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Efficacy of Single Level Versus Double Levels Surgery of Percutaneous Disc Nucleoplasty (PDN) Approach in Treating Lumbar Disc Herniation

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Background: Although percutaneous disc nucleoplasty (PDN) has been widely applied in treating lumbar disc herniation (LDH) in recent years, the efficacy of surgical levels for PDN on LDH has been reported in limited studies. This study aimed to explore and compare the efficacy of surgical levels (single level vs double level) of PDN in treating LDH.





Material/Methods: All patients diagnosed with LDH from January 2012 to December 2014 in our hospital who underwent PDN were included in this study. Patients were divided into a single-level group and double-level group based on the number of discs/surgical treatment levels. The improvement of visual analog scale (VAS) score, patient satisfaction, and reoperation occurrence were compared between the 2 groups.

Results: Of 105 total patients, 75 patients were treated with single-level treatment and 30 patients with double-level treatment. VAS for leg pain and patient satisfaction scores in the double-level group were worse than those in the single-level group at 6 months after surgery ($P < 0.05$). Among all 105 patients, the incidence of reoperation was 11.4%. Also, there was a marked difference in reoperation occurrence at 6 months after surgery between the single-level (6.7%) and double-level (23.3%) groups; however, the difference was not statistically significant ($P = 0.05$).

Conclusions: PDN is a safe and minimal-invasive approach, which could effectively treat LDH. The number of surgical levels might be an important factor influencing the efficacy of PND. Caution should be exercised to strictly follow the clinical indications for nucleoplasty.

Keywords: **Encephalocele • Intraoperative Complications • Lumbar Vertebrae • Vertebroplasty**

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Background

Approximately 80% of individuals suffer from low back pain at least once during their lifetime, and approximately 55% of that low back pain is related to radicular syndromes [1]. In 1934, Mixter and Barr first reported that lumbar intervertebral discs intruding into the spinal canal is the main cause of sciatica. As awareness of the relationship between herniated discs and radiculopathy increased [2,3], the traditional open discectomy operation proved to be the standard procedure for treating leg pain caused by the radiculopathy of lumbar disc herniation (LDH) [3,4]. In recent years, minimally invasive spinal surgery techniques have been developed. Therefore, intradiscal therapy targeting discs through the percutaneous approach has become a popular procedure in clinical practice [5-8].

Percutaneous disc nucleoplasty (PDN) was approved as a therapy for treating LDH by the FDA in the US in July 2000 [9]. This technique creates a disproportionately large reduction of pressure with a small reduction of volume in a closed hydraulic space [7-9]. In China, PDN, which was accepted there in 2002, has been widely applied for treating chronic low back pain and LDH in the past years [10,11]. Although the nucleoplasty procedure has been applied for treating LDH for more than 20 years, only a few studies focused on the effects of surgical disc numbers (levels) on the satisfaction of patients and reoperation occurrence, even though patient satisfaction and reoperation occurrence have been proven to be critical references for evaluating the efficacy and feasibility of the nucleoplasty procedure [12]. Therefore, this study aimed to explore and compare the efficacy of different surgical levels (single level vs double level) of PDN in treating LDH.

Material and Methods

Patients

In this study, patients who were diagnosed with LDH and underwent PDN from January 2012 to December 2014 were retrospectively monitored and analyzed. Magnetic resonance imaging (MRI) was used to diagnose contained disc herniation. Inclusion criteria mainly included the following: (1) X-ray showed lumbar degenerative changes and preservation of disc height $\geq 50\%$; (2) MRI showed disc herniation, but the integrity of the annulus fibrosus was maintained; (3) there was no leakage of contrast agent on discography; and (4) the participants failed conservative treatment (>3 months). Exclusion criteria mainly included the following: (1) patients aged more than 60 years; (2) patients with segmental instability, spinal canal, or foraminal severe stenosis; (3) extreme lateral disc herniation; (4) demonstrated loss of disc height $>50\%$; (5) calcification of posterior longitudinal ligament or annulus fibrosus; (6) patients

presented with reduced strength of lower limb muscles or cauda equina symptoms; and (7) a history of lumbar surgery.

Ethics Approval and Consent to Participate

The present study was conducted in accordance with the principles of the 1975 Declaration of Helsinki, as revised in 2008. All of the protocols involving patients were approved by the Ethics Committee of the Panyu Hospital of Chinese Medicine. All patients gave their written informed consent to participate in this research.

PDN Procedure

The PDN procedure was performed in an operating room, with patients in the prone position and under mild sedation. The soft tissues were locally anesthetized at a position of 8 to 10 cm laterally to midline spine. The introducer cannula was placed into the target disc's nucleus pulposus, under guidance of fluoroscopy, and at a 30 to 45 degree angle via the annulus fibrosus. During the above procedure, the appropriate cannula placement was verified and directed using anterior-posterior and lateral fluoroscopic images. Importantly, the discography was completed first via the introducer cannula to verify annulus integrity, and then a Perc-DLG Spine Wand (Arthrocare Corporation, Austin, TX, USA) was used (Figure 1). The disc nucleoplasty protocol involved advancing the catheter in ablation-mode and withdrawing the wand in coagulation-mode. A total of 6 channels were made.

Trial Grouping of Patients and Assessment of Clinical Outcomes

Patients in this study were classified into a single-level group ($n=75$) and a double-level group ($n=30$), based on the number of surgical levels used. Patients were assigned to the single-level group when 1 lumbar disc was treated with PDN. Patients were assigned to the double-level group when 2 lumbar discs were treated with PDN. Patients who did not receive single- or double-level treatments were assigned as the control group ($n=184$).

Clinical Outcomes and Follow-Up

The grading of patient sciatica or leg pain was evaluated with a 10-point visual analog scale (VAS) scoring system at various time points. The satisfaction of patients was evaluated using MacNab criteria. Patient satisfaction was categorized into 4 levels, including excellent (without pain, discomfort, or specific neurological signs or symptoms), good (without pain or specific neurological signs, but with mild discomfort), fair (partial relief of neurological signs or symptoms and pain), and poor (without relief of neurological signs and pain).

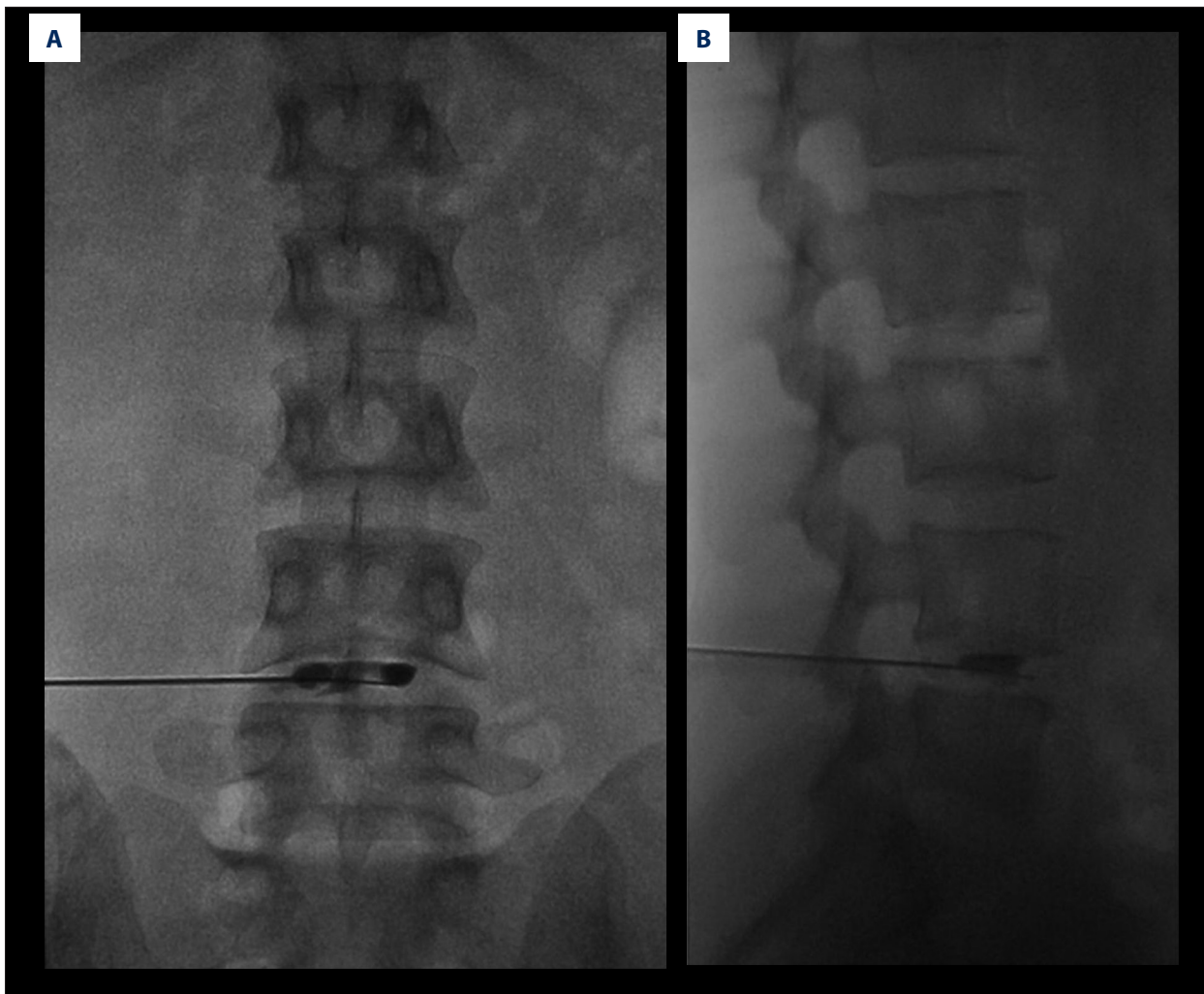


Figure 1. Examination of annulus integrity was necessary prior to nucleoplasty procedure. Fluoroscopic images showed no leakage of contrast agent at the L4/5 level. (A) Anterior-Posterior view. (B) Lateral view.

The clinical outcomes were evaluated before and after surgery. All patients were followed for at least 24 months and follow-up was recorded at 1 month, 6 months, 12 months, and 24 months. The shortest follow-up time was 25 months and the longest follow-up time was 66 months, with a mean follow-up time of 30 ± 20.5 months. The follow-up was conducted by a blinded evaluator.

Statistical Analysis

Data comparisons were analyzed using SPSS version 20.0 (IBM Corp, Armonk, NY, USA). According to the sample size calculation, the samples had sufficient power to perform a correct analysis. Non-normally distributed data, including age of patients, disease history, VAS scores for leg pain, and follow-up time, were compared using the Wilcoxon rank-sum test. Patient satisfaction and incidence of reoperation were evaluated with the chi-squared test or Fisher's exact test. Results

were considered statistically significant when *P* values were less than 0.05.

Results

Basic Characteristics of Patients

Of the recruited patients, 75 patients were assigned to the single-level group (including L3/4, 16 patients; L4/5, 36 patients; and L5/S1, 23 patients), 30 patients were assigned to the double-level group (including L3/4+L4/5, 14 patients; L4/5+L5/S1, 14 patients; and L3/4+L5/S1, 2 patients), and 184 patients were assigned to the control group (**Table 1**). Of a total of 112 patients, 105 patients were finally recruited. A total of 7 patients were excluded for the following reasons: aged more than 60 years ($n=1$), reduced strength of lower limb muscles before surgery ($n=3$), previous lumbar surgery ($n=1$),

Table 1. Basic characteristics of patients in the single-level group and double-level group. *P* values: single-level group vs double-level group.

Characteristics	Single level group (n=75)	Double levels group (n=30)	Control group	<i>P</i> value
Medical history (months)	12.3±6.7	14.1±6.1	13.5±7.5	0.44
Age (years)	44.5±8.8	46.0±10.2	41.7±17.2	0.23
Follow-up time (months)	38.3±8.5	37.5±7.7	29.5±18.8	0.56
Surgical level				
L3/4	16	0		
L4/5	36	0		
L5/S1	23	0		
L3/4+L4/5	0	14		
L4/5+L5/S1	0	14		
L3/4+L5/S1	0	2		

Table 2. Visual analog scale scores of leg pain for patients in the single-level group and double-level group. *P* values: single-level group vs double-level group.

Characteristics	Single level group (n=75)	Double levels group (n=30)	Control group (n=184)	<i>P</i> value
VAS score of leg pain				
Pre-operation	6.4±2.2	6.7±2.4	4.8±1.8	0.65
1 month post-operation	2.5±0.6	2.9±0.7	2.7±1.9	0.29
6 months post-operation	2.7±0.3	3.4±0.2	2.9±1.7	0.02
12 months post-operation	2.8±0.2	3.5±0.3	2.5±1.5	0.01
24 months post-operation	2.7±0.4	3.7±0.3	2.4±1.6	0.01
Final follow-up	2.9±0.3	3.9±0.4	2.3±1.7	0.007

and lost to follow-up (n=2). The medical history, age, and follow-up time of patients in the single-level group and double-level group are illustrated in **Table 1**. The results showed that there were no remarkable differences in medical history ($P=0.44$), age ($P=0.23$), and follow-up time ($P=0.56$) among all the 3 groups (**Table 1**). All study protocols were carried out successfully, without any procedure-associated complications.

Comparison of VAS Scores Between the Single-Level and Double-Level Groups

There were no significant differences in the preoperative VAS scores of leg pain among the single-level group, double-level group, and control group (**Table 2**, $P=0.65$). Also, there were no significant differences in the preoperative VAS scores and the final follow-up VAS scores between the single-level group and the control group (**Table 2**, $P>0.05$). The postoperative

VAS scores were significantly improved compared to the preoperative VAS scores in both the single-level group and double-level group (**Table 2**, all $P<0.05$). No significant difference was found in VAS scores for leg pain at 1 month after surgery between the single-level group and the double-level group (**Table 2**, $P=0.29$). However, the VAS scores of leg pain from 6 months after PDN to the final follow-up visit in the double-level group were significantly worse than those in the single-level group (**Table 2**, all $P<0.05$).

Patients in Single-Level Group Reported Higher Satisfaction

Results showed the patient satisfaction in the control group was significantly lower than that in the single-level and double-level groups at all time points (**Table 3**, $P<0.05$). The findings illustrated that no remarkable differences were found for

Table 3. Patient satisfaction (excellent or good) for patients in the single-level group and double-level group. *P* values: single-level group vs double-level group.

Characteristics	Single level group (n=75)	Double levels group (n=30)	Control group (n=184)	<i>P</i> value
Patient satisfaction				
Excellent or good				
1 month post-operation	84.0% (63/75)	80.0% (24/30)	42.4% (78/184)	0.62
6 months post-operation	80.6% (58/72)	66.7% (18/27)	46.2% (85/184)	0.15
12 months post-operation	77.5% (55/71)	52.0% (13/25)	44.6% (82/184)	0.02
24 months post-operation	74.3% (52/70)	41.7% (10/24)	50.5% (93/184)	0.01
Final follow-up	71.4% (50/70)	39.1% (9/23)	52.7% (97/184)	0.01

Table 4. Reoperation occurrence of patients in the single-level group and double-level group. *P* values: single-level group vs double-level group.

Characteristics	Single level group (n=75)	Double levels group (n=30)	Control group (n=184)	<i>P</i> value
Re-surgery occurrence				
≤6 months	3 (3/75, 4.0%)	3 (3/30, 10.0%)	7 (7/184, 3.8%)	0.23
>6 months	2 (2/75, 2.7%)	4 (4/30, 13.3%)	10 (10/184, 5.4%)	0.05

Table 5. Reoperation at the index level in the single-level group and double-level group.

Characteristics	Single level group (n=75)	Double levels group (n=30)	Control group (n=184)
Within 6 months after PDN			
Discectomy	1	1	3
Decompression	1	2	2
Spondylodesis	1	0	2
More than 6 months after PDN			
Discectomy	1	0	4
Decompression	0	1	2
Spondylodesis	1	3	4

satisfaction of patients at 1 month (84.0% vs 80.0%, $P=0.62$) and 6 months after surgery (80.6% vs 66.7%, $P=0.15$) between the single-level group and the double-level group (Table 3). The combined ratings of “excellent” or “good” satisfaction in patients in the single-level group were markedly higher than those of the double-level group at 12 months after surgery (77.5% vs 52.0%, $P=0.02$), 24 months after surgery (74.3% vs 41.7%, $P=0.004$), and final follow-up (71.4% vs 39.1%, $P=0.005$) (Table 3).

Occurrence of Reoperation

Of the total 105 patients in the single-level and double-level groups, 12 patients (12/105, 11.4%) required reoperation

during follow-up (Table 4). Among these 12 patients, there were only 5 patients (5/75, 6.7%) from the single-level group requiring reoperation; however, 7 patients (7/30, 23.3%) in the double-level group required reoperation (Table 4). Moreover, the reoperation occurrence rate (>6 months) in the single-level group was lower than that in the double-level group (Table 4, $P=0.05$); however, there was no statistically significant difference between the 2 groups. The reoperation occurrence rates in patients of the control group were significantly lower than those of the double-level group ($P<0.05$); however, they were equal to those of the single-level group (Table 4).

Operative Level of Reoperation in the Single-Level and Double-Level Groups

Among the patients requiring reoperation within 6 months after PDN, there was 1 patient with discectomy, 1 patient with decompression, and 1 patient with spondylolysis in the single-level group, and 1 patient, 2 patients, and 0 patients, respectively, in the double-level group (Table 5). Among the patients requiring reoperation more than 6 months after PDN, there was 1 patient with discectomy, 0 patients with decompression, and 1 patient with spondylolysis in the single-level group, while there were 0 patients, 1 patient, and 3 patients, respectively, in the double-level group (Table 5). Moreover, when the reoperation occurred within 6 months after PDN, there were 3 patients with discectomy, 2 patients with decompression, and 2 patients with spondylolysis; and when the reoperation occurred more than 6 months after PDN, there were 4 patients with discectomy, 2 patients with decompression, and 4 patients with spondylolysis (Table 5).

Discussion

In the general population, the incidence of LDH ranges from 1% to 2%. The open discectomy technique is the criterion standard therapeutic strategy for patients diagnosed with large disc herniation with extruded fragments [12,13]. However, in clinical practice, most cases of LDH consist of small and contained disc herniation, without obvious indications for open surgery. In previous years, for LDH patients undergoing poor treatment and without specific surgery indications for open discectomy, interventional protocols would be considered only if necessary [14-17]. The common mechanism for these interventional therapies is that partial removal of the nucleus pulposus can result in intradiscal decompression, pain reduction, and relieved pressure on nerve roots [8,18]. Owing to its high risk of complications, including neurologic injury, anaphylactic shock, and infection, chemo-nucleolysis has not been used in the clinic in recent years [5,8].

Similar to the mechanism of previous percutaneous intradiscal therapies, PDN works through the volumetric reduction of the nucleus pulposus [9,10,18]. The PDN technique implements coblation technology with radiofrequency energy, producing controlled and localized ablation and removal of the partial nucleus pulposus, without increasing damage on surrounding tissues [8,9,11,19]. Mirzai et al [20] reported that nucleoplasty is applicable only for patients with contained disc herniation more than 6 mm and with a disc height equal to or more than 50% [20]. However, Liguori et al [21] documented that disc herniation of patients larger than 1/3 of the sagittal diameter in the spinal canal is appropriate for nucleoplasty [21]. Most researchers acknowledged that annulus fibrosus

integrity is essential to achieve the optimal therapeutic effect of nucleoplasty [8-10,18,20]. Therefore, it is necessary to use discography to examine and verify annulus integrity just prior to nucleoplasty [8,10,20].

There is still controversy in the literature about the effectiveness of nucleoplasty in treating LDH. As Mirzai et al [20] reported, among 52 LDH patients undergoing lumbar disc nucleoplasty, the mean VAS score decreased from a pre-procedural score of 7.5 to 3.5 at 2 weeks after the procedure and to 2.1 at 1 year after the procedure. Further, patient satisfaction was 81% at 2 weeks after the procedure, 85% at 6 months after the procedure, and 88% at the final follow-up. However, Ogbonnaya et al [22] reviewed 27 LDH patients treated with nucleoplasty and observed that 14 patients (51.9%) underwent reoperation of an open microdiscectomy due to a lack of significant improvement of clinical outcomes after nucleoplasty. Wu et al [23] showed that nucleoplasty combined with nerve root injection could significantly improve symptoms of pain and promote patients' functional level compared with a single nucleoplasty treatment at the early stage after surgery.

Among the 105 patients in our study, 75 had 1 disc treated (single-level group) and 30 had 2 discs treated (double-level group). The postoperative VAS scores of leg pain in both groups were significantly better than those before surgery. Further, we found that from 6 months after PDN administration to the final follow-up, VAS scores of leg pain in the double-level group were significantly worse than those in the single-level group. This result suggests that the single-level surgery could alleviate the leg pain of patients. The pain relief rate ((preoperative VAS-postoperative VAS)/(preoperative VAS)×100% [24]) at 1 month after surgery in the single-level group and double-level group was 60.9% and 56.7%, respectively. Moreover, the overall patient satisfaction scores at 1 month after surgery in the single-level group and double-level group were 84.0% and 80.0%, respectively. The VAS improvement and patient satisfaction at 1 month after PDN in the 2 groups were similar to the results reported by Mirzai et al [20]. We found that the improvement of VAS and patient satisfaction in the double-level group decreased from 6 months after surgery, with remarkable differences in clinical outcomes between the single-level group and double-level group. Ren et al [10] reported that nucleoplasty treatment remarkably reduced nonspecific low back pain, with excellent or good satisfaction of 75% (21/28) at the single level, but only 38.5% (5/13) at multiple levels. Carragee et al [25] demonstrated that the removal of the remaining intervertebral disc of patients could significantly reduce risk of re-herniation; however, with less clinical satisfaction. Therefore, we hypothesized that the number of surgical levels could be a factor influencing the effectiveness of nucleoplasty.

Additionally, clinicians should pay attention to the occurrence of reoperation after the PDN procedure. Klessinger et al [26] reported that among 203 patients diagnosed with contained disc herniation or discogenic low back pain, only 18.7% of patients had additional surgery after PDN treatment. In our study, the overall incidence of reoperation was 11.4% (12/105), which was considerably lower than that described by Klessinger et al (18.7%) and Ogbonnaya et al (51.9%), and was similar to the previous open discectomy results (3-13%) [27-31] and former tubular discectomy findings (4-15%) [27,29]. In the present study, patients in the double-level group had more reoperation occurrence than those in the single-level group. A possible explanation is disc re-herniation or the accelerated degeneration of surgical disc after nucleoplasty [26,32]. For successful treatment, it is essential to strictly select diagnostic criteria of the surgical disc and to decrease iatrogenic injury to the target disc. Therefore, compared with some previous studies, the present study not only demonstrated the therapeutic influence of the number of surgical levels of nucleoplasty, but also investigated the reoperation occurrence after nucleoplasty for treating contained LDH. However, the above findings for the efficacy of surgical levels of nucleoplasty on satisfaction and reoperation occurrence after nucleoplasty are not consistent with a former study [33], which reported that multilevel disc decompression was not a risk factor for the failure of treatment. Thus, the efficacy of single or multiple surgical levels on clinical outcome should be further determined in future studies.

There were several limitations in the present study. First, the design of this study was retrospective and observational, therefore it does not represent a high level of evidence. Second, the average follow-up time was about 3 years, and longer follow-up is needed to observe the clinical outcomes. Therefore, longer follow-up results should be collected in the future. Third, we did not compare the treated patients with patients who recovered spontaneously, which would be an interesting and valuable comparison. Finally, this study was not designed with a control group of patients without PDN treatment.

Conclusions

PDN used for patients diagnosed with contained LDH is a minimally invasive technique demonstrating 71.4% satisfaction in patients who are treated at a single level. However, multilevel intervention (double-level surgery PDN) resulted in less patient satisfaction (39.1%). The PDN technique could be used as part of a stepwise strategy for treating LDH. Caution should be exercised to strictly follow the clinical indications for nucleoplasty.

Acknowledgments

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Conflicts of Interest

None.

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