLE 1	Baseline Demographic and Self-reported Variables			
Variable	Manipulation Group (n = 22)	Sham Manipulation Group (n = 21)		
Age, y*	48.8 ± 11.5	43.1 ± 10.8		
Sex (female), n (%)	17 (77.3)	12 (57.1)		
Height, m*	1.64 ± 0.1	1.67 ± 0.1		
Weight, kg*	70.6 ± 19.6	83.9 ± 18.4		
Dominant hand (right), n (%)	21 (95.5)	20 (95.2)		
Symptomatic side (right), n (%)	12 (54.5)	10 (47.6)		
Most troublesome symptom, n (%)				
Pain	19 (86.4)	17 (81.0)		
Numbness and tingling	3 (13.6)	3 (14.3)		
Unknown		1 (4.8)		
Previous treatment, n (%)				
Rest	8 (36.4)	4 (19.0)		
Cervical collar	1 (4.5)	0 (0)		
Medication	11 (50)	16 (76.2)		
Injection	4 (18.2)	7 (33.3)		
Cervical traction	2 (9.1)	4 (19.0)		

12 (54.5)

12 (54.5)

3 (13.6)

6 (27.3)

5 (22.7)

8 (36.4)

and the deep neck flexor endurance test. A 2-by-2, repeated-measures ANOVA was used to assess differences between groups at baseline and the 48-to-72-hour follow-up for NDI score. For both analyses, given a significant interaction, an independent t test (1-tailed) was used to assess whether the manipulation group had greater ROM, longer duration on the deep neck flexor endurance test, and lower NDI score compared to the sham manipulation group.

For each group, the average between-group difference for the change in cervical ROM and the deep neck flexor endurance test from baseline to immediate follow-up and from baseline to follow-up after 48 to 72 hours was calculated. The average between-group difference in change over time for the NDI was calculated between baseline and the 48-to-72-hour follow-up. The 95% CI and effect size (Cohen d) for all variables were calculated.

The proportion of participants reporting centralization of symptoms was compared between groups using a chi-square test. A chi-square test was also used to determine whether the proportion of participants who believed they were receiving an active versus an inactive intervention in each group differed. For all analyses, the alpha level was set at .05 a priori. Bonferroni correction was used to adjust the alpha level to .025 for all post hoc analyses of the significant ANOVAs.

RESULTS

ONSECUTIVE PATIENTS (N=71) were screened for study eligibility, and participants (n=43) who met the criteria and agreed to participate were enrolled in the study (**FIGURE 2**) and randomized to receive either thoracic manipulation (n=22) or sham manipulation (n=21). In each of the 6 clinics there were 5, 8, 7, 7, 8, and 8 participants, respectively.

Recording of adverse events indicated that no increases in neck, arm, or hand symptoms were reported immediately after treatment or at the 48-to-72-hour follow-up. Moreover, no participants reported soreness lasting more than 3

hours after the treatment. Audible cavitations were recorded in 100% of the manipulation group, while none were recorded in the sham manipulation group. A greater proportion of participants in the manipulation group (90%) believed they received the active treatment compared to those in the sham manipulation group (57%, P = .01).

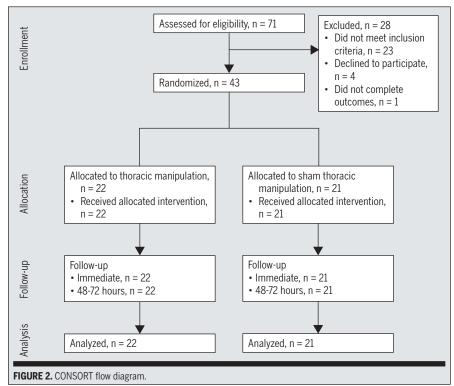
Primary Outcomes

A significant group-by-time interaction was found for both neck and upper extremity pain (P<.01). The subsequent independent t tests indicated that the manipulation group reported significantly less neck pain at both follow-up time points compared to the sham group (TABLE 2). There was no significant betweengroup difference for upper extremity pain at the 2 follow-up time points. At both follow-up time points, the manipulation group had a greater decrease in both neck and upper extremity pain compared to the sham group, and these changes were associated with large effect sizes (TABLE 2).

A significantly greater proportion of participants randomized to the manipulation group reported at least moderate improvement, with a GROC score of +4 or greater, in both neck and upper extremity symptoms compared to the sham manipulation group at both follow-up time points (TABLE 2). Similarly, the odds ratio values indicate that patients randomized to the manipulation group were more likely to report at least moderate improvements in their neck and upper extremity symptoms compared to the sham manipulation group at both followup time points (TABLE 2). At the 48-to-72hour follow-up, the number needed to treat was 2.2 (95% CI: 1.5, 4.5) for the GROC for neck symptoms, and 3.1 (95% CI: 2.0, 8.1) for the GROC for upper extremity symptoms.

Secondary Outcomes

Significant group-by-time interactions were found for the NDI (P<.01) (**FIGURE 3**), deep neck flexor endurance test (P<.01) (**FIGURE 4**), and active cervical ROM in flex-



ion (P<.01), extension (P<.01), rotation to the symptomatic (P<.01) and asymptomatic sides (P<.01), and sidebending to the symptomatic side (P<.01) (**FIGURE 5**). Immediately after treatment, the manipulation group had greater active cervical flexion (mean difference, 10.8°; 95% CI: 4.2°, 17.6°; P<.01), extension (mean difference, 10.0°; 95% CI: 3.1°, 17.0°; P<.01), and rotation to the symptomatic (mean difference, 14.2°; 95% CI: 7.1°, 21.3°; P<.01) and asymptomatic sides (mean difference, 9.2°; 95% CI: 1.8°, 16.7°; P = .02) compared to the sham manipulation group. At 48 to 72 hours after treatment, the manipulation group demonstrated greater active cervical flexion (mean difference, 13.7°; 95% CI: 7.1°, 20.3°; P<.01), extension (mean difference, 11.1°; 95%

CI: 4.5° , 17.8° ; P < .01), rotation to the symptomatic (mean difference, 13.9°; 95% CI: 7.4°, 20.5°; P<.01) and asymptomatic sides (mean difference, 11.4°; 95% CI: 5.0°, 17.9°; P<.01), sidebending on the symptomatic side (mean difference, 8.6°; 95% CI: 3.2°, 14.1°; P<.01), and deep neck flexor endurance (mean difference, 6.3 seconds; 95% CI: 0.5, 12.2; P = .02) compared to the sham manipulation group. Figure captions provide the between-group differences for changes in deep neck flexor endurance (FIGURE 4) and cervical AROM (FIGURE 5) between baseline and follow-up time points. The NDI score was lower in the manipulation group at 48 to 72 hours after the intervention compared to the sham manipulation group (mean difference, -7.8 points; 95%

CI: -13.3, -2.4; *P*<.01). The caption of **FIGURE 3** provides the between-group differences for changes in the NDI between baseline and follow-up time points.

A significantly greater proportion in the manipulation group versus the sham manipulation group reported centralization of symptoms immediately (55% versus 5%, P<.01) and at 48 to 72 hours (64% versus 5%, P<.01) after treatment.

DISCUSSION

HIS RANDOMIZED CLINICAL TRIAL ASsessed the effects of a single session of upper thoracic and mid-thoracic thrust manipulation in individuals with cervical radiculopathy. Patients randomized to receive thoracic manipula-

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PRIMARY OUTCOMES AT EACH DATA-COLLECTION TIME POINT

Outcome/Time Point	Manipulation Group (n = 22)*	Sham Manipulation Group (n = 21)*	Between-Group Differences†‡	Odds Ratio†	P Value
Baseline	6.8 ± 2.0	7.5 ± 1.9			
Immediate	5.0 ± 2.4	7.4 ± 1.7	-2.4 (-3.7, -1.2)		<.011
Change from baseline to immediate [†]	1.9 (0.9, 2.8), <i>d</i> = 0.9	0.1(-0.2, 0.5), d = 0.2	1.8 (0.7, 2.7), <i>d</i> = 1.1		
48-72 h	4.4 ± 2.5	7.5 ± 2.0	-3.1 (-4.5, -1.7)		<.019
Change from baseline to 48-72 h [†]	2.4 (1.3, 3.5), <i>d</i> = 1.0	0.1(-0.4, 0.5), d = 0.1	2.3 (1.2, 3.5), <i>d</i> = 1.3		
NPRS for upper extremity pain§					<.01"
Baseline	7.4 ± 2.2	6.6 ± 2.0			
Immediate	5.1 ± 2.4	5.9 ± 2.8	-0.8 (-2.4, 0.8)		.341
Change from baseline to immediate [†]	2.2 (1.2, 3.2), <i>d</i> = 1.0	0.7 (-0.2, 1.6), d = 0.4	1.5(0.2, 2.8), d = 0.7		
48-72 h	5.1 ± 2.0	6.0 ± 2.6	-1.0 (-2.4, 0.5)		.181
Change from baseline to 48-72 h [†]	2.3 (1.5, 3.2), <i>d</i> = 1.2	0.6 (-0.3 , 1.5), $d = 0.3$	1.7 (0.5, 2.9), <i>d</i> = 0.9		
GROC for neck symptoms, n (% improved)#					
Immediate	11 (50.0)	2 (9.5)		9.5 (1.8, 50.7)	<.01**
48-72 h	11 (50.0)	1 (4.8)		20.0 (2.3, 176.1)	<.01**
GROC for upper extremity symptoms, n (% improved)#					
Immediate	9 (40.9)	2 (9.5)		6.6 (1.2, 35.5)	.02**
48-72 h	7 (31.8)	0 (0.0)		Infinity	<.01**

 $Abbreviations: GROC, global\ rating\ of\ change;\ NPRS,\ numeric\ pain-rating\ scale.$

^{*}Values are mean \pm SD unless otherwise indicated.

[†]Values in parentheses are 95% confidence interval.

[‡]Calculated as manipulation group minus sham group at each time point.

[§]A 0-to-10 scale, where 0 is no pain.

[&]quot;Interaction effect.

^{*}Between-group post hoc comparison (independent-samples t test).

^{*}Those who reported at least +4 ("moderately better") were categorized as "improved."

^{**}Between-group comparison (chi-square test).

tion as compared to sham manipulation had greater improvements in neck pain, neck-related patient-rated disability, and cervical impairments (ROM and deep neck flexor endurance) immediately and up to 48 to 72 hours after treatment. At both follow-up time points, a greater proportion of patients in the manipulation group reported at least a moderate change in their neck and upper extremity symptoms and centralization of their symptoms compared to patients in the sham manipulation group.

Primary Outcomes

NPRS (Neck Pain) and GROC (Neck Symptoms) Immediately after manipulation, the average reduction in NPRS for neck pain was 1.9 points in the manipula-

NPRS (Neck Pain) and GROC (Neck Symptoms) Immediately after manipulation, the average reduction in NPRS for neck pain was 1.9 points in the manipulation group, compared to 0.1 points in the sham manipulation group, for a betweengroup mean change of 1.8 points. These changes over time and associated large effect sizes may indicate a large treatment effect for thoracic manipulation in patients with cervical radiculopathy.

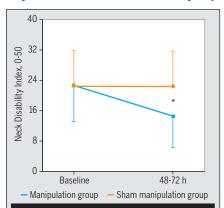


FIGURE 3. Mean Neck Disability Index score for the manipulation group (blue line) and the sham manipulation group (orange line). Error bars represent 1 SD. There was a significant group-bytime interaction (*P*<.01). *Significant between-group difference at 48-to-72-hour follow-up (independent t test *P*<.025). Mean between-group difference for the change in Neck and Disability Index score was calculated as mean change in the manipulation group minus mean change in the sham manipulation group, and reported with 95% confidence interval (CI) and effect size. From baseline to 48 to 72 hours, the mean between-group difference of the change in Neck Disability Index score was 8.0 points (95% CI: 4.5, 11.6 points) and the effect size was 1.4.

However, it should be noted that the lower-bound CI (0.7) does not meet the MCID (TABLE 2).

Similar results were found at the 48-to-72-hour follow-up (TABLE 2). Cleland et al6 reported an immediate reduction of 15.4 mm on a 0-to-100-mm visual analog scale for neck pain when patients with neck pain were treated with thoracic manipulation. Direct comparison to the study by Cleland et al⁶ is cautioned, as the study included patients with mechanical neck pain and used a different pain scale. Further, the specific manipulation techniques used in these studies differed. Cleland et al6 used a flexion-based technique that more likely targeted the mid-thoracic spine, whereas the current study used an extensionbased technique, which enabled a closer fulcrum contact to the cervicothoracic junction during the upper thoracic manipulation. In the current study, the av-

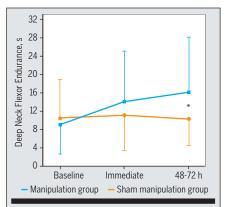


FIGURE 4. Mean deep neck flexor endurance for the manipulation group (blue line) and sham manipulation group (orange line). Error bars represent 1 SD. There was a significant group-by-time interaction (P<.01). *Significant between-group difference at 48-to-72hour follow-up (independent t test P<.025). Mean between-group difference for the change in deep neck flexor endurance was calculated as mean change in the manipulation group minus mean change in the sham manipulation group, and reported with 95% confidence interval (CI) and effect size. From baseline to immediately after treatment, the mean betweengroup difference of the change in deep neck flexor endurance was 4.5 seconds (95% CI: 0.9, 8.0 seconds) and the effect size was 0.8. From baseline to 48 to 72 hours, the mean between-group difference of the change in deep neck flexor endurance was 7.8 seconds (95% CI: 3.7, 11.9 seconds) and the effect size was 1.2.

erage reduction in NPRS score for neck pain (2.4 points) in the manipulation group exceeded the MCID at the 48-to-72-hour follow-up.

When evaluated using the GROC, 50% of patients who received thoracic manipulation reported at least a moderate positive change in their neck symptoms compared to those who received the sham manipulation at both time points. This is a proportion nearly as high as that reported by Young et al42 (68%) in patients with cervical radiculopathy who were treated with a 4-week multimodal intervention of manual therapy and exercise, with or without traction. The low number needed to treat associated with immediate and short-term moderate improvements in neck symptoms may indicate that thoracic manipulation should be considered as an intervention in patients with cervical radiculopathy.

NPRS (Upper Extremity Pain) and GROC (Upper Extremity Symptoms) Post hoc testing indicated no between-group differences for the upper extremity NPRS at either time point. However, the betweengroup difference for the change in upper extremity NPRS score indicated greater reduction in arm pain of 1.5 points at the immediate follow-up and 1.7 points at the 48-to-72-hour follow-up, favoring the manipulation group. Although these changes were associated with moderate to large effect sizes, respectively, it should be noted that the lower-bound CIs at both follow-up points did not meet the MCID (TABLE 2).

However, these changes in arm pain after manipulation may still be clinically meaningful, as those patients in the manipulation group were significantly more likely to report at least a moderate change in the GROC score for upper extremity symptoms compared to patients in the sham manipulation group. The distal symptoms of patients with cervical radiculopathy are often treated with a comprehensive multimodal approach, which primarily targets both the cervical spine and neurodynamic system. ^{7,9,39,42} Therefore, larger between-group differences

in upper extremity pain might have been less likely to occur, as the participants received only a single session of manipulation to the thoracic spine.

Secondary Outcomes

Neck Disability Index At the 48-to-72-hour follow-up, the NDI score was lower in the manipulation group compared to the sham manipulation group, but the between-group difference for the change in NDI score (8.0 points) did not exceed the MCID of 8.5 points. ⁴¹ Cleland et al⁸ examined the effect of thoracic manipu-

lation in patients with neck pain, and reported that the manipulation group had a 6-point greater reduction in NDI score compared to the mobilization group at 48-to-96-hour follow-up. Unfortunately, the isolated effects of thoracic manipulation cannot be estimated, as additional cervical ROM exercise was included in the treatment of both groups. Although between-group differences of this magnitude generated with a single treatment technique may be clinically important, these effects may wash out at longer-term follow-up, as demonstrated by a recent

study that pragmatically applied thoracic thrust and nonthrust manipulation in patients with mechanical neck pain.¹⁸

Active Cervical ROM From baseline to 48 to 72 hours after treatment, greater increases in cervical ROM flexion, extension, rotation on the symptomatic and asymptomatic sides, and sidebending on the symptomatic side were measured in the manipulation group compared to the sham manipulation group. These findings are consistent with the results of previous studies of thoracic manipulation for neck pain. 11,43

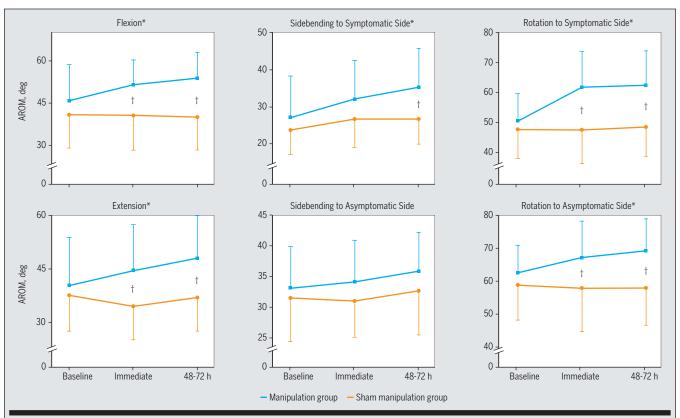


FIGURE 5. Mean cervical AROM for the manipulation (blue line) and sham manipulation (orange line) groups. Error bars represent 1 SD. *Significant group-by-time interaction (*P*<.01). 'Significant between-group difference at designated follow-up time point (independent *t* test *P*<.025). Mean between-group difference was calculated as mean change in the manipulation group minus mean change in the sham manipulation group, and reported with 95% Cl and effect size. For flexion, the mean between-group difference for the change from baseline to immediately after treatment was 5.7° (95% Cl: 0.7°, 10.8°) and the effect size was 0.7; from baseline to 48 to 72 hours it was 8.6° (95% Cl: 2.3°, 14.8°) and the effect size was 0.8. For extension, the mean between-group difference for the change from baseline to immediately after treatment was 7.2° (95% Cl: 1.9°, 12.5°) and the effect size was 0.8; from baseline to 48 to 72 hours it was 8.4° (95% Cl: 3.0°, 13.7°) and the effect size was 1.0. For sidebending on the symptomatic side, the mean between-group difference for the change from baseline to immediately after treatment was 2.2° (95% Cl: -2.5°, 6.9°) and the effect size was 0.3; from baseline to 48 to 72 hours it was 5.3° (95% Cl: -2.3°, 4.9°) and the effect size was 0.9. For sidebending on the asymptomatic side, the mean between-group difference for the change from baseline to immediately after treatment was 1.3° (95% Cl: -2.3°, 4.9°) and the effect size was 0.2; from baseline to 48 to 72 hours, it was 11.5° (95% Cl: -2.6°, 5.6°) and the effect size was 0.2. For rotation on the symptomatic side, the mean between-group difference for the change from baseline to 48 to 72 hours it was 11.2° (95% Cl: 6.3°, 16.2°) and the effect size was 1.4. For rotation on the asymptomatic side, the mean between-group difference for the change from baseline to immediately after treatment was 5.6° (95% Cl: 0.7°, 10.5°) and the effect size was 0.7; from baseline to 48 to 72 hours it was 7.8° (95% Cl: 2.1°, 13.5°) and the effect size was 0.

The measures of rotation and sidebending toward the symptomatic side are particularly interesting, as the diagnostic criteria for cervical radiculopathy37 include a positive Spurling A test (sidebending on the symptomatic side with overpressure) and restricted rotation on the symptomatic side (less than 60°). Greater mobility in these specific, and often provocative, measures may have had a clinical effect, as suggested by the between-group differences in pain/disability found in this study. In contrast, a recent systematic review questioned the clinical utility of using cervical ROM as an outcome measure following manipulation in patients with neck pain.34 The authors suggest that there is conflicting evidence as to whether cervical ROM increases or decreases following mobilization/manipulation, and caution clinicians in making clinical judgments primarily based on cervical ROM.34

Deep Neck Flexor Muscle Endurance Test A greater increase in endurance of the deep neck flexors was measured in the manipulation group from baseline to the 48-to-72-hour follow-up compared to that measured in the sham manipulation group. The average between-group difference for the change in deep neck flexor endurance hold time was 7.8 seconds. However, this difference may not be meaningful, as it does not exceed the MDC measured in patients with neck pain (16.2 seconds).

These results should be interpreted with caution because patients with cervical radiculopathy may have shorter average times on the deep neck flexor endurance test compared to both patients with neck pain and controls.19 In a prior study, patients with neck pain treated with a single session of thoracic thrust manipulation demonstrated greater deep neck flexor endurance compared to those receiving nonthrust mobilization.15 The very short-term follow-up for reassessment may reduce the likelihood of muscle endurance changes, as these would be expected with a longer period of muscle training.23 The improvement in

deep neck flexor muscle performance in participants with cervical radiculopathy may be due to pain inhibition, as the participants in the manipulation group had greater reductions in pain at follow-up. In summary, it is likely that manipulation does not have a direct effect on muscle endurance but promotes changes in pain/symptoms/disability.

Tingling and Numbness and Distribution of Symptoms (Centralization) Fourteen (64%) of the participants in the manipulation group and 1 (5%) of the participants in the sham manipulation group reported centralization of symptoms at 48 to 72 hours. This phenomenon was originally associated with performance of repeated movements in patients with low back pain. 13,40 Although centralization has not specifically been assessed in prior studies of participants with cervical radiculopathy, multiple studies have reported reductions in upper extremity symptoms and symptom distribution following mobilization/manipulation, neurodynamic techniques, exercise, and traction. 1,10,12,17,26,27,42 The repeated motion of cervical retraction has been reported to help reduce nerve root compression and upper extremity pain in patients with C7 radiculopathy.1 The movement of retraction involves upper cervical flexion and, more importantly, lower cervical extension. Interestingly, the upper thoracic manipulation performed in this study promotes translatory extension of the lower cervical and upper thoracic spinal segments while the upper cervical spine is resting in neutral/slight flexion (similar to end-range retraction).

Further, it has been proposed that restoration of normal biomechanics to the cervicothoracic motion segment may have a role in lowering mechanical stresses and improving distribution of joint forces in the cervical spine. ²⁸ In light of these mechanical constructs, it is interesting to note that the manipulation group had greater active cervical extension compared to the sham manipulation group at both follow-up time points (**FIGURE 5**). The reduction in local

and distal symptoms of the manipulation group may have been a result of a mechanical effect on the lower cervical spinal joints, disc derangements, or nerve root impingement.

Limitations

One limitation of this study is the very short-term follow-up. There has been some speculation on the limited importance of the immediate effects of a treatment intervention, as longer-term follow-up is ideal. However, for daily clinical practice, the investigation of immediate/short-term effects of an isolated technique can be useful. Moreover, this trial provides a foundation for future studies with longer follow-up.

Further, the sham manipulation procedure utilized in this study may not have been an adequate control. A greater proportion of participants in the manipulation group believed they received the intervention compared to those in the sham manipulation group. This might have influenced the outcomes between groups through different patient expectations. Future research should ensure the believability of sham procedures for use in clinical trials.

CONCLUSION

In this study, 1 session of thoracic manipulation to patients with cervical radiculopathy resulted in improved pain, disability, cervical ROM, and deep neck flexor endurance compared to those patients treated with sham manipulation. Patients treated with manipulation were also more likely to report at least moderate change in their neck and upper extremity symptoms up to 48 to 72 hours following treatment. The findings of this study aid clinician decision making in treatment selection for immediate and short-term benefits for patients with cervical radiculopathy.

Output

Description:

KEY POINTS

FINDINGS: One session of upper thoracic and mid-thoracic thrust manipulation

provided immediate and short-term benefits in perceived recovery, pain, disability, and neck impairments in patients with symptoms of cervical radiculopathy.

IMPLICATIONS: The results suggest that thoracic manipulation in patients with cervical radiculopathy is an effective early treatment option.

CAUTION: The results should not be generalized to a comprehensive multimodal treatment strategy or longer-term follow-up. Patients' beliefs of treatment received may have influenced the outcomes.

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APPENDIX A

DESCRIPTION OF HIGH-VELOCITY, LOW-AMPLITUDE THRUST AND SHAM PROCEDURES

High-Velocity, Low-Amplitude Thrust Manipulation

Manipulation technique directed bilaterally to the upper thoracic (C7-T3) and mid-thoracic (T4-T9) spine. Participants were positioned supine with their arms and forearms flexed across the chest, with the elbows aligned in a superoinferior direction (FIGURE 1). The therapist contacted the transverse processes of the lower vertebrae of the target motion segment with the thenar eminence and middle phalanx of the third digit. The upper lever was targeted by adding the secondary levers of rotation away from and sidebending toward the therapist. The lower lever, or underside hand, used pronation and radial deviation to achieve rotation (toward) and sidebending (away) moments. Participants were instructed to deeply inhale and exhale. During the exhalation phase, the space inferior to the xiphoid process and costochondral margin was used as the contact point against the patient's elbows to deliver a high-velocity, low-amplitude thrust manipulation in an anterior-to-posterior direction. If there was no audible cavitation with the manipulation, a second attempt was performed to further isolate the motion segments. An audible cavitation was expected for each manipulation to be considered a success.

Sham Manipulation

Participants were placed in the identical setup position as that for participants included in the active manipulation group, except for hand positioning. An open hand (extended fingers) was placed over the inferior vertebrae of the motion segment. Once the "premanipulative position" was achieved, the patient was instructed to take a deep inhalation and then exhale. No high-velocity, low-amplitude thrust manipulation was performed during the exhalation phase in the sham manipulation group.

APPENDIX B

DESCRIPTION OF CENTRALIZATION

Patient #____

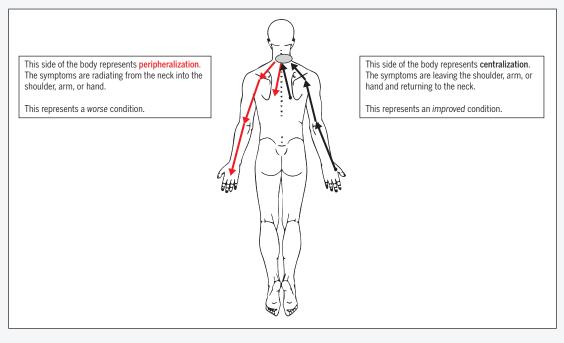
Please read carefully

The symptoms (pain/tingling/numbness) you have in your shoulder/arm or hand are likely a result of a problem in your neck. Although you may not have neck pain at this time, the test the physical therapist has performed on you today helped him or her identify your neck as the cause of your symptoms in the shoulder/arm/hand area.

Centralization

Joints, nerves, and disc material in your neck can send symptoms (pain/tingling/numbness) into the shoulder, arm, or hand. This process is called *peripheralization*. When pressure is relieved in the neck, the shoulder, arm, or hand symptoms may disappear or move toward the area that produced them (the neck). This concept is called *centralization*.

For example, let's say you have pain or numbness in the arm or hand that is coming from the neck. You then receive treatment to try and relieve the pressure in the neck area. Following treatment, you notice that the pain and numbness in the arm/hand is gone, but your neck feels a bit worse. This is the centralization process. It is very important to understand that this treatment is considered a success, and the therapist would consider you "better" even though your neck pain may be somewhat worse. We consider the symptoms away from your neck the more severe symptoms with your injury, and we want to eliminate them or get them closer to the neck.



*I have read and understand the information above. (1) Yes (2) No