Ian A. Young, Lori A. Michener, Joshua A. Cleland, Arnold J. Aguilera, Alison R. Snyder. Manual Therapy, Exercise, and Traction for Patients with Cervical Radiculopathy: A Randomized Clinical Trial. Physical Therapy 2009; 89(7):632-642.

Design: Randomized clinical trial

Population /sample size/setting:

- 81 patients (26 men, 55 women) were treated for cervical radiculopathy at orthopedic physical therapy clinics in 4 states. All participants received manual therapy, postural education, and exercise; randomization was to either cervical traction (MTEXTraction group n=45, mean age 47.8 years) or to sham traction (MTEX group n=36, mean age 46.2 years).
- Eligibility criteria included all adults aged 18-70 years with unilateral upper-extremity pain, paresthesia, or numbness.
    - Diagnosis based on 3 or 4 tests of clinical predication rule positive (Spurling test, distraction test, upper limb Tension test 1, ipsilateral cervical rotation < 60 degrees).
- Exclusion criteria included history of previous cervical or thoracic spine surgery, bilateral upper extremity symptoms, signs or symptoms of upper motor neuron disease, medical red flags (e.g. tumor, fracture, rheumatoid arthritis, osteoporosis, prolonged steroid use), cervical spine injections in past 2 weeks, current use of steroidal medication for radiculopathy symptoms.

Main outcome measures:

- Treating physical therapists were aware of treatment allocation, but support staff who administered all patient self-report measures was unaware of group assignment. Patients were blinded.
- Outcome measures were taken at baseline, 2 weeks, and 4 weeks. Participants were treated an average of 7 times over a period of 4 weeks.
- Postural education was done on the initial visit, educating patients on correct postural alignment during sitting and standing.
- Manual therapy consisted of either high-velocity low-amplitude thrust manipulation or nonthrust manipulation. Initial manipulation was directed at the thoracic spinal segments, with separate treatment of the upper and midthoracic spine; after the thoracic manipulation was finished, a set (30 seconds of 15-20 repetitions) of nonthrust manipulation was directed at the cervical spine, with the choice of segment based on the therapist judgment of the patient response.
- Exercise was done after completion of the manual therapy procedures, and included at least one exercise during each visit. Cervical and scapular exercises were performed.
- Traction, true or sham, was done after the exercise and lasted 15 minutes in each session

    - The true traction was done with the patient supine at 15 degrees of cervical flexion, with the traction force beginning at 20 pounds, increasing 2 to 5 pounds at each subsequent visit to a maximum force of 35 pounds; the traction cycle was set to 50 seconds on and 10 seconds off.
    - The sham traction was identical to the true traction, except that the force was set at 5 pounds at each visit.
- Each group lost 6 patients to follow-up before the end of the fourth week of the study.
- The primary outcomes were the Numeric Pain Rating Scale (NPRS), the Patient-Specific Functional Scale (PSFS), and the Neck Disability Index (NDI), with additional secondary outcomes including fear-avoidance beliefs, satisfaction with treatment, and global rating of change.
    - For each of the 3 primary outcomes, there were no differences between the true and the sham traction groups.
    - There were significant and equal improvements in both groups in pain, function, and disability between the start and end of the trial period.
- Statistically significant changes (improvements) over time were found in both groups with all 3 of the primary outcome measures. All primary outcome measures for both groups at 4 weeks exceeded the threshold for minimum clinically important change in patients with neck pain compared to baseline.
    - Adjusted mean Neck Disability Index change scores improved 8.7 points in the MTEXTraction group and 7.5 points in the MTEX group at 4 weeks. A minimum clinically important change for NDI is $\geq$7 points.
    - Adjusted mean Patient-Specific Functional Scale change scores improved 3.5 points in the MTEXTraction group and 3.4 points in the MTEX group at 4 weeks. A minimum clinically important change for PSFS is $\geq$2 points.
    - Adjusted mean Numeric Pain Rating Scale change scores improved 2.9 points in the MTEXTraction group and 3.3 points in the MTEX group at 4 weeks. A minimum clinically important change for NPRS is $\geq$1.3 points.
- For the secondary outcomes, no differences were noted between the true and the sham traction groups.
    - Participants' overall self-assessment of improvement did not differ between groups at 4 weeks. 68% of participants in the MTEXTraction group and 69% in the MTEX group rated themselves as improved.

Authors' conclusions:

- The addition of mechanical intermittent traction does not appear to improve outcomes for patients with cervical radiculopathy who are also receiving postural education, manual therapy, and exercise at both 2 and 4 weeks of follow-up.
- There were no significant differences in outcomes between the two treatment groups in the 3 primary outcome measures or any of the secondary outcome measures.
- There was a significant main effect of time for the 3 primary outcome measures indicating there were significant improvements in pain, function, and disability regardless of group assignment.

Comments:

- This is a well-designed and documented study.
- Both interventions did show improvement in the first 4 weeks, but the improvements were similar for both interventions.
- The study lacked a true control group (no treatment at all), thus leaving uncertainty as to whether or not the improvements observed in both groups was merely a spontaneous resolution of symptoms over the course of this 4-week treatment or actually due to the intervention. Therefore, this study cannot be used as evidence one way or the other about the effectiveness of the intervention (manual therapy, postural education, and exercise) compared to "no treatment".
- Red flags are associated with not addressing adverse effects, and lack of protocol availability. In addition, the lack of follow-up is short (4 weeks).
- The magnitude of the group differences do appear to be small and not significant between the true and sham intervention groups.
- In Table 3, it was unclear which variables were taken into account for the calculation of the adjusted means and the adjusted mean differences.
- The study authors derived their own clinical prediction rule to identify the presence of cervical radiculopathy that was not validated which could result in decreased diagnostic accuracy.
- Patients were not asked whether they could identify which group they were in at the 4-week follow-up, and so blinding effectiveness was not assessed.

Assessment:

Adequate for evidence that intermittent cervical traction does not add therapeutic benefit to a brief course of manual therapy combined with exercise and postural education.