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Research Article

Clinical Outcomes Based on Oswestry Disability Index After Lumbar Disc Ablation and Disc Prolapse in Eastern Province, Saudi Arabia

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Abstract

Introduction: Lower back pain has been defined as pain arising from the back between the costal arch and the natal cleft, regardless if there's any radiation. Lower back pain is further subcategorized into chronic and acute, with 3 months being the cutoff period.

Aim: This study aimed to determine the difference in the disability of patients before and after lumbar disc ablation procedure.

Materials and Methods: This is a retrospective study design conducted among patients who underwent lumbar disc ablation and disc prolapse in the Eastern Province of Saudi Arabia. Data were gathered in the patient chart from September 2018 to May 2020. Patients' data were taken from their files including basic demographic profiles, radiculopathy symptoms, pervious spine operation, and chronic illnesses. Pain scale and Oswestry disability index preoperative and postoperative were also obtained. All statistical data were analyzed using Statistical Packages for Software Sciences version 21.

Results: Patients' mean age was 50.3 (SD 10.5) years old with more than a half (57.7%) were females. Statistical tests showed that the mean score of Oswestry disability index was significantly improved from mean 42.1% (SD13.9%) at baseline to mean 20.6% (SD 13.6%) post intervention (mean diff: 21.497%; 95% CI = 6.934 - 12.339; p < 0.001). None of the patients presented with crippled disability level after the treatment. In addition, unemployed and patients with chronic diseases had significantly higher ODI score than their counterparts which was measured after the procedure.

Conclusion: There was a significant improvement of functional status after the procedure for lumbar disc ablation. Unemployed patients and those with chronic disease were more prone to disability than their counterparts.

***Keywords**: Adult Idiopathic Scoliosis; Schroth; SEAS; Traditional Chinese Medicine*

Abbreviations

BMI: Body Mass Index; CI: Confidence Interval; CT: Computed Tomography; MCID: Minimal Clinically Importance Difference; MRI: Magnetic Resonance Imaging; NRS: Numerical Rating Scale; ODI: Oswestry Disability Index; PDD: Percutaneous Disc Decompression; PT: Physiotherapy; RF: radiofrequency; SD: Standard Deviation; SPSS: Statistical Packages for Software Sciences; VAS: Visual Analogue Scale

Introduction

Lower back pain has been defined as pain arising from in the back between the costal arch and the natal cleft, regardless if there's any radiation [9]. Lower back pain is further subcategorized into chronic and acute, with 3 months being the cutoff period [17]. Several studies have been done to calculate the prevalence of lower back pain, with a point prevalence of 37.1%, a one-year prevalence of 76% [9], and a global prevalence ranging from 75% to 85% [9,3,17]. Lower back pain has been considered one of the most frequent types of pain [9,15].

There is a variety of structures or diseases that can cause lower back. These include, but are not limited to, lumbar facet joints, the intervertebral discs (also known as discogenic lower back pain), sacroiliac joint, and coccyx [17]. Lumbar disc herniation has been defined as the protrusion or displacement of the disc material (annulus fibrosis of nucleus pulposus) past the intervertebral disc space causing back and/or leg pain [12]. In recent studies, the incidence of lumbar disc herniation has been reported to be between 15.2% and 30% worldwide [20,12], making it the most common disc injury and most common cause of back and/or leg pain [20,25]. In addition, there's further increase in the incidence due the increases of factors such as, obesity, physical inactivity, postural problems, trauma, and population aging [25].

As per other surgical disorder, treatment almost always starts with conservative management. Lumbar disc herniation isn't an exception. First-line treatment to lumbar disc herniation starts with physiotherapy alongside effective analgesia. Furthermore, braces can be added to aid patients. Another treatment option before undergoing surgery is conservative surgical treatments, being fluoroscopy guided epidural corticosteroid injection [2,13]. Before coming to a decision of ineffective conservative management, a very long time has to be given [20].

Epidural corticosteroid injection is considered the second-line treatment option for lumbar disc herniation, and in fact a significant part of conservative management [9]. Lumbar epidural injection has been done for more than a hundred years. It was first recorded in 1901 by Sicard, using concaine. Then, steroid was first used in 1952. There are three different approaches: caudal, interlaminar, and transforaminal. Despite having three approaches, epidural injections are always performed with fluoroscopic guidance. Neither the exact mechanism of these corticosteroid injections has been fully understood, nor has the best approach been determined [3]. Guidelines on treating chronic back pain using interventional techniques recommend epidural injections for cases of cervical and lumbar disc herniation [9].

Many other spine invasive interventions and devices are being developed to expand the surgical advantages and diminish its disadvantages. One of them is radiofrequency (RF) thermocoagulation, which is a minimally invasive approach lately used for lumbar disc herniation. A RF electrode produces an electric field, breaking down the covalent bonds maintaining the three-dimensional structure of collagen, which will decrease the size of collagen and dropping intradiscal pressure, ablating the nociceptors that extend into the annulus fibrosus. Therefore, blocking nerve growth and reducing the stimulation from intervertebral disc degenerative tissues to the nerves. Moreover, a monopolar RF thermocoagulation is a classic method in lumbar disc herniation treatment. The recent technique is bipolar RF thermocoagulation, which is more intense [30]. Shealy in 1975 was the first to use it to treat low back pain. It was offered for low back regardless of the pathology (infection, tumor, fracture or osteoporosis) [17]. Nowadays, clear indications are put for this procedure, including persistent, nociceptive low back, irregularly groin and leg pain that is typically worse with axial loading and improved with recumbency, moderate or severe neurological deficit that is clinically confirmed, unclear response to the oral analgesics, and/or a high risk of relapse with no other available therapeutic options [13,15].

Materials and Methods

The study protocol was approved by the institutional review board, and written informed consent was obtained from all patients. Files were gathered for patient that had underwent RF ablation from September 2018 to May 2020. It included 60 patients. All patients who had been complaining from chronic lower back pain unresponsive to conservative management (medications or physical therapy) were included in this study. Patients' data where taken from their files including age, height, weight, body mass index (BMI), occupation, date of operation, pain scale preoperative and postoperative, duration of the pain preoperatively, radiculopathy symptoms, pervious spine operation, and chronic illnesses. Also, function of the lower limb and daily living of patients were evaluated using the Oswestry disability index (ODI) preoperatively and postoperatively (Appendix I). All procedures where done by the same surgeon with same technique.

The chronic lower back pain was assessed clinically and concordant with image findings magnetic resonance imaging (MRI) or computed tomography (CT). Disc herniation was no more than 1/3 the sagittal diameter of the spinal canal.

Inclusion criteria were as follows:

- Single-level lumbar intracanal disc herniation.
- Age between 18 years and 75 years.
- Contained disc prolapse proven by clinical examination and MRI or CT.
- Conservative management including medications, physical therapy and epidural steroid injections documented as ineffective.

Exclusion criteria were as follows:

- Spinal stenosis (including lateral and foraminal) as determined by MRI or CT scans.
- Disc sequestration.
- Cauda equina syndromes and any neurological emergencies.
- Associated tumors.
- Acute spinal trauma with fracture.
- Previous spinal surgery at the level to be treated.
- Patient is morbidly obese (body mass index > 40).
- Associated infection.
- Radiological evidence of spondylolisthesis at the level to be treated.
- Severe disc degeneration (with > 50% loss of disc height).

Statistical analysis

Descriptive statistics were expressed using numbers, percentage, mean ± standard deviation, whenever appropriate. Between comparisons of mean score, and Mann Whitney U test were applied. Paired t-test was also performed to examine the difference in mean score of ODI before and after the treatment. Normality tests were also conducted using Shapiro Wilk test. P-value < 0.05 has been accepted as the significant level for all statistical tests. All Statistical data were analyzed using Statistical Packages for Software Sciences (SPSS) version 21 Armonk, New York, IBM Corporation.

Results

We analyzed 26 Saudi patients who underwent lumbar disc ablation in the Eastern province of Saudi Arabia. The mean age of the 26 patients was 50.3 (SD 10.5) years old with more than a half were females and nearly two third (61.5%) were unemployed. Nearly all (84.6%) detected to have radiculopathy and without having history of previous spine operation (92.4%). The proportion of patients who were having both analgesia and physical therapy for non-operative management was 92.4%. In addition, the mean value of BMI was 28.9 kg/m^2 (SD 3.37) (Table 1).

Study Data	N (%)
Gender	
• Male	11 (42.3%)
• Female	15 (57.7%)
Occupation	
• Employed	10 (38.5%)
• Unemployed	16 (61.5%)
Radiculopathy	
• Yes	22 (84.6%)
• No	04 (15.4%)
Previous history of spine operation	
• Yes	02 (07.6%)
• No	24 (92.4%)
Non-operative management	
• None	01 (03.8%)
• Analgesia	02 (03.8%)
• Physiotherapy	0
• Both	24 (92.4%)
	Mean ± SD
Age in years	50.3 ± 10.5
BMI (kg/m2)	28.9 ± 3.37

Table 1: *Baseline characteristics of patients who underwent Disc Ablation procedure (n=26).*

Figure 1 depicted the associated chronic diseases of 26 patients. It was found that the most commonly mentioned chronic disease was hypertension (34.6%) and diabetes type 2 (26.9%) (Figure 1).

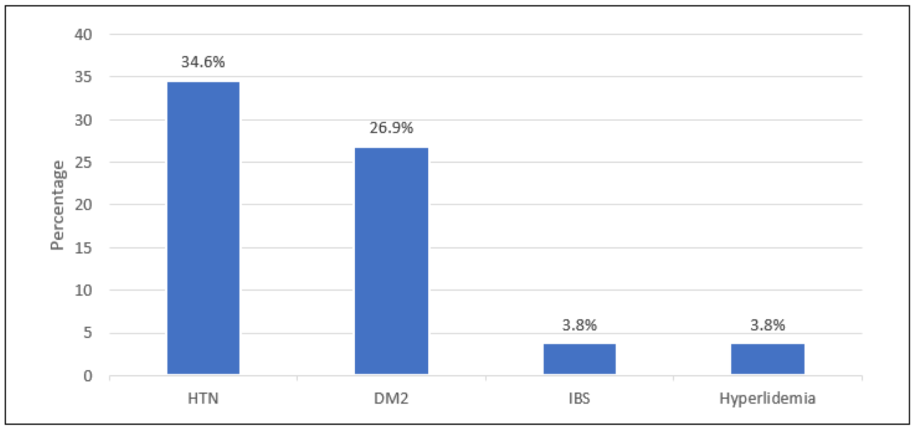

Figure 1: *Chronic illness of patients.*

Table 2 showed the paired t-test of mean score between pain scale and ODI before and after the treatment. Based on the results, we have learned that the mean difference of mean pain scale after the procedure was statistically significant lower when compared to baseline (mean diff = 4.307; 95% CI = 3.127 - 5.488; $p < 0.001$). In the ODI, the mean difference of ODI after the treatment was also statistically significantly lower when compared to the mean score of ODI at baseline (mean diff: 21.497%; 95% CI = 15.428 - 27.568; $p < 0.001$) (See table 2).

Pair 1	Mean ± SD	Mean Differences	95% CI	P-Value
Pain scale (1 – 10)				
• Before	8.50 ± 1.42	4.307	3.127 – 5.488	<0.001 **
• After	4.19 ± 2.91			
Pair 2				
Oswertry disability				
• Before	42.1 ± 13.9	21.497	15.428 – 27.568	<0.001 **
• After	20.6 ± 13.6			

Table 2: *Paired T-Test of Pain Scale and ODI before and after the Lumbar Disc Ablation Procedure (n=26)*
*** Significant at p < 0.05 Level.*

In table 3, the correlation between age in years and ODI before the procedure was positively highly statistically significant ($r = 0.659$; $p < 0.001$) while after the procedure, age in years was also showed significant correlation with ODI ($r = 0.389$; $p < 0.05$), this indicates that as the age increased the disability would also likely to increase. On the other hand, an inverse correlation was found between BMI and pain scale before the procedure ($r = -0.508$; $p < 0.05$) which indicates that as the pain increased the BMI could also likely to decrease (Table 3).

	Before Procedure		After Procedure	
Variables	Pain scale	ODI	Pain scale	ODI
Age in years	0.635	0.659 **	0.186	0.389 *
BMI (kg/m2)	-0.508 *	-0.081	-0.080	-0.084

Table 3: *Correlation (Pearson-r) between age in years and BMI among pain scale and ODI before and after lumbar disc ablation procedure (n=26).*

*** Correlation was significant at p=0.01 level (2-tailed).*

** Correlation was significant at p=0.05 level (2-tailed).*

Figure 2 depicted the comparison of the level of disability before and after the treatment. It was revealed that at baseline there were 7.7% of patients who were classified as crippled, however after the procedure, none of the patients were classified in the crippled category. In contrast, at baseline only 4.8 of the patients were classified as having minimal disability however, after the treatment, 42.3% of them were classified as minimal disability which showed a significant improvement of 37.5% (See figure 2).

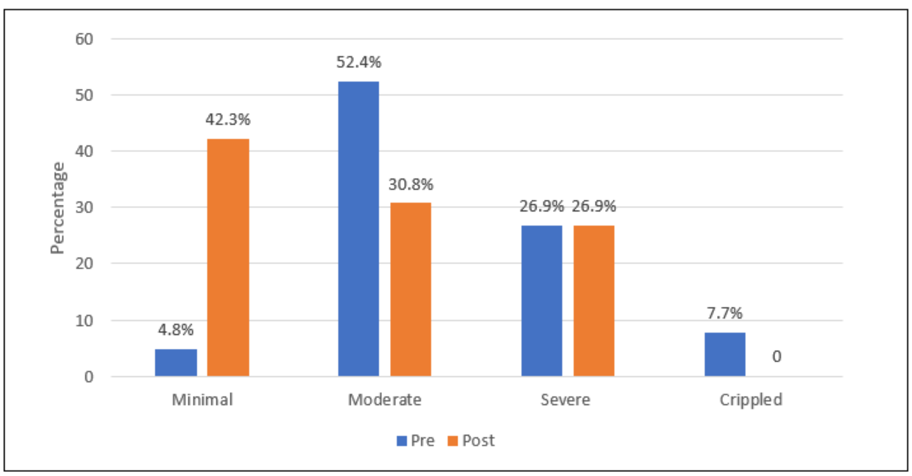

Figure 2: *Comparison of the level of disability pre and post treatment.*

Table 4 described the statistical association between ODI and the baseline characteristics of patients before and after disc ablation procedure. Our investigation showed that, the ODI score of females before the procedure was statistically significantly higher compared to males (T = -2.299; p = 0.009) while after the procedure, the difference was not statistically significant (T = -1.168; p = 0.384). We also observed that at baseline, the ODI score of unemployed patients was statistically significantly higher than those who were employed (T = -1.986; p = 0.043) while post treatment the trend remained the same with unemployed being more with ODI score (T = -3.054; p = 0.006). Additionally, after the procedure, those with associated chronic diseases showed significantly higher ODI score than those without chronic diseases (T = 1.946; p = 0.018) (Table 4).

Study data	Pre-ODI		Post-ODI	
	Mean ± SD Score (100%)	T-test; P-value §	Mean ± SD Score (45)	T-test; P-value §
Gender				
• Male	34.8 ± 12.5	-2.299; 0.012 **	21.2 ± 11.7	-1.168; 0.384
• Female	47.6 ± 12.7		29.2 ± 20.2	
Occupation				
• Employed	36.2 ± 11.8	-1.986; 0.043 **	14.4 ± 9.84	-3.054; 0.006 **
• Unemployed	47.5 ± 13.9		32.9 ± 17.4	
Radiculopathy				
• Yes	41.2 ± 11.3	-0.631; 0.635	27.3 ± 17.9	1.009; 0.471
• No	46.1 ± 24.0		17.8 ± 12.7	
Chronic Illness				
• Yes	47.8 ± 13.6	1.514; 0.121	33.1 ± 12.4	1.946; 0.018 **
• No	38.6 ± 13.4		20.4 ± 18.8	

Table 4: *Statistical Association between ODI and the baseline characteristics of patients before and after Disc Ablation procedure (n=26).*

§ P-value has been calculated using Mann Whitney U test.

*** Significant at p < 0.05 level.*

Discussion

The present study sought to determine the efficacy of lumbar radiofrequency ablation among patients with lower back pain. To the best of our knowledge, this is the first study in Saudi Arabia that examined the effectiveness of lumbar disc ablation among those patients who complained from lower back pain. In this study the mean ODI score after the procedure was significantly improved when compared to the baseline ODI score (mean: 20.6%; SD 13.6% vs mean: 42.9%; SD 13.9%; $p < 0.001$). This indicated a significant improvement showing a mean difference of 21.5%. This result is consistent from the paper of Kim., *et al.* [15] where they studied the patients who underwent radiofrequency focal ablation. They reported that the ODI score before surgery was 50.9% (SD 17.2%) and after the treatment the ODI score reduced to 20.3% (SD 14.6%). In Brazil [26], the mean ODI score preoperative was lower than our report with 26.0 after the treatment the average disability was reduced in 39.6% of patients. Other papers reported a significantly improved in ODI score after the necessary treatment [1,7,18,21], which were in line with our results. Furthermore, we grouped and compared the outcome of the patients before and after the procedure in accordance to the given criteria of the severity of disability [8]. According to the results, before the treatment we identified 7.7% of patients who were classified in the crippled disability level however, after the procedure none of the patients were recorded with the extreme disability. On the other hand, before the treatment, only 4.8% reported to have minimal disability however, after the procedure, 42.3% turned to minimal disability which indicated significant improved among the patients. There were various authors expressed the improvement in accordance to the proportion of the respondents achieving the minimal clinically importance difference (MCID) for ODI [5,22,26]. Others considered the mean variation of the ODI score [6,15,19,23], which was also the main output in this study.

Moreover, the data of this project revealed that ODI score showed significant and high correlation with age both before and after the treatment, indicating that that as the age increased the disability score was also likely to increase. This report is not consistent from the paper of Lee., *et al.* [24] where they accounted that age was not a factor of ODI before and after percutaneous disc decompression (PDD). Similarly, we noted that ODI scores after intervention on patients who were not working and with chronic diseases were statistically significantly higher than their counterparts while the difference at baseline did not vary significantly between the groups. Furthermore, at baseline female patients exhibited significant ODI scores than males however, after the treatment the difference were not significant between the groups. There were limited literatures that demonstrated the association between the ODI score and the basic demographic profiles of the patients. Thus, the findings of this study are subjected for further validation.

Typically, the main goal of the treatment either surgical or non-surgical treatment is to relieve from the pain. Thus, in this study, we also measured the pain experienced by the patients. Using a Numerical Rating Scale (NRS), denoted from 1 to 10, we identified that the pain score of patients before the procedure was 8.50 (SD 1.42), after the procedure, the pain was significantly reduced to 4.19 (SD 2.91). The mean difference of improvement was 4.307 ($p < 0.001$). This result is higher than the papers reported in Korea [15,24]. The authors reported a lower mean pain score before intervention with 7.1 (SD 1.7) and 6.59 (SD 2.00), respectively while after the intervention investigators indicated significant decreased of pain with 2.1 (SD 1.9) and 2.46 (SD 2.00), respectively. In United Kingdom [24], authors documented that using Visual Analogue Scale (VAS) to measure the pain scale, the patients showed significant improvement after the primary discectomy and even after the revision of surgery. The used of VAS was widely prevalent among literatures [7,11,15,23,24]. In our study, we used NRS to measure the experienced pain of the patients which was consistent from the previous studies [10,22,27,29]. An advantage of this method is the fact that it is simple, comprehensive and sensitive to small changes in pain. In addition, we have learned that at baseline, an inverse correlation was noted between BMI and pain score, suggesting that while the pain score increased the BMI level was likely to decrease. However, after the treatment the correlation between pain score and BMI did not differ significantly. Due to the scarcity of literatures in this type of analysis, we hope to serve this as a basis for further investigation.

Conclusion

There was a significant improvement of functional status after the procedure for lumbar disc ablation. Unemployed patients and those with chronic disease were more prone to disability than their counterparts. Further researches are needed in the same study discipline in order to determine the efficacy of lumbar radiofrequency ablation among patients with lower back pain.

Appendix I

Oswestry Disability Index

Patient Info		
MRN		
Name		
Age		
Gender		
Occupation		
Height		
Weight		
BMI		
Symptoms and operation Info		
Date of operation		
Pain Scale (1-10) Pre Vs post		
Duration of the pain preoperatively		

Radiculopathy		
Non operative management Analgesics Vs Physiotherapy		
Any pervious spine operation?		
Chronic Illnesses?		

Pain intensity	
I have no pain at the moment	
The pain is very mild at the moment	
The pain is moderate at the moment	
The pain is fairly severe at the moment	
The pain is very severe at the moment	
The pain is the worst imaginable at the moment	
Lifting	
I can lift heavy weights without extra pain	
I can lift heavy weights, but it gives extra pain	
Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed e.g. on a table	
Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned	
I can lift very light weights	
I cannot lift or carry anything at all	
Walking	
Pain does not prevent me walking any distance	
Pain prevents me from walking more than1 mile	
Pain prevents me from walking more than ½ mile	
Pain prevents me from walking more than 100 yard	
I can only walk using a stick or crutches	
I am in bed most of the time	
Standing	
I can stand as long as I want without extra pain	
I can stand as long as I want but it gives me extra pain	
Pain prevents me from standing for more than 1 hour	
Pain prevents me from standing for more than 30 minutes	
Pain prevents me from standing for more than 10 minutes	
Pain prevents me from standing at all	
Social life	
My social life is normal and gives me no extra pain	
My social life is normal but increases the degree of pain	

Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport	
Pain has restricted my social life and I do not go out as often	
Pain has restricted my social life to my home	
I have no social life because of pain	
Personal care (washing, dressing etc.)	
I can look after myself normally without causing extra pain	
I can look after myself normally, but it causes extra pain	
It is painful to look after myself and I am slow and careful	
I need some help but manage most of my personal care	
I need help every day in most aspects of self-care	
I do not get dressed, I wash with difficulty and stay in bed	
Sitting	
I can sit in any chair as long as I like	
I can only sit in my favorite chair as long as I like	
Pain prevents me sitting more than one hour	
Pain prevents me from sitting more than 30 minutes	
Pain prevents me from sitting more than 10 minutes	
Pain prevents me from sitting at all	
Sleeping	
My sleep is never disturbed by pain	
My sleep is occasionally disturbed by pain	
Because of pain I have less than 6 hours sleep	
Because of pain I have less than 4 hours sleep	
Because of pain I have less than 2 hours sleep	
Pain prevents me from sleeping at all	
Travelling	
I can travel anywhere without pain	
I can travel anywhere but it gives me extra pain	
Pain is bad but I manage journeys over two hours	
Pain restricts me to journeys of less than one hour	
Pain restricts me to short necessary journeys under 30 minutes	
Pain prevents me from travelling except to receive treatment	

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