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, and 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, transformaminal, 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 IdisQ 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 neuropathy), and location of pain (lower back, leg pain).

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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 (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
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 only in the lower back.

| N=43 | 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; L5-51: 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 |

| NRS (N=43) | Mean ± SD | P value |
|---|---|---|
| Pre NRS | 7.4 ± 0.8 | 0 |
| Post 1 month NRS | 3.7 ± 1.8 | 0 |
| Post 6 month NRS | 3.7 ± 1.9 | 0 |

Table 1: Patients Characteristics.

| 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 | 0.321 |
| | Leg pain | 5 | 4.6 ± 2.1 | 0.363 |
| Post 6 months | LBP + leg pain | 14 | 3.7 ± 1.7 | 0.789 |
| | LBP | 24 | 3.8 ± 2.1 | 0.85 |
| | Leg pain | 5 | 4.0 ± 2.4 | 0.977 |

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 |
| | Extraduction | 21 | 3.8 ± 1.9 | 0.977 |
| Post 6 months | Protrusion | 21 | 3.4 ± 1.6 | 0.294 |
| | Extraduction | 20 | 4.1 ± 1.9 | 0.363 |

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

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

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 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].

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