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Exercise Only, Exercise With Mechanical Traction, or Exercise With Over-Door Traction for Patients With Cervical Radiculopathy, With or Without Consideration of Status on a Previously Described Subgrouping Rule: A Randomized Clinical Trial

STUDY DESIGN: Randomized clinical trial.

OBJECTIVES: To examine the effectiveness of cervical traction in addition to exercise for specific subgroups of patients with neck pain.

BACKGROUND: Cervical traction is frequently used, but its effectiveness has not been adequately examined. Existing studies have failed to target patients most likely to respond. Traction is typically recommended for patients with cervical radiculopathy. A prediction rule has been described to identify a narrower subgroup of patients likely to respond to cervical traction.

METHODS: Patients with neck pain and signs of radiculopathy were randomized to 4 weeks of treatment with exercise, exercise with mechanical traction, or exercise with over-door traction. Baseline assessment included subgrouping-rule status. The primary outcome measure (Neck Disability Index, scored 0-100) and secondary outcome measure (neck and arm pain intensity) were assessed at 4 weeks, 6 months, and 12 months after enrollment. The primary analyses examined 2-way treatment-by-time interactions. Secondary analyses examined validity of the subgrouping rule by adding 3-way interactions.

RESULTS: Eighty-six patients (53.5% female; mean age, 46.9 years) were enrolled in the study. Intention-to-treat analysis found lower Neck Disability Index scores at 6 months in the mechanical traction group compared to the exercise group (mean difference between groups, 13.3; 95% confidence interval: 5.6, 21.0) and over-door traction group (mean difference between groups, 8.1; 95% confidence interval: 0.8, 15.3), and at 12 months in the mechanical traction group compared to the exercise group (mean difference between groups, 9.8; 95% confidence interval: 0.2, 19.4). Secondary outcomes favored mechanical traction at several time points. The validity of the subgrouping rule was supported on the Neck Disability Index at the 6-month time point only.

CONCLUSION: Adding mechanical traction to exercise for patients with cervical radiculopathy resulted in lower disability and pain, particularly at long-term follow-ups. The study protocol was registered at http://clinicaltrials.gov (NCT00979108).

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Cervical radiculopathy is a common diagnosis, based clinically on the presence of neck pain extending into the arm accompanied by signs of nerve root compression during the physical examination.[39] The pathology underlying cervical radiculopathy is typically presumed to involve narrowing of the intervertebral foramen due to inflammation and/or degenerative changes.[45] Rates of surgical procedures for cervical radiculopathy and degenerative conditions have grown rapidly in the United States,[1,44] with the attendant costs and complication risks,[29] highlighting the need to identify the most effective nonop-

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erative management strategies.

Few randomized clinical trials have investigated nonoperative management strategies in patients with cervical radiculopathy.[30,40] Various types of therapeutic exercise have been found to be effective for patients with nonspecific neck pain[2,30] but have been studied only sparsely for patients with cervical radiculopathy. Cervical traction is another frequently recommended, yet inadequately researched, treatment for patients with cervical radiculopathy.[35,36] Despite its common use by physical therapists and other providers,[15,16] clinical trials that have examined cervical traction have not found the intervention to be superior to other strategies.[18,40,48]

Several factors might have influenced the effectiveness of cervical traction in prior clinical trials. Previous studies[6,34] have suggested that inadequate specificity in patient selection may be at least partly responsible for the lack of effectiveness. Improved targeting of treatment to patients most likely to benefit has shown promise toward enhancing effect sizes in clinical trials,[26] yet the characteristics of patients likely to benefit from cervical traction remain mostly a matter of opinion and low-level evidence. Observational studies and practice guidelines suggest that traction may be most effective in the subgroup of patients with neck pain who exhibit signs of cervical radiculopathy.[6,8,9,16] Raney and colleagues[34] identified even more-specific criteria associated with clinical benefit from treatment that includes cervical traction. Five clinical factors were predictive of benefit: (1) peripheralization of symptoms with lower cervical mobility testing, (2) positive shoulder abduction sign, (3) positive manual distraction test, (4) positive upper-limb tension test, and (5) age of 55 years or older. The presence of at least 3 of these 5 factors provided optimal predictive validity and was proposed to define a subgroup of patients highly likely to respond to cervical traction.[34] Only a few previous clinical trials have exclusively evaluated patients with cervical radiculopathy, and the validity of the more-specific traction subgroup remains unexamined.

Additional factors that could have influenced the results of previous clinical trials examining cervical traction include the particular treatment parameters used. Clinical studies have used protocols with varying patient positioning (seated versus supine), traction force, and mode of delivery (motorized devices, manual application, or over-door units). Additional research comparing well-defined protocols with varying treatment parameters is needed to determine optimal delivery strategies.

The purpose of this study was to evaluate the ability of cervical traction to improve clinical outcomes when added to a standard exercise program in specific groups of patients with neck pain. Our primary research question was to evaluate the effectiveness of cervical traction in a sample of patients with signs of radiculopathy and to evaluate the effect on outcomes of the manner in which cervical traction was provided by comparing traction using a motorized device to an over-door unit designed for home use. Secondarily, we examined if targeting traction to a more-specific subgroup of patients, defined by the presence of at least 3 of the 5 previously defined factors,[34] would improve clinical outcomes.

METHODS

This study was a randomized clinical trial involving 3 groups. Institutional Review Boards at Intermountain Healthcare, University of Utah, and Wilford Hall Medical Center approved the study. Patients gave written informed consent for participation. The study protocol was registered at http://clinicaltrials.gov (NCT00979108).

Patients

Patients were recruited from physician and physical therapy offices in Salt Lake City, UT (University of Utah and Intermountain Healthcare systems) and San Antonio, TX (San Antonio Military Medical Center) from July 2009 through March 2012. Eligibility criteria were a chief complaint of neck pain with symptoms (pain or numbness) extending distal to the acromioclavicular joint or caudal to the superior border of the scapula, age between 18 and 70 years, and a Neck Disability Index (NDI) score of 10 or greater (0-100 scale). Patients were excluded if they had a history of surgery to the neck or thoracic spine, a recent motor vehicle accident (past 2 weeks), any red flags indicative of a serious or possible nonmusculoskeletal condition (eg, spinal tumor, fracture, metabolic or infectious disease), a diagnosis of cervical spinal stenosis based on magnetic resonance imaging or computed tomography imaging, or evidence of cervical myelopathy or central nervous system involvement (eg, hyperreflexia, nystagmus, loss of visual acuity, impaired facial sensation, pathologic reflexes). Patients were excluded if they knew they would be unable to comply with the treatment or follow-up schedule.

Measures

Self-reported demographic characteristics (age, gender, height, weight, history of current and past neck pain, prescription pain medication use, employment status, past medical history, smoking status, education level, and marital status) were collected at baseline. A physical examination was used to evaluate the specific subgrouping criteria and additional measures.[34,43] Symptom responses were assessed for active cervical movements (flexion, extension, sidebending, and rotation) with the patient seated and for passive cervical mobility testing (posterior-to-anterior mobilization) with the patient prone. Symptom responses were categorized as centralization if the movement abolished or resulted in change of location of distal symptoms toward the spinal midline, peripheralization if the result was distal changes of symptoms away from midline, and no effect if neither response occurred. Additional examination procedures included the shoulder

abduction test. With the patient seated, the examiner asked the patient to place 1 hand on his or her head. Reduction or resolution of symptoms within 30 seconds was considered a positive test. The manual distraction test was performed with the patient supine, with the examiner flexing the patient's neck for comfort and then applying a distraction force of about 14 kg (30 lb). Reduction or resolution of distal symptoms was considered a positive test. The upper-limb tension test was performed with the patient supine. The examiner sequentially placed the patient's upper extremity into scapular depression, shoulder abduction, forearm supination, wrist and finger extension, shoulder external rotation, elbow extension, and contralateral and then ipsilateral cervical sidebending. Symptom reproduction, a side-to-side difference of 10° or more in elbow extension, or an increase in symptoms with contralateral cervical sidebending or a decrease in symptoms with ipsilateral cervical sidebending defined a positive test.[34]

The Tampa Scale of Kinesiophobia was used to assess patients' fear of movement.[28] The Tampa Scale of Kinesiophobia includes 17 items, each scored 1 to 4, resulting in a final score of 17 to 68, with higher scores indicating greater fear. The Pain Catastrophizing Scale was used to assess patients' catastrophic thinking related to pain.[37] The Pain Catastrophizing Scale includes 13 items, each scored 0 to 4, for a final score ranging from 0 to 52, higher scores representing greater catastrophic thinking. Kinesiophobia and pain catastrophizing are risk factors for poor recovery from neck pain.[5,23] The European Quality of Life-5 Dimensions was used to assess patients' perception of their overall health, with a visual analog scale anchored at 100 ("best imaginable health state") and 0 ("worst imaginable health state").[13]

The primary outcome was the NDI,[42] a 10-item measure of disability due to neck pain, with a total score ranging from 0 to 100, higher numbers indicating greater disability. The NDI has documented reliability, validity, and responsiveness as a measure of disability due to neck pain.[11,41] A secondary outcome was the intensity of neck pain, evaluated with an 11-point numeric pain rating scale, on which patients rated their current pain intensity and the best and worst pain intensity over the past 24 hours. The mean of the 3 ratings was used as the measure of neck pain intensity. Similar ratings were used to assess the intensity of arm pain.

Follow-up assessments were conducted at 4 weeks, 6 months, and 12 months after enrollment by a researcher who was blinded to the patients' treatment group. Primary and secondary patient-reported outcomes were repeated. Additional secondary outcomes evaluated at the follow-up assessments were patients' self-reported global rating of change from beginning of treatment to present, using a 15-point scale ranging from "a very great deal worse" to "a very great deal better,"[21] and health care utilization of either epidural steroid injections or a surgical procedure (cervical fusion, discectomy, etc) for neck pain. At the 4-week follow-up, patients completed a questionnaire to record adverse reactions perceived as treatment related.[20] Patients were asked, "Did you experience any discomfort or unpleasant reaction from treatments during the past 4 weeks?" Those who answered yes were provided with a list of possible symptoms (increased pain, stiffness, headaches, nausea, etc) and could add other symptoms. For each symptom, patients rated its severity (mild, moderate, severe) and duration (less than 1 hour, 1-24 hours, greater than 24 hours).

Blinding

Based on the study design, it was not possible to blind the patients or the physical therapists who provided treatments. Research personnel conducting assessments were blinded to patients' treatment group. Patients were reminded not to reveal information about their treatment allocation to the researchers at the follow-up examinations.

Randomization

Patients were assigned to treatment after completion of baseline procedures. Randomization was stratified based on specific subgrouping status (positive or negative). Subgrouping status was based on prior research[34] and involved 5 baseline factors: (1) peripheralization of symptoms with lower cervical (C4-7) mobility testing, (2) positive shoulder abduction test, (3) positive manual distraction test, (4) positive upper-limb tension test, and (5) age of 55 years or older. Patients were categorized as positive if 3 or more factors were present, and negative if 2 or fewer factors were present. Randomization was conducted using opaque, sealed envelopes prepared prior to beginning enrollment. Allocation sequences were generated in block sizes of 6, 8, or 10, using a web-based randomization generator (www.randomization.com). A research assistant opened randomization envelopes after completing all baseline activities.

Treatment

Patients were randomized to 1 of 3 treatment groups: exercise alone, exercise plus mechanical traction, or exercise plus over-door traction. All patients were scheduled to receive 10 individual physical therapy sessions over a 4-week treatment period: 3 sessions per week for the first 2 weeks, and 2 sessions per week for the final 2 weeks. Each session was 30 to 45 minutes in duration and was provided by a licensed physical therapist trained by the researchers in all study procedures.

Exercise Group

Patients in the exercise group received an active exercise program commonly used for patients with neck pain and supported by research.[4,24,25,46] All patients were instructed to remain as active as possible and to perform all exercises daily on the days between therapy sessions. Written exercise instructions were provided. The exercise program had 2 components: scapula strengthening and cervical strengthening. Cervical strengthening exercises included supine craniocervical

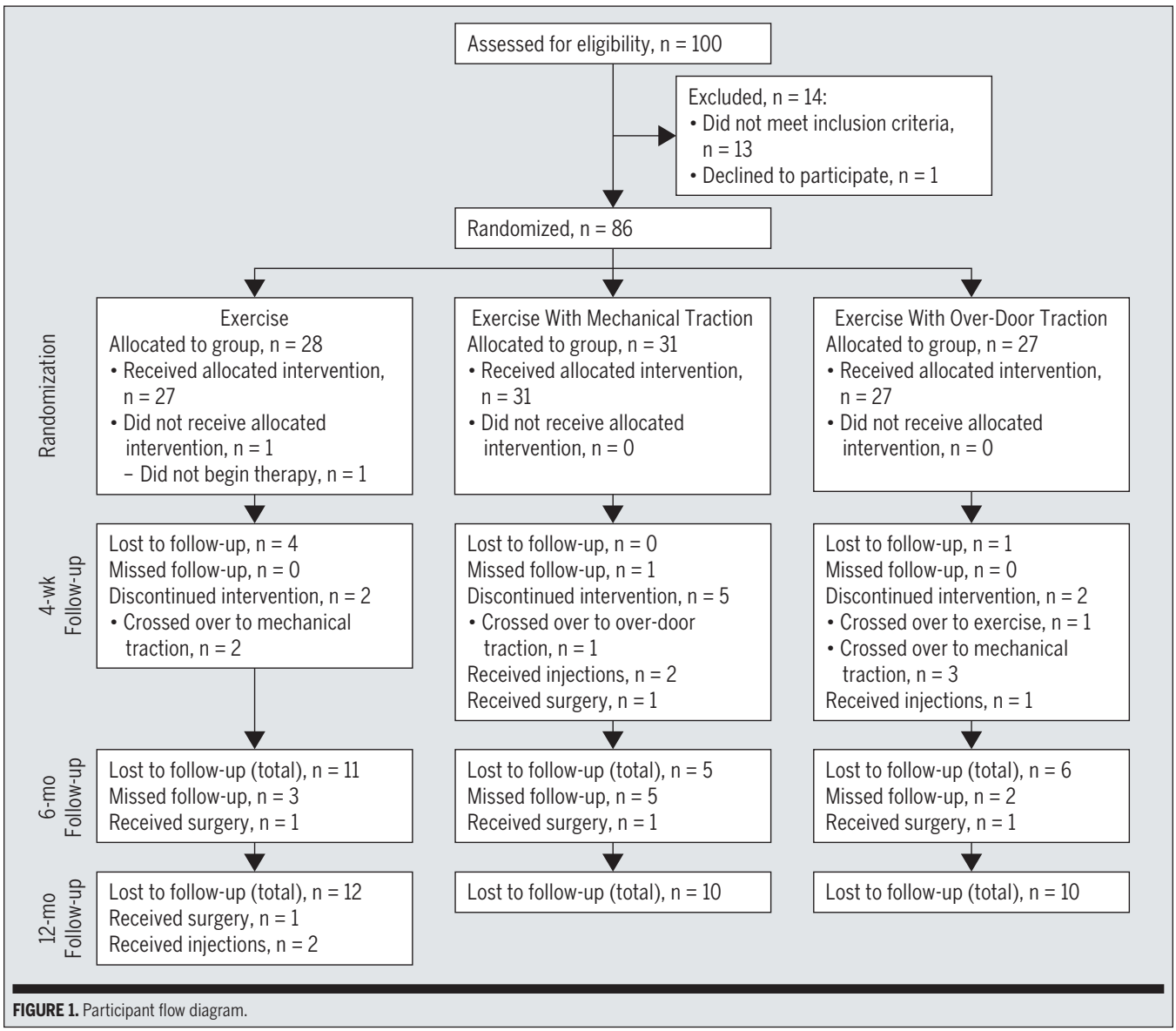

FIGURE 1. Participant flow diagram.

flexion to elicit contraction of the deep neck flexor muscles without contraction of superficial neck muscles.[14] Feedback using an air-filled pressure sensor or tactile cues was permitted. The goal was to perform 10 contractions of 10 seconds with proper muscle activation. Supine cervical flexion was performed by asking the patient to maintain craniocervical flexion while lifting the head to improve endurance of deep cervical flexors. Three sets of 15 repetitions was the goal, and resistance could be added. Craniocervical flexion contractions were also performed with the patient seated, with the goal of 30 repetitions of 10-second contractions. Scapular retraction against resistance using elastic bands or pulleys could be added. Scapular-strengthening exercises included prone horizontal abduction, sidelying forward flexion, prone extension of each shoulder, as well as prone push-ups with emphasis on shoulder protraction. The goal was 3 sets of 10 repetitions, with resistance added as tolerated.

Mechanical Traction Group

The mechanical-traction group received the same interventions as the exercise group, with the addition of mechanical cervical traction during treatment sessions. Traction was applied with a Saunders 3D ActiveTrac or Chattanooga Triton table (DJO, LLC, Vista, CA). The traction protocol has been previously described.[34] The patient was supine. The angle of pull for the traction was 15° of cervical flexion but could be adjusted to maximize comfort. Intermittent traction with 60 seconds of pull force and 20 seconds of relaxation force was used. An initial pull force of 5.44 kg (12 lb) was used

TABLE 1 Baseline Patient Characteristics*

	All Patients (n = 86)	Exercise Group (n = 28)	Mechanical Traction Group (n = 31)	Over-Door Traction Group (n = 27)
Age, y	46.9 ± 10.7	44.9 ± 11.3	48.1 ± 10.0	47.6 ± 10.9
Female, n (%)	46 (53.5)	18 (64.3)	13 (41.9)	15 (55.6)
BMI, kg/m^2	29.6 ± 6.1	29.3 ± 5.0	29.1 ± 5.8	30.7 ± 7.5
Duration of current symptoms, median d (IQR)	53 (30-151)	100 (36-682)	46 (28-85)	48 (19-123)
Duration of current symptoms greater than 6 wk, n (%)	33 (38.4)	8 (28.6)	12 (38.7)	13 (48.1)
Prior neck pain episode, n (%)	41 (47.7)	15 (53.6)	15 (48.4)	11 (40.7)
Positive for specific subgrouping criteria, n (%)	41 (47.7)	11 (39.3)	17 (54.8)	13 (48.1)
Bilateral symptoms, n (%)	8 (9.3)	3 (10.7)	4 (12.9)	1 (3.7)
Symptoms into hand(s), n (%)	76 (88.4)	27 (96.4)	27 (87.1)	22 (81.5)
Missed work for current episode of neck pain, n (%)	29 (33.7)	12 (42.9)	9 (29.0)	8 (29.6)
Anxiety/depression comorbidity, n (%)	29 (33.7)	8 (28.6)	11 (35.5)	10 (37.0)
Current smoker, n (%)	9 (10.5)	2 (7.1)	3 (9.7)	4 (14.8)
Married or live with significant other, n (%)	62 (72.1)	17 (60.7)	24 (77.4)	21 (77.8)
Education level: college degree, n (%)	37 (43.1)	15 (53.6)	11 (35.5)	11 (40.7)
Currently taking prescription pain medication, n (%)	62 (72.1)	20 (71.4)	24 (77.4)	18 (66.7)
Currently taking opioids, n (%)	27 (31.4)	10 (35.7)	9 (29.0)	8 (29.6)
Currently taking muscle relaxants, n (%)	25 (29.1)	9 (32.1)	7 (22.6)	9 (33.3)
Self-rated general health (0-100)	66.9 ± 18.9	65.4 ± 17.6	65.9 ± 20.3	72.2 ± 18.1
Neck Disability Index (0-100)	32.8 ± 14.1	35.0 ± 13.9	30.9 ± 14.8	32.7 ± 13.8
Neck pain intensity (0-10)	4.2 ± 2.1	4.4 ± 2.0	3.8 ± 2.1	4.5 ± 2.1
Arm pain intensity (0-10)	4.3 ± 2.4	4.1 ± 2.5	4.2 ± 2.2	4.6 ± 2.6
Tampa Scale of Kinesiophobia (17-68)	36.2 ± 7.1	35.7 ± 7.0	36.1 ± 6.9	36.7 ± 7.6
Pain Catastrophizing Scale (0-52)	18.9 ± 12.0	20.7 ± 12.3	18.9 ± 11.7	17.1 ± 12.2
Treatment sessions attended	8.4 ± 2.4	7.8 ± 2.7	8.8 ± 2.3	8.6 ± 2.3

Abbreviations: BMI, body mass index; IQR, interquartile range.
**Values are mean ± SD unless otherwise indicated.*

and incrementally adjusted based on the patient tolerance and symptom response, with the goals of maximum symptom reduction and centralization of symptoms. The relaxation force was 50% of pull force. Each traction treatment was 15 minutes in duration, and at the completion of the traction the patients remained supine for 2 minutes before standing up. Traction could be provided either before or after the exercise intervention, based on the physical therapist's discretion.

Over-Door Traction Group

Patients in the over-door traction group received the same exercise interventions plus traction using a Chattanooga Overdoor Traction Device (DJO, LLC) during treatment sessions and provided to patients for daily use at home on days between sessions. The protocol was based on previous studies.[12,32] Patients were instructed to set up the traction unit according to the manufacturer's instructions, with the over-door bracket-and-pulley assembly on the top edge of a door, with a straight-back chair directly beneath the assembly. Traction was applied with the patient seated facing the door, with feet flat on the floor. An initial traction force of 3.63 to 5.44 kg (8-12 lb) was used, based on tolerance and symptom response, with the goal of maximizing symptom reduction and centralization. Force was adjusted to the maximum of 9.07 kg (20 lb), as permitted by the device. Traction treatment time was 15 minutes, after which patients remained seated for 2 minutes. Traction could be provided either before or after the exercise intervention, based on the physical therapist's discretion.

Data Analysis, Sample Size, and Power

Descriptive statistics were computed for the sample and by treatment group. Baseline prognostic variables were examined between groups to identify potentially important imbalances. Important imbalances were judged based on clinical importance of differences and potential to bias outcomes instead of statistical significance.[33] Analyses were based on intention-to-treat principles, with all patients analyzed with the group to which they were randomized. Primary end points were between-group comparison

TABLE 2 Primary and Secondary Outcome Scores at Baseline and Follow-ups, Based on Mixed Models, Adjusted for Covariates From the Intention-to-Treat Analyses

	Baseline	4 wk	6 mo	12 mo
Neck Disability Index (0-100)				
Exercise group (n = 28)*	35.5 ± 13.9	11.0 ± 5.6	22.5 ± 14.1	20.1 ± 18.4
Mechanical traction group (n = 31)*	30.9 ± 14.8	9.1 ± 9.4	9.2 ± 9.4	10.3 ± 9.0
Over-door traction group (n = 27)*	32.4 ± 13.8	9.6 ± 9.5	17.3 ± 11.7	17.8 ± 18.4
Exercise versus mechanical traction†		2.0 (−2.3, 6.2), *P* = .36	13.3 (5.6, 21.0), *P* = .001	9.8 (0.2, 19.4), *P* = .046
Exercise versus over-door traction†		1.5 (−2.8, 5.9), *P* = .48	5.2 (−2.6, 13.0), *P* = .19	2.2 (−7.9, 12.4), *P* = .66
Mechanical versus over-door traction†		−0.4 (−4.6, 3.7), *P* = .84	−8.1 (0.8, 15.3), *P* = .031	−7.6 (−17.2, 2.0), *P* = .12
Neck pain intensity (0-10)				
Exercise group (n = 28)*	4.5 ± 2.0	2.6 ± 2.0	3.0 ± 2.3	2.7 ± 2.3
Mechanical traction group (n = 31)*	3.9 ± 2.1	1.4 ± 1.4	1.1 ± 1.4	1.6 ± 1.7
Over-door traction group (n = 27)*	4.7 ± 2.1	2.0 ± 2.2	2.3 ± 2.0	2.4 ± 2.2
Exercise versus mechanical traction†		1.2 (0.2, 2.2), *P* = .020	1.9 (0.7, 3.2), *P* = .003	1.1 (−0.3, 2.4), *P* = .12
Exercise versus over-door traction†		0.6 (−0.4, 1.7), *P* = .23	0.7 (−0.6, 2.0), *P* = .27	0.2 (−1.2, 1.7), *P* = .75
Mechanical versus over-door traction†		−0.6 (−1.6, 0.4), *P* = .24	−1.2 (−2.4, −0.03), *P* = .045	−0.8 (−2.2, 0.6), *P* = .23
Arm pain intensity (0-10)				
Exercise group (n = 28)*	4.1 ± 2.5	1.6 ± 2.0	3.2 ± 3.0	2.2 ± 2.6
Mechanical traction group (n = 31)*	4.3 ± 2.2	1.4 ± 1.6	0.9 ± 1.9	0.8 ± 1.1
Over-door traction group (n = 27)*	4.6 ± 2.6	1.6 ± 2.0	1.0 ± 1.4	1.2 ± 1.6
Exercise versus mechanical traction†		0.2 (−0.9, 1.2), *P* = .76	0.0 (−1.1, 1.1), *P* = .96	−0.2 (−1.2, 0.9), *P* = .75
Exercise versus over-door traction†		2.4 (0.9, 3.8), *P* = .002	2.2 (0.8, 3.7), *P* = .004	−0.1 (−1.6, 1.2), *P* = .84
Mechanical versus over-door traction†		1.4 (0.3, 2.2), *P* = .017	1.0 (−0.3, 2.2), *P* = .12	−0.4 (−1.6, 0.7), *P* = .45

**Values are mean ± SD.*
†Values are mean (95% confidence interval) between-group difference. Baseline scores may differ from values in **TABLE 1** *due to additional variables in the models.*

of NDI scores, analyzed with linear mixed models with repeated measures. This has the advantage of retaining all patients in the analysis, despite missing observations, by using maximum-likelihood estimation to estimate missing values, which maximizes the probability as a function of the observed values and the unknown parameters and avoids assumptions of independence of repeated observations. The physical therapist nested within a clinic was modeled as a random effect, with a variance-components covariance structure. Covariates, treatment group, and treatment-group-by-time interaction were included with treatment-group-by-time interaction to examine the primary hypothesis related to the effectiveness of the different treatments. Pairwise mean differences with 95% confidence intervals (CIs) were calculated for each follow-up. The hypothesis that traction would be most effective among patients who met the specific subgrouping criteria was examined with similar procedures, by including a 3-way, time-by-group-by-subgrouping status interaction term. Because the specific criteria were developed using a mechanical-traction protocol, we were specifically interested in pairwise comparisons between patients positive for subgrouping criteria who received mechanical traction and those who received mechanical traction and were negative for subgrouping criteria, and those who met the subgrouping criteria and received other treatments. An alpha of .05 was used for all analyses. Similar procedures were used to examine neck and arm pain intensity outcomes.

Self-reported global rating of change at each follow-up was categorized as successful for patients who rated their change from the beginning treatment as "quite a bit better," "a great deal better," or "a very great deal better." All other responses were categorized as nonsuccessful. Missing values for global rating scores were imputed using all available baseline demographic variables, as well as primary and secondary outcome variables. Results of 5 imputation iterations were averaged. The proportion of successful outcomes within each group was examined using the Fisher exact test for each follow-up.

Secondary analyses evaluated only patients compliant with treatment protocols by excluding data from those who received either surgery or injections. An "as-treated" secondary analysis examined patients who, during the treatment period, received treatment other than that of their randomized group assignment.

The original sample-size projection was based on detecting a significant pair-

wise difference for the 3-way interaction effect on the primary outcome (NDI). Considering a 10-point NDI difference as clinically important, with a 14-point standard deviation, and presuming that 35% of patients would be positive on the subgrouping criteria, a sample of 32 patients per cell or an overall sample of 192 patients was required to achieve 80% power.[7,47] This sample size would provide 98% power for the primary hypothesis related to the 2-way interaction. Slower-than-anticipated recruitment resulted in a smaller sample of 86 patients, which provided 80% power for the primary hypothesis and 70% for the secondary hypothesis, using the same assumptions.

RESULTS

Of the 100 persons examined for eligibility, 86 were enrolled and randomly assigned to treatment (**FIGURE 1**). Slightly over half (53.5%) were female (mean ± SD age, 46.9 ± 10.7 years). Most patients (88.4%) had symptoms extending into the arm and hand. Median symptom duration was 53 days, with 33 patients (38.4%) having a symptom duration of greater than 6 weeks and 11 (12.8%) reporting a symptom duration of greater than 1 year. Thirty-two patients (37.2%) were lost to follow-up during the study period. There were no significant differences in age, gender, body mass index, duration of symptoms, Tampa Scale of Kinesiophobia score, Pain Catastrophizing Scale score, or baseline values on any outcome measure between patients lost to follow-up and those assessed at follow-up.

Treatment groups were similar across most of the baseline variables (**TABLE 1**), with the exception of symptom duration, gender, and marital and education status, which were judged sufficiently different among the treatment groups to potentially bias outcomes. These variables were added to analytic models as covariates.

Mean ± SD number of treatment sessions was 8.4 ± 2.4, with no differences among treatment groups (**TABLE 1**). Thirteen patients (15.1%) attended fewer than 6 sessions (5 exercise, 5 over-door traction, 3 mechanical traction). Two patients crossed over from exercise to

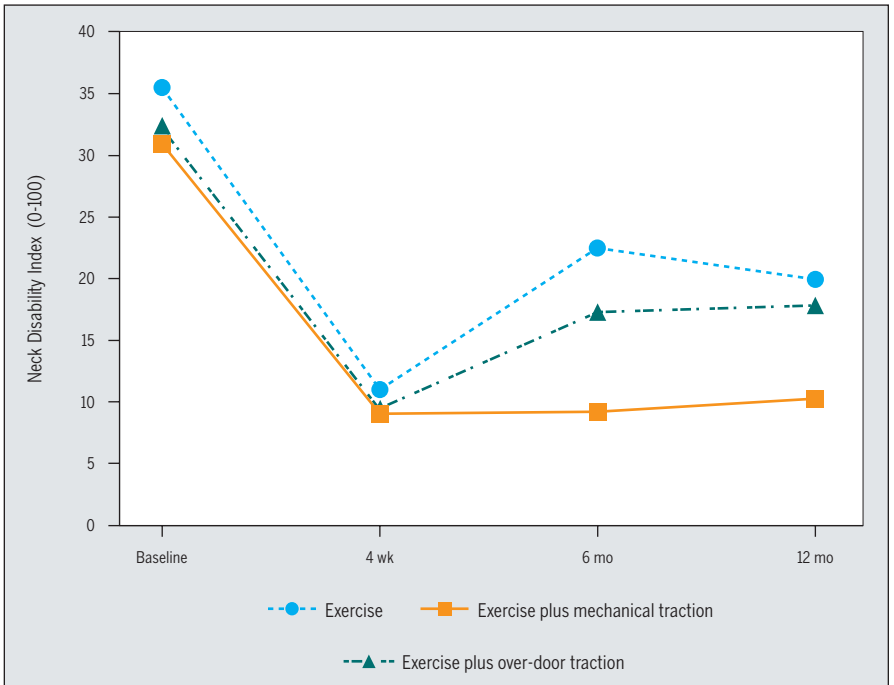

FIGURE 2. Adjusted mean Neck Disability Index scores at baseline, 4 weeks, 6 months, and 12 months by treatment group from the intention-to-treat analysis.

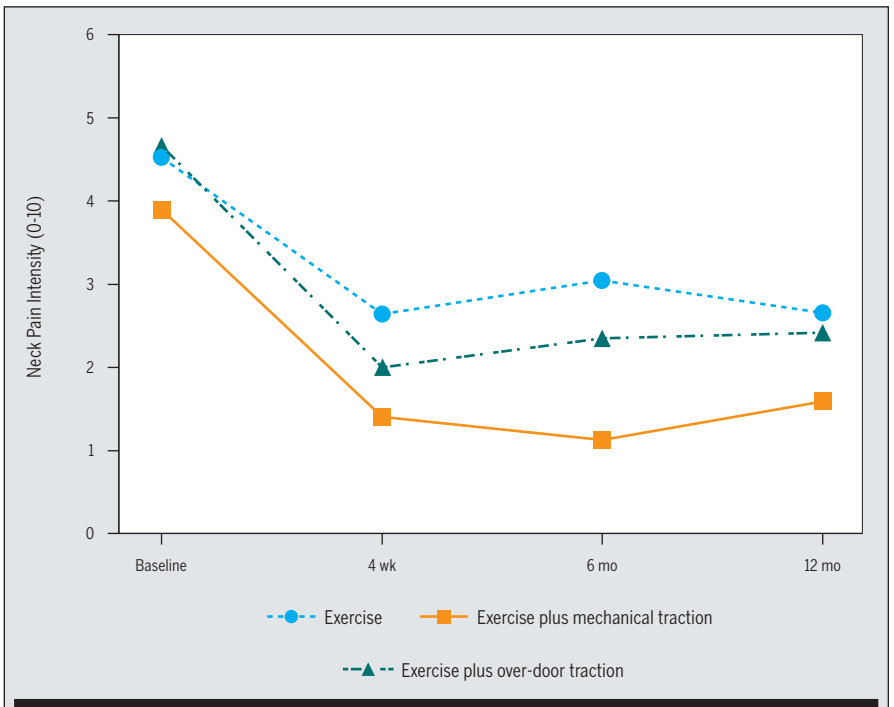

FIGURE 3. Adjusted mean neck pain intensity scores at baseline, 4 weeks, 6 months, and 12 months by treatment group from the intention-to-treat analysis.

TABLE 3 Primary and Secondary Outcome Scores at Baseline and Follow-ups, Based on Mixed Models, Adjusted for Covariates From the As-Treated Analyses

	Baseline	4 wk	6 mo	12 mo
Neck Disability Index (0-100)				
Exercise group (n = 27)*	36.2 ± 15.2	12.1 ± 7.3	23.4 ± 14.1	21.2 ± 22.3
Mechanical traction group (n = 35)*	32.1 ± 15.1	8.6 ± 7.1	10.0 ± 9.2	12.9 ± 11.6
Over-door traction group (n = 24)*	30.3 ± 10.9	9.2 ± 8.3	16.4 ± 12.2	13.9 ± 12.9
Exercise versus mechanical traction†		3.5 (−0.7, 7.7), *P* = .10	13.3 (5.5, 21.2), *P* = .001	8.3 (−1.5, 18.1), *P* = .093
Exercise versus over-door traction†		2.8 (−1.5, 7.2), *P* = .20	7.0 (−1.0, 15.0), *P* = .084	7.3 (−3.2, 17.8), *P* = .17
Mechanical versus over-door traction†		−0.7 (−4.8, 3.5), *P* = .75	−6.3 (−13.5, 0.9), *P* = .084	−1.0 (−10.7, 8.6), *P* = .83
Neck pain intensity (0-10)				
Exercise group (n = 27)*	4.5 ± 2.1	3.0 ± 2.3	3.1 ± 2.4	2.5 ± 2.2
Mechanical traction group (n = 35)*	4.2 ± 2.3	1.3 ± 1.4	1.2 ± 1.4	1.9 ± 1.9
Over-door traction group (n = 24)*	4.3 ± 1.7	1.8 ± 1.8	2.2 ± 2.0	2.1 ± 2.2
Exercise versus mechanical traction†		1.6 (0.7, 2.6), *P* = .001	1.9 (0.7, 3.2), *P* = .004	0.6 (−0.7, 2.0), *P* = .35
Exercise versus over-door traction†		1.2 (0.1, 2.2), *P* = .029	0.9 (−0.4, 2.2), *P* = .16	0.4 (−1.1, 1.9), *P* = .58
Mechanical versus over-door traction†		−0.5 (−1.5, 0.5), *P* = .31	−1.0 (−2.2, 0.2), *P* = .089	−0.2 (−1.6, 1.1), *P* = .73
Arm pain intensity (0-10)				
Exercise group (n = 27)*	4.1 ± 2.5	1.8 ± 2.2	3.3 ± 3.1	2.1 ± 2.6
Mechanical traction group (n = 35)*	4.5 ± 2.4	1.2 ± 1.5	1.0 ± 1.9	0.93 ± 1.2
Over-door traction group (n = 24)*	4.3 ± 2.3	1.6 ± 1.9	0.87 ± 1.3	1.1 ± 1.6
Exercise versus mechanical traction†		0.6 (−0.4, 1.7), *P* = .24	2.3 (0.9, 3.8), *P* = .002	1.2 (0.05, 2.4), *P* = .042
Exercise versus over-door traction†		0.3 (−0.9, 1.4), *P* = .64	2.5 (1.0, 4.0), *P* = .002	1.1 (−0.2, 2.3), *P* = .094
Mechanical versus over-door traction†		−0.4 (−1.4, 0.7), *P* = .49	0.1 (−1.2, 1.5), *P* = .85	−0.2 (−1.3, 1.0), *P* = .79

**Values are mean ± SD.*
†Values are mean (95% confidence interval) between-group difference.

mechanical traction due to lack of progress. One patient crossed from mechanical to over-door traction due to difficulty lying supine. Four patients crossed over from the over-door traction group, 1 to exercise at the request of the patient's physician and 3 to mechanical traction (2 due to difficulties with the over-door device and 1 who desired greater traction force). Adverse-reaction data were completed by 76 patients (88.4%), with 43 (56.6%) reporting at least 1 reaction perceived as treatment related. Most commonly reported reactions were increased neck pain (42.1%), increased arm pain (25.0%), and increased stiffness (19.7%). Among all reported reactions, 19.4% lasted longer than 24 hours and 5.6% were rated as severe. There were no differences among treatment groups in number, type, duration, or severity of adverse reactions.

Results of intention-to-treat analyses for the primary outcome found lower NDI scores in the mechanical traction group after 6 months (mean difference compared to the exercise group, 13.3; 95% CI: 5.6, 21.0; mean difference compared to the over-door traction group, 8.1; 95% CI: 0.8, 15.3) (**TABLE 2**, **FIGURE 2**). Lower NDI scores persisted at 12-month follow-up in the mechanical traction group compared to the exercise group (mean difference, 9.8; 95% CI: 0.2, 19.4). Results for secondary outcomes found lower neck pain intensity ratings in the mechanical traction group compared to the exercise group at 4 weeks, and compared to the exercise group and over-door traction group at 6 months (**TABLE 2**, **FIGURE 3**). Arm pain intensity ratings were lower in the mechanical traction group compared to the exercise group at 6 and 12 months. The over-door traction group also had lower arm pain intensity than the exercise group at the 6-month follow-up (**TABLE 2**, **FIGURE 4**). As-treated secondary analyses produced a similar pattern of results (**TABLE 3**), as did the analyses that excluded data from patients receiving injections or surgery (data not shown).

Fifty-three patients (61.6%) reported a successful outcome on the global rating scale after 4 weeks, 32 (37.2%) after 6 months, and 35 (40.7%) after 12 months. Percentages generally favored the traction groups relative to the exercise group but failed to reach statistical significance for the primary analysis at the 4-week (P = .14), 6-month (P = .09), and 12-month (P = .30) follow-ups (**FIGURE 5**). Secondary analyses produced similar results.

Evaluation of the more-specific subgrouping criteria resulted in a 3-way interaction effect at 6 months that approached significance for the primary outcome (P = .07) (**FIGURE 6**) and was significant for the secondary outcome of arm pain intensity (P = .009) (**FIGURE 7**). The 3-way interaction for the outcome

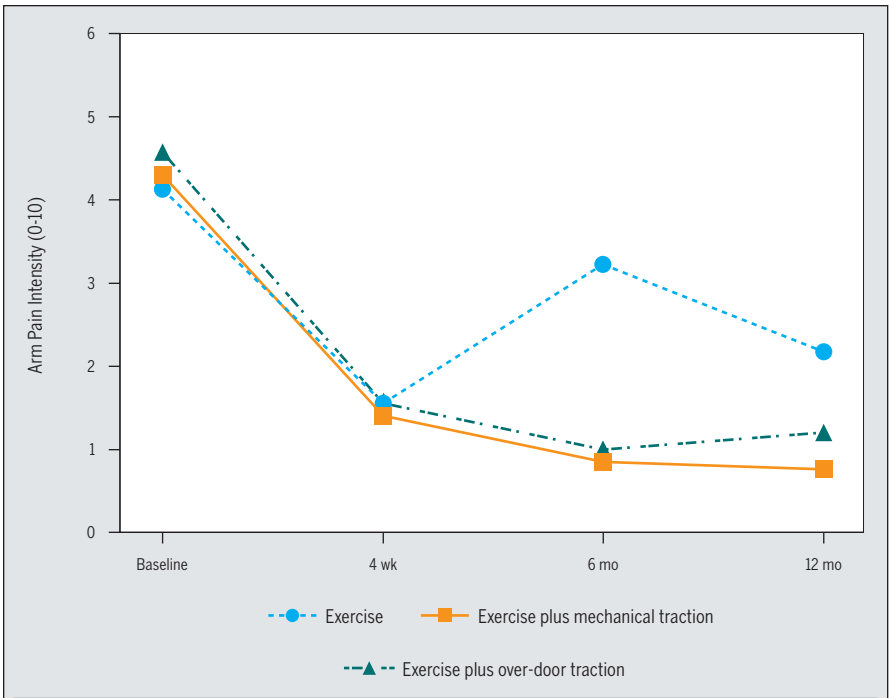

FIGURE 4. Adjusted mean arm pain intensity scores at baseline, 4 weeks, 6 months, and 12 months by treatment group from the intention-to-treat analysis.

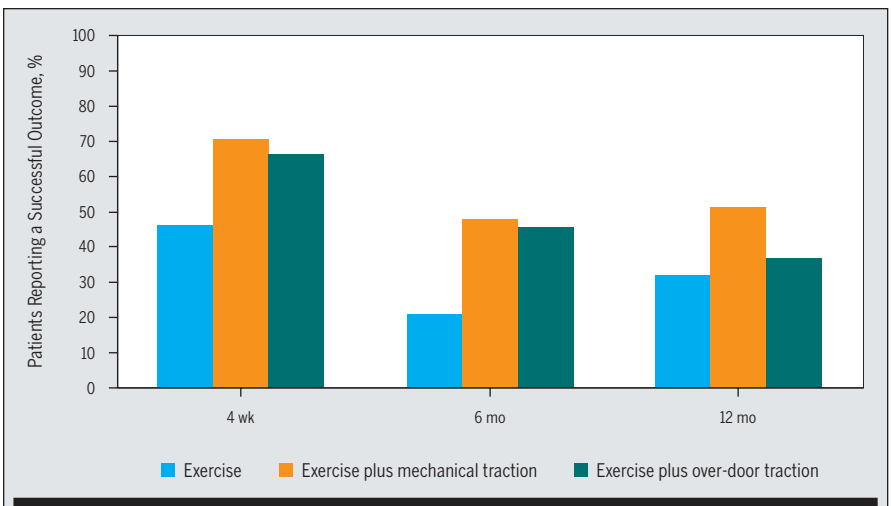

FIGURE 5. Percentage of patients reporting a successful outcome based on the patient-reported global rating of change at 4 weeks, 6 months, and 12 months for the intention-to-treat analysis.

of neck pain was not significant ($P = .77$). Pairwise differences were generally supportive of the subgrouping criteria for the primary outcome, with those who received mechanical traction and were positive on subgrouping criteria having lower NDI scores, which were at or near the level of significance relative to the comparison groups of interest, including (1) those receiving mechanical traction who were negative on subgrouping criteria (mean difference, 9.1; 95% CI: −0.5, 18.6; $P = .06$), (2) those positive for subgrouping criteria who received over-door traction (mean difference, 15.4; 95% CI: 5.3, 25.4; $P = .003$), and (3) those positive for subgrouping criteria who received exercise (mean difference, 11.9; 95% CI: −0.8, 24.5; $P = .06$). For the outcome of arm pain intensity, the comparisons of interest at 6 months were not significant. The significant differences were all in comparison to those in the group receiving exercise who were negative for the subgrouping criteria (**FIGURE 7**).

DISCUSSION

This clinical trial found that adding cervical traction to a standard exercise program for patients with cervical radiculopathy resulted in lower disability and pain intensity ratings. These differences were most pronounced at the 6-month follow-up. Cervical traction with a motorized device had some advantage compared to an over-door traction unit for the primary outcome. Several patients experienced some difficulty with the over-door unit and crossed over to other treatments. Examination of the more-specific subgrouping criteria described by Raney et al[34] did provide a degree of validation for these criteria based on the NDI scores at the 6-month follow-up; however, the magnitude of the overall treatment effects for mechanical traction supports the use of mechanical traction in patients with cervical radiculopathy, regardless of subgrouping status. In other words, though patients who fit the more-specific subgrouping criteria may be particularly likely to benefit, limiting the use of mechanical traction to this narrower subgroup may result in suboptimal outcomes for patients with cervical radiculopathy who are negative for the subgrouping criteria but may benefit from the treatment.

Previous systematic reviews have generally not supported the effectiveness of cervical traction in patients with neck pain but also note a lack of high-quality evidence on which to base conclusions.[18,19,40] Despite a lack of evidence, traction appears to be a common intervention provided by physical therapists,

particularly for patients with neck pain accompanied by signs of radiculopathy.[8,16,17] Most studies examining the effectiveness of traction, however, have included patients with nonspecific neck pain and generally have not supported the intervention.[3,10,31,49] The few previous studies examining only patients with radiculopathy have produced mixed results. Klaber Moffett et al[27] randomized 100 patients with neck and arm pain to receive supine mechanical traction or placebo traction with no exercises and found no differences. Jellad and colleagues[22] randomized 39 patients with radiculopathy to standard rehabilitation alone (modalities, mobilization, neck strengthening and stretching exercises) or standard rehabilitation with either supine mechanical or manual cervical traction. Disability and pain outcomes favored patients receiving either form of traction.[22] Finally, Young et al[48] randomized 81 patients with cervical radiculopathy to a program of manual therapy and neck strengthening and stretching exercises plus either supine mechanical or placebo traction and found no differences between groups.

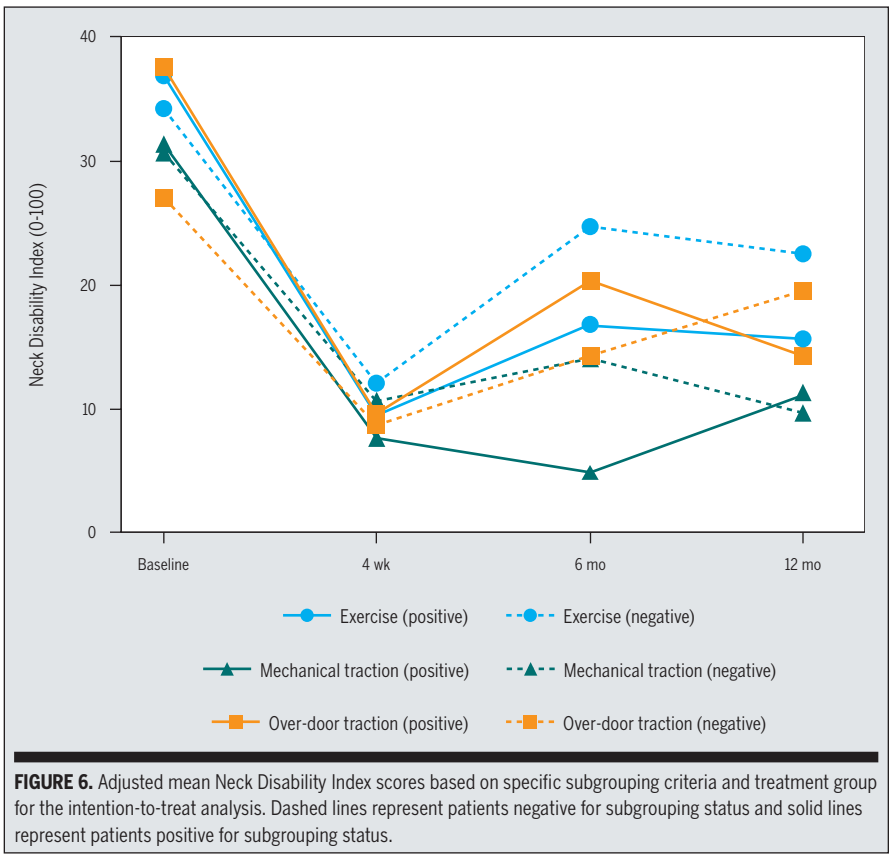

FIGURE 6. Adjusted mean Neck Disability Index scores based on specific subgrouping criteria and treatment group for the intention-to-treat analysis. Dashed lines represent patients negative for subgrouping status and solid lines represent patients positive for subgrouping status.

The results of this study found cervical traction delivered in supine using a motorized device to be more effective than prior studies have found. There may be several explanations for these findings. First, the effectiveness of cervical traction may be enhanced when provided in conjunction with an exercise program. This hypothesis was not directly addressed in our study; however, our results and those of Jellad et al,[22] who also combined traction with exercise, contrast those of Klaber Moffett et al,[27] who examined traction as a singular intervention. The study by Young et al[48] may challenge this presumption; the study sample, mechanical traction protocol, and exercise program of that study[48] were very similar to those of the current study, yet that study found no benefit from the addition of traction. A few explanations are possible. First, the benefits of traction in the current study were more evident at longer-term follow-ups, which were not included in the previous study. Second, the current study did not include a placebo traction intervention, and the benefits of traction noted could be attributable to a nonspecific placebo effect. Finally, Young and colleagues[48] included a manual therapy component in their standard treatment, which might have enhanced the effectiveness of standard treatment to a point at which traction no longer produced additional benefit. Additional research is needed to clarify optimal combinations of treatments for patients with cervical radiculopathy.

Cervical traction can be delivered in several different ways, and the influence of the mode of delivery on outcomes has not been adequately examined. Motorized devices are typically used in clinical settings, but home units that use an over-door suspension system are also commonly provided to patients. Anecdotal reports suggest that home units may provide clinical benefit for patients with cervical radiculopathy,[6,12,38] but the effectiveness of these devices had not been previously evaluated in clinical trials. We found some benefit relative to an exercise-only approach, particularly among patients who seemed comfortable with the devices. Our results were better, however, for those who received mechanical traction solely during clinic sessions than for those provided with the home over-door device. These differences were identified for the outcomes of disability and neck pain at the 6-month follow-up, an interesting result considering that the patients provided with the home unit could continue using the device beyond the study treatment period, whereas those receiving mechanical traction could not.

Equivocal findings in prior studies of cervical traction suggest that this treatment may best be targeted to a subgroup

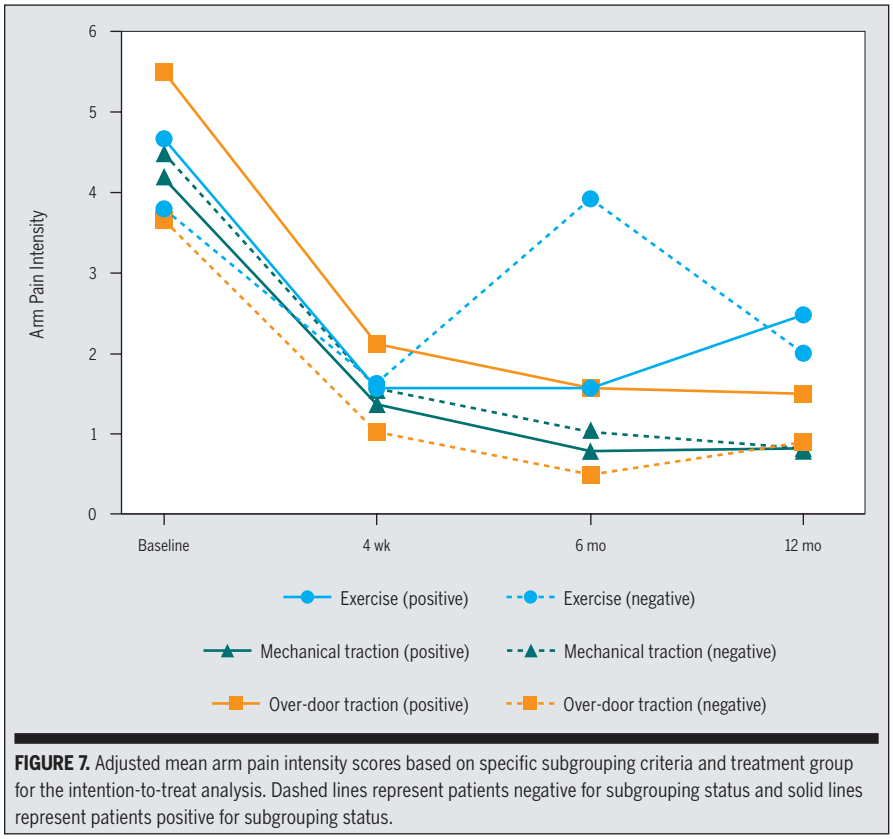

FIGURE 7. Adjusted mean arm pain intensity scores based on specific subgrouping criteria and treatment group for the intention-to-treat analysis. Dashed lines represent patients negative for subgrouping status and solid lines represent patients positive for subgrouping status.

of patients with neck pain even more narrowly defined than just those with signs of radiculopathy.[6,34] In this study, we examined previously defined subgrouping criteria[34] and found that the validity of these criteria was underpowered and only suggestive of a subgroup-specific effect, based on the disability outcome after 6 months. The overall findings of this study indicate that patients who have cervical radiculopathy but do not meet the subgrouping criteria are still likely to optimize outcomes with mechanical traction in addition to an exercise program. It is important to note that the patients in our study were required to have distal symptoms to be enrolled, thus it is possible that the magnitude of the interaction between status on the subgrouping criteria and treatment outcome might have been larger had we enrolled a broader group of patients with neck pain, similar to that included in the study by Raney and colleagues.[34] However, our results indicate a benefit from targeting cervical traction to the subgroup of patients with neck pain who have signs of cervical radiculopathy and do not support a benefit of further narrowing the targeted group to those who fit the criteria described by Raney et al.[34]

The results of this study need to be considered in light of several important limitations. The rate of loss to follow-up was higher than anticipated and might have biased the results. Several patients crossed over to a different treatment during the first 4 weeks. Although we included as-treated analyses, the desired effects of randomization on selection bias were somewhat compromised in these secondary analyses. We also had several baseline differences among the treatment groups that we considered potentially important, such as duration of symptoms. Additionally, we were unable to recruit our original sample-size target, and therefore some of our analyses, particularly those related to the 3-way interaction effects, were likely underpowered.

CONCLUSION

We found that adding mechanical traction to a standard exercise program, particularly with an in-clinic, motorized device, for patients with cervical radiculopathy led to greater improvements in disability and neck and arm pain. These improvements were particularly notable at the longer-term follow-ups. Further research is needed to identify the most effective nonsurgical treatments for patients with cervical radiculopathy, and whether clinical decision making can be enhanced by consideration of more narrow subgrouping strategies. ◉

KEY POINTS

FINDINGS: Adding mechanical traction to a standard exercise program for patients with neck pain and signs of cervical radiculopathy resulted in lower disability and pain intensity ratings when compared to exercise alone or exercise with the addition of an over-door traction device. The validity of a previously described subgrouping rule to assist in selecting patients most likely to benefit from cervical traction was upheld only for the outcome of disability at the 6-month follow-up.

IMPLICATIONS: Physical therapists should consider the addition of mechanical traction for treatment of patients with neck pain and signs of radiculopathy. The additional benefit of considering a patient's subgrouping status in the decision-making process may be minimal.

CAUTION: The study had a higher-than-anticipated loss to follow-up and was likely underpowered for examining the validity of the subgrouping rule.

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