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Research Article
Impact of Cervical Lordosis Rehabilitation on Disability and Pain in Non-specific Neck Pain

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Abstract

Background and Objective: Neck pain is an important social and economic health problem affecting up to two thirds of adults at some point in their lives. This study aimed to determine the effect of cervical lordosis rehabilitation on disability and pain on cervical lordosis. **Materials and Methods:** About 60 patients (38 females and 22 males) diagnosed with non-specific neck pain were assigned randomly into 2 equal groups (group A 'experimental', group B 'control') whose ages ranged from 25-45 years. Measurements include functional neck disability and pain intensity outcome. Group A received a traditional physical therapy program using Cervical Denneroll equipment, whereas group B 'control' received only the traditional physical therapy program respectively. The frequency of treatment was 3 times/week for 8 weeks with total sessions of 24 sessions. **Results:** When comparing between both groups, the results revealed that there was significant improvement of all measured parameters in groups A ($p<0.05$), while there was no significant improvement of all measured parameters in group B. **Conclusion:** Cervical Denneroll equipment is an important factor to be considered in the management of cervical lordosis in cases of non-specific neck pain.

Key words: Neck pain, cervical lordosis, neck disability, Denneroll, nonspecific neck pain

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Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

For a number of years of functional disability, cervical pain is considered as the most important condition in the world of health problem, socially and economically. It affects up to one third of adults among population worldwide. Moreover, it has an effect on their activities and work performance and consequently, it is indirectly associated with high cost[1].

The cervical spine is directed normally inward. This curve is called lordosis when it is seen from side. When lordosis is diminished, it is described as straightening of cervical lordotic curve. This cervical spine curvature does not only depend on the musculature tone of the cervical spine but it also depends on the postural adaptation. The line of gravity plays a major role in balance between agonist and antagonist of cervical spine, when it shifts, it leads an imbalance between them[2]. A systematic review states that one year prevalence of neck pain ranges between 16.7 and 75.1% (mean, 37.2%)[3].

The cervical spine normal curvature is important to maintain its sagittal alignment and normal balance in spine[4]. The reverse or imbalance of normal curvature as in kyphosis, can lead to mechanical pain, functional disabilities and neurological deficts[5].

Normal cervical alignment presents with a lordotic curve, maximally 43 degrees measured from posterior tangents of C2-C7. Without this lordosis, an imbalance occurs and hence, leads to tilting forward of the weight of the head and thus creates a wear and tear on the intervertebral discs and vertebral bodies. This progressively leads to changes, such as osteophytes, that is assumed to lead to decreasing the mobility of the cervical curvature and causes what is called cervical pain[6].

Loss of normal cervical lordosis has been manifested to contribute to decrease R.O.M, pain and health problems[7]. From a biomechanical point of view, cervical pain and muscle imbalance are caused due to the loss of normal lordotic curve of cervical spine[8]. So, the aim of this randomized controlled trial was to evaluate the efficacy of cervical lordosis rehabilitation using Denneroll orthotic tool on disability and pain in patients with non-specific neck pain.

MATERIALS AND METHODS

Study design: The study was conducted between June, 2015-August, 2016 and designed as a prospective, randomized, single-blind, pre-post test and controlled trial. Ethical approval was obtained from the institutional review board at the Faculty of Physical Therapy, Cairo University, before the study commencement. In addition, an informed consent regarding the use of patients' details in publication was obtained from the entire subjects.

Study participants: This study is a controlled randomized trial study that determined the effect of the restoration of sagittal cervical curve alignment on disability and pain of cervical region on 60 patients of both sexes, 30 patients in each group (38 females and 22 males) suffering from non-specific neck pain. They were assigned randomly into two equal groups: group (A) received physical therapy rehabilitation program in form of infra-red therapy, ultrasound therapy, TENS and posto-anterior unilateral pressure (PAUP) mobilization, plus Denneroll equipment, group B received only physical therapy rehabilitation program, diagnosed of non-specific neck pain and selected from outpatient clinic of the Faculty of Physical Therapy, October 6 University, in 2 months. Aged between 25 and 45 years, they were diagnosed by hypolordosis mild to moderate nonspecific pain of cervical spine. Exclusion criteria were patients with fracture, osteoporosis, positive extension-rotation test, any symptom of vertebrobasilar insufficiency, history of whiplash injury, history of cervical surgery, diagnosis of cervical radiculopathy or myelopathy and diagnosis of fibromyalgia syndrome.

Randomization and allocation concealment: After all baseline criteria have been met, participants were randomized into 2 equal groups: group (A) and group (B). With randomly permuted blocks, subjects are assigned to treatment in blocks to insure that equal number of subjects have been assigned to each treatment. Each time the number of subjects is a multiple of the block size. Participants were enrolled in blocks using random number generator software, software of randomization.com.

Interventions: Participants in group A received Cervical Denneroll orthotic tool and traditional physical therapy program for cervical spine rehabilitation three sessions per week for 2 successive months. The Cervical Denneroll Orthotic Device is a simple, pillow-like device engineered with curves, angles and ridges designed from the CBP (Chiropractic BioPhysics), evidence based cervical spinal model. The Cervical Denneroll device is used for low-stress and comfortable mirror-image traction (spinal remodeling) treatments. The current study used the medium Denneroll size for the dimensions to fit the typical adult cervical spine, approximately under 175 cm in height[9]. At the first time of starting a treatment session, a patient used the Denneroll. The

participants were instructed to lie flat on their back on the ground with their legs extended and arms by their sides of their body. The patient in supine position and initially started with 4 min of traction on the Denneroll and his/her time was increased by 2 min each visit, until he/she was able to lay reasonably comfortable on the Denneroll for 15-20 min per treatment session. Sustained loading periods of 10-20 min are necessary to cause visco-elastic deformation to the resting length of the spinal muscles and ligaments. Moreover, after he/she finishes using Denneroll, he/she comes to sit to tolerate his/her blood pressure and/or to feel drowsing. The traditional program of physical therapy for cervical rehabilitation was used in the form of infrared therapy. Participants received an infra-red light therapy in either sitting position or in prone position, while the infra-red lamp was directed perpendicularly on the patient cervical spine at a distance of 50 cm for about 20 min or presence of hyperemia. The Infra-red therapy device used is (ENRAF NONIUS (UV-S), Netherlands), ultrasound therapy. Participants received a continuous therapeutic ultrasound application in the paravertebral area of the cervical region by mobile technique while they were sitting. Physiotherapist moved ultrasound probe (transducer head) at a speed of about 4 cm sec^{-1}, a tilt of the ultrasound head is 7 degrees at maximum. Moveable ultrasound applicator, head size of 5 cm, has been carried out in one direction of a rotational movement, thus achieving a uniform distribution of ultrasound energy through tissues. Intensity of ultrasound energy was 0.5 W cm^{-2}, 1 MHz frequency and duration of application 5 min. Between the ultrasound head and participants skin, commercial contact gel has been applied to prevent the discontinuation of ultrasound energy. The Ultrasound device used is (PRIMO Ultrasound Therapy, THERASONIC 3601, England). Transcutaneous Electrical Nerve Stimulation (TENS), using Burst-mode TENS, combines elements of both high and low frequency modes. In burst mode, the carrier frequency of the current is high (70-100 Hz) but it is delivered in small bursts at a low rate (3-4 bursts sec^{-1}). Burst mode also uses motor-level stimulation. Electrode placements are placed over motor points of muscles in the myotomes related to the painful site. This method produces longer-lasting pain relief applied for about 30 min, the device used for deliver TENS is (ENRAF NONIUS, Endomed 480, Netherlands)[10]. In addition, in the traditional program, the participant received manual therapy in the form of one technique of Maitland mobilization, posto-anterior unilateral pressure (PAUP) technique. The position of the participant was prone for PAUP and the therapist was in the proper position of application. Maitland mobilization technique is administered with proper instruction. Mobilization (grade I and grade II), specific to the segment involved, was administered appropriate direction for 2 min followed by 2 min rest per vertebrae, i.e., 10 oscillations min^{-1} [11]. Participants in group B received traditional physical therapy program only for cervical spine rehabilitation three sessions per week for two successive months, 24 sessions as administered above.

Outcome measures

Primary outcome (Functional neck disability): The primary outcome was functional neck disability, disability related to neck pain was measured by the neck disability index (NDI). NDI have been shown to be reliable and valid. The NDI consists of 10 items, each with a score up to 5, for a total score of 50. The lower the score, the less self-rated disability is Dr. Vernon[12] established the following guide for the interpretation of a patient's score: 0-4 = No disability, 5-14 = Mild disability, 15-24 = Moderate disability, 25-34 = Severe disability, 35 or over = Complete disability.

Secondary outcome (Pain level): The secondary outcome was pain, assessed on a 10 cm visual analogue scale (VAS), where 0 cm represented no pain and 10 cm (killing pain). The patient places a mark along the line to denote his/her level of pain[13].

Sample size and statistical analysis: To avoid a type II error, a preliminary power analysis [power (1-α error P) = 0.80, α = 0.05, effect size = 1.1, with a two-tailed for a comparison of 2 independent groups] determined a sample size of 30 for each group in this study. This effect size was calculated according to a pilot study on 12 participants (6 in each group) considering neck disability index as a primary outcome. Sample size and power calculations were performed using G power 3.1 Software. All statistical measures were performed using the statistical package for social science (SPSS) for windows, version 22 (SPSS, Inc., Chicago, IL). The current test involved two independent variables. The first one was the tested group including 'between the subject factor' which had two levels: Group A received the traditional program of cervical rehabilitation and used Cervical Denneroll orthotic tool, whereas, group B received only the traditional program of cervical rehabilitation. The second one was the measuring periods within the subject factor which had two levels (pre and post). In addition, this test involved 2 tested dependent variables [neck disability index (NDI) and visual analogue

Table 1: The 2×2 mixed design multivariate analysis of variance (MANOVA) for all dependent variables in different measuring periods between both groups

Source of variation	f-value	p-value
Groups	6.704	0.0001*
Measuring periods	195.105	0.0001*
Interaction	29.177	0.0001*

*Significant at alpha level <0.05

Table 2: Physical characteristics of patients in both groups (A and B)

Characteristics	Group A Mean±SD	Group B Mean±SD	p-value	S
Age	29.66±5.56	29.13±5.83	0.719	NS
Height	164.30±9.29	166.36±11.08	0.437	NS
Weight	76.56±8.56	76.63±9.94	0.978	NS

SD: Standard deviation, P: Probability, S: Significance, NS: Non-significant

scale (VAS)]. The p<0.05 was considered to be statistically significant. Normality test of data, Shapiro-Wilk test, was used and reflected the normal distribution of data for NDI and VAS. Statistical analysis using 2×2 mixed design MANOVA indicated that there were significant effects of the tested group, the first independent variable, on the all tested dependent variables, NDI, VAS. However, there were significant effects of the measuring periods, the second independent variable, on the tested dependent variables. However, the interaction between the two independent variables was significant, it indicates that the effect of the tested group, the first independent variable, on the dependent variables was influenced by the measuring periods, the second independent variable as mentioned in (Table 1).

RESULTS

The current study was conducted on 60 patients (38 females and 22 males) suffering from non-specific neck pain. They were assigned randomly into two equal study groups. Group (A) consisted of 30 patients, Group (B) consisted of 30 patients. As tested, the mean values of both groups and as indicated by the independent test, there were no significant differences (p>0.05) in the mean values of age, weight and height between both tested groups as in Table 2.

Neck disability index (NDI)

Within groups: As illustrated in Fig. 1, within group's comparison, the Mean±SD values of NDI in the "pre" and "post" tests were 38.69±12.32 and 23.40 ±6.15, respectively, in group A. Multiple pairwise comparison tests (*Post hoc* tests) revealed that there was significant reduction of NDI at post-treatment in comparison to pre-treatment (p = 0.0001). While, the Mean±SD values of NDI in the "pre" and "post" tests were 36.72±10.56 and 30.87±8.85, respectively, in group B. Multiple pairwise comparison tests (*Post hoc* tests) revealed that there was significant reduction of NDI at post treatment in comparison to pre treatment (p = 0.0001).

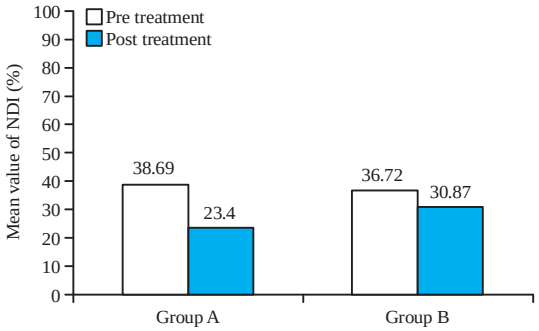

Fig. 1: Mean values of NDI pre and post tests in both groups

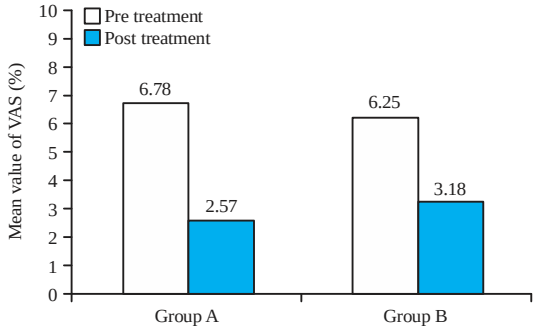

Fig. 2: Mean values of VAS pre and post tests in both groups

Between groups: Considering the effect of the tested group (first independent variable) on NDI, multiple pairwise comparison tests (*Post hoc* tests) revealed that the mean values of the "pre" test between both groups showed no significant differences with p = 0.529. Likewise, multiple pairwise comparison tests (*Post hoc* tests) revealed that there was significant differences in the mean values of the "post" test between both groups with p = 0.001 and this significant reduction was in favor to group A.

Visual analogue scale (VAS)

Within groups: As illustrated in Fig. 2, within groups' comparison, the Mean±SD values of VAS in the "pre" and "post" tests were 6.78±0.95 and 2.57±0.57, respectively, in group A. Multiple pairwise comparison tests (*Post hoc* tests) revealed that there was significant reduction of VAS at post treatment in comparison to pre treatment (p = 0.0001). While the Mean±SD values of VAS in the "pre" and "post" tests were 6.25±1.19 and 3.18±1.07, respectively in group B. Multiple

pairwise comparison tests (*Post hoc* tests) revealed that there was significant reduction of VAS at post treatment in comparison to pre treatment (p = 0.0001).

Between groups: Considering the effect of the tested group (first independent variable) on VAS, multiple pairwise comparison tests (*Post hoc* tests) revealed that the mean values of the "pre" test between both groups showed no significant differences with (p = 0.077). Likewise, multiple pairwise comparison tests (*Post hoc* tests) revealed that there was significant difference of the mean values of the "post" test between both groups with (p = 0.01) and this significant reduction was in favor to group A.

In the same context, within the subject effect, the multiple pairwise comparison tests revealed that there was significant reduction ($p<0.05$) in the pain level in the post treatment condition compared with the pre-treatment at both groups. As well as, there was significant reduction ($p<0.05$) in NDI the post treatment condition compared with the pre-treatment at group A only. Regarding between the subject effects, multiple pairwise comparisons revealed that there was significant difference of pain level and NDI between both groups ($p<0.05$) and this significant reduction was in favor to group A. In conclusion, there was a positive significant improvement in all dependant variables in post treatment rather than pre treatment in both groups.

DISCUSSION

This study was conducted to determine the effect of the restoration of sagittal cervical curve alignment on disability and pain of cervical region on 60 patients of both sexes, 30 patients in each group (38 females and 22 males) suffering from non-specific neck pain. They were assigned randomly into two equal groups: group A; Received physical therapy rehabilitation program in the form of 'infra-red therapy, ultrasound therapy, TENS and posto-anterior unilateral pressure (PAUP) mobilization', plus Denneroll equipment, group B; received only the traditional physical therapy rehabilitation program. The treatment program was conducted through three sessions per week, day after day within 8 weeks.

Patients in this study have mild to moderate non-specific neck pain. The 2 groups were assessed pre and post treatment program including neck disability function by using NDI (Neck disability index) and pain level by using VAS (visual analogue scale). The result of this study showed that there were statistically significant positive changes detected in the pain level and in the scores of neck disability index in group A comparing with the other group B. The percentages of improvement were as the following: Group A; visual analogue scale (VAS) (62%) and neck disability index (NDI) (39.51%). Group B; visual analogue scale (VAS) (49.12%) and neck disability index (NDI) (15.93%).

This reflects that the Denneroll orthotic tool, in addition to the traditional physical therapy program for cervical, showed marked improvement in the pain and functional disability of neck compared to the traditional physical therapy program. Ylinen *et al.*[14] analyzed the effects of 12 month strength training subsequent to 12 month stretching exercise in treatment of chronic neck pain on 59 women. Statistically and clinically, significant decreases in neck pain and disability indices occurred. Stretching and aerobic exercising during the first follow-up year produced only minor changes in both subjective and functional measures. Adding progressive strength training for the second year led to a significant improvement in neck strength as well as to a considerable decrease in the pain and disability scores.

The findings of this study were in agreement with the result of Rakel and Barr[15], who stated that there was limited but positive evidence that the physical modalities selected were effective in managing chronic pain associated with specific conditions and experienced by adults and older individuals. Generally, studies have provided the most support for the modality of therapeutic exercise. Different physical modalities have similar magnitudes of effects on chronic pain. Vernon and Mior[12] studied the reliability and validity of neck disability index. A modification of the Oswestry low back pain index was conducted producing a 10-item scaled questionnaire entitled the neck disability index (NDI). This study demonstrated that the NDI achieved a high degree of reliability and internal consistency. McCormack *et al.*[16] in their study on clinical application of visual analog scales, described the visual analog scale (VAS) and provided a simple technique for measuring subjective experience, it has been established as valid and reliable in a range of clinic and research applications. Hence, visual analog scale (VAS) is valid and is considered one of the most frequently used measurement scale of pain in healthcare research and practice. The visual analogue scale (VAS) is a unidimensional measure of pain intensity, which has been widely used in diverse adult populations[17]. Reliability of the VAS for acute pain measurement appears to be high. Ninety percent of the pain ratings were reproducible within 9 mm. This data suggest that the VAS is sufficiently reliable to be used to assess acute pain[18]. The VAS provides a high degree of resolution and it is probably the most sensitive single-item measure for clinical pain research[19].

Furthermore, the findings of the current study are in agreement with the result of Shields *et al.*[20] stated that both groups demonstrated a highly significant improvement in reducing pain as measured by NPRS, decreasing neck disability and improving functional activities as measured by NDI. Moreover, it showed that the reduction in pain and neck disability significantly increases in the ICT combined with the conventional physiotherapy group in comparison with the conventional physiotherapy group. For the use of pillows alone, some studies in two SRs showed positive effects on pain reduction. No evidence for the use of pillows in isolation found[21]. One RCT showed a significant effect for the use of a neck support while sleeping in combination with exercises[22]. Mechanically though, it seems logical and is generally accepted that the loss of cervical lordosis is usually accompanied with axial or ventroflexion traction. Extension cervical traction has not shown any problems due to the lack of axial loading on the spine. Moreover, it has been shown that the use of extension cervical traction is essential in the treatment to restore lordosis cervical curve[23]. Harrison *et al.*[24,25] predicted that altered cervical lordosis and forward head posture increase the axial and flexural stresses by a factor of 6-10 times. Increasing the cervical lordosis and reducing the anterior head translation in the experimental group likely reduced or normalized the loads acting on the cervical spine tissues resulting in a decreased perception of reported neck pain intensity.

This study is also in agreement with Escortell-Mayor *et al.*[26] Similarly, the systematic review of Gaid and Cozens[27] provides evidence to support the use of TENS as a short-term effective treatment modality. Likewise, the transient (short-term) effect of manual therapy alone and/or in combination with exercise is in general agreement with Gross *et al.*[21]. Also, in many studies, pain has been argued to interfere with the transmission of the afferent input in the dorsal horn and to interfere with processing of input at cortical and subcortical levels[28]. It is generally accepted that the control of neck posture and movement is dependent on appropriate motor responses from mechanoreceptive input of joints and muscle spindles. Thus, maintaining or improving proprioceptive integration seemingly is an important mechanism for improving repositioning accuracy[29]. The current study was limited by: (1) Variation of functional activity level between different subjects, (2) The psychological condition of the subjects at the time of performance and (3) Lack of treatment that provides blinding due to the nature of the study.

CONCLUSION AND FUTURE RECOMMENDATIONS

This study shows that Cervical Denneroll equipment is an important factor to be considered in the management of cervical lordosis in cases of non-specific neck pain.

Recommendations for further studies:

- Follow up studies should be undertaken on greater sample
- Follow up studies should be undertaken on long run time follow up
- Further research needs to be conducted to investigate the effect of Denneroll versus kinesio tape in treatment of non-specific neck pain
- Further studies should be conducted to investigate the difference between mechanical traction and Denneroll on blood flow in cervical rehabilitation

SIGNIFICANT STATEMENT

This study discovers the effect of Denneroll orthotic traction tool in combination of traditional physical therapy program that can be beneficial for rehabilitation of cervical lordosis in cases of nonspecific neck pain. This study will help the researchers to uncover the critical areas of using a new modality in rehabilitation of cervical pain that many researchers were not able to explore. Thus a new theory on treating and make a possible effect of combination in rehabilitation of neck pain on functional disability and pain among Egyptian population, may be arrived at.

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