

Spinal decompression therapy as an alternative modality for management of low back pain and radicular pain caused by lumbar disc herniation or protrusion

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Background

Recent studies have suggested that motorized nonsurgical spinal decompression AQ5 can reduce chronic low back pain (LBP) due to lumbar disc herniation or protrusion.

Aim

The purpose of this study was to evaluate the efficacy of motorized nonsurgical spinal decompression by the DRX9000 device in the reduction of LBP and radicular pain caused by lumbar disc herniation or protrusion and whether it correlated with MRI changes in disc height or not.

Patients and methods

This study was carried out on 73 patients with chronic LBP attributed to disc protrusion selected from outpatients of rheumatology and rehabilitation clinics at Abdul Latif Jameel Hospital for Medical Rehabilitation, Jeddah, Saudi Arabia; these patients were divided into two groups. The first group comprised 39 patients who underwent a 6-week treatment protocol of motorized nonsurgical spinal decompression via the DRX9000, and the other group comprising 34 patients underwent a 6-week physiotherapy with deep heat modalities and ordinary traction; pain assessment using a visual analog scale with MRI was carried out before and after treatment. Paired t-test or linear regression was used, as appropriate, with P less than 0.05 considered to be statistically significant.

Results

The main outcomes were a significant improvement in LBP in both groups using visual analog scale, but radicular pain and disc height using MRI were significantly improved in group 1 compared with group 2.

Conclusions

The study concluded that nonsurgical spinal decompression was associated with a reduction in back pain and radicular pain and with an increase in disc height and can be used as an alternative modality for discogenic LBP.

Keywords:

decompression system, DRX9000, lumbar disc prolapse, LBP

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Introduction

More than 80% of the population will suffer from low back pain (LBP) at some point in their lives [1]. LBP is the main factor causing limiting activity in patients less than 45 years old, the second most frequent cause for doctor's visits, and the third most common reason for surgical procedures [2]. LBP is of significant socioeconomic relevance, as it affects patients' quality of life, may lead to a loss of productivity temporarily and enormous medical and indirect costs, or even permanent disability [3].

The two most common diseases causing chronic LBP are discogenic LBP, which is caused by disc degeneration, responsible for 39% of cases, and disc herniation, accounting for just less than 30% of cases of LBP. The clinical pathology of both discogenic LBP and disc herniation is related to the anatomical structure of the intervertebral disc [4].

The traditional management of LBP was nonsurgical treatment with analgesia supplemented by physiotherapy. There are many modalities of physiotherapy such as massage, spinal manipulation, exercises, acupuncture, back school, and cognitive behavioral therapy [4]. They also report some of the problems associated with simple traction, such as fatigue, triggering of muscle spasm, the patient's inability to tolerate the force or position, and the exacerbation of pain [5].

Thus, the other treatment modality is motorized decompression, a technique designed to decrease

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pressure on the discs, vertically expand the intervertebral space, and restore disc height [6].

Spinal decompression systems such as the DRX9000 have been launched into clinical practice in the last few years for the treatment of LBP. These systems provide a noninvasive intervention for the treatment of LBP of discogenic origin.

DRX9000 True Nonsurgical Spinal Decompression System was FDA (the US Food and Drug Administration) approved; it applies spinal distraction forces by using a sensitive computerized feedback mechanism to provide relief of LBP and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome, and sciatica [7].

Richmond *et al.* [7] stated that the DRX9000 aims to relieve pain by enlarging intradiscal spaces, reducing herniation, and decreasing intradiscal pressure during treatment.

Aim

The goal of this study was to evaluate the efficacy of motorized nonsurgical spinal decompression by the DRX9000 device in the reduction of LBP and radicular pain caused by lumbar disc herniation or protrusion and whether it correlated with MRI changes in disc height or not.

Patients and methods

This study was carried out on 73 patients; their ages ranged from 21 to 45 years; they had chronic LBP with radicular pain caused by disc protrusion or herniation, as diagnosed by MRI of the lumbosacral spine, and the duration of the disease was more than 12 weeks [8]. They were selected from outpatients attending the rehabilitation clinic in Abdul Latif Jameel Hospital for Medical Rehabilitation, Jeddah, Saudi Arabia, during the period spanning from January 2016 to September 2017; consent was taken from every patient for the treatment and to be included in this study.

Patients with other causes of LBP, the presence of osteoporosis, vertebral fracture, displacement, weakness in the lower limbs, impaired sensation in both lower limbs or spondylolisthesis and pregnant women were excluded from the study.

The patients were divided into two groups.

- (1) First group: this group comprised a total of 39 patients, 23 (58.97%) male patients and 16 (41.03%) female patients; their ages varied between 21 and 43 years with a mean age of 32.06 ± 7.09 years, and the duration of disease varied from 16 to 56 weeks, with a mean duration of 34.26 ± 13.45 weeks. Their weights varied between 64 and 97 kg. This group underwent decompression using the DRX9000.
- (2) Second group: this group comprised a total of 34 patients, 19 (55.88%) male patients and 15 (44.22%) female patients; their ages varied between 23 and 45 years with a mean age of 33.21 ± 7.23 years, and the duration of disease varied from 18 to 53 weeks, with a mean duration of 32.43 ± 12.22 weeks. Their weight varied between 61 and 93 kg. This group underwent physiotherapy including deep heating modalities and ordinary traction.

All patients were subjected to full history taking; clinical examination including site of tenderness, straight leg raise (SLR) test, motor and sensory assessment, and range of motion of the lumbar spine were carried out before and after completion of sessions. Visual analog scale (VAS) from 0 to 10 was used before and after completion of the treatment course for assessment of LBP during a flexion-extension range of motion and for assessment of radicular pain in the lower limbs. Radiological assessment included radiographic lumbosacral spine anteroposterior and lateral view and MRI lumbosacral spine to support a diagnosis of chronic discogenic LBP due to bulging, protruding or herniated intervertebral discs that may have been brought on by degenerative disc disease.

MRI was also repeated after completion of the treatment course to assess whether there were changes in disc height or not.

MRI was performed before the start of treatment and after the end of treatment using a 3.0 T magnetic resonance unit (MAGNETOM Verio, A Tim System; Siemens, Erlangen, Germany). The patients were positioned in the supine position and scans were performed: (a) sagittal T1 images from T12 to the sacrum (repetition time: 670 ms; echo time: 12 ms, slice thickness: 4 mm), (b) sagittal T2 images from T12 to sacrum (repetition time: 3000–3600 ms; echo time: 87–114 ms, slice thickness: 4 mm), and (c) axial T2 images from L1 to S1 (repetition time: 3000–3600 ms; echo time: 87–114 ms, slice thickness: 4 mm).

Intervertebral disc height

Intervertebral disc height of the lumbar spine was measured on midsagittal MRI from the middle of the superior border of the disc to the middle of the inferior border of the disc with the inclusion of both end plates. In our study, we detect the difference of disc height between two MRIs to avoid personal variation in disc height.

Paired *t*-test or linear regression was used, as appropriate, with *P* less than 0.05 considered to be statistically significant.

Treatment protocol

- (1) First group: a total of 39 patients received treatment with the DRX9000 (Axiom Worldwide, Tampa, Florida, USA) according to the intervention's operating guidelines [9].
- (2) Second group: a total of 34 patients received physiotherapy including ultrasound, transcutaneous electrical nerve stimulation (TENS), and vertebral traction.

The protocol of the DRX9000 includes 20 sessions of spinal decompression over a 6-week period with 30-min active treatment sessions. Each patient was administered treatment five times per week for the first 2 weeks and three times per week for a further 2 weeks, and it was then tapered down to two sessions per week for the last 2 weeks. At the start of the session, the patient is fitted into the supine position. To start active treatment, the machine pulls the patient gently on the lower harness while the upper harness remains stationary, thus distracting the patient's spine. A safety button can be pushed at any time by the patient to release all tension immediately.

The initial decompression force was adjusted to patient tolerance, starting at 4.54 kg (10 lbs) less than half their body weight. If a patient described the decompression pull as 'strong or painful,' this distraction force was decreased by 10–25%. In subsequent treatment sessions, the distraction force was increased as tolerated to final levels of 4.54–9.07 kg (10–20 lbs) more than half their body weight. After the end of each therapy session, a cold pack with electrical muscle stimulation was applied to help paravertebral muscles consolidate after treatment.

Results

First group

Before patients underwent the treatment sessions, the mean of LBP by VAS was 7.66 ± 1.62 , and, after

sessions, it was 2.23 ± 1.67 with *P* value less than 0.005 considered as significant difference. With regard to the lower extremity radicular pain assessed by VAS, before taking sessions, the mean was 7.43 ± 2.50 , and, after sessions, it was 1.33 ± 1.79 with *P* value less than 0.005 considered as significant difference. There was one (2.56%) patient who presented with severe LBP after five sessions, and the patient stopped undergoing the sessions. There were six (15.38%) patients who had muscular pain during the sessions, but they continued the sessions; pain persisted in four of them (10.25%) until the end of the sessions.

MRI

There were improvements of disc height in 27 (72.97%) patients, ranging from 1.1 up to 5.3 mm, with a mean of 2.31 ± 1.24 mm.

LBP was improved in 29 (74.36%) patients while radicular pain improved in 33 (84.61%) patients; disc height improved in 27 (72.97%) patients.

Second group

Before patients underwent the treatment sessions, the mean of LBP by VAS was 7.55 ± 1.78 , and, after sessions, it was 4.14 ± 1.52 , with *P* value less than 0.005 considered as significant difference. With regard to lower extremity radicular pain by VAS, before patients underwent the treatment sessions, the mean was 7.32 ± 2.32 , and, after sessions, it was 6.82 ± 1.95 with no significant difference, *P* value greater than 0.005.

MRI

There were improvements of disc height in four (11.76%) patients, ranging from 0.1 up to 0.3 mm, with a mean of 0.043 ± 0.091 mm.

LBP was improved in 25 (73.53%) patients while radicular pain improved in seven (20.59%) patients; disc height improved in four (11.76%) patients.

When we compared both groups, we found that there were nonsignificant differences in the improvement of LBP and a highly significant difference in the improvement of radicular pain and disc height between both groups (Figs 1–4 and Tables 1–4).

Discussion

Discogenic pain is a major problem in the lumbar area, and it may be caused by progressive annular breakdown and tearing, which cause pain by stimulating pain fibers

in the outer one-third of the annulus and by compression over the nerves' roots.

Spinal decompression systems using the DRX9000 have become a noninvasive intervention for the treatment of LBP caused by disc protrusion or herniation by expanding the intervertebral space and reducing the disc protrusion.

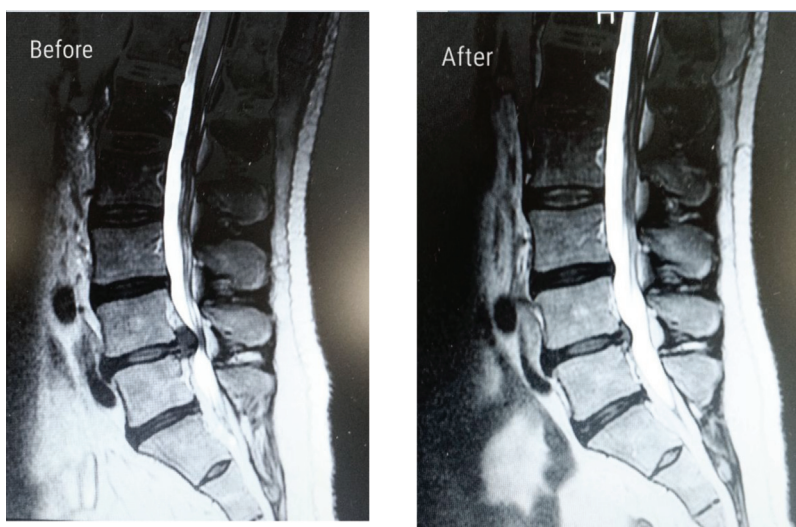
Our study showed that there was an improvement in back pain and lower extremities' radicular pain with the decompression system; the improvement was more significant in lower extremities' pain than back pain.

Figure 1



DRX9000.

Figure 2

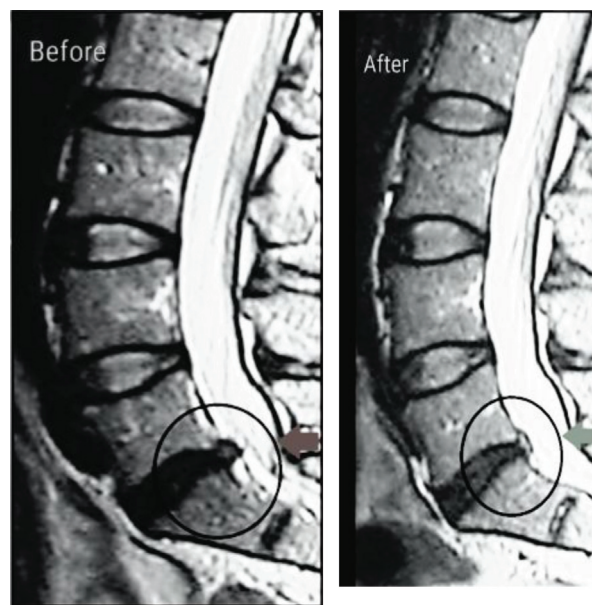


MRI performed before decompression therapy showing protruded disc L4-L5. MRI performed after completion of decompression therapy course using DRX9000 showing nearly completely improved protruded disc.

There was a significant improvement in the disc heights of the majority of patients by the decompression system. Comparing with the control group, we found highly significant improvement in patients treated with the decompression system with regard to radicular pain and disc height compared with other physiotherapy modalities.

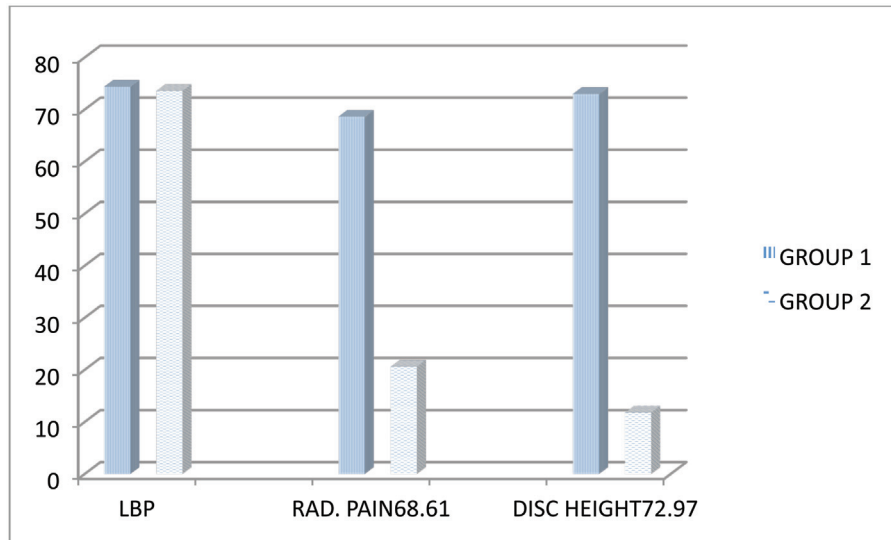
Our study was in agreement with Richmond *et al.* [7] who stated that Nonsurgical Spinal Decompression

Figure 3



MRI performed before decompression therapy showing protruded disc L5-S1. MRI performed after completion of the decompression therapy course using DRX9000 showing improved protruded disc with an increase in its hydration.

Figure 4



Percentage of improvement in both groups.

Table 1 Comparison between the two groups

	Group 1	Group 2
LBP before treatment	7.66±1.62	7.55±1.78
LBP after treatment	2.23±1.67	4.14±1.52
LBP % of improvement	74.36	73.53
Radicular pain before treatment	7.43±2.50	7.32±2.32
Radicular pain after treatment	1.33±1.79	7.32±2.32
Radicular pain % of improvement	84.61	20.59
Improvement in disc height	2.31±1.24	0.043±0.091
% improvement in disc height	72.97	11.76

LBP, low back pain.

Table 2 Percentage of improvement between the two groups

	Group 1 (%)	Group 2 (%)	P value
LBP % of improvement	74.36	73.53	>0.05
Radicular pain % of improvement	84.61	20.59	<0.01
% improvement in disc height	72.97	11.76	<0.01

LBP, low back pain.

System by using the DRX9000 resulted in relief of LBP and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome and sciatica by using a sensitive computerized feedback mechanism.

In another study, Apfel *et al.* [10] found that spinal decompression by DRX9000 for treating chronic discogenic LBP caused relief of pain and restoration of disc height, and there was a correlation between pain reduction and degree of restoration of disc height, which agreed with our study; however, the difference between this study

Table 3 Group 1 before and after treatment

	Before	After	P value
LBP	7.66±1.62	2.23±1.67	<0.05
Radicular pain	7.43±2.50	1.33±1.79	<0.05

LBP, low back pain.

Table 4 Group 2 before and after treatment

	Before	After	P value
LBP	7.55±1.78	4.14±1.52	<0.05
Radicular pain	7.32±2.32	7.32±2.32	>0.05

LBP, low back pain.

and our study was that they assessed disc height by using CT scan but we used MRI.

Thomas *et al.* [11] agreed with our study, as they stated that nonsurgical spinal decompression (DRX9000) had effective treatment of discogenic back pain by decompressive force, as pain was reduced in 86% of patients who were candidates for surgery, and mechanical function was restored in 92%, but 2% of patients presented with pain after 90 days and 3% of patients suffered a relapse.

Leslie *et al.* [9] also stated that, when patients are treated with DRX9000 completing the full 6-week course of spinal decompression, patients' pain reduced and patient activity function became better, as measured by the Oswestry Disability Index.

The decompression system is a good modality for treating discogenic LBP, as it reduces pain, improves function and decreases surgical intervention.

Conclusion

Overall, this study suggests that treatment with the DRX9000 nonsurgical spinal decompression system, reduced patient's chronic LBP and radicular lower extremities' pain, with patients requiring fewer analgesics, compared with other modalities. Moreover, improvement in disc height measured by MRI has been found.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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