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Research Article

# Efficacy of Spinal Decompression Therapy in Individuals with Lumbar Disc Herniation - A Randomized Controlled Trial

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## ABSTRACT

**Background:** Pain, sensory abnormalities, muscle weakness and movement limitation are typical symptoms of lumbar intervertebral disc herniation. Lumbar area is the most prone to slipped disc characterized by herniation of degenerated disc material out of its original position. Pain is currently managed via drug therapy, physiotherapy or, as the last option, surgical care. Spinal decompression therapy is recently gaining popularity due to non-invasive approach and clinical effectiveness.

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

**Methods:** The male and female participants willing to participate within the age range 30-50 years diagnosed with Lumbar disc herniation suffering from pain in the lumbopelvic region radiating in lower extremities with Positive Straight Leg Raise Test at hip flexion from 30-70° were included. Patients were randomly assigned into experimental and control groups. Nine treatment sessions were scheduled within 3 weeks (3 therapy sessions/week) for each patient. Experimental group: 14 patients underwent treatment with spinal decompression device (BTL Industries Ltd.) along with conventional therapy and lumbar stability exercises. Control group: 14 patients underwent conventional therapy along with lumbar stability exercises. At baseline, 10th and 21st day of the trial, patients were asked to fill in an Oswestry low back pain questionnaire and determine level of the pain via Numeric Pain Rating scale.

**Results:** Significant improvement in Oswestry Disability Index (ODI) and Numeric Pain Rating scale (NPR) for both patients groups was reported. Therapeutic benefit of spinal decompression therapy in terms of disability and pain reduction was proved. The experimental group achieved about 15% better ODI and 14% better NPR score difference than the control group.

**Conclusion:** A significant improvement in patients suffering from lumbar disc herniation in both experimental and control groups was observed. Spinal decompression therapy further enhanced results in terms of decreased disability and pain score and proved to be an effective tool in the treatment of lumbar disc herniation.

## INTRODUCTION

Amongst the population of adults, 80 % experience pain in the lumbar region at least once in their lifetime [1,2]. Most of the structures causing pain in the lower back region are related to intervertebral discs. Annually, disc herniation is found in about 5-20out of 1000 adults, twice as often in men than in women. The most at-risk age group is among 30-50 years old. About 95% of herniated discs occur at level L4-L5 or L5-S1 mostly in patients between 25-55 years old [3]. Herniation can occur at any vertebrae level from lumbar to cervical spine, but lumbar herniation is more prevalent (80%) than cervical herniation (20%) [4]. The primary signs and symptoms of lumbar disc herniation include radicular pain, sensory abnormalities, and weakness in the distribution of one or more lumbosacral nerve roots. Focal paresis, restricted trunk flexion, and increases in leg pain with straining, coughing, and sneezing are also indicative. Patients frequently report increased pain when sitting, which is known to increase disc pressure by nearly 40% [1]. There are a number of treatment methods for stabilizing the symptoms of disc herniation including drug therapy, physiotherapy rehabilitation and surgical care.

The very first choice of disc herniation treatment includes drug therapy in the form of painkillers, anti-inflammatory drugs, muscle relaxant and sometimes morphine derivatives [6]. Once medication is not sufficient, physiotherapy is becoming a next treatment option. Physiotherapy program usually consists of manual manipulation technique, physical exercise and application of medical device therapy. Even though it is generally believed that these conventional methods, in certain cases, could result in similar or even better results than surgical intervention, the effectiveness of the individual procedures varies and their mutual comparison would deserve bigger scientific attention. When the conservative medical approach fails to succeed, the next approach opted by the affected population is surgical decompression. Such invasive intervention is considered as expensive and the success rate is not good as in some cases it does cause some major complications. Gugliotta et al. [7] gathered evidence for prospective cohort study comparing outcomes of surgical and conservative treatment in patients with lumbar disc herniation. Short-term results in terms of pain symptoms showed significant difference in favor of the surgical group but midterm and long-term follow-up results were similar for both groups.

Recently, non-surgical spinal decompression therapy is gaining popularity as a non-invasive alternative to disc decompression surgery. Ma et al. [8] was investigating whether multimodal approach including spinal decompression, spinal mobilization and lumbar stabilization exercises would cause significant improvement in patients with discogenic low back pain. Even though study confirmed impact on both straight leg raise 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. Randomized controlled study involving spinal decompression device was performed on patients suffering from low back pain due to lumbar intervertebral disc herniation by Gaowgzeh[3]. He was comparing core stabilization exercise with the core stabilization exercise combined with spinal decompression therapy. Conclusion was made that the multimodal approach of 20 sessions of spinal decompression combined therapy had significant impact on pain and disability score reduction. These results are very promising, but 20 therapies might be too much time and cost consuming, considering the limited coverage by most health insurance. Although studies of various treatment methods for back pain have been conducted, the present study is focused on the effect of spinal decompression therapy along with other conservative interventions on various domains of the affected individuals. The aim is to prove that the currently investigated spinal decompression device is capable of delivering significant effect in the course of only 9 sessions which is significantly less than the number of sessions covered by existing clinical evidence.

## MATERIALS AND METHODS

The current double blinded controlled trial was conducted at Punjabi University, Department of Physiotherapy between January and April 2021.

**Inclusion criteria**

The male and female participants willing to participate within the age range 30-50 years diagnosed with Lumbar disc herniation suffering from pain in the lumbopelvic region radiating in lower extremities with Positive Straight Leg Raise Test at hip flexion from 30-70° were included.

**Exclusion criteria**

Participants diagnosed with lumbar canal spinal stenosis, with

history of spinal tumors, infections and lumbar vertebra fracture or previous lumbar spinal surgery were excluded from the trial. Non cooperative, pregnant and severely diseased (including vascular, pulmonary or coronary artery disease) were not accepted.

**Study design**

Enrolled patients were equally distributed into experimental and control groups. The allocation sequence was generated by block randomization of size 10 performed by computer-generated algorithm. Participants were enrolled by clinician and based on the allocation sequence assigned to the respective group by the chief physiotherapist. Chief physiotherapist was also providing the spinal decompression treatment while another clinician, who had no information about patient allocation, performed conservative physiotherapy including stability exercises, and collected outcome measures questionnaires. For data processing purposes, all questionnaires were forwarded to a dedicated researcher responsible for assessment and evaluation who was not aware of group distribution. For the allocation blinding purposes, participants in the control group were given sham decompression therapy with the decompression force of 5%. Based on published data showing the baseline Oswestry disability index of patients with lumbar disc prolapse and reported improvement induced by conventional methods [5,9] it was estimated that at least eight patients in each group would give 80% power to detect a significant ($p < 0.05$) difference between the groups.

**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, Punjab was obtained prior to the commencement of the study (No. 193/IEC, 27.1.2021) (Figure1).

**Treatment protocol**

Patients from both groups received conventional physiotherapy and lumbar stability exercises during each treatment session. Experimental group was treated with spinal decompression prior to each physiotherapy and stability exercises session. Treatment program consisted of 9 treatment sessions during the 3 weeks course (3 therapies/ week).

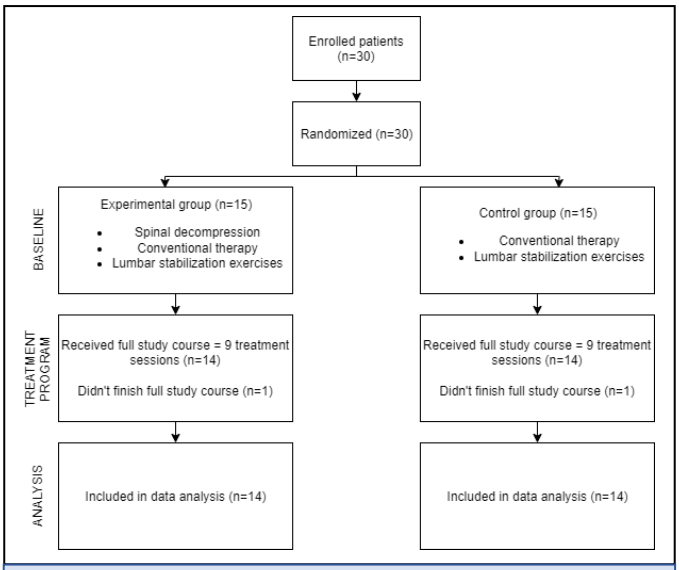


Figure 1: Study design and number of patients included in different stages.

**The device**

During spinal decompression treatment (BTL Industries Ltd.) a patient is lying on a treatment couch positioned in a pain relieving position via multiple movable parts for cervical, thoracic and pelvico-lumbar regions and decompressive forces are delivered into a precise spot by embedded computerized mechanism. Innovative approach involves innumerable adjustment options of movable parts within the treatment couch plus the most precise force delivery guaranteed by a 100-gram force increment. With such a small force increment therapy is becoming gentle even in sensitive patients suffering from pain (Figure 2).

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

BTL spinal decompression treatment couch enables precise patient positioning into pain relieving position. Patients can lie

on the prone, supine or in the side position and multiple areas can be tilted to different angles depending on the directional preferences and impaired segment. For lumbar disc herniation, the patient was fixed via lumbar belt and the lumbar region was further tilted within the range of 0-25° depending on theexact location of the herniated disc. Prior to every therapy, a traction test was performed in order to determine the patient's tolerance. Total therapy time was between 20-30 minutes as per patient's condition. The decompression force didn't exceed 50% of the patient's body weight and after each therapy, the patient had to remain still for half of the therapy time to relax and stabilize.

**Study outcomes**

As the primary outcome measure, the level of patient's disability was determined by the Oswestry Disability Index (ODI). Secondary outcome measure represented the Numeric Pain Rating (NPR) scale. Both collected outcomes were reported before the initial intervention (baseline), at 10th day and at 21st day of the clinical trial. The Oswestry disability index was obtained via Oswestry Low Back Pain questionnaire [10]. It is a globally used evaluation tool, one of the most commonly used for patientswith low back pain. Its validity and reliability was approved by multiple studies [11-13]. ODI questionnaire contains 10 questions concerning limitations in daily life activities of patients suffering from low back pain. Filling out by the patient himself requires approximately 5 minutes and scoring about 1 minute [12]. Final score is a simple sum of the ODI items multiplied by two [13]. It describes the degree of a patient's disability from minimal to bedbound. Its ease to administer, score and interpret has made it an integral part of examination practice for low back pain symptoms [12]. A Numeric Pain Rating scale 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" [14].

**Statistical analysis**

Custom-written MatLab program (MatLab software processes, MatLab R2010b, Mathworks, Inc., Natick, MA, USA) was used for statistical analyses and other calculations required for basic data comparison. ODI and NPR results obtained at the baseline, at 10th and at 21st day of the clinical trial were statisticaly analyzed and compared for both treatment groups. Data normality was verified via Shapiro-Wilk test. For further within-group evaluation, a paired t-test was used for ODI data which were evaluated as normally distributed while non-parametric Wilcoxon sign rank test was used for NPR data as normal data distribution has been rejected [15]. Between-group comparison was performed by the t-test (ODI) or Mann-Whitney U test (NPR). ODI outcomes were expressed as mean with standard deviation (SD) and NPR outcomes as median (interquartile range (IQR)). $P < 0.05$ was considered significant. For analysis purposes, ODI and NPR values were presented in two different ways. Mean ODI/ Median NPR represents the standard averaging/median of an individual group at a certain time frame while Mean ODI Diff/ Median NPR Diff is characterized by averaging/median the difference between ODI/NPR scores at 10th and 21st day of the trial and baseline for each patient across the specific study group.

## RESULTS

A total of 30 patients diagnosed with lumbar disc herniation; aged 39.2±5.7; with different spinal conditions - radiculopathy, spinal stenosis, anterolisthesis, retrolisthesis and disc extrusion of various extent were randomized into two groups. Two patients (1 from each group) were excluded as they weren't able to finish the full study course. The study was generally well tolerated with no adverse events reported.

**Oswestry disability index**

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

Table 1: Oswestry disability index outcome score (max 100 points) obtained throughout the study course for experimental and control groups.

| | | Experimental | Control |
|---|---|---|---|
| Baseline | Mean ODI (SD) | 31.29 (7.48) | 40.14 (4.83) |
| 10th day | Mean ODI (SD) | 23.71 (6.65) | 33.71 (6.97) |
| | Mean ODI Diff (SD) | 7.57 (3.82) | 6.43 (3.13) |
| 21st day | Mean ODI (SD) | 17.57 (5.93) | 28.43 (7.19) |
| | Mean ODI Diff (SD) | 13.71 (5.41) | 11.71 (3.69) |
| T-test P(0.05) | Baseline vs 21stday | <0.001 | <0.001 |
| Between groupT-test P (0.05) | Baseline | 0.001 | |
| | 21st day | <0.001 | |

Both Mean ODI and Mean ODI Diff values are reflecting the decreasing trend of ODI score throughout the study period for both patient groups. Overall improvement was visualized via box plot graph (Figure 3).

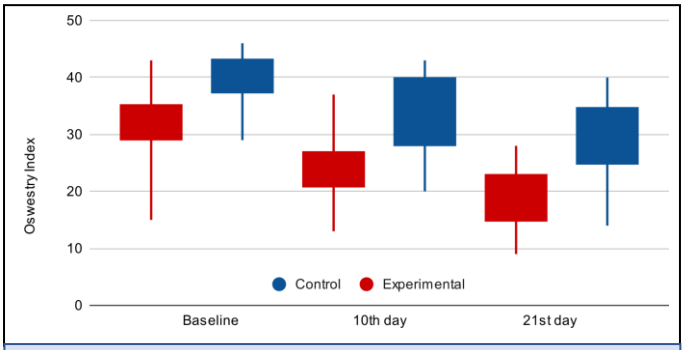


Figure 3: Visualized distribution of Oswestry Index values obtained throughout the study course for experimental and control groups. Bottom and upper boxes edges are representing first and third quartile, respectively while bottom whiskers are showing minimum and upper whiskers maximum values.

There was significant improvement of ODI score for both groups after 10 and 21 days of the trial. Patients within the experimental group reported by 15% better impact on ODI than patients within the control group. The between group comparison of data reported both at baseline and at 21st day were statistically significant.

**Numeric pain rating scale**

NPR values for both groups reported at the baseline, 10th day and 21st day of the trialare shown in Table 2.

Table 2: Numeric Pain Rating scale outcome score (max 10 points) obtained throughout the study course for experimental and control groups.

| | | Experimental | Control |
|---|---|---|---|
| Baseline | Median NPR (IQR) | 8.5 (1) | 9 (1) |
| 10th day | Median NPR (IQR) | 6.5 (1) | 7(1) |
| | Median NPR Diff(IQR) | 2(1) | 2(1) |
| 21st day | Median NPR (IQR) | 4 (1.5) | 5.5 (1.5) |
| | Median NPR Diff(IQR) | 4 (1.75) | 3 (1.75) |
| Wilcoxon P(0.05) | Baseline vs 21stday | <0.001 | <0.001 |
| Between groupMann-Whitney P (0.05) | Baseline | 0.19 | |
| | 21st day | 0.028 | |

Both Median NPR and Median 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 4).

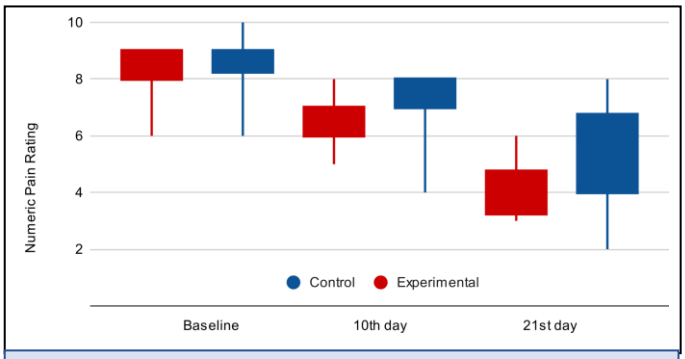


Figure 4: Visualized distribution of Numeric Pain Rating values obtained throughout the study course for experimental and control groups. Bottom and upper boxes edges are representing first and third quartile, respectively while bottom whiskers are showing minimum and upper whiskers maximum values.

There was significant improvement of NPR score for both groups after 10 and 21 daysof the trial. Patients within the experimental group reported by 14% better impact on NPR than patients within the control group. The between group comparison of data reported at baseline was statistically insignificant while there was significant difference between control and experimental data collected at 21st day.

## DISCUSSION

The aim of this randomized controlled trial was to evaluate the effect of the conventional therapy and lumbar stability exercises with spinal decompression combined treatment in individuals with lumbar intervertebral disc herniation. Results confirmed that conventional therapy along with lumbar stability exercise and combined treatment of both methods and spinal decompression therapy have a significant impact on patients' quality of life. Spinal decompression therapy proved to enhance overall results by 15% and 14% for disability and pain score, respectively. Both measured outcomes reported significant differences when compared control and experimental after data. However the statistically significant difference in the ODI after data could only be due to the difference at baseline. Patients from the treatment group were of significantly worse condition than patients from the experimental group in terms of disability index.

To justify the enhanced disability and pain reduction it is essential to understand the spinal decompression mechanism of action. Extensive pressure within the spinal canal due to protrusion of degenerated disc leads to irritation of nerve

roots and other structures causing symptoms such as pain, movement limitations and sensory abnormalities. The aim of the spinal decompression therapy is to decrease the pressure by supplying nutrients and oxygen into the intervertebral disc, subsequently increase intervertebral space and restore disc height [2,5]. From an efficiency point of view it is crucial to precisely dose repetitive decompressive forces and deliver them in the proper pain-relieving position (in supine, prone or side-line position) with lumbar area tilted under specific angle depending on the exact location of impaired segment. This enables more accurate energy delivery to the herniated disc plus effective therapy to sensitive patients suffering from pain.

Previous studies [2,5,8,9,16-18] investigating impact of spinal decompression therapy on patients with low back pain associated with intervertebral disc herniation, were consistent with findings of the present trial. Both pain and disability index had a declining tendency throughout the course of the study. Study with the similar design by Gaowgzeh [5] has concluded spinal decompression combined therapy to be significantly more effective on pain and disability score reduction than stand-alone physiotherapy program. However, enrolled patients underwent significantly more therapy sessions (20) than patients of a current trial (9). It is believed that it has to do with the fact that the current trial was performed with the innovative technology involvingaforementioned features such as precise patient positioning and force delivery. Therapy was better targeting the impaired segment and less treatment sessions were required. Hence present study, as the first one, confirmed impact of multimodal treatment including spinal decompression on pain and disability score in patients with lumbar disc herniation after as few as 9 therapy sessions. This finding may be crucial for patients who are looking for fast recovery or are limited by the number of therapies covered by insurance.

## LIMITATIONS OF THE STUDY

We acknowledge that the following study has certain limitations. Assumption of worse condition of patients from control group was done based on higher baseline scores (ODI). As the group distribution was performed by randomization via computer-generated algorithms, the possible way to reduce this would be to significantlyincrease the number of patients. In order to minimize the impact of this limitation, the score difference of each patient was calculated and averaged across the specific study group. Aforementioned 15% and 14% improvement within the experimental group was extracted from Mean ODI Diff/ Median NPR Diff data instead of pure Mean ODI/ MedianNPR.

As a limitation, the absence of follow-up, which is considered essential for providing long-term impact, has to be admitted. It is important to note that although the NPR scale and Oswestry Low Back Pain questionnaire are subjective tools in assessing pain and discomfort, these are commonly used among studies related to lumbar intervertebral disc herniation [2,5,8, 9,16-18].

## CONCLUSION

This is the first randomized controlled study proving the impact of multimodal treatment including spinal decompression therapy on patients with lumbar disc herniation after as few as 9 therapy sessions. 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. Decreasing the number of sessions might make this treatment more affordable, mostly for patients relying on a contribution from the insurance company.

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