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The efficacy of a home-mechanical traction unit for patients with mild to moderate cervical osteoarthrosis: A pilot study

Batoul Bagheripour[1], Mojtaba Kamyab*[2], Fatemeh Azadinia[3], Ali Amiri[4]
Mohammad Akbari[5]

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Abstract

Background: Traction has been suggested to be an effective treatment for symptoms of neck disorder in patients with no contraindications. However, according to previous researches, the effectiveness of traction is controversial, particularly compared to other conservative treatments. This trial was conducted to evaluate the effect of sustained traction, using an over-the-door home cervical traction unit in combination with routine physical therapy on reducing cervical osteoarthrosis symptoms including neck pain, medication use and disability level compared to routine physical therapy alone.

Methods: In this double- blinded pilot study with a pre-post test design and a control group, 20 women with mild to moderate osteoarthrosis were systematically assigned to the over-the-door home cervical traction (mean±SD age: 50.5±4.45yrs) or control groups (mean±SD age: 55.6±7.34yrs). Pain, level of disability, and drug consumption were evaluated before and after 10 sessions of intervention. Data were analyzed using parametric or non-parametric statistic including the paired-sample t-test, independent sample t-test, and Wilcoxon and Mann-Whitney u test for intra and inter groups comparison based on the Kolmogorov-Smirnov test results.

Results: Patients in both groups showed a significant decrease in pain intensity and disability level ($p<0.05$). Despite the greater improvement in pain levels and disability in the experimental group compared to the controls, the differences were not significant ($p>0.05$). No significant differences were found in terms of drugs consumption within and between the groups at the end of the treatment ($p>0.05$).

Conclusion: The results revealed that applying sustained traction using an over-the-door home cervical traction unit was not significantly superior to the routine physical therapy and ergonomic training to manage symptoms including neck pain and disability in a small group of mild to moderate cervical osteoarthrosis patients.

Keywords: Osteoarthritis, Neck, Pain, Traction.

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Introduction

Traction is a conservative treatment often prescribed for patients with neck pain (1). A variety of theories exists about the positive effects of traction. Traction can increase circulation in cervical blood vessels, stretch paraspinal muscles and ligaments and facilitate muscles relaxation. Additionally, traction can decrease nerve root compression by distraction of vertebrae and expanding the intervertebral foramen (2-4). Traction also seems to reduce pain transmission in sensory fibres at the spin al cord by stimulating the large afferent fibres of joints and muscles in the presynaptic space (5). Based on previous studies, applying traction may lead to pain relief, an increase in cervical range of motion, and improved

[1]. MSc, Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran. bagheripourb.TO@gmail.com
[2]. (**Corresponding author**) PhD, Assistant Professor, Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran. kamyab.m@iums.ac.ir
[3]. PhD Candidate, Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran. azadinia.Fatemeh@yahoo.com
[4]. PhD, Assistant Professor, Department of Physiotherapy, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran. amiri.a@iums.ac.ir
[5]. PhD, Professor, Department of Physiotherapy, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran. akbari.mo@iums.ac.ir

functional status (6-8). In spite of these theories and studies, a numbers of researchers have reported no significant difference between the efficacy of traction and other physical treatments or placebo interventions on symptoms of cervical diseases (9,10). Researchers have tried to evaluate the effects of continuous and intermittent types of traction on neck pain, using different methods and compare it to other conservative treatments. However, a systematic review reported that the efficacy of traction is inconclusive due to poor methodology in the trials (2). Therefore, there is not enough evidence to support or reject the efficacy of applying a pulling force on the cervical spine. This suggests that additional research is needed on this topic.

There are three modes of traction application: Mechanical, positional, and manual (11). An over-the-door home cervical traction unit is a device that provides mechanical traction. Patients can use it at home according to their therapist's guidance. Despite the common prescription of this cost-effective, home-based mechanical cervical traction approach, to our knowledge, only one retrospective study attempted to show the effectiveness of this traction device, and the presented results were not compared to other treatments or a control group (8). Therefore, it remains questionable if traction can provide superior outcomes compared with no traction. This study, therefore, aimed to investigate the efficacy of sustained traction, using an over-the-door home cervical traction unit in reducing neck pain, medication use and disability level in patients with cervical osteoarthrosis compared to standard therapy.

Methods

Patients and Study Design

This was a double-blinded pilot study with a pre-post test design and a control group. Twenty-four patients were recruited from the outpatient physical therapy clinic of Hazrat-e-Rasoul Hospital affiliated to Iran University of Medical Sciences. Patients were screened by a clinician and included in the study if they met the following criteria: 30 (12) to 65 (9) years of age; having cervical pain with or without upper extremity symptoms (13); having mild to moderate (grade 2 and 3) cervical osteoarthrosis based on radiography classification by Lawrence in 1977 (grade 1/doubtful: Minute osteophyte of doubtful significance is the only feature; grade 2/mild: Definite osteophyte and joint apace unimpaired; grade 3/moderate: Diminution of joint space; grade 4/severe: Joint space greatly impaired and subchondral sclerosis) (3, 14); obtaining 10% or more in a neck disability index questionnaire and score of 2 or more out of 10, in numerical pain rating scale (7), and having a positive cervical distraction and compression test (15). Exclusion criteria were as follows: Any history of cervical or upper thoracic (T_1-T_6) trauma (10); cervical surgery (7,9,10); severe cervical osteoarthrosis (grade 4) diagnosis based on radiography (3,14); spinal canal stenosis (9,13); non-skeletal symptoms (7, 13); a previous cervical spine fracture (7); severe vertebral osteoporosis (16) and rheumatoid arthritis (6); upper cervical instability (17), including Down (18) and Marfan (19) syndromes; congenital deformities of the cervical spine (10); vertebral artery (13,16) or temporomandibular joint (TMJ) (20) dysfunction a history of unsuccessful traction treatment (16); or if they had undergone any cervical exercise or physical therapy in the last three months due to neck pain (9, 10). Pregnant women were excluded from the trial (7,13). All participants signed an informed consent form. The Ethics Committee of Iran University of Medical Sciences approved the experimental procedure (Ethical code: 1433). Patients were systematically assigned to an experimental or control group. Both groups received typical physical treatments including a hot pack, transcutaneous electrical nerve stimulation (TENS), ultrasound therapy (US), exercise therapy, and ergonomic training. Patients in the experimental group received sustained traction via an over-the-door home traction

unit. None of the patients was aware of the group they were allocated. This trial was registered in Iranian Registry of Clinical Trials with IRCT2014081118762N1 identification.

Treatment intervention was conducted over 10 sessions (2 weeks). Efficacy criteria, which were compared between the baseline measured before the first session and the end of the last session (9) included changes in pain intensity, disability level and the consumption of medication. Pain intensity was assessed using a numerical pain rating scale ranging from 0 (no pain) to 10 (extreme pain). Patients were instructed to indicate the intensity of current pain and the maximum and minimum pain levels experienced during the past 24 hours on the scale. The average of the three points was reported as the patients' neck pain intensity (21).

Disability level was assessed using the validated Iranian version of the neck disability index questionnaire (22). It contains 10 sections, each of which is scored from 0 to 5; the final score is expressed as a percentage (21,23). The highest rating indicates the maximum disability. It was explained to the patient that this questionnaire expresses the effect of neck pain on the ability to perform daily activities. Patients answered all the sections and marked the item that best described their problem (22, 24). In addition, the type, dosage, and number of analgesic medications consumed including nonsteroidal anti-inflammatory drugs (NSAIDs) and non-NSAIDs were recorded during the 24 hours prior to the first and last sessions (3). The same assessor, who was not aware of group allocation, conducted all the evaluations (blinding of the assessor).

Interventions

Patients in the control group received the usual physiotherapy treatments. Superficial moist heat was applied with a hot pack for 20 minutes (25). Conventional TENS was applied for 20 minutes using a Stimulator 710L (Novin Medical Engineering, Miremad St, Tehran, Iran). Electrodes were placed within the dermatomes of area where pain was present and intensity was determined based on the patients' tolerance (26,27). Ultrasound therapy was applied over the posterior aspect of the cervical region (9, 28) with focusing on the spasmodic and painful soft tissues for five minutes with a Sonopuls 490 (Enraf Nonius B.V., P.O. Box 12080, NL-3004 GB Rotterdam, The Netherlands). The movement pattern of the applicator was in a series of overlapping circles. The rate of movement was slow enough to allow the tissues to deform and thus remain in complete contact with the rigid treatment head of applicator but fast enough to prevent hot spot developing (applicator size: $5cm^2$, frequency: 1MHz, mode: Continuous, intensity: Up to $1.2W/cm^2$ based on the patients' tolerance and the physical therapists' diagnosis) (27). Isotonic shoulder girdle exercises and isometric and isotonic neck exercises were performed twice a day (at home and at the clinic), with 10 repetitions for neck exercises and 30 repetition for shoulder girdle exercises. Each position was held for 10 seconds (3). Ergonomic training to address neck pain problems included instruction on reading positions, doing overhead work, stooping and lifting, and using the telephone and computer (12).

Patients in the experimental group received sustained traction (10,16) using an over-the-door home cervical traction unit in addition to the physiotherapy care and ergonomic training described above. Traction was applied to the neck at the end of each physiotherapy treatment session before patients performed the exercises (9). Traction weight started at 10-12lb. (≈ 4.5 to 5.5kg) and was increased based on the reduction of the patients' symptoms and their tolerance within the first session. In subsequent sessions, the traction weight was increased based on the patients' symptoms, his or her tolerance, and maximum force applied to the cervical region in the previous session (13). Patients were asked to stay as relaxed as possible and report any problems to the

therapist when the traction was applied (16). It was explained to patients that they could experience moderate to relatively severe traction loads without increasing symptoms (13). Optimum traction weight was considered to be up to 30lb. (≈ 13.60kg) (6,11). However, there was no compulsion to reach this amount of force, and the maximum load varied depending on the patient's symptoms and tolerance in each case. The water bag of the traction unit could accommodate up to 10kg (≈ 22.05lb.) and it was possible to use an extra bag if needed. Patients sat on a chair in front of the over-the-door traction unit, and a head halter was fitted under the chin and occiput. All patients were fixed to the back of the chair with two non-elastic crossed bands for the duration of traction (29) (20 minutes) (6). Neck was held in a 15° to 35° flexion angle (25,29-31) as measured by a plastic goniometer. The fulcrum of the goniometer was centred on the ear lobe, and the stationary arm was perpendicular to the floor. The moving arm was aligned with the base of the nares. The moving arm was realigned with each change in cervical angle, and the new flexion angle was recorded (29). None of the patients used cervical collar at least during the last three months before the beginning of the trial and during the treatment period based on their own reports.

Data Analysis

Data normality assumption was tested with the Kolmogorov-Smirnov test. Demographic and baseline clinical characteristics were compared between groups, using an independent samples t-test. A paired sample t-test was used to determine changes in clinical variables within each group. The differences between pre-treatment and post-treatment outcome measures were calculated and an independent samples t-test was used to compare the two groups. Variables without a normal distribution were analysed using a non-parametric test. Data were coded so that the analyses could be performed in an unbiased manner; and the statistician was blind to group assignments. SPSS version 16.0 was used for all analyses, and statistical significance was set at a $p<0.05$.

Results

In total, 51 patients (12 men, 39 women) were screened for this study and 27 patients (11 men, 16 women) were excluded due to ineligibility. Of the 24 patients who met the inclusion criteria, 4 (1 man, 3 women) were dropped from the study because they failed to complete the two weeks of treatment due to time restrictions. The remaining 20 patients (10 women in each group) were evaluated. Table 1 demonstrates the severity of osteoarthrosis and symptom distribution in both groups. The consideration of data normality, using the Kolmogorov-Smirnov test, showed normal distribution in age, body mass index, pain score and neck disability index percentage before and after treatment duration in both groups ($p>0.05$). Drug consumption was normally distributed in the control group at the baseline examination. No differences were found between the demographic and clinical specifications of the two groups prior to the first session (Table 2).

Significant decreases were observed in pain intensity and disability index in both groups ($p<0.05$) (Table 3). The experimental group showed greater improvements in the levels of pain and disability than the

Table 1. Clinical Categories: The Severity of Osteoarthrosis and Symptom Distribution

Variables		Experimental group (N =10)	Control group (N =10)
Osteoarthrosis[a]	Grade 2 (Mild)	1	0
	Grade 3 (Moderate)	9	10
Symptoms[b]	Local	2	1
	Referral	4	3
	Radicular	4	6

[a] According to the radiography result
[b] According to the patient's reports

Table 2. The demographic and clinical specifications at baseline

Variables	Experimental group (N = 10)	Control group (N = 10)	P-value (Independent-Samples T-test)
Age (years)	50.50±4.45	55.6±7.34	0.077
Body mass index (kg/m2)	26.14±3.92	29.9±5.64	0.999
Pain (Score)	5.63±1.49	4.47±1.83	0.136
Neck disability index (%)	30.03±11.04	31.2±14.8	0.843
			p (Mann-Whitney)
Non-NSAID (Number)	0.2±0.63	0.4±0.97	0.543
NSAID (Number)	0.3±0.67	0.4±0.67	0.654

Table 3. The Results of Comparison within and between Groups

Change of Variables	Experimental group (N=10)	Control group (N=10)	P-value (Paired-Sample T-test)		P-value (Independent-Samples T-test)
			Experimental group	Control group	
Pain (Score)	2.97±1.94	1.63±2.19	0.001*	0.043*	0.166
Neck disability index (%)	13.11±8.48	12.54±13.27	0.001*	0.015*	0.910
			P-value (Wilcoxon)		P-value (Mann-Whitney)
Non-NSAID (Number)	0.2±0.42	0.1±0.32	0.317	0.317	0.942
NSAID (Number)	0.2±0.63	0.2±0.42	0.157	0.157	0.999

Mean ± standard deviation
*The difference is significant at the 0.05 level

control group, but the differences were not significant (p>0.05). No significant differences were detected in terms of NSAID and non-NSAID consumption within or between the groups at the end of intervention period (p>0.05).

Discussion

This study aimed to clarify whether applying traction via an over-the-door home cervical traction unit would provide a greater benefit than the standard therapy for patients with cervical osteoarthrosis. Based on the results of our statistical analysis, after ten sessions of treatment, neck pain and disability of patients in both groups were significantly decreased. Despite the improvements in pain and disability level of patients in the experimental group, the differences were not significant compared to the control group. Additionally, the findings of this study did not reveal any comparable decrease in NSAID and non-NSAID consumption during the treatment period.

A small number of previous studies have investigated the effect of cervical traction on cervical osteoarthrosis patients (3,8), and the results of this study were consistent with those of previous reports (9,16). In line with our findings, the results obtained by Borman et al. (9), Akbari and Bayat (3) and Moffett et al. (16) demonstrated no significant improvement in favour of experimental groups who received intermittent or sustained traction in addition to standard physical therapy or neck-care education. However, the results of studies that have evaluated cervical range of motion (ROM), in addition to the above mentioned clinical effectiveness criteria (pain intensity, disability level, drug consumption), have found the efficacy of traction in improving cervical ROM (6,16). Taken together, these findings suggest that cervical range of motion may be a worthwhile outcome measure for investigating the efficacy of traction in treating cervical osteoarthrosis. Chiu et al. conducted a randomized controlled trial to compare intermittent traction and sham heat treatment on chronic neck pain patients. They did not find any differences between the two groups in terms of pain relief, efficacy of improving symptoms affecting life and daily activities, or in cervical active ROM. However, a lack of a standard treatment protocol was mentioned as a possible weakness and the use of standardized protocols was suggested for future studies (10). Therefore, in this study, we utilized routine physical therapy modal-

ities as a standardized treatment. This did not result in obvious improvement differences between the two groups. The greater, but not significant, improvement seen in the traction group could indicate a possible effectiveness of traction. However, the small sample size of this pilot study was not able to statistically demonstrate its efficacy.

Cai et al. have identified the type of patients who have an increased chance of benefiting from home-based mechanical cervical traction. These patients had to meet three of the four following criteria: Pain intensity equal to or greater than 7/10, pain below the shoulders, relief of pain possible via manual traction, and scoring lower than 13 points in a fear-avoidance belief questionnaire work subscale (7). A possible explanation for our outcomes may be that the pain intensity of patients at the time of enrolment was lower than what was introduced by Cai et al. except for two patients in the traction group and one in no-traction group. Moreover in our study, only eight participations had pain below the shoulders (four participants in the experimental; 4 four in the control group). Raney et al. suggested that patients 55 years of age or older might benefit more from the use of traction than younger patients (13). All the participants in traction group in this study were younger than 55 years of age except for one patient. Therefore, this may be an additional reason why there were no significant differences between the two groups. Our findings are different from those of Zylbergold and Piper, who demonstrated a significant improvement in patients who received intermittent traction compared to a no-traction group in terms of pain and cervical flexion and rotation. Additionally, patients who received traction did not need further treatments and used less medications compared to patients in the control group. There were four groups in the Zylbergold and Piper study: Static traction, intermittent traction, manual traction, and no traction. Disagreement between our result and that of Zylbergold and Piper may be due to the dissimilarity in treatment protocols, method of tractions, number of treatment sessions and patients, and the disorders causing neck pain. However, our findings on symptom reduction in the control group are in agreement with those of Zylbergold and Piper research, which suggested that these changes are likely to be caused by natural recovery, neck care education, and exercises (6). Nevertheless, due to ethical issues, we could not allocate patients into a placebo or non-treatment group and it was not feasible to prevent patients with neck pain from initiating self-care. Hence, with respect to the study design, determining whether the outcomes stemmed from the natural recovery of pain or modified life style was not possible.

The results of this study should be considered in light of several limitations. First, this was a pilot study with a small sample size, particularly for mild cases. Second, all of the patients who completed the full course of the interventions were female, so caution should be taken when generalizing these findings to men. The next limitation was a lack of long-term follow-up to confirm the stability of the results. Finally, patients in interventional group complained about the increasing traction load because of the TMJ pain that was created by head halter. However, no one left the trial due to TMJ pain. The maximum traction weight in our study was 22.05lb., while Kisner and Colby determined that 25-35lb. is essential in a sitting position for the weight lifting to counteract the muscle tension (11). This may be another reason that the efficacy of traction was not significantly superior to physical treatments.

Conclusion

In summary, sustained traction using an over-the-door home cervical traction unit was not significantly superior to the routine physical therapy for managing symptoms, including neck pain and disability in our study group although applying traction can increase the rate of improvement in both outcomes.

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