

Retrospective Cohort Study

 **Prognostic Factors for Successful Percutaneous Disc Decompression Using the Navigable Device L'DISQ™ in Patients with Lumbar Discogenic Pain**

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Background: The navigable percutaneous disc decompression (PDD) device L'DISQ is an effective and safe option for the treatment of lumbar discogenic pain. However, few studies have evaluated the prognostic factors of successful PDD using this device.

Objective: This study aimed to evaluate the prognostic factors associated with the successful outcome of PDD using the L'DISQ for treating lumbar discogenic pain by following up patients before and one, 2, 3, and 6 months after the procedure.

Study Design: Retrospective cohort study.

Setting: Tertiary university hospital.

Methods: A successful outcome was defined as a $\geq 50\%$ reduction in the numeric rating scale scores for pain and a $\geq 40\%$ reduction in the Oswestry Disability Index scores at 6 months after the procedure. Clinical parameters and patient demographics, including pain duration, history of surgery, number of treatment levels, and the radiographic findings of lumbar magnetic resonance imaging (MRI), were also examined.

Results: Of the 106 patients included, 80 (75.5%) had successful outcomes at 6 months. Multivariable logistic regression analysis revealed that the presence of high-intensity zones (HIZs) ($P = 0.016$) was an independent positive predictor of successful PDD outcomes; conversely, migration of the herniated disc ($P = 0.017$) and bilaterally herniated discs ($P = 0.001$) were negative predictors.

Limitations: The limitations of this study were its retrospective design, absence of a control group, and difficulty in predicting the effect when multiple levels were involved because of the use of MRI characteristics of the disc as a predictor.

Conclusions: The presence of HIZs, the absence of migration of herniated discs, and the presence of unilaterally herniated discs are positive predictors of successful outcomes of PDD using the L'DISQ.

Key words: Percutaneous disc decompression, L'DISQ, lumbar discogenic pain, successful outcomes, numeric rating scale, Oswestry Disability Index, high-intensity zones, herniated disc migration

IRB approval and clinical trial registration: The study was approved and informed consent was waived by The Catholic University of Korea, Seoul St. Mary's Hospital Institutional Review Board (IRB No. KC21IRSI0101). This study was registered with CRIS (Clinical Research Information Service of the Korea National Institute of Health, <https://cris.nih.go.kr/cris/index.jsp>, KCT0005967).

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Lumbar discogenic pain accounts for 40% of cases of chronic lower back pain (1). The most common pathophysiology of this pain is annular disruption (2). When posterior annular damage causes the nucleus pulposus to migrate to the outer annulus, the protruded disc stimulates the nociceptors in the posterior annulus and posterior longitudinal ligament of the dural sac (3,4). Inflammatory cytokines produced by ingrowing nerve endings also stimulate nociceptors. These chemical and mechanical processes contribute to the development of lumbar discogenic pain (5-7). Although no standardized treatment for lumbar discogenic pain is currently available, open disc surgery could be considered if conservative treatments, such as medication or physiotherapy, are ineffective (8-11). However, open disc surgery is invasive and can cause severe complications in some cases (12,13). As an alternative, minimally invasive disc decompression has been used over the past several decades. Compared to open surgery, this procedure reduces pain severity while maintaining the normal disc tissue (14-17). Moreover, it can be performed using various techniques, such as intradiscal electrothermal therapy, intradiscal injection, and nucleoplasty (18-23).

Partial disc decompression is certainly safer than open surgery, but most studies have shown that it has a lower success rate than that of open and microdiscectomy in reducing radicular pain (18,24,25). Introduced in 1999, nucleoplasty (Arthrocare Co., Sunnyvale, CA) is a representative nuclear decompression technique that removes nuclear tissue using bipolar radiofrequency energy—the so-called coblation technology—applied to a saline-conducting medium (24,26). However, like most decompression techniques, this is also limited by the difficulty in accessing the outer annulus. Moreover, nuclear decompression via nucleoplasty mainly relies on lowering the pressure rather than directly removing the extruded disc.

The navigable percutaneous disc decompression (PDD) device L'DISQ™ (U&I Co., Uijeongbu, Korea) was designed to direct herniated disc material through a de novo wand that can be curved by rotating a control wheel. This device ablates the herniated nucleus by using bipolar radiofrequency energy similar to that used in nucleoplasty. It also coagulates the sinuvertebral nerve that innervates the intervertebral disc. Several previous studies have reported the clinical effects of PDD using the L'DISQ in lumbar discogenic pain, but none have yet reported the prognostic factors of the procedure (27,28). Herein, we evaluated various factors

associated with the efficacy of PDD using the L'DISQ for managing lumbar discogenic pain.

METHODS

Patients

We reviewed the medical records of patients who underwent PDD using the L'DISQ following a diagnosis of lumbar discogenic pain from January 2015 through July 2020 at a tertiary university hospital. All procedures were performed by a single physician. The study was approved and informed consent was waived by the Institutional Review Board. This retrospective cohort study was registered with CRIS (Clinical Research Information Service of the Korea National Institute of Health, <https://cris.nih.go.kr/cris/index.jsp>). All procedures were performed in accordance with the tenets of the 2013 version of the Helsinki Declaration.

All medical data were collected via a standardized protocol, and only analyzed after anonymization. The inclusion criteria were as follows: 1) age at least 20 years old; 2) numeric rating scale for pain (NRS pain) score of 5 or more; 3) a diagnosis of lumbar intervertebral disc herniation confirmed using magnetic resonance imaging (MRI) and patient-reported concordant back pain or radicular pain in the lower extremity, or both; 4) pain duration of 3 months or more; and 5) failure to respond to previous epidural injections combined with exercise and pharmacotherapy. The exclusion criteria were as follows: 1) absence of a lumbar spine MRI; 2) a poorly controlled coexisting psychiatric diagnosis; 3) postherpetic neuralgia in the lumbar spinal nerve, or any other condition potentially accounting for the signs and symptoms; 4) lumbar myelopathy or any evidence of central nervous system injury; and 5) the presence of coagulopathy, malignancy, fever, or local infection at the puncture site.

PDD using the L'DISQ

Intravenous access was prepared in advance, and prophylactic antibiotics were injected 30 minutes before the start of the procedure. The vital signs of the patient, including pulse oximetry, electrocardiogram, and blood pressure, were monitored continuously during the procedure. The patient was kept prone, and a pillow was placed under the abdomen to minimize lumbar lordosis. The skin was disinfected with povidone-iodine and draped in a sterile manner. The endplate of the target disc was aligned and the C-arm and was then rotated until the lateral margin of the

contralateral superior articular process passed the posterior three-fifth of the vertebral body. Local anesthesia was administered in this view, while ensuring the needle entry site was 12–15 cm from the midline.

The introducer needle was directed toward the lateral edge of the contralateral superior articular process, where it met the disc margin at the line drawn between the medial borders of the adjacent pedicles in the anteroposterior view. When the needle passed through the annulus fibrosus, the physician felt a sudden loss of resistance. When the needle reached the border of the annulus fibrosus and nucleus pulposus, it stopped advancing (Fig. 1A). The stylet was then removed, and only the introducer was retained. The wand of the L'DISQ was placed into the introducer (Fig. 1B). Depending on the position of the target disc, the lever was pulled and the tip of the wand was adjusted to finally reach the target area of the lesion (Fig. 1C).

After reaching the target area, a low-voltage (0.5–1 V) electrical stimulation was applied. If the patient experienced a momentary, sharp, or sudden aching sensation in the back or the buttock, the tip of the wand was repositioned. The ablation and coagulation modes were used as per established protocols (27,28).

All adverse events that occurred during and after the procedure were recorded. After the procedure, the patient was transferred to the recovery room and vital signs were monitored. After a few hours of recovery, the patient was discharged once a neurological examination confirmed the absence of any abnormalities.

Data Collection

Patient demographic and clinical data, including age, gender, height, weight, smoking history, pain duration, and history of surgery were recorded. The NRS pain scores before and at one, 2, 3, and 6 months after the procedure were assessed. Functional status was estimated using the Oswestry Disability Index (ODI) before and at one, 2, 3, and 6 months after the procedure. The findings of radiographic examinations, including plain radiography and lumbar MRI, were thoroughly reviewed to assess the side of the lesions (unilateral or bilateral), migration of the herniated disc, broadly herniated discs, decreased intensity of the disc on T2-weighted MRI, as well as the presence of high-intensity zones (HIZs), thecal sac compression, spondylolisthesis, central stenosis, and foraminal stenosis. Decreased intensity of the disc on T2-weighted MRI indicated a lack of homogeneity with a hypointense gray or black

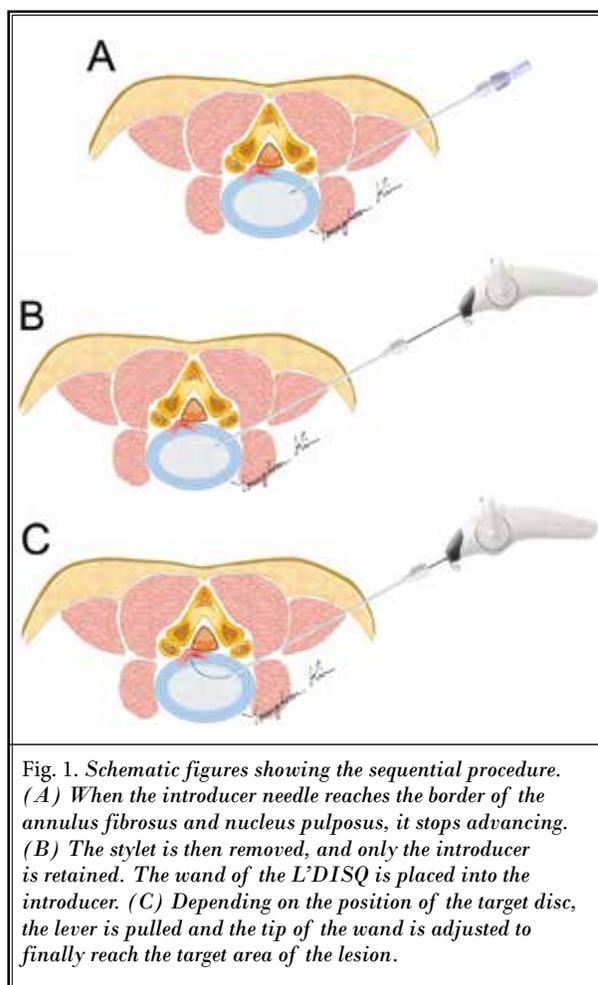


Fig. 1. Schematic figures showing the sequential procedure. (A) When the introducer needle reaches the border of the annulus fibrosus and nucleus pulposus, it stops advancing. (B) The stylet is then removed, and only the introducer is retained. The wand of the L'DISQ is placed into the introducer. (C) Depending on the position of the target disc, the lever is pulled and the tip of the wand is adjusted to finally reach the target area of the lesion.

signal intensity and the loss of distinction between the nucleus and annulus (29,30). Procedure-related variables, including the number of treatment levels and complications over 6 months after the procedure, were also recorded.

Definition of a Successful Outcome

The NRS pain and ODI scores before and at one, 2, 3, and 6 months after the procedure were determined through chart reviews. Patients whose NRS pain scores decreased by 50% or more and whose ODI scores decreased by 40% or more at 6 months after the procedure compared to before the procedure were placed into the successful outcome group. Patients who were lost during the 6-month follow-up ($n = 4$) were placed into the unsuccessful outcome group. According to these definitions, 80 patients had successful outcomes and 26 had unsuccessful outcomes at 6 months after the procedure.

Statistical Analysis

Normality of data was analyzed using the Kolmogorov–Smirnov test for all continuous parameters. Continuous variables were presented as mean and standard deviation (SD) or median and interquartile range, depending on normality. Categorical demographic variables were reported as a number or a percentage. For continuous variables, comparisons of patient characteristics between the groups were made using Student's t-test or the Mann–Whitney U test. Categorical demographic data were analyzed using Pearson's χ^2 test or Fisher's exact test. *P* values less than 0.05 were considered statistically significant. To compare the NRS pain and ODI scores before and after the procedure, the Wilcoxon signed-rank test was performed. The *P* level was adjusted ($0.05/4 = 0.0125$) for the multiple comparisons of the differences in the scores at one, 2, 3, and 6 months versus those before the procedure. To quantify the relationship between successful outcomes and the patients' clinical and

demographic characteristics, binary logistic regression techniques were used. To determine independent positive prognostic factors of the procedure, multivariable logistic regression analysis was performed using variables that were statistically significant in the univariable analysis. By implementing the Hosmer–Lemeshow goodness-of-fit test, the regression model was determined to be appropriate. All data were analyzed using IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Armonk, NY).

RESULTS

Demographics

Patient demographics and clinical characteristics are listed in Table 1. Of the 106 patients included, 74 (69.8%) had unilaterally herniated discs. Migrations of the herniated discs were found in 18 patients (17.0%). HIZs and thecal sac compression were found in 63 (59.4%) and 69 patients (65.1%), respectively.

Table 1. Comparison of demographic and clinical variables between the successful and unsuccessful outcome groups according to the NRS pain and ODI scores.

Variable	Total (n = 106)	Successful (n = 80)	Unsuccessful (n = 26)	<i>P</i> value
Age (years), mean \pm SD	49.8 \pm 14.5	48.7 \pm 12.8	53.3 \pm 18.6	0.244
Gender (men), n (%)	56 (52.8)	41 (51.3)	15 (57.7)	0.568
BMI (kg/m ²), mean \pm SD	23.5 \pm 3.4	23.7 \pm 3.5	22.9 \pm 3.0	0.248
Duration of symptoms (months), median (IQR)	180 (300)	180 (292.5)	210 (300)	0.718
History of smoking, n (%)	16 (15.1)	9 (11.3)	7 (26.9)	0.064
Number of treatment levels, n (%)				
One level	78 (73.6)	55 (68.8)	23 (88.5)	0.048*
2 levels or more	28 (26.4)	25 (51.3)	3 (11.5)	
Side of lesion, n (%)				
Left or right side	74 (69.8)	65 (81.3)	9 (34.6)	< 0.001*
Both sides	32 (30.2)	15 (18.8)	17 (65.4)	
Migration of the herniated disc, n (%)	18 (17.0)	9 (11.3)	9 (34.6)	0.013*
Broadly herniated disc, n (%)	37 (34.9)	12 (46.2)	25 (31.3)	0.166
Decreased intensity of the disc on T2-WI, n (%)	97 (91.5)	74 (92.5)	23 (88.5)	0.686
High-intensity zone, n (%)	63 (59.4)	53 (66.3)	10 (38.5)	0.012*
Thecal sac compression, n (%)	69 (65.1)	46 (57.5)	23 (88.5)	0.004*
Spondylolisthesis, n (%)	15 (14.2)	11 (13.8)	4 (15.4)	1.000
Central stenosis, n (%)	46 (43.4)	32 (40.0)	14 (53.8)	0.216
Foraminal stenosis, n (%)	77 (72.6)	55 (68.8)	22 (84.6)	0.115
History of surgery, n (%)	6 (5.7)	5 (6.3%)	1 (3.9%)	1.000

P values were obtained using Pearson's χ^2 test or Fisher's exact test and Student's t-test or the Mann–Whitney U test. * indicates a significant difference. NRS pain: Numeric rating scale for pain; ODI: Oswestry Disability Index; SD: standard deviation; BMI: body mass index; IQR: interquartile range; T2-WI: T2-weighted magnetic resonance image.

Characteristics of the Successful and Unsuccessful Outcome Groups

Table 1 shows a comparison between the demographic and clinical variables among the patients in the successful versus unsuccessful outcome groups. Among the 106 patients, 80 (75.5%) experienced a successful outcome after PDD using the L'DISQ (Fig. 2). The outcome was significantly better among patients who underwent the procedure at one vertebral level than among patients who underwent the procedure at 2 or more levels ($P = 0.048$). The successful outcome group also included more patients with unilateral disc lesions than those with bilateral lesions ($P < 0.001$). Migration of the herniated disc ($P = 0.013$) and thecal sac compression ($P = 0.012$) were more frequent in the unsuccessful outcome group than in the successful outcome group. However, HIZs were more frequent in the successful outcome group than in the unsuccessful outcome group ($P = 0.012$).

Clinical Efficacy of PDD using the L'DISQ

Figure 3 and Table 2 show the changes over time in the NRS pain and ODI scores after PDD using the L'DISQ. The mean baseline NRS pain and ODI scores

were not significantly different between the successful and unsuccessful outcome groups ($P = 0.391$ for NRS pain score; $P = 0.151$ for ODI score). However, the mean NRS pain scores \pm SD were lower at one month after the procedure than before (77.6 ± 16.2 versus 40.8 ± 23.7 , $P < 0.001$), and were even lower at 6 months after the procedure than before (28.7 ± 22.8 , $P < 0.001$). The mean ODI scores \pm SD were also lower at one month after the procedure than before (56.6 ± 20.3 versus 33.2 ± 17.5 , $P < 0.001$), and were even lower at 6 months after the procedure than before (24.4 ± 16.4 , $P < 0.001$).

Factors Associated with the Prognosis after PDD using the L'DISQ

Table 3 shows the factors associated with the outcomes determined using both univariable and multivariable analyses. Demographic characteristics and variables showing a trend toward statistical significance in the univariable analyses, including bilaterally herniated discs ($P < 0.001$), migration of the herniated disc ($P = 0.009$), HIZs ($P = 0.014$), and thecal sac compression ($P = 0.008$), were included in the multivariable logistic regression analyses. Among the selected clinical

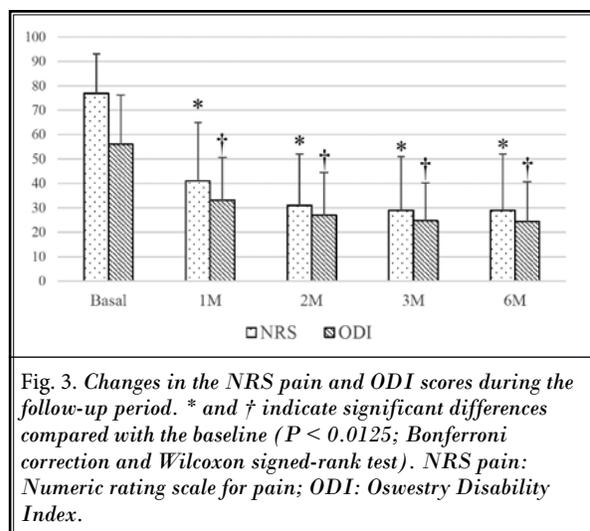
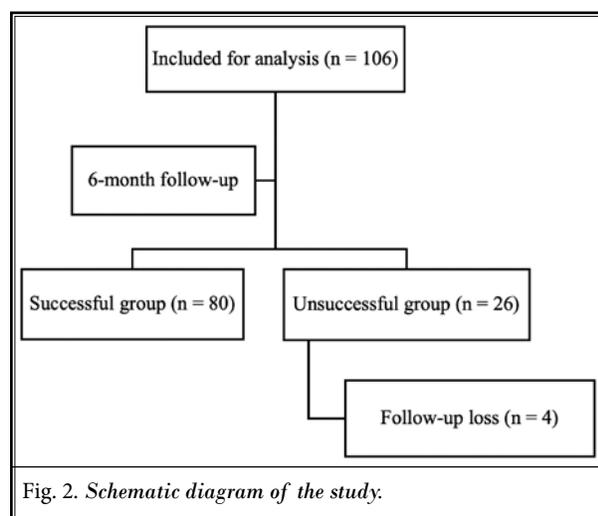


Table 2. Comparison of the NRS pain and ODI scores before and after the procedure.

	Before the procedure (n = 106)	One month (n = 106)	2 months (n = 105)	3 months (n = 105)	6 months (n = 102)	P value
NRS pain	77.6 ± 16.2	40.8 ± 23.7	31.1 ± 21.1	29.1 ± 21.9	28.7 ± 22.8	< 0.001*
ODI	56.6 ± 20.3	33.2 ± 17.5	27.0 ± 17.4	24.7 ± 15.6	24.4 ± 16.4	< 0.001*

Values are the mean \pm standard deviation. Wilcoxon signed-rank test was used to compare the mean \pm standard deviation. Bonferroni correction was used to adjust for the differences in values at one, 2, 3, and 6 months after the procedure versus those before the procedure. * indicates a significant difference. NRS pain: Numeric rating scale for pain; ODI: Oswestry Disability Index.

Table 3. Factors associated with unsuccessful outcomes after PDD using the L'DISQ.

Variable	Univariable analysis		Multivariable analysis (RN2 = 0.407)	
	OR (95% CI)	P value	Adjusted OR (95% CI)	P value
Age	1.023 (0.991 to 1.056)	0.158		
Women	0.771 (0.316 to 1.883)	0.568		
BMI	0.922 (0.804 to 1.058)	0.247		
Duration of symptoms	0.999 (0.998 to 1.001)	0.350		
History of smoking	2.906 (0.958 to 8.818)	0.060		
Procedure at 2 or more levels	0.287 (0.079 to 1.045)	0.058		
Both sides	8.185 (3.060 to 21.894)	<0.001*	6.757 (2.233 to 20.446)	0.001*
Migration of the herniated disc	4.176 (1.440 to 12.112)	0.009*	5.116 (1.337 to 19.576)	0.017*
Broadly herniated disc	1.886 (0.763 to 4.659)	0.169		
Decreased intensity of the disc on T2-WI	0.622 (0.144 to 2.684)	0.524		
High-intensity zone	0.318 (0.127 to 0.796)	0.014*	0.254 (0.083 to 0.774)	0.016*
Thecal sac compression	5.667 (1.572 to 20.426)	0.008*	3.017 (0.723 to 12.595)	0.130
Spondylolisthesis	1.140 (0.330 to 3.945)	0.836		
Central stenosis	1.750 (0.718 to 4.267)	0.219		
Foraminal stenosis	2.500 (0.779 to 8.019)	0.123		
History of surgery	0.600 (0.067 to 5.384)	0.648		

* indicates a significant difference. OR: Odds ratio; CI: confidence interval; BMI: body mass index; T2-WI: T2-weighted magnetic resonance image.

variables, the presence of bilaterally herniated discs (adjusted odds ratio [aOR] = 6.757; $P < 0.001$), migration of the herniated disc (aOR = 5.116; $P = 0.017$), and absence of HIZs (aOR = 0.254; $P = 0.016$) were negative predictors of successful PDD using the L'DISQ.

Complications

Two cases of adverse events were observed in which pain did not improve after the procedure. In one case, the patient subjectively complained of mild weakness immediately after the procedure, but no abnormalities were noted on a neurologic examination. After a few hours of observation in the recovery room, these symptoms disappeared and the patient was discharged. In another case, cauda equina syndrome occurred after one month, regardless of the procedure. This patient opted to undergo spine surgery. Notably, only 4 of the 106 patients who underwent PDD using the L'DISQ received subsequent spine surgery because of insufficient reduction in their pain intensity. No other severe complications associated with the procedure were noted during follow-up.

DISCUSSION

To the best of our knowledge, this is the first study to propose the prognostic predictors for successful PDD using the L'DISQ for the treatment of lumbar discogenic pain. The presence of HIZs, absence of migra-

tion of the herniated disc, and presence of unilaterally herniated discs were positive prognostic factors. A HIZ is a high-intensity signal on T2-weighted MRI located in the annulus fibrosus and is distinct from that in the nucleus pulposus. Aprill and Bogduk (31) reported that HIZs were observed in 28% of patients with symptoms. HIZs have clinical significance as highly specific markers for painful lumbar discs; nevertheless, this notion has been controversial because HIZs are also found in patients without symptoms. In a symptomatic patient with an HIZ and without other causes of lumbar discogenic pain, the HIZ could indicate the problematic disc that causes pain (32). In our study protocol, the target levels were determined on the basis of a combination of the patients' symptoms, physical examination findings, presence of HIZs on lumbar MRI, and response to prior diagnostic epidural blocks. Provocative discography was not performed because previous reports have proved that it could cause disc tissue damage and exacerbate disc degeneration (33,34). Therefore, detecting the presence of HIZs as a definite sign of a pathologic lesion might contribute to successful treatment outcomes because it could help lower the likelihood of overlooking the lesion and delaying treatment.

Migration of the herniated disc may also contribute to lowering the rate of successful outcomes. We postulated that advancing the tip of the wand to the

migrated part of the disc may be technically difficult in such cases. Additionally, if the patient has bilaterally herniated discs, the target treatment area will be wider than that in patients with unilaterally herniated discs. Insufficient lesioning of the disc would also make it difficult to obtain a successful outcome. Minimally invasive disc decompression could be less effective in reducing pain because of insufficient removal of disc tissue in patients with a large disc herniation, disc extrusion, or disc sequestration. This could also be the reason why Sharps and Issac (24) set herniation greater than one-third of the sagittal diameter of the spinal canal, disc extrusion, or disc sequestration as a contraindication to nucleoplasty.

Among the various minimally invasive decompression techniques previously implemented to mitigate lumbar discogenic pain, the current technique differs from nucleoplasty, which also uses coblation technology, because the protruded disc can be removed by directly accessing it using a navigable wand. To date, no study has directly compared nucleoplasty and PDD using the L'DISQ. However, on reviewing studies that reported the effects of nucleoplasty, we noted that Sharps and Isaac's study (24) showed a success rate of 79% based on a 2-point reduction in the pain score at the one-year follow-up after the procedure. In Singh et al's study (26), when the pain score decreased by 2 points or more, the success rates were only 56% 6 months after and 59% one year after the procedure. Although we defined a successful outcome as a 50% or greater reduction in the NRS pain scores and a 40% or greater reduction in the ODI scores after the procedure than the scores before, our success rate was still higher than that of nucleoplasty. We attribute this better clinical effect to the lesioning in the target disc, which was possible via the direct access afforded by the navigable wand, rather than a mere reduction in disc pressure.

Our study differs from existing ones on the L'DISQ (27,28) in that we analyzed a much higher number of patients and obtained a different success rate. Lee et al (27) reported a success rate of 88% 6 months after PDD using the L'DISQ, but their criterion of a successful outcome was based only on a greater than 50% decrease in the pain score. In contrast, we considered not only the pain score but also the functional score in defining a successful outcome; these stricter criteria used for defining a successful outcome could explain the difference in findings. In addition, Lee et al (27) limited the procedure to a single vertebral level, whereas we also analyzed patients with lesioned discs at 2 or more

levels. This could be an additional factor that explains the difference in the success rates.

Since the L'DISQ ablates tissues using bipolar radio-frequency energy, it poses a risk of damaging normal tissues owing to high temperatures, but a previous study using cadavers demonstrated the temperature-related safety of this technique (35). The temperature in the center of the nucleus pulposus did not increase by more than 13°C, and no pathological changes occurred in the surrounding tissues. Nevertheless, buttock or leg pain should be thoroughly monitored during the procedure to avoid any complications. Moreover, if muscle contraction in the lower extremity occurs because of electrical stimulation, the wand tip should be repositioned. In our study, no cases of serious complications were noted because of the careful attention paid during the procedure.

This study has a few limitations. First, owing to the retrospective design, we could not include a control group. It would not be ethically possible to use a sham procedure. Further clinical trials are warranted to ascertain additional objective data about the efficacy of the L'DISQ compared to other procedures. Second, because the characteristics of the disc on MRI were used as a predictor of the procedure, predicting the effect when 2 or more levels were involved became more complicated.

CONCLUSION

In this study, PDD using the L'DISQ was found to be a safe and effective option for treating lumbar discogenic pain. Approximately 75.5% of the included patients showed a 50% or greater pain reduction and at least a 40% functional improvement without any severe complications. The presence of HIZs, absence of migration of the herniated disc, and presence of unilaterally herniated discs could be considered positive predictors for a successful outcome after PDD using the L'DISQ. We hope that these findings will have clinical implications in helping improve the efficacy of PDD.

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Data Availability

The datasets obtained in the current study are available from the corresponding author upon reasonable request.

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