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Efficacy of Nucleo-Annuloplasty Using Disc-Fx in Lumbar Disc Herniation

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Abstract

Background: Lumbar radicular pain may be caused by lumbar disc herniation, spinal stenosis, or degenerative spondylolisthesis. It is most often caused by lumbar disc herniation and presents as pain radiating from the back into the leg, usually in a dermatomal pattern corresponding to the compressed nerve root. In patients whose pain does not respond to epidural steroid injections, other treatment modalities can be considered. Minimally invasive disc decompression procedures have been developed to treat radicular pain caused by disc herniation. The Disc-FX system combines percutaneous manual discectomy using forceps, nuclear ablation, and annular modification using radiofrequency equipment. To our knowledge, no reports of a correlation between response to Disc-FX and type of lumbar disc herniation have been published. The aim of this study was to determine patients' responses to and short-term outcomes of Disc-FX procedures.

Methods: This single-center study enrolled 43 patients and followed them for 6 months. Disc-FX procedures were performed in the operating room using local anesthesia. Outcome measures were obtained with a numeric rating scale at 1 and 6 months post-treatment.

Results: Patients' mean pain scores were significantly lower 1 and 6 months after treatment than before treatment. The percentage of patients who experienced pain relief (numeric rating scale scores less than 50% of baseline scores) was 55.8% at 1 month and 56.1% at 6 months after the procedure. There were no statistically significant correlations between pain relief and type of herniation, pain location (lower back and/or leg pain), pain duration, or presence of an annular tear.

Conclusion: Our results suggest that the Disc-FX procedure is a reasonable treatment option for carefully selected patients with lower back and radicular pain of discogenic origin.

Keywords: Disc herniation; Lumbar; Annuloplasty; Nucleoplasty

Introduction

Lumbar radicular pain is often caused by lumbar disc herniation, spinal stenosis, and degenerative spondylolisthesis. When disc herniation is the cause, lumbar radicular pain presents as pain radiating from the back into the leg, usually in a dermatomal pattern corresponding to a compressed nerve root. Patients may experience a strong inflammatory reaction to the herniated nucleus pulposus in addition to feeling pain from the compressed nerve root; therefore, epidural injection of corticosteroids is a reasonable treatment option [1,2]. Epidural corticosteroid injections are effective for this type of pain and may be given via an interlaminar, transforaminal, or caudal route [3,4]. In previous studies, between 55% and 84% of patients reported short- to moderate-term pain relief [5,6]. When pain does not respond to epidural steroid injections, other treatment modalities can be considered.

Minimally invasive disc decompression procedures have been developed to treat radicular pain caused by disc herniation [7,8]. The major advantages of minimally invasive techniques for treatment of degenerative pathology are better preservation of spinal architecture, less tissue destruction, and lower risk. Percutaneous interventions used to treat lumbar disc herniation can be separated into three major categories: those that use dissolution (chymopapain), ablation (nucleoplasty), and vaporization (application of laser to the nucleus pulposus).

Nucleoplasty achieves nuclear decompression by removing nuclear tissue through introducer needles. Two systemic reviews have presented different conclusions. One reported that nucleoplasty reduces long-term pain and improves functional mobility. The other concluded that the level of evidence that nucleoplasty improves radicular pain due to contained disc herniation is limited to fair [7]. A device called the DiscQ is effective for treatment of lumbar disc herniation, discogenic pain, and symptomatic lumbar disc disease [8-10].

The Disc-FX system combines percutaneous manual discectomy using forceps, nuclear ablation, and annular modification using radiofrequency equipment. Two previous articles have reported its efficacy for contained lumbar disc herniation [10,11]. Sequestration or extruded disc herniation does not include.

To our knowledge, no reports of the correlation between the response to Disc-FX and the type of lumbar disc herniation have been published. The aim of this study is to determine patients' responses and short-term outcomes of Disc-FX procedures.

Methods

This study was conducted with the full approval of the local Institutional Review Board, and written informed consent was obtained from all participants. This single-center study enrolled 43 patients and followed them for 6 months. All 43 patients received further tests or had recently undergone lumbar radiography or magnetic resonance imaging (MRI). The patients, who were between 22 and 77 years of age, had all been diagnosed with lumbar radicular pain and/or axial lower back pain based on their pain distribution and MRI results showing intervertebral disc herniation related to spinal root compression. Data collected included age, sex, type of disc herniation (protrusion or extrusion), duration of pain, nature of the symptoms (location of

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the pain), and presence or absence of an annular tear. Protrusion was present when the distance between the edges of the herniated disc material was less than that at the base of the disc; extrusion was present when the distance between the edges of the herniated disc material was greater than that at the base. Exclusion criteria included normal MRI findings; a previous surgical operation at the level of the herniated disc; symptoms or signs of lumbar canal stenosis; psychological problems revealed by examination or history; tumor; systemic infection; localized infection at the anticipated needle entry sites; traumatic spinal fracture; a history of coagulopathy, unexplained bleeding, or use of aspirin, clopidogrel, warfarin, or heparin in the previous 2 weeks; other peripheral neuropathies of the lower extremities; and patient refusal.

All procedures were performed in the operating room using local anesthesia. Each patient was placed in a prone position on the table. Before the procedure, the skin entry point was measured from the midline using MRI. A conventional posterolateral approach was used. The skin entry point was marked under fluoroscopic guidance.

The side of the pathology was the preferred side of approach. The skin entry point and needle track were infiltrated with an injection of 1% lidocaine. A 15-gauge spinal needle was inserted at the previously identified entry point and directed lateral to the superior articular pillar toward the target (Figure 1). The needle was inserted into the nucleus pulposus until it reached the center of the disc, as confirmed on anteroposterior and lateral radiographic views (Figure 2). After the needle was positioned, a discogram was obtained using an intradiscal instillation of diluted 0.8% indigo carmine 40 μg/5 mL (Carmine, Korean United Pharma, Seoul, Korea) (Figure 3), meglumine ioxitalamate (a radiopaque dye) 300 μg/mL (Telebrix 30, Guerbet, France), and normal saline in a 2:1:2 proportion. A guide wire was inserted through the spinal needle after removal of the stylet. An incision 0.7 cm long was made through the skin over the guide wire. A cannula and soft tissue dilator were inserted into the annulus over the guide wire with continuous fluoroscopic monitoring (anteroposterior and lateral views) (Figure 4). After placement of the cannula, disc material could be visualized with frequent use of Lase® equipment. Manual discectomy of the intra-annular or subligamentary disc material was performed with small disc forceps or disc rongeurs (Figure 5). The steerable Trigger-Flex (Elliquence) probe was inserted through the cannula, and nuclear ablation was performed with the Surgi-Max (Elliquence) generator set at Bipolar-Turbo mode (Figure 6). Six strokes of ablation were made in 6 different directions through the nucleus. Nuclear material was extracted with disc irrigation. Modulation of the dorsal annulus was then carried out by placing the Trigger-Flex probe under the pathological annulus and using the Bipolar-Hemo mode of the Surgi-Max generator. Four strokes of modulation were performed in different directions through the annulus, covering its width. During the procedure, the surgical

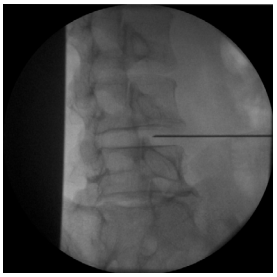

Figure 1: A 15-gauge spinal needle was inserted at the previously identified entry point and directed lateral to the superior articular pillar toward the target.

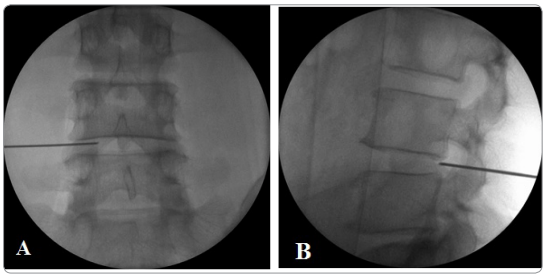

Figure 2: The needle was inserted into the nucleus pulposus until it reached the center of the disc, as confirmed on anteroposterior (A) and lateral radiographic views (B).

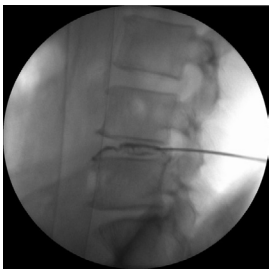

Figure 3: Discogram was obtained using an intradiscal instillation of diluted 0.8% indigo carmine, meglumine ioxitalamate, and normal saline.

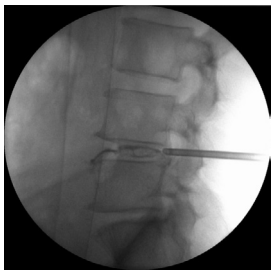

Figure 4: A cannula and soft tissue dilator were inserted into the annulus over the guide wire with continuous fluoroscopic monitoring in lateral views.

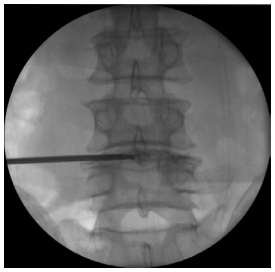

Figure 5: Anteroposterior C-am view; small disc forceps are seen.

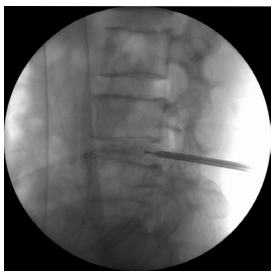

Figure 6: The steerable Trigger-Flex (Elliquence) probe was inserted through the cannula and nucleus ablation was performed.

site was irrigated through the cannula with normal saline mixed with antibiotics.

After the procedure, each patient was observed for neurological deficits or other procedure-related problems. Patients were typically discharged the same or the following day.

The main outcome parameter was radicular pain in the lower limb as measured by a numeric rating scale score (NRS). Patients were evaluated at baseline and at 1 and 6 months after the procedure. For the first 2 weeks, all patients received nonsteroidal anti-inflammatory drugs and muscle relaxants. Patients whose pain did not respond to this treatment were given opioid or non-opioid analgesics after the first follow-up visit.

An independent *t* test and analysis of variance were used to analyze the data. A type I error rate of less than .05 was considered significant. All statistical analyses were performed with SPSS software, version 19 (IBM, Armonk, NY, USA).

Result

The 43 study participants ranged in age from 22 to 77 years (mean age, 44.9 years); 30 were men and 13 were women. Table 1 shows the patient characteristics, the herniation levels, and the pain locations. L4-5 was the most frequently implicated level. Twenty-five patients had pain duration of less than 3 months, 14 had an annular tear, and 24 had pain only in the lower back.

N=43	
Age	44.1 ± 14.1
Gender (M : F)	30 (69.8%) : 13 (30.2%)
Level	
L1-2	1
L2-3	1
L3-4	6
L4-5	24
L5-S1	9
Pain Duration	
3 months <	25
< 3-6 months <	12
< 6 months	6
Annular tear	
Yes	14
No	29
Pain Nature	
Low back pain with leg pain	14
Low back pain	24
Leg pain	5

Table 1: Patients Characteristics.

NRS (N=43)	Mean ± SD	P value
Pre NRS	7.4 ± 0.8	
Post 1 month NRS	3.7 ± 1.8	0
Post 6 month NRS	3.7 ± 1.9	0
NRS : numeric rating scale score		

Table 2: Change of numeric rating scale score.

NRS	Type	N	Mean ±SD	P value
Post 1 month	Protrusion	22	3.7 ±1.8	0.886
	Extrusion	21	3.8 ±1.9	
Post 6 months	Protrusion	21	3.4 ±1.8	0.294
	Extrusion	20	4.1 ±1.9	
NRS: numeric rating scale score				

Table 3: Correlation between post-procedure numeric rating scale score and lumbar disc herniation type.

NRS	Pain nature	N	Mean ± SD	P value
Post 1 month	LBP + leg pain	14	3.6 ± 1.6	0.268
	LBP	24	3.7 ± 1.8	
	Leg pain	5	4.6 ± 2.1	
Post 6 months	LBP + leg pain	14	3.7 ± 1.7	0.789
	LBP	24	3.8 ± 2.1	
	Leg pain	5	4.0 ± 2.4	
NRS: numeric rating scale score, LBP : low back pain				

Table 4: Correlation between post- procedure numeric rating scale score and low back pain or low back pain with leg pain.

NRS	Pain duration	N	Mean ±SD	P value
Post 1 month	3 months <	25	3.2 ± 1.5	0.077
	<3-6 months <	12	4.4 ± 2.5	
	< 6 months	6	4.5 ± 1.8	
Post 6 months	3 months <	24	3.2 ± 1.7	0.085
	<3-6 months <	11	4.3 ± 1.9	
	< 6 months	6	4.8 ± 1.8	
NRS: numeric rating scale score				

Table 5: Correlation Between post-procedure numeric rating scale sore and pain duration.

NRS	Annular tear	N	Mean ±SD	P value
Post 1 month	yes	14	3.4 ± 1.5	0.321
	no	29	3.9 ± 1.9	
Post 6 months	yes	14	3.4 ± 1.9	0.363
	no	27	3.9 ± 1.8	
NRS: numeric rating scale score				

Table 6: Correlation Between post-procedure numeric rating scale score and annular tear.

Patients' mean pain scores 1 and 6 months after treatment were significantly lower than before treatment (Table 2). The percentage of patients who experienced pain relief (NRS scores less than 50% of the baseline scores) was 55.8% at 1 month and 56.1% at 6 months after the procedure. There were no statistically significant correlations between pain relief and type of disc herniation, pain location (lower back and/or leg pain), pain duration, or presence of an annular tear (Tables 3-6).

None of the patients experienced any complications, and all the patients completed the follow-up visits. Two patients underwent surgery

Discussion

In this study, patients experienced significant improvement in pain regardless of the type of disc herniation, pain location, pain duration, or presence of an annular tear. In a previous study, patients with sustained, contained disc herniation's whose pain had not responded to conservative treatment were very likely to have good outcomes 4 years after manual decompression combined with radiofrequency-assisted decompression and annulus modulation [11].

In this study, the type of disc herniation did not affect the procedure. Herniated discs may be either contained or uncontained. Contained herniated discs have an intact outer annulus containing the displaced disc material. With uncontained herniated discs, a breach in the outer annulus allows for localized displacement of disc material beyond the intervertebral disc space.

Nucleoplasty is generally performed for a contained disc herniation of less than 6 mm and a disc height that is 50% or more than the

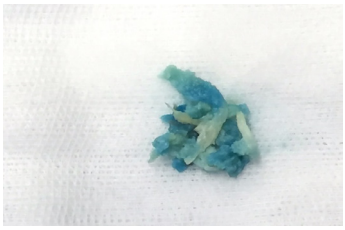

Figure 7: Herniated disc materials was removed with blue stained.

height of a normal adjacent disc [12]. The role of nucleoplasty is radiofrequency and thermal treatment [7,13]; therefore, neucloplasty may be recommended contained disc herniation. However, Disc-Fx procedure has both radiofrequency effect and removal of herniated disc material (Figure 7). Disc-Fx could be removing of disc material with the intent of reducing intradiscal pressure and decompressing nerve roots. Disc-FX can also be used to ablate or cauterize disc material or annular tears using the steerable Trigger-Flex (Elliquence) probe. High radiofrequency has been shown to have positive effects in endoscopic spinal operations and in neurosurgical applications [7,14].

In one study, the Disc-FX procedure was less effective for patients with a focal disc prolapse than for those with a generalized disc bulge. The patients with a focal disc prolapse may have had a preexisting thinning of the annulus fibrosus; creation of a 2.7-mm annulotomy near the weakened area may have predisposed them to recurrent disc prolapse [10]. Carragee et al. [15] studied clinical outcomes after lumbar discectomy for treatment of sciatica and demonstrated that patients with lumbar disc herniation's containing no fragments experienced poorer treatment outcomes than did those with other types of herniation's, with 38% having recurrent or persistent sciatica. Patients in the fragment-fissure group, who had disc fragments and small annular defects, had the best overall outcomes and the lowest rates of reherniation (1%) and reoperation (1%). Dewing et al. [16] showed that patients with sequestered or extruded lumbar disc herniation's had significantly better outcomes than those with contained herniation's.

In the present study, there was no significant difference in pain relief between patients with leg pain and those with axial pain. Results of another study indicated that although improvement seen in the degenerative disc disease was not significantly different from that of the contained lumbar disc herniation subgroup, the contained group required re-intervention within 1 year of the procedure [10].

One limitation of our study is that the significant improvements in pain were not corroborated by any secondary outcomes. A second is that the follow-up period was less than 6 months, so we do not have mid- or long-term follow-up results.

Our results suggest that the Disc-FX procedure is a reasonable treatment option for carefully selected patients with lower back and radicular pain of discogenic origin.

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