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Efficacy of Spinal Decompression Therapy in Individuals with Cervical Disc Herniation: A Randomized Controlled Trial

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Abstract

Cervical disc herniation is characterized by breakage of disc material into the spinal canal leading to various symptoms such as arm and neck pain, paresthesias and movement limitations. Current options for pain management include drug therapy, physiotherapy, acupuncture and surgical care. Alternative spinal decompression therapy achieves clinical effectiveness in reducing pain, disability and improving quality of life.

The primary aim of this randomized controlled trial was to evaluate the effect of spinal decompression therapy along the conventional therapy and cervical stability exercises in treatment of individuals with cervical intervertebral disc herniation.

The male and female participants within the age range 30-50 years diagnosed with cervical disc herniation experiencing pain in cervical region and irradiation to upper extremities willing to participate were included. Patients were randomly assigned into two groups. Each patient underwent nine treatment sessions over the course of three weeks (3 therapy sessions/ week). Experimental group: 15 patients underwent treatment with spinal decompression device (BTL Industries Ltd.) along with conventional therapy and cervical stability exercises. Control group: 15 patients underwent conventional therapy along with cervical stability exercises. All patients' pain and disability perception were evaluated via Numeric Pain Rating (NPR) scale and Neck Disability Index (NDI) obtained prior to the first treatment and at day 10 and 21 of the clinical trial.

The non-parametric Wilcoxon sign rank test confirmed a significant improvement in Neck Disability Index and Numeric Pain Rating scale for both patients groups. Spinal decompression therapy proved to be effective as the experimental group achieved about 19% better NDI and 24% better NPR score difference than the control group.

Spinal decompression therapy as a part of conventional physiotherapy program proved to have a significant impact on pain and disability enhancement in patients with cervical intervertebral disc herniation.

Keywords: Spinal decompression therapy; Cervical intervertebral disc herniation; Neck disability index; Numeric pain rating scale

Introduction

Human cervical spine comprises seven cervical vertebrae containing intervertebral discs absorbing stress during loading and unloading of the spine. Simultaneously these intervertebral discs allow various degrees of movement in order to maintain the flexibility in different segments of the spine. Due to constant strain on the intervertebral disc during antigravity postures and movements these discs get predisposed to various stress related traumatic and non-traumatic injuries. One of the commonest problems seen in discs is disc herniation, abnormal protrusions of a portion of the disc material [1-3].

Herniated disc represents a global health issue as it affects about 1%-2% of the world population. Herniation can occur at any vertebrae level from lumbar to cervical spine, but lumbar herniation is more prevalent (80%) than cervical herniation (20%) [4]. Incidence and prevalence of cervical disc herniation increases as the age advances for both males and females. More than 60% of all cases appeared in females, with the highest incidence for both genders within the age group 51 to 60. The most common areas of predilection are C5-C6 and C6-C7 vertebral bodies. Individuals with cervical disc prolapse often suffer from the symptoms like axial neck pain and ipsilateral arm pain or paresthesias in the associated dermatomal distribution [2,3,5].

The commonest site of herniation is posterolateral disc herniation. Many treatment options exist for alleviating neck pain which include drug therapy, non-pharmacological therapies like physical therapy, acupuncture etc. and surgical treatment. The primary pain management treatment for neck pain remains drug therapy. Once the medication does not bring pain relief, most of the individuals rely on non-pharmacological therapies in order to get complete relief. Surgery is the last choice of treatment for most of the patients as it is associated with possible complications and high costs. Surgery has been often used as the last solution for patients with cervical dysfunction and disc prolapse [6]. It is predicted that in the next 20 years, there will be a significant increase in cervical decompression surgeries in people aged 45-54, mainly affecting the working population [7].

Physiotherapy utilizes multimodal treatment approaches including application of external energy via medical device, physical exercise and manual therapy techniques in order to reduce patients' disability and improve quality of life. These conventional methods are known and widely used and generally are considered the second choice of treatment (after medication). It is believed that in certain cases they are capable of the same or better results as surgical intervention. Despite its general popularity, the effectiveness of the individual procedures varies and their mutual comparison would deserve some scientific attention. Danazumi conducted a literature review of studies observing impact of non-surgical physiotherapy approaches on patients suffering from lumbar disc herniation with radiculopathy. The

author concluded extension-oriented treatment (spinal manipulation and lumbar stabilization exercise in combination with low power laser) to be more effective than any other physiotherapy method.

Unfortunately the study focused on patients struggling with lumbar rather than cervical disc herniation [8]. Gross, et al. has conducted a similar review for patients suffering from neck pain with the conclusion that using specific strengthening exercises as a part of routine practice for chronic neck pain, cervicogenic headache and radiculopathy may be beneficial [9]. However there is still uncertainty about the effectiveness of exercise for neck pain and thus further research is required. Study investigating whether adding stabilization exercises to the standardized cervical physiotherapy program would increase the outcome in patients with cervical radiculopathy did not find a significant difference in achieved pain severity or neck disability index between the patients groups [10]. However, both groups achieved significant improvement in all parameters.

Engquist, et al. conducted a randomized controlled trial comparing the effect of physiotherapy to combined physiotherapy and surgical intervention in patients with cervical radiculopathy [11]. Neck disability index and arm pain intensity showed no between-group difference while neck pain intensity and patients' subjective symptoms rate showed significant difference in favor of the surgical group. These between-group differences decreased during 24-month follow-up.

Symptoms associated with disc herniation such as pain, movement limitations and sensory abnormalities are caused by extensive pressure on nerve roots inside the spinal canal due to herniation of degenerated disc.

Spinal decompression therapy represents a new non-invasive treatment of lumbar disc herniation. It is capable of retracting and repositioning affected disc via negative intradiscal pressure and thus decreasing the pressure within the spinal canal [12,13]. It is believed that with very precise motion control and proper positioning, the same mechanism of action could be applied in patients with cervical disc herniation. Currently, the market lacks spinal decompression devices offering energy dosing in small precise steps and positioning extension essential for neck treatment.

Although spinal decompression technology is gaining popularity as a non-invasive alternative of disc decompression surgery, existing clinical evidence is insufficient. Ma, et al. was investigating whether a multimodal approach including 20 sessions of spinal decompression, spinal mobilization and cervical stabilization exercises would cause significant improvement in patients with neck radiculopathy [14]. Even though study confirmed impact on both pain and disability score improvement, it is not clear how large the proportion of the spinal decompression effect was as the control group was completely missing. Therefore it is not possible to evaluate whether a 450-gram force increment step is sufficient for cervical treatment. Fritz, et al. were comparing impact on patients with cervical radiculopathy within three treatment groups - exercises only, exercise combined with mechanical traction and exercise with over-door traction [15]. Study concluded that adding mechanical traction to exercise resulted in an improved disability and pain score. It should be emphasized that mechanical traction works on a similar principle as spinal decompression, but it is purely a mechanical device without the option to position patients and dose energy precisely into impaired segment. Study involving spinal decompression device was performed on patients suffering from low back pain due to lumbar intervertebral disc herniation. Gaowgzeh was comparing core stabilization exercise with the core stabilization combined with spinal decompression therapy [13]. Conclusion was made that spinal decompression combined therapy was significantly more effective on pain and disability score reduction.

Currently there is no existing randomized controlled study investigating the effect of spinal decompression therapy in individuals with cervical intervertebral disc herniation. Innovative approach of modality enabling precise positioning and force adjustment for effective neck treatment has not been properly evaluated yet. This was the primary aim of the present study via comparison of results achieved by innovative spinal decompression as adjunctive therapy to the conventional physiotherapy methods with results of conventional physiotherapy standalone procedures.

Materials and Methods

Inclusion criteria

The male and female participants within the age range 30-50 years diagnosed with cervical disc herniation experiencing pain in cervical region and irradiation to upper extremities willing to participate were included.

Exclusion criteria

The participants diagnosed with spinal stenosis at cervical level, with history of spinal tumors, infections and cervical vertebra fracture or previous cervical spinal surgeries were excluded from the trial. Non cooperative, pregnant and severely diseased (including vascular, pulmonary or coronary artery disease) were not accepted.

Study design

The study was designed as a double blinded controlled trial. Patients were randomized into 2 groups (n=30). Randomization was performed by block randomization using a computer-generated algorithm. Patients did not know to which group they were assigned. Outcome Assessment and evaluation was performed by an individual completely unaware of the groups' distribution. Therapy was provided by the chief physiotherapist.

Ethical standards

All participants were informed about the study protocol and each gave written informed consent for study participation and for publication of the results. Furthermore, an approval from the Institutional Ethical Committee of Punjabi University, Patiala, and Punjab was obtained prior to the commencement of the study (No. 192/IEC, 27.1.2021).

Treatment protocol

Treatment protocol for both groups consisted of conventional physiotherapy techniques (soft tissue release combined with active and/or passive stretching) and cervical stability exercises. Preceding these conventional physiotherapy techniques, patients among the experimental group underwent spinal decompression treatment during each therapy session. In total, patients completed 9 therapies over the course of 3 weeks (3 therapies/week). The total duration of one therapy session took 1 hour (Figure 1).

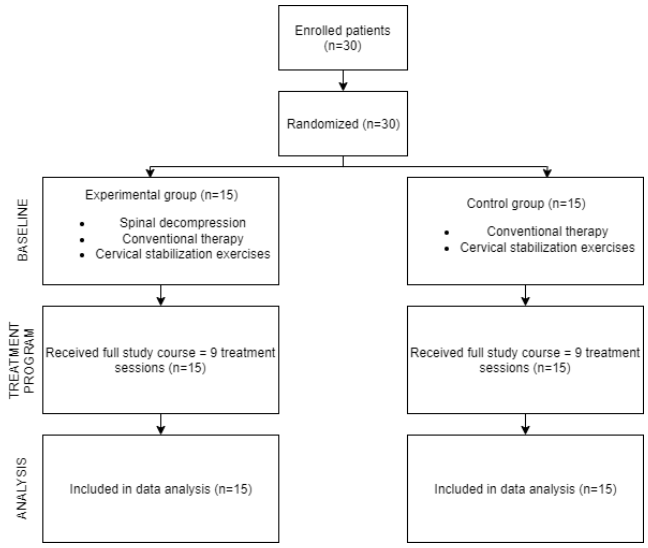

Figure 1: Study design and number of patients included in different stages.

The device

Spinal decompression device (BTL Industries Ltd.) comprises a treatment couch containing multiple movable parts for cervical, thoracic and pelvico-lumbar regions for proper patient positioning into pain relieving position. Furthermore, the cervical region is treated by an integrated cervical slider that is the first of its kind available. The main unit is embedded with a computerized mechanism for precise dosing of decompressive forces. The delivery of energy to the target segment is ensured by moving parts with various adjustment options while the precision of the delivered decompressive forces is guaranteed by a 100-gram force increment. Such force increment makes the therapy extremely gentle even in very sensitive patients (Figures 2 and 3).

Figure 2: The BTL spinal decompression therapy device and couch (Source: www.btlnet.com, Courtesy of BTL).

Figure 3: The BTL spinal decompression therapy with integrated cervical slider (Source: www.btlnet.com, courtesy of BTL).

The patient was set in a supine position on the spinal decompression treatment couch. Patient's head position was fixed into a cervical adapter that was further positioned to target the herniated cervical vertebra. Traction test was applied to determine the patient's tolerance prior to every therapy. The decompressive force did not exceed 20% of the patient's body weight. Total therapy time was between 10-15 minutes as per patient's condition. After each therapy, the patient remained on the decompression couch for half of the therapy time to relax and stabilize.

Study outcomes

Level of patient's disability was determined by the most commonly used questionnaire for the measurement of neck pain disability Neck Disability Index (NDI) [16]. It is a globally used evaluation tool whose validity and reliability was approved by multiple studies. The NDI questionnaire contains 10 questions considering the impact of disability on different limitations in a patient's daily life [17]. Seven questions are examining functional activities, 2 focuses on symptoms and the last question considers concentration. Questionnaire was answered by patients before the initial intervention (baseline), at 10th day and at 21st day of the clinical trial. A Numeric Pain Rating scale (NPR) was used to evaluate the subjective perception of pain intensity. The scale consists of a 10 cm line divided into 10 equal sections, with 0 representing "no pain" and 10 representing "worst pain" [18]. Each participant was asked to indicate on the scale the level of pain in the affected cervical area at baseline, at 10th day and at the 21th day of the clinical trial.

Statistical analysis

All calculations required for basic data comparison and for more advanced statistical analysis were performed via a custom-written MatLab program (MatLab software processes, MatLab R2010b, Mathworks, Inc., Natick, MA, USA).

Each group's NDI and NPR results were statistically analyzed to compare scores obtained at the baseline, at 10th and at 21st day of the clinical trial. The shapiro-wilk test was used to verify data normality. Normal data distribution has been rejected at the 0.05 significance level and therefore the non-parametric Wilcoxon sign rank test was used for further evaluation [19].

NDI and NPR results were further averaged in two different ways for analysis purposes. Average NDI/NPR was calculated by averaging the NDI/NPR score of an individual group at a certain time frame. Average NDI/NPR Diff was calculated by averaging the difference between NDI/NPR scores obtained at baseline and at 10th and 21st day of the trial for each patient across the specific study group.

Results

A total of 30 patients diagnosed with cervical disc herniation; aged 41.3 ± 6.2; were randomized into two groups. All enrolled patients completed the full course of the therapy. The study was generally well tolerated with no adverse events reported.

Neck disability index

NDI values for both experimental and control groups obtained at the baseline, 10th day and 21st day of the trial are shown in Table 1.

	Baseline		10th day	21st day		
	Average NDI	Average NDI Diff	Average NDI	Average NDI Diff	Average NDI	Average NDI Diff
Experimental	38.13 ± 4.14	NA	31.13 ± 3.66	7.00 ± 2.88	21.67 ± 5.43	16.47 ± 5.22
Control	40.60 ± 3.54	NA	36.80 ± 3.59	4.80 ± 2.31	31.60 ± 3.36	10.00 ± 2.36

Table 1: Neck disability index values obtained throughout the study course for experimental and control groups.

Both average NDI and average NDI Diff values are reflecting the decreasing trend of NDI score throughout the study period for both patient groups. Overall improvement was visualized via box plot graph (Figure 4).

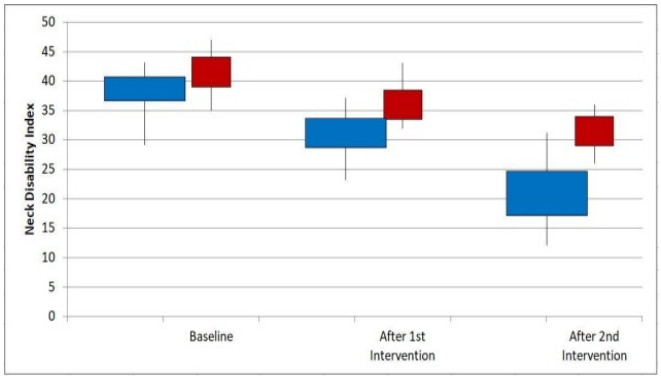

Figure 4: Visual evaluation of neck index values obtained throughout the study course for experimental (blue) and control (red) groups.

There was significant ($p<0.01$) improvement of NDI score for both groups after 10 and 21 days of the trial. Patients within the experimental group reported by 19% better impact on NDI than patients within the control group.

Numeric Pain Rating scale

Average NPR values for both groups at the baseline, 10th day and 21st day of the trial are shown in Table 2. Both Average NPR and Average NPR Diff values are reflecting the decreasing trend of NPR score throughout the study period for both patient groups. Overall improvement was visualized via box plot graph (Figure 5).

There was significant ($p<0.01$) improvement of NPR score for both groups after 10 and 21 days of the trial. Patients within the experimental group reported by 24% better impact on NPR than patients within the control group.

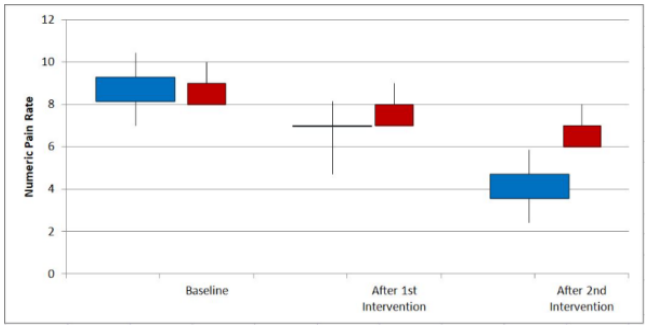

Figure 5: Visual evaluation of numeric pain rating scale values obtained throughout the study course for experimental (blue) and control (red) groups.

Discussion

The aim of this study was to evaluate the effect of spinal decompression therapy along the conventional therapy and cervical stability exercises in treatment of individuals with cervical intervertebral disc herniation. Results confirmed that conventional therapy along with cervical stability exercise and both methods supplemented by spinal decompression therapy have a significant impact on patients' quality of life. Spinal decompression therapy proved to enhance overall results by 19% and 24% for disability and pain score, respectively. We believe that the innovative technology of the tested device including unique features such as precise positioning and force dosing contributed to these results.

In order to better understand the improvement in terms of disability and pain reduction we need to understand the mechanisms behind spinal decompression therapy. Symptoms associated with disc herniation such as pain, movement limitations and sensory abnormalities are caused by extensive pressure on nerve roots inside the spinal canal due to herniation of degenerated disc. Spinal decompression therapy is targeting the desired slipped disc by delivering force in exact direction and angle. It is reducing intervertebral disc pressure by supplying nutrients and oxygen, increasing intervertebral space and restoring disc height [12,13]. We

	Baseline		10th day	21st day		
	Average NPR	Average NPR Diff	Average NPR	Average NPR Diff	Average NPR	Average NPR Diff
Experimental	8.73 ± 0.96	NA	6.87 ± 0.74	1.87 ± 0.64	4.40 ± 0.99	4.33 ± 1.18
Control	8.87 ± 0.74	NA	7.73 ± 0.70	1.13 ± 0.52	6.60 ± 0.63	2.27 ± 0.46

Table 2: Numeric Pain Rating scale values obtained throughout the study course for experimental and control groups.

assume that it is essential to deliver repetitive and precisely-dosed forces in pain-relieving position of the impaired segment.

Previous studies investigating impact of spinal decompression therapy on patients with cervical pain associated with intervertebral disc herniation, were consistent with aforementioned results [1,14,20-22]. Both pain and disability index had a declining tendency throughout the course of the study.

Although there are a growing number of patients suffering from cervical disc herniation and non-invasive spinal decompression therapy is gaining popularity as an alternative to surgical intervention, clinical evidence supporting its efficiency is lacking. Present study is the first randomized controlled trial confirming the significant impact of spinal decompression therapy on patients with cervical intervertebral disc herniation.

Existing studies evaluating impact of spinal decompression on patients diagnosed with cervical disc herniation are either case studies or retrospective studies missing comparison between experimental and control group. Study with similar design was performed on patients suffering from low back pain due to lumbar intervertebral disc herniation. Gaowgzeh who was comparing spinal decompression therapy along with the core stabilization exercise with the core stabilization stand-alone therapy has concluded spinal decompression combined therapy to be significantly more effective on pain and disability score reduction [13].

Limitations of the study

We acknowledge that the following study has certain limitations such as the small sample size; lack of long-term follow-up data and the fact that, based on higher baseline scores (NDI), patients from the control group were of a slightly worse condition [23]. Due to the study randomization, the only solution would be to significantly increase the number of patients. With regard to this limitation, the score difference for each patient was calculated and averaged across the specific study group [24,25]. Aforementioned improvement was extracted from average ODI/NPR diff data instead of pure Average ODI/NPR.

It is important to note that although the NPR scale and NDI questionnaire are subjective tools in assessing pain and discomfort, these are commonly used among studies related to cervical intervertebral disc herniation [1, 10,11,15,14,20-22,]

Conclusion

This is the first randomized controlled study investigating the impact of spinal decompression therapy on patients with cervical disc herniation. Findings suggest that spinal decompression as adjunctive to conventional physiotherapy can contribute to improvement of disability and pain index. Current trend of increasing numbers of patients suffering from herniated disc symptoms together with the high costs of the operative intervention place high demands on the available physiotherapy program. The inclusion of spinal therapy in the standard physiotherapy package for patients with a herniated cervical disc could significantly increase the effectiveness of these non-invasive methods.

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