Follow-Up Magnetic Resonance Imaging Study of Non-surgical Spinal Decompression Therapy for Acute Herniated Intervertebral Disc: A Prospective, Randomized, Controlled Study

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Research

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Abstract

Background

Non-surgical spinal decompression therapy has been used for treating the lumbosacral herniated intervertebral disc as one of the conservative treatments. This study aimed to evaluate the effectiveness of the therapy in acute lumbosacral herniated intervertebral disc through magnetic resonance imaging.

Methods

Prospective, randomized, controlled study. Sixty patients with acute lumbar herniated intervertebral disc were randomized into either the decompression group (n = 30) or non-decompression group (n = 30). In the decompression group, non-surgical spinal decompression therapy was performed ten times in eight weeks. In the non-decompression group, pseudo-decompression therapy (no force) was performed with the same protocol. The change in the lumbosacral disc herniation index was evaluated through follow-up magnetic resonance imaging at three months after the therapy.

Results

The change in herniation index after the therapy was −27.6 ± 27.5 (%) in the decompression group and −7.1 ± 24.9 (%) in the non-decompression group, with significant difference (P = 0.017). Approximately 26.9% of patients in decompression group and no patients in the non-decompression group showed over 50% reduction in herniation index (P = 0.031).

Conclusion

Non-surgical spinal decompression therapy can be a good treatment option for conservative treatment of acute lumbosacral herniated intervertebral disc.

Trial registration

Korean Clinical Research Information Service (https://cris.nih.go.kr/cris/search/search_result_st01_en.jsp?seq=5355&ltype=&rtype=), Registration No. KCT0002614. Registered 26 December, 2017.

Background

The lumbar herniated intervertebral disc (L-HIVD) is a common cause of low back pain and radiculopathy of lower extremities [1]. L-HIVD, even with massive disc herniation, usually has a favourable clinical course [2]. Surgical treatments should be chosen when patients present with neurologic deficits; however, approximately 60–90% of L-HIVD cases are known to be treated with only conservative treatments [3]. Conservative treatments for L-HIVD include education, medication, physiotherapy, and epidural steroid injection. Lumbar traction therapy, among various physiotherapy, reduces the pressure of herniated disc

and helps to recover from L-HIVD. The effects of lumbar traction therapy have been evaluated in various ways by measuring pain relief, improvement in function, or change in magnetic resonance imaging (MRI) [4-6]. However, the effectiveness of lumbar traction therapy remains questionable because lumbar traction therapy has various forms (motorized, gravitational, and manual type), and each type has not been properly evaluated through a well-designed randomised controlled study [7-9].

Non-surgical spinal decompression therapy (NSDT) can be modified as one of the motorized traction therapies. It has a device that can fix the upper and lower body on a splitting bed that allows bending, rotating, and stretching, and a computer program can adjust the direction and angle of traction according to the target disc. The advantage of NSDT, when compared with traditional traction therapy, is that it can steadily increase the traction intensity by the relaxation of contracted paraspinal muscles during decompression [10, 11]. Additionally, NSDT is believed to create a state of non-gravitation in targeted herniated disc using a precise computer program [12]. Although there have been studies comparing the effectiveness of NSDT with other modalities (conservative treatment or traditional traction therapy) [6, 13], there is no previous randomised controlled study that evaluated the change in herniated disc after NSDT using MRI.

We hypothesized that NSDT for acute lumbar herniated disc could decrease the volume of the disc, and the change in the herniated disc volume was monitored through MRI. Additionally, clinical effectiveness, as determined using pain relief and improvement in the patient's function, was evaluated following NSDT.

Methods

Patients

A prospective, randomized, controlled study was conducted in pain clinic of Seoul National University Bundang Hospital. This study was approved by the institutional review board of Seoul National University Bundang Hospital (IRB No. E-1412-278-002) and was registered in the Clinical Research Information Service (Registration No. KCT0002614). All participants were provided written and verbal information about the trial before providing written consent. The inclusion criteria were as follows: 1) 18–60 years old patients, 2) patients with low back pain and radicular symptoms, 3) patients diagnosed with lumbar disc herniation using MRI, 4) patients with pain duration of four weeks to three months, and 5) patients with a visual analogue scale (VAS) score of 4 or more. The exclusion criteria were as follows: 1) patients with a history of spinal surgery, 2) patients with a neurological deficit that requires emergency surgery, 3) patients receiving osteoporosis medications, 4) patients with compressed fracture, and 5) patients with malignant tumours. Overall, 60 patients were randomly assigned to each group before NSDT using a computer-generated randomization program. The experimental group (n = 30, decompression group, group D) was treated with decompression treatment, and the control group (n = 30, non-decompression group, group N) was treated with pseudo-decompression treatment.

Non-surgical decompression therapy

Non-surgical spinal decompression therapy was performed with Spine MTK-1 (Shinhwa Medical, Busan, Republic of Korea). The NSDT apparatus has built-in air bladders, disc angle pulls adjustments, and harnesses and can increase the distraction force more slowly in the latter part of the decompression. Three split table designs were used for reducing friction in the lumbar muscles.

Group D received 10 treatment sessions for 30 mins for eight weeks. The sessions were provided twice a week for the first two weeks and once a week for the remaining eight weeks. The distraction force and angle were determined using computer programming that puts the patient's weight and the target disc level. The distraction force was increased by 1 kg per treatment session, starting from half of the body weight minus 5 kg. If the patient complained of pain during treatment, the distraction force was reduced by 25%. Patients laid in the supine position with a flexed knee with a support on the table. They were fastened to the table using two belts, one below the rib cage and the other one on the iliac crest. Decompression therapy was applied with 60 s of hold and 30 s of rest [8, 14, 15]. A safety button can be pushed at any time by the patient to release tension. Group N underwent NSDT using the same protocol and treatment sessions as group D, but no weight loading (distraction force was zero) was applied.

Both groups received nonsteroidal anti-inflammatory drugs and muscle relaxants. When the patient's VAS score increased by >20%, the daily dosing frequency was increased. Nevertheless, the patient received a weak opioid, such as tramadol, when the patient's pain was not controlled; however, the patient was excluded if their pain was persistent or aggravated.

Measurement of herniated disc through MRI

Magnetic resonance imaging was performed before NSDT and three months after all sessions to determine the change in herniated disc following NSDT. T2 weighted axial images were used for calculating the herniation index (HI) of the disc. The HI was measured on the axial plane with maximal herniation of the intervertebral disc on MRI (Fig. 1). MRI images were analysed by two experienced pain clinicians, who were not involved in this study. The maximal anteroposterior disc height (AB, mm), which is the diameter of the herniated disc material extended maximally from the posterior border of the vertebral body, was measured. The width of the herniated disc material at the level of the middle AB distance (CD, mm) of the herniated disc material from the coronal plane of the MRI, the maximal anteroposterior canal length (EF, mm), and mid AB distance (GH, mm) were measured. Then, the HI was calculated using the following formula [16]:

$$\mathrm{HI} = \frac{(AB)\times(CD)}{(EF)\times(GH)} \times 1000$$

Increased HI means that the herniated disc aggravated.

Clinical effectiveness

Pain intensity in the low back and lower extremities with respect to the VAS (0 = no pain and 10 = worst pain) was measured before NSDT (baseline), 1, 2, and 3 months after the last session. Additionally, the Korean Oswestry Disability Index (K-ODI) was employed for evaluating the degree of disability at the same time point. Information regarding age, gender, height, weight, symptom duration, and diagnosis (the type of HIVD) were obtained from each patient.

Statistical analyses

A total sample size of 54 achieved an effect size of 0.55 and 80% power with a type 1 error of 0.05. Effect size was calculated based on the assumption that 50% of patients in the group D would have 50% reduction in pain intensity. To allow for a 10% dropout rate, the final sample size was 30 patients per group. All measurements were expressed as mean ± standard deviation or standard error of the mean (%). Patients' age, height, weight, symptom duration, and HI change rate (%) after treatment were compared using the *t*-test or Mann-Whitney U test. For cases in which a significant time-dependent change in pain intensity (VAS) and K-ODI occurred within the same group, a repeated-measures analysis of variance was performed. Additionally, logistic regression was performed for calculating the adjusted odds ratio with a 95% confidence interval for identifying patient factors associated with a successful NSDT. The Hosmer-Lemeshow goodness of fit was used for testing the estimated logistic regression model. All statistical analyses was performed using SPSS Statistics program version 21.0 (IBM Corp, Armonk, NY, USA). A *P*-value of <0.05 was considered statistically significant.

Results

Among the 77 patients screened for eligibility, 60 patients were randomised to either group D (n = 30) or group N (n = 30) (Fig. 2). Four patients in group D (two patients refused procedures and others were lost to follow-ups) and 13 patients in group N (one patient refused procedures, three patients were lost to follow-ups, and others had worsening symptoms) were excluded. Thus, data from 43 patients (26 in group D and 17 in group N) were included in the final analysis.

The demographics and clinical variables of patients are presented in Table 1. The central type of L-HIVD was the most common in both the groups, with no significant difference. Other variables had no significant difference between the two groups.

Table 1. Comparison of demographic and clinical variables between the decompression and non-decompression groups

	Decompression group (*n* = 26)	Non-Decompression group(*n* = 17)	*P*-value
Age	40.3 ± 11.5	47.4 ± 8.9	0.149
Sex, Male/Female (%)	11/15 (42.3/57.7)	10/7 (58.8/41.2)	0.358
Height	165.8 ± 9.5	168.5 ± 8.3	0.630
Weight	69.2 ± 13.2	69.5 ± 11.1	0.658
Symptom duration (weeks)	7.6 ± 2.6	7.7 ± 2.1	0.906
Level of L-HIVD			0.133
L4-5	12	12	
L5-S1	14	5	
Type of L-HIVD			0.516
Central	20	10	
Paracentral	2	3	
Foraminal	1	2	
Mixed	3	2	

*P-value <0.05

L-HIVD lumbar herniated intervertebral disc

The difference in baseline HI was not significant (P = 0.295, Table 2), and post HI of group D after NSDT was significantly less than that of group N (P = 0.007). The change in HI after procedure was −27.6 ± 27.5 (%) in group D and −7.1 ± 24.9 (%) in group N, with significant difference (P = 0.017). Approximately 26.9% of patients in group D and none of the patients in group N showed over 50% reduction of HI (P = 0.031).

Table 2. Comparison of demographic and clinical variables between the decompression and non-decompression groups

	Decompression group (*n* = 26)	Non-Decompression group(*n* = 17)	*P*-value
Baseline HI	348.6 ± 183.1	412.4 ± 206.8	0.295
Post HI	232.1 ± 130.3	369.1 ± 186.1	0.007*
Change in HI (%)	−27.6 ± 27.5	−7.1 ± 24.9	0.017*
≥30% of reduction, n (%)	11 (42.3)	3 (17.6)	0.086
≤30% of reduction, n (%)	15 (57.7)	14 (82.4)	
≥50% of reduction, n (%)	7 (26.9)	0 (0)	0.031*
≤50% of reduction, n (%)	19 (73.1)	17 (100)	

Data are reported as mean ± standard deviation or number of patients.

*P-value <0.05

HI herniation index

Both groups exhibited a significant decrease in the VAS scores for low back pain from baseline to three months ($P < 0.001$) (Fig. 3A). However, there were no significant differences in VAS scores between groups D and N at all time points during the follow-up period. The lower leg pain showed significant decrease in VAS scores from baseline to three months ($P < 0.001$) (Fig. 3B), and the lower leg pain in group D was lower than that in group N at two months only ($P = 0.028$). K-ODI significantly decreased in both the groups at three months than at baseline ($P < 0.001$). Additionally, there were significant lower scores of K-ODI in group D at two months ($P = 0.023$) and three months ($P = 0.019$) (Fig. 4).

Discussion

Our result demonstrated that NSDT for acute L-HIVD significantly reduced the size of the herniated disc as observed using MRI examination and contributed to the partial improvement in pain and function. Compared to previous research, our study investigated whether actual decompression works for acute L-HIVD, and MRI examination was used as a measuring tool. Previous studies were not randomised controlled studies investigating the clinical effects of NSDT when compared to conventional traction therapy [13] or comparing herniated disc size before and after segmental traction therapy without the control group [6]. Acute L-HIVD and the associated pain are known to often restore spontaneously [17, 18], while nerve oedema and fibrous tissues around the L-HIVD decreased over weeks or months. Therefore, it was challenging to identify the therapeutic effects (pain relief, reduction of disc volume, etc.)

on acute L-HIVD by comparing with the control group. Our randomized control study is meaningful because the decompression power of NSDT itself contributes to the recovery of acute L-HIVD.

Non-surgical spinal decompression therapy, in contrast to conventional traction therapy, can lower the pressure of the nucleus pulposus in the intervertebral disc to <−100 mmHg, and the sound pressure in the intervertebral disc increases blood flow for nutrition and regeneration of the disc [19, 20]. It can also reduce the pressure on the nerve and facet joints by increasing the width of the intervertebral foramen [8, 21, 22]. The difference between NSDT and conventional traction therapy is that the relaxation of back muscle during axial traction happens with NSDT and not conventional traction therapy. One of the important mechanisms of the traction therapy is to restore the herniated mass by increasing the tension of the posterior longitudinal ligament. The axial traction can increase stress on the posterior longitudinal ligament, and it can cause contraction of the muscles around the vertebrae and increase the internal pressure of the disc [12, 23]. In contrast, NSDT can reduce the stress on the posterior segment of the lumbar spine by relaxing the contracted paraspinal muscle and posterior fibres during traction. A study comparing NSDT with conventional traction therapy showed that NSDT was more effective in terms of the mechanical advantage of NSDT [10].

In our study, the overall change in HI in group D (−27.6% ± 27.5 %) showed approximately 30% decrease following NSDT, with a significant difference (P = 0.017) when compared with group N (−7.1% ± 24.9%). Additionally, there were patients (n = 7/26, 26.9%) with a decrease of >50% in HI in group D. In a previous study, segmental traction therapy with physiotherapy showed an effective reduction of herniated mass size as observed using MRI examination [6]. Since the previous study results were not because of traction therapy alone, and the measure of disc volume was different, our findings showed the effect of NSDT more accurately.

There were no significant differences in relief of lower back pain between group D and group N at all time points during the follow-up period, and the lower leg pain in group D was lower than that in group N at two months. Moreover, there were significantly lower scores of K-ODI in group D at two and three months, and this shows an improvement in function in the decompression group. Although the size of the disc was reduced more as observed in the MRI examination and functionally improved in group D, the decrease in lower back pain or leg pain showed little or no difference between the two groups. In a recent meta-analysis, lumbar traction exhibited significantly more pain reduction and functional improvements for short term only [24]. We observed similar results for functional improvements observed at two and three months; however, the long-term effect of NSDT could not be confirmed. Although lower back and leg pain significantly decreased in both the groups at three months, a comparison of the two groups showed no significant difference. The reason may be found in the natural courses of L-HIVD. Although the principle of reabsorption of the L-HIVD is unclear, the nucleus pulposus of the disc is exposed to the vascular tissue in the epidural space, and chemokines secreted from macrophages play an important role in phagocytosis. Shrinkage of L-HIVD is caused by decreased nutrient supply [25]. It is expected that this natural course of L-HIVD was actively conducted in acute phase, and our study was performed on acute

L-HIVD patients (4 weeks to 3 months). Therefore, both the groups would be expected to recover spontaneously [26], and the difference in pain relief may be minimal.

In a previous study, 77 patients treated non-operatively were followed up for an average of five months and reported a reduction in herniation of the disc in 63.7% of the patients [18]. Another study analysed MRI scans of 32 patients with L-HIVD, and the mean disc volume reduction was 64% (range, 31–78%) during an average period of 13.2 months (range, 3–42 months) [27]. In our study, group D showed an approximately 30% reduction in HI at three months. It is thought that applying NSDT for L-HIVD in acute periods can reduce disc volume more quickly and contribute to the partial improvement in pain and function. Additionally, the surgical treatment was superior to the non-surgical treatment in the acute phase, but there was no significant difference in the reduction of pain and recovery of neurological deficit thereafter [28]. It may be advisable to apply NSDT for patients with L-HIVD in the acute phase, considering the cost and risk of surgery [29]. Since pain relief and functional improvement in acute L-HIVD cannot be achieved using NSDT alone, other conservation therapies (analgesics, physiotherapy, exercise, etc.) may need to be incorporated if necessary.

There are several limitations to this study. First, group N (13/30, 43.3%) had a significantly higher dropout rate than group D (4/30, 13.3%). Some patients in group N (9/13, 30.8%) withdrew even after first or second session owing to worsening of symptoms. After the end of the study, patients were contacted, and the reasons were analysed. During the follow-up period, patients complained of unbearable pain, and additional medications were prescribed for controlling their aggravated pain; patients' symptoms may have exacerbated by the absence of pressure during NSDT. Second, previous studies included 12–15 sessions of traction therapy during three or four weeks [24, 30]. However, the period of our study was long (three months). We had to set a rather long period because it was difficult to observe changes of L-HIVD during short periods.

Conclusions

In summary, acute L-HIVD has a natural recovery course; however, pain can be severe and may require multidisciplinary treatments. This study showed that NSDT significantly reduced the HI based on follow-up MRI examination. Additionally, patients who received NSDT had partial improvement in pain and function. NSDT can be a good treatment option for conservative treatment of L-HIVD in the acute phase.

Abbreviations

L-HIVD: Lumbar herniated intervertebral disc; MRI: Magnetic resonance imaging; NSDT: Non-surgical spinal decompression therapy; VAS: Visual analogue scale; HI: Herniation index; K-ODI: Korean Oswestry Disability Index

Declarations

Ethics approval and consent to participate

This study was approved by the institutional review board of Seoul National University Bundang Hospital (IRB No. E-1412-278-002). All participants were provided written and verbal information about the trial before providing written consent.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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There was no external funding for this study.

Authors' contributions

Conceptualization, PBL.; methodology, EC.; formal analysis, FSN.; investigation, JJ. and WKH.; data curation, JJ. and WKH.; writing—original draft preparation, HYG.; writing—review and editing, EC. and FSN.; supervision, PBL. All authors read and approved the final manuscript.

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Figures

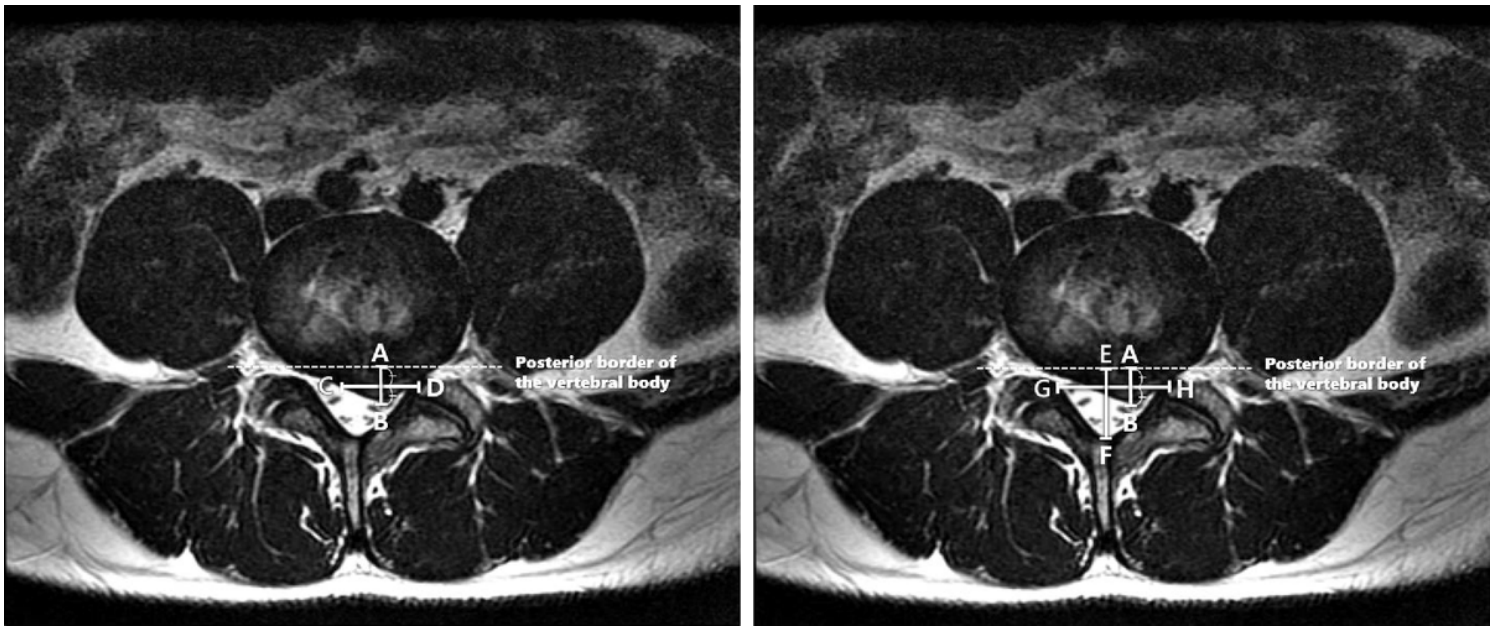

Figure 1

Methods for calculating the herniation index (HI) in the axial plane of the magnetic resonance imaging (MRI) scan. AB: the maximal anteroposterior disc height, which is the diameter of the herniated disc material extended maximally from the posterior border of the vertebral body, was measured. CD: the width of the herniated disc material at the level of the middle AB distance of the herniated disc material from the coronal plane of the MRI scan. EF: the maximal anteroposterior canal length. GH: mid AB distance was measured. HI was calculated using the following formula: (AB)x(CD)/(EF)x(GH) x 100

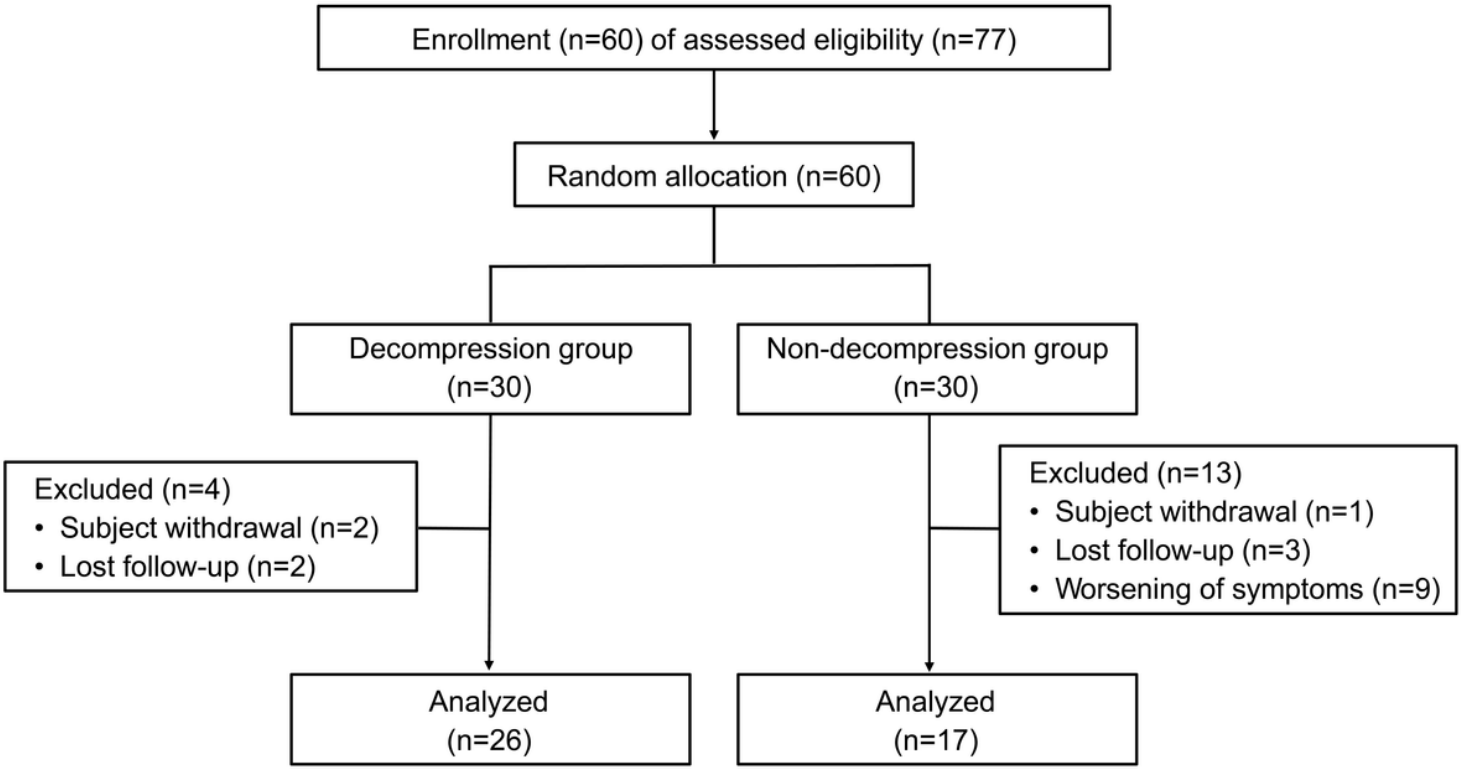

Figure 2

CONSORT diagram of patients enrolled in the study

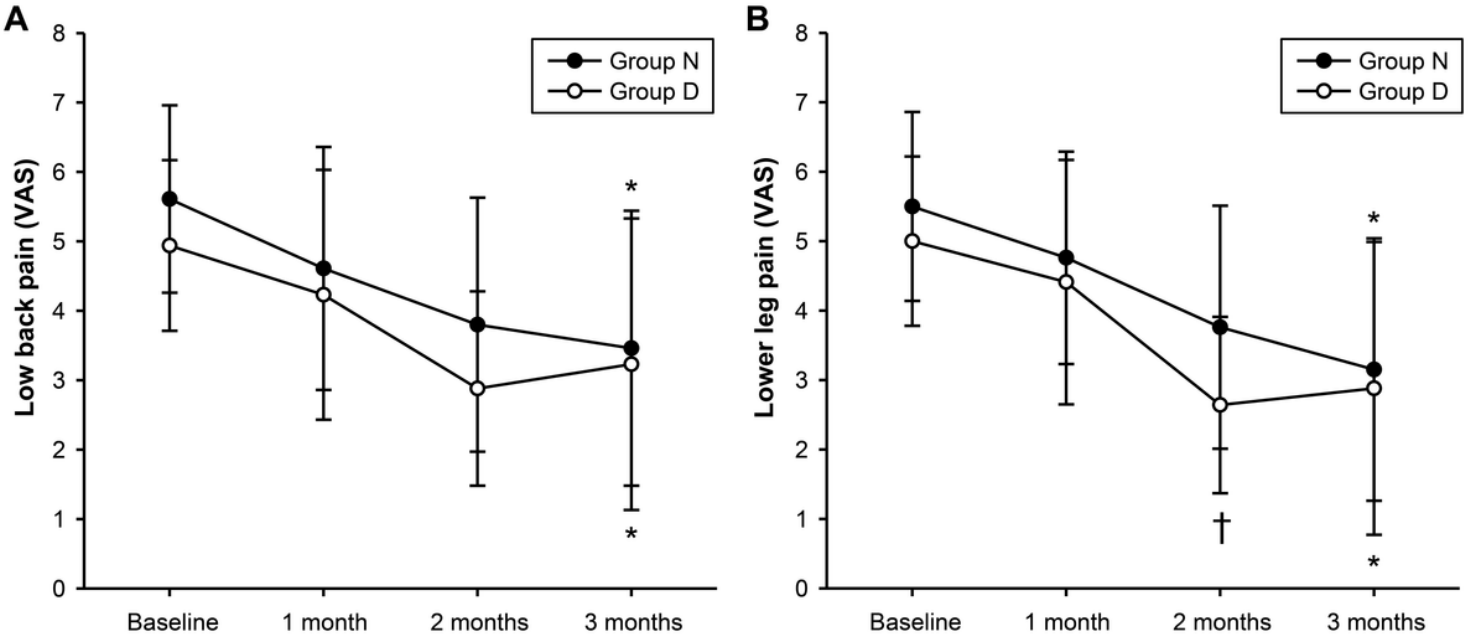

Figure 3

Changes in visual analogue scale (VAS) scores (0 = no pain, 10 = the worst pain imaginable) of lower back pain (a) and lower leg pain (b) between group D and group N. Both the groups showed a decrease in lower back pain from baseline to 3 months ($P < 0.001$). However, lower back pain was not significantly

different between the groups at any time. The lower leg pain showed significant decrease in VAS scores from baseline to 3 months (P < 0.001) and the lower leg pain in group D showed significantly lower VAS score than that in group N at 2 months (P = 0.028). Error bar indicates standard deviation. *Significant at P < 0.001 when compared to the baseline VAS score. †Significant at P < 0.001 between D and N groups

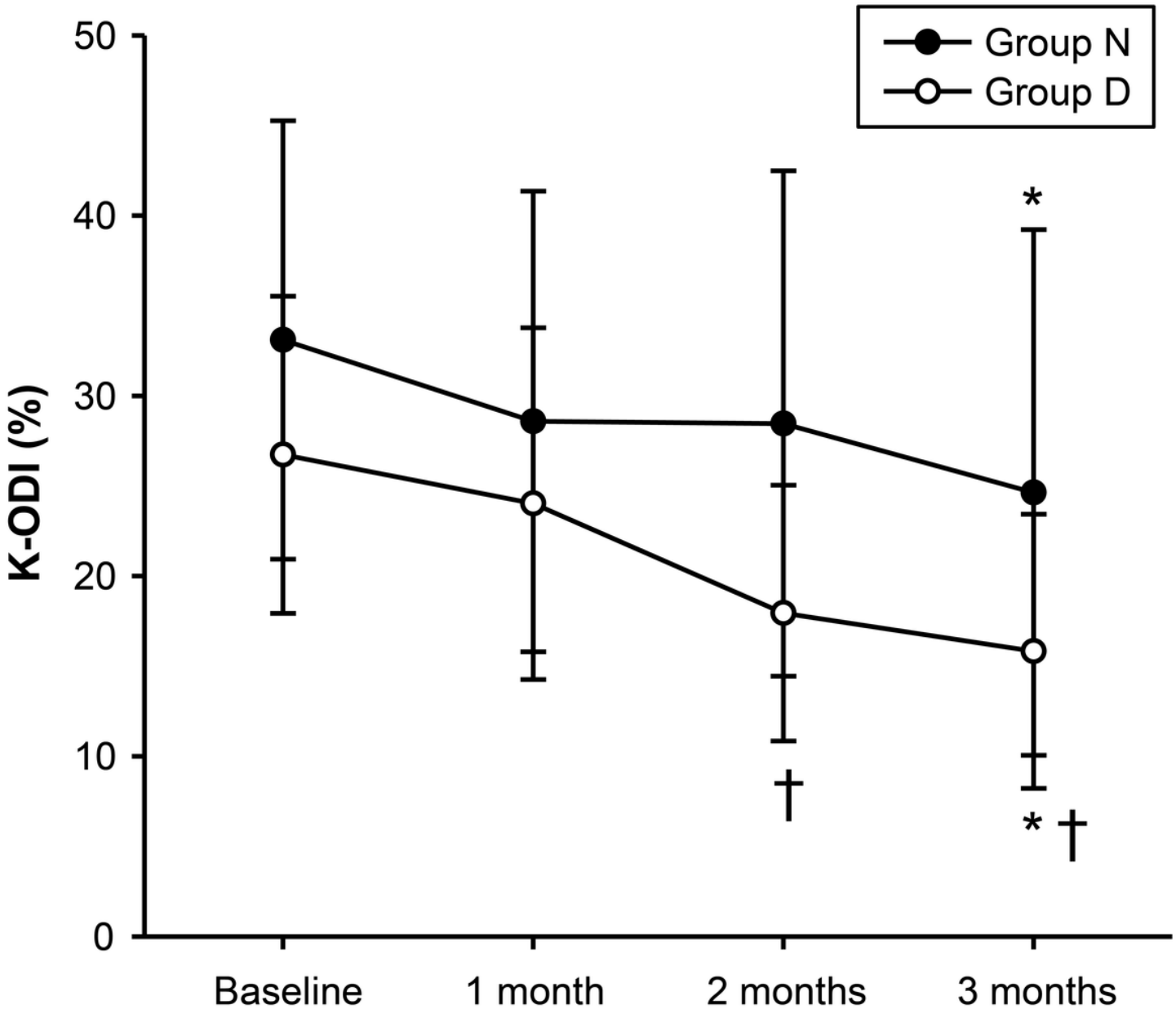

Figure 4

Changes in the Korean Oswestry Disability Index (K-ODI) between group D and group N. The K-ODI significantly decreased in both the groups at 3 months than at baseline (P < 0.001). There were significant lower scores of K-ODI in Group D at 2 months (P = 0.023) and 3 months (P = 0.019). Error bar indicates standard deviation. *Significant at P < 0.001 when compared to the baseline visual analogue scale score. †Significant differences between D and N groups