The comparison of the efficacy of radiofrequency nucleoplasty and targeted disc decompression in lumbar radiculopathy

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ABSTRACT

Chronic low back pain is a common clinical condition causing medical, socioeconomic, and treatment difficulties. In our study, we aimed to compare early and long-term efficacy of lumbar radiofrequency thermocoagulation (RFTC) nucleoplasty and targeted disc decompression (TDD) in patients with lumbar radiculopathy in whom previous conventional therapy had failed. The medical records of 37 patients undergoing TDD and 36 patients undergoing lumbar RFTC nucleoplasty were retrospectively examined and assigned to the Group D and Group N, respectively. In all patients Visual Analogue Scale (VAS) and Functional Rating Index (FRI) were recorded before treatment and after one, six and twelve months after the procedure. The North American Spine Society Satisfaction Scale (NASSSS) was also recoreded twelve months after the therapeutic procedure. Statistically significant postprocedural improvement in VAS and FRI was evident in both groups. VAS scores after one, six, and twelve month were slightly higher in Group N, compared to Group D. The overall procedure-related patient satisfaction ratio was 67.5% in the Group D, compared to 75% in the Group N. Regardless of the different mechanism of action, both methods are effective therapies for lumbar radiculopathy, with TDD showing long-term lower pain scores.

KEYWORDS: Lumbar radiculopathy; nucleoplasty; targeted disc decompression; chronic pain; radiofrequency thermocoagulation
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INTRODUCTION

Chronic low back pain is a common clinical condition causing medical, socioeconomic, and treatment difficulties [1-3]. Chronic pain treatment requires knowledge of modern diagnostic and therapeutic approach [4].

The weakness and degeneration of fibrous ring and posterior longitidunal ligament may cause posterior herniation of nucleus pulposus towards the spinal canal. This hernia tion compresses the adjacent nerve roots and produces pain, namely radiculopathy, along particular dermatome [1-3].

Intervertebral disc hernia is the most frequent cause of lumbosacral radiculopathy and surgery is required in 10-15% of patients [1-5]. Patients with radiculopathy generally respond well to conservative treatment, shifting thus the therapeuticoptions for low back pain from surgery to nonsurgical methods in recent years [6].

Oral medications, exercise, lifestyle changes are some of the frequently used conservative methods in treatment of low back pain or radiculopathy. Bed rest, use of underbust, and physical rehabilitation should be considered nonsurgical treatments, too [6].

Up to the present, volumetric reduction of nucleus pulposus has been achieved using various methods, such as chemonucleolysis, percutaneous laser discectomy and percutaneous discectomy. Radiofrequency thermocoagulation (RFTC) nucleoplasty and targeted disc decompression (TDD) are the minimally invasive percutaneous intradiscal treatment methods, and options that could be preferred in the treatment of radicular pain caused by disc herniation [7].

RFTC nucleoplasty is performed using a transmitter device called Coblation technology (Coblation: Perc DLE SpineWand™ [ArthroCare Spine, Sunnyvale, CA]), based on transmission of radiofrequency energy. The core tissue of the disc is partially destroyed with radiofrequency energy using a

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bipolar device of 1 mm in diameter; the energy particles have the potency to lyse the soft part of the disc tissue to molecules. It works at relatively low temperatures (40-70 degrees Celsius), preventing thus the damage in the surrounding tissues. At low temperatures, heat is applied to the open channels with coagulation mode. This opens the intervertebral space and decreases a possible hemorrhage. A total of 1 mL of nucleus tissue is evaporated, which decreases the volume of disc tissue at a rate of approximately 10-20% [7, 8]. Reduction of nucleus pulposus and decrease in pressure causes elimination of pain by means of the decrease in chemical and mechanical factors.

TDD is a minimally invasive procedure, which is used in the treatment of painful degenerative disc diseases. This procedure is performed using a heat resistant intradiscal catheter (SpineCATH®, Smith & Nephew, Memphis, TN) that diverts thermal energy directly into the disc. At first, the targeted disc is determined under fluoroscopy and then a 17-gauge trocar needle is inserted to the annulus and advanced until the inner part of the annulus. The flexible intradiscal catheter, by passing through trocar, is pushed forward to the nucleus. The wire is advanced like a coil between the inner annulus and the nucleus. After securing the location of the heat-resistant catheter, within a period of 10-30 minutes, the disc is heated to 90 degrees (the target temperature). By this heating, the temperature of the inner part of disc is increased only to 60-65 degrees C, while the temperature of the epidural space is increased up to 30 degrees C. However, it is thought that this temperature is high enough for denaturation of collagen fibers and destruction of pain receptors present in posterior annulus [8].

In the present study, patients with lumbar radiculopathy, who had undergone RFTC nucleoplasty and TDD, were retrospectively compared in terms of early and long-term effects of these therapeutic approaches.

MATERIALS AND METHODS

The study was registered at clinicaltrials.gov (Registration number NCT02025283). After obtaining Institutional Ethics Committee approval, files of 120 patients with lumbar radiculopathy, who had undergone nucleoplasty (n=76) and targeted disc decompression (n=44) in the period between 2010 and 2012, were retrospectively evaluated. The inclusion criteria were: patients' age 35-60 years, BMI 20-32, and height 155-180 cm, with no response to conventional medical treatment, physical therapy and simple interventional pain procedures (lumbar and transforaminal steroid injections and facet joint blockade). The patients with diabetes mellitus were excluded. The indications for these two intradiscal pain procedures were: presence of bulging and protrusion without neurological deficit. Complete data were available for 73 patients which were included in the study. Of these, 37 patients who had undergone TDD were assigned to the Group D, while 36 patients who had undergone RFTC nucleoplasty were assigned to the Group N. Informed consent was obtained and strict patient confidentiality was maintained during the study.

The smoking history, age, weight, height, and body mass index (BMI) were recorded. The preoperative visual analogue scale (VAS) (a 10-point scale, with point 0 representing no pain and point 10 representing worst pain imaginable), presence of nonsteroidal antiinflammatory drug use and conservative treatment before the procedure were also recorded. The MRI characteristics of disc pathologies and levels of therapeutic procedires were determined. The effects of these characteristics on pain scales were assessed.

To assess the intensity of low back pain, VAS scores before the procedure and one, six and twelve months after the procedure were obtained from the medical records of the patients [9].

Functional rating index (FRI) before the procedure and after one, six and twelve months after the procedure were alseo recorded from the medical files, and the percentage differences were calculated. FRI is a 10-item scoring system which includes eight items focusing on daily activities such as sleeping, self-care, travel, work, recreation, lifting, walking and standing and two items focusing on intensity and frequency of pain. Each item is scored in a five-point scale, ranging from 0 (no pain or full ability) to 4 (worst pain or inability to perform a function). The index score was calculated by the following formula: FRI = (total score/40) × 100%, while the percentage difference from preprocedural values was calculated by the following formula: Δ FRI = (pre FRI % - post FRI%)/pre FRI% [9].

Complications related to the procedures were also recorded. The presence of analgesic use after the procedure was recorded. The patient satisfaction index (North American Spine Society Satisfaction Scale-NASSSS) at the end of twelfth month following the procedure was also obtained. In NASSSS, the patients were asked to choose one of the responses according to the level of the satisfaction with treatment (Table 1). The score of 1 or 2 on the NASS scale was accepted as a satisfaction success [10].

Statistical analysis

The data analysis was done with SPSS 15.0 statistical package (SPSS Inc., IBM Corporation, USA). For descriptive

TABLE 1. North American Spine Society Satisfaction Scale-NASS

Score	
1	The treatment met my expectations
2	I did not improve as much as I had hoped, but I would undergo the same treatment for the same outcome
3	I did not improve as much as I had hoped, and I would not undergo the same treatment for the same outcome
4	I am the same or worse than before treatment

statistics we used mean± SD when distribution was normal; otherwise, a median (min–max) was used. Nominal variables were expressed as number of cases and percentage (%). The importance of intertime differences in mean values within groups was assessed with variance analysis test in repeated measures and the importance of intertime differences in median values was assessed with the Friedman test. When a difference was found, multiple intertime comparisons were evaluated with proper post-hoc tests. The significance of difference in intertime changes between groups in terms of mean values was assessed with the independent t-test and the significance of difference in terms of median values was evaluated with the Mann-Whitney test.

RESULTS

Targeted disc decompression and nucleoplasty procedures were performed in a total of 120 patients. However, only 37 patients in whom decompression was performed and 36 patients in whom nucleoplasty was performed were selected and included in the study.

Demographic data were similar in both groups (Table 2). Nonsteroidal anti-inflammatory drug use before procedure was high in both groups (64.9% in the Group D and 50% in the Group N).

A significant improvement was observed in all VAS and FRI scores when compared with the preprocedure values, in both groups. The VAS scores after one, six and twelve months were significantly lower the Group D compared to Group N (Table 3), but there was no statistically significant difference in FRI scores (p>0.05).

In both study groups, there was a significant improvement in FRI values after one, six and twelve months when compared with the preprocedural values (p<0.0125) (Table 4). The degree of disability was determined by calculating the percentage change in FRI (Table 5). There was no significant difference between groups in terms of percentage change in FRI (p > 0.05).

When the patients' opinions about the procedure were assessed with NASS at the end of the twelfth month, 45.9% of the patients in the Group D and 41.7% of the patients in the Group N were satisfied with the procedure (p > 0.05). According to the NASSS scores at twelfth month, the overall procedure-related patient satisfaction ratio (NASSSS =1 or 2) was 67.5% and 75% in Group D and Group N, respectively (Figure 1).

The percentage of analgesic use in the Group D was significantly lower when compared with the Group N (23.5 % and 76.5%, respectively) (p<0.001).

The effects of the intervention level, the presence of analgesic use before and after the procedure, the presence of conservative treatment before the procedure, all measured on pain scales, were examined by area under curve (auc). The effects of these parameters on pain scales were not found to be statistically significant in both study groups (p>0.05).

Discitis was observed only in one patient in TDD, occurring 15 days after the procedure, and this patient was discharged without any sequela following antibiotic therapy. At the end of the study, VAS scores of this patient had increased from 7 to 9, while the NASSSS score was 4.

TABLE 2. Demographic data

	Group D	Group N
n	37	36
Female/male	20/17	12/24
Age	47±12	52±10
Height (cm)	168.27±9.69	166±8.38
Weight (kg)	76.32±12.85	76.56±7.19
BMI (kg/cm^2)	26.95±3.96	27.85±2.65
Preoperative VAS	7 (7-8)	7 (5-9)
Cigarette smoking (+/-)	11/26	13/23
MRI finding (n=number of patients; %)		
Bulging	14 (66.7)	7 (33.3)
Protrusion	21 (43.8)	27 (56.2)
Extrusion	2 (50)	2 (50)
Localization of the intervention (n=number of patients)		
L_{3-4}	0	1
L_{4-5}	7	14
L_5-S_1	4	0
L_{3-4}, L_{4-5}	2	4
L_{4-5}, L_5-S_1	23	17
L_{3-4}, L_{4-5}, L_5-S_1	1	0

Group D: Decompression; Group N: Nucleoplasty; MRI: Magnetic resonance imaging. Data were expressed as mean±standard deviation, median (minimum-maximum) and (%)

TABLE 3. Assessment of VAS

	Basal	1st month	6th month	12th month	p value
Group D	7 (7-8)	3 (0-8)	2 (0-8)	2 (0-8)	<0.001
Group N	7 (5-9)	5 (0-9)	4 (0-9)	4 (0-9)	<0.001
Group P value	0.001*	0.001*	0.001*	0.020	

Median (min-max), Group D: Decompression; Group N: Nucleoplasty

TABLE 4. Functional rating index (FRI)

	Basal	1st month	6th month	12th month	p value
Group D	70 (3-90)	45 (20-70)	30 (0-70)	30 (0-70)	<0.001
Group N	70 (60-94)	50 (10-85)	45 (5-85)	42 (5-85)	<0.001
Group P value	0.021	0.510	0.073	0.077	

Group D: Decompression; Group N: Nucleoplasty; median (min-max)

TABLE 5. The percentage change in FRI (FRI%)

	1st month	6th month	12th month
Group D	33 (0-66)	50 (0-86)	45 (0-94)
Group N	30 (0-83)	45 (0-91)	50 (0-93)
Group P value	0.694	0.610	0.636

Group D: Decompression; Group N: Nucleoplasty; median (min-max)

DISCUSSION

In the retrospective analysis of 73 patients who underwent RFTC nucleoplasty or TDD, there was a significant reduction in VAS and FRI scores at all the measurement time points. Calculated FRI changes after one, six and twelve months were 33%, 50%, and 45%, respectively, in the decompression group, while they were 30%, 45%, and 50 %, respectively, in the nucleoplasty group. Achieving a functional change percentage of more than 30% in both groups suggested that significant recovery was observed. In addition, the patients' satisfaction was evaluated with NASSSS; accordingly, 45.9% of the patients in the decompression group and 41.7% of the patients in the nucleoplasty group were satisfied with the procedure.

In a one-year follow-up study, Mirzai et al presented the nucleoplasty results of 52 patients and found a decrease in VAS score from 7.5 to 2.1 in the twelfth month [11]. Similarly, our study showed a decrease in VAS score from 7.0 to 4.0 in the nucleoplasty group.

Gerges et al. reported VAS scores in published nucleoplasty studies and found the highest recovery rate in the study of Mirzai et al as 72% (Table 6) [12]. In our study, a recovery rate of 46% was detected (Table 6).

There is no known serious side effect related to the procedures of RFTC nucleoplasty and TDD. In the current study, discitis was observed in only one patient, 15 days after the TDD procedure. This patient was discharged after completion of antibiotic therapy without any sequela.

Schaufele et al. evaluated VAS, bodily pain and physical functioning scores in 22 patients with lumbar radiculopathy undergoing TDD. They detected a statistically significant recovery in all follow-up periods. Furthermore, they observed a significant decrease in protrusion comparing to the preprocedural MRI findings. They also reported that targeted disc decompression could be beneficial in patients with radiculopathy related to lumbar disc herniation that had no response to conservative therapy [13].

TABLE 6. Published studies related to VAS scores and percentage of recovery in nucleoplasty [14]

Study	Basal VAS	VAS at the end of 1st year	Basal change	Recovery %
Sharps 2002	7.9	4.3	3.6*	46*
Reddy 2005	8.08	-	3.67*	45*
Bhagia 2006	6.74	4.27	2.47*	37*
Mirzai 2007	7.5	2.1	5.4*	72*
Calisaneller 2007	6.95	4.53	2.42*	35*
Yakolev 2007	7.6	3.6	4*	53*
Al Zain F 2008	6.59	3.36	2.50	58*
Hui Z 2011	7.7	3.8	4*	53.2*
Alaa A 2011	8.2	1.3	-	-
Shay S 2012	9.2	4.9	4.3	63*
Present study 2013	7.0	4.0	4.2	46*

*Statistically significant

In the present study, VAS scores of 37 patients undergoing TDD were evaluated. Initial VAS score and VAS scores after one, six and twelve months were 7.0, 3.0, 2.0 and 2.0, respectively, which was statistically significant decrease. Percentage of change in initial and VAS scores after one, six and twelve months were calculated, and recovery rates of 57%, 71%, and 71%, respectively, were observed. A significant decrease in pain scores measured with FRI was found after one, six and twelve months. The percentage change in FRI was found to be 33%, 50%, and 45% after one, six and twelve months, respectively. This decreased disability compared to initial values was found to be statistically significant; however, no difference was found between months. According to the NASSSS, in the Group D, 45.9% of the patients reported that they were completely satisfied with the procedure, while 21.6% reported that the procedure had not met their expectations, but they could have had the same procedure again. As a result, a positive thought at a rate of 67.5% is similar to the satisfaction ratio of 63% in the study of Lee et al, in which they included 51 patients who underwent disc decompression in a 2 year follow-up prospective study [14]. Furthermore, a satisfaction ratio of 78% was reported in the prospective study of Derby et al, which included 32 patients [15].

To date, many minimally invasive procedures were performed on patients with disc rupture and lumbar radiculopathy who had no benefit from conservative treatment. However, to our knowledge, there are no studies comparing the techniques of RFTC nucleoplasty and TDD. More research is necessary to understand the possible superiority of these procedures over the others. One of such studies by Lemcke et al. [16] prospectively evaluated the results of 96 patients undergoing nucleoplasty and 67 patients undergoing disc decompression. A significant decrease in VAS scores was observed in both decompression and nucleoplasty procedures [16].

In the present study, when the pain scores after RFTC nucleoplasty and TDD were evaluated, the recovery was significantly higher in the decompression group. Moreover, based on a VAS scores, the recovery after six months was found to be significantly greater in the decompression group than in the nucleoplasty group. Although the recovery estimated on the basis of FRI scores was greater in the decompression group, this difference wasn't statistically significant. The percentage of analgesic use following the procedure was 76.5% and 23.5% in the nucleoplasty and decompression groups, respectively.

In the study of Singh et al. [17], early and long-term recovery results of the published studies in disc decompression were presented. We compared those results with ours in Table 7.

CONCLUSION

In conclusion, our study indicates that minimally invasive procedures, such as RFTC nucleoplasty and TDD, are effective

TABLE 7. Characteristics of published studies in lumbar disc decompression [19].

Study	Number of patients (n)	Satisfaction percentage	Early and long-term recovery
Duarte & Costa, 2012	205	67	+
Menchetti 2011	585	70	+
Iwatsuki 2007	65	80	+
Tassi 2006, 2004	500	84	+
Nerubay 1997	50	74	+
Present study	73	67.5	+

and safe methods that can be used in hernia nucleus pulposus as an alternative to surgery. TDD resulted in lower pain scores. These procedures can yield a more rapid and long-term functional recovery, decrease analgesic requirements, and increase quality of life.

DECLARATION OF INTERESTS

The authors declare no conflict of interests.

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