Title: A Retrospective Report of Patients Treated for Lumbar Disc Herniation; Percutaneous Laser Disc Decompression and Open Micro-Discectomy

Running Title: PLDD and Opens Surgery in LDH

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ABSTRACT

Background: Lumbar disc herniation (LDH) is one of the most common pathologies leading to radiculopathy. Open microdiscectomy is the gold standard of treatment for LDH; however, minimally invasive techniques such as percutaneous laser disc decompression (PLDD) are gaining further attention. In this study, we retrospectively reviewed the clinical outcomes of patients who underwent PLDD and compared their results with a group of patients who underwent open micro-discectomy.

Methods: Our report included patients diagnosed with protruded LDH with severe refractory pain for at least 6 to 8 weeks who underwent the interventions. Baseline outcome parameters were recorded before the procedures and questionnaires were filled at two follow-up sessions. Pain intensity was measured using the visual analog scale (VAS), patients were asked to fill the 36-item short-form health survey (SF36) to report their quality of life and we used the Oswestry disability index (ODI) to obtain information about patients' daily functional status.

Results: A total of 165 patients were enrolled. At the final follow-up, there was no statistically significant difference in the level of VAS between the groups. However, the differences between the two groups regarding the SF36 and ODI were statistically significant.

Conclusions: Our study report showed that both methods significantly improved the clinical outcomes of the patients with protruded disc herniation.

KEYWORDS: Lumbar spine; Percutaneous laser disc decompression; Micro discectomy; Protruded lumbar disc herniation; Disc pathologies.

1. INTRODUCTION

Lumbar disc herniation (LDH) is one of the most common pathologies leading to radiculopathy and it has been reported that most of the LDHs occur at the level of L4-L5 or L5-S1 (Amin et al., 2017, Manchikanti et al., 2014). With aging, the spinal disc's proteoglycans production reduces which leads to disc dehydration and collapse. Consequently, annulus fibrosus undergoes strain and tear, resulting in nucleus pulposus herniation. On the other hand, applying heavy biomechanical axial force or inappropriate spinal kinetics also can lead to the extrusion of disc materials (Schoenfeld, Weiner, 2010). LDH is two times more prevalent in males compared to females and often occurs in the third to fifth decade of life (Fjeld, 2019).

Parallel to open micro-discectomy -ass the gold standard intervention for LDH (Sørlie et al., 2016)- minimally invasive techniques such as percutaneous laser disc decompression (PLDD) has recently gained further attention (Ren et al., 2017, Singh et al., 2009). PLDD is believed to be effective in reducing the intra-disc pressure by thermal destruction of intra-disc material and it therefore leads to the indirect relief of nerve root compression which is speculated to deduce the discogenic pain (Choy, 1996, Gangi et al., 1998, Chiarotto et al., 2016). Less invasion to soft tissue structures, faster recovery, and shorter periods of hospital stays are some of the clinical advantages of PLDD comparing to conventional methods. In addition, PLDD can be performed in awake status and this further facilitates its application in patients with concurrent comorbidities (van den Akker-van Marle, 2017). Although, (Botsford, 1994) argued that PLDD is more effective in patients with protruded (versus extruded) herniated discs, there are reports which showed the effectiveness of PLDD in the treatment of other herniated disc subtypes (Choy, 2001).

On the other hand, spine surgeons often select the patients for open micro-discectomy or PLDD based on the intensity of their clinical symptoms, their neurologic status, and the morphology and location of the pathologic disc in the imaging studies (Choy, 1995). Although it has been reported that comparing to open discectomy, PLDD correlates with shorter operative time, less blood loss, and no further complications (Ali et al., 2013), long-term studies have shown no superiority of PLDD over open microdiscectomy regarding the clinical or radiological outcomes (Kreiner et al., 2014, Heider et al., 2017). Moreover, the cost-effectiveness of PLDD is another factor affecting its global acceptance among surgeons (van den Akker-van Marle, 2017).

Reviewing the literature, there are scarce data on the clinical role of PLDD in the treatment of patients with LDH. In the current study, we retrospectively reviewed the short- and mid-term outcomes of patients who underwent PLDD and compared their results with an age- and sex-matched group of patients who underwent conventional open micro-discectomy.

2. MATERIAL AND METHODS

In the present retrospective case series, we gathered the outcome data regarding the patients who underwent lumbar disk herniation intervention between 2017 and 2020 at our university hospital.

2.1. Patients

Patients diagnosed with LDH with severe refractory pain for at least 6 to 8 weeks were eligible to be included in the study. The diagnosis was made based on the clinical evaluations and MRI findings. According to the guidelines of our center, patients with the protruded discs with more chronic yet less severe imaging (Figure 1) and clinical presentations were referred for PLDD while those with a protruded disc with any neurologic compromise were assigned to conventional surgery. All patients with a history of an extruded disc, previous vertebral surgeries, cauda equina syndrome, bone disorders, generalized bulging disc, neurologic disorders (movement disorders, urinary and fecal incontinences), pregnancy, any coagulopathy disease, and reduction of disc height more than 50%, were excluded.

Besides, since coping with the complications of any intervention is relatively subjective and heavily depends on the physical and mental capacity of each patient, the final decision to assign patients into open micro-surgery or PLDD was made based on a surgeon-patient meeting.

2.2. Ethical consideration

This study was conducted in accordance with the ethical standards of the Declaration of Helsinki and was approved by our institutional ethical committee. Written informed consent was provided by all the participants.

2.3. Interventions

All conventional microdiscectomy surgeries were done with the patient in a prone position and under general anesthesia. In this regard, the senior author incised the skin in midline and used the unilateral approach for muscle and soft tissue dissection. In this regard, after subperiosteal muscle dissection and exposure of the lamina, drilling of the lower part of the lamina and the base of the spinous process with minimum resection of the ipsilateral facet joint were done. To overcome the narrow field of the surgery and lighting the surgical field, we used the surgical microscope and under its visualization, the base of the spinous process was further resected. This maneuver provided adequate view of the ligamentum flavum from its superior to the inferior pole where it binds to bony elements. After precise removal of the flavum ligament, thecal sac and nerve roots were retracted medially and herniated disc was completely removed and decompression of the thecal sac and nerve roots were achieved. Finally, the wound was closed in separate layers.

According to the standard technique, PLDD was performed using fluoroscopy guidance and under local anesthesia (Hashemi et al., 2020). The patients were positioned prone and using a posterolateral approach, a 500-micron fiber was placed into the disc space parallel to the inferior endplate. Laser energy of up to 2000 J was delivered to the disc and vaporization of disc water content was confirmed by the interventionist.

Both procedures were performed by expert spine surgeon-interventionists with extensive experience in performing minimally invasive spine procedures. Also, no specific conservative protocol was advised to neither of the groups after the intervention.

2.4. Outcome measures

In this study, multiple validated parameters were used for the evaluation of clinical outcomes. Baseline outcome parameters were recorded before the surgery and questionnaires were filled at two follow-up sessions following the interventions (at 2- and 6-months post-operation). The pain intensity was measured using a visual analog scale (VAS) which ranged from 0 (no pain) to 10 (worst pain imaginable). Also, patients were asked to fill a validated version of the 36-item short form health survey (SF36) to report their quality of life (Montazeri et al., 2005). SF36 measures the physical and social status of the patients in 8 domains. It ranges from 0 to 100 and higher scores indicate lower disability. Furthermore, as the Oswestry disability index (ODI) is one of the most principal tools in the spinal disability's assessment, we used the validated version of ODI to obtain information about patients' daily functional status (Mousavi et al., 2006). The score ranges from 0 to 100 and the higher scores represent higher disability.

2.5. Statistical methods

Kolmogorov-Smirnov test was used to test the normality of the variables. Baseline data were compared between the two treatment groups using the Chi-square, Independent sample t-test, or Mann-Whitney, as applicable. The outcome measures were also assessed in a repeated measurements analysis of variance. The scores were presented as means and standard deviations (SD). Analyses were carried out using SPSS software version 26 (SPSS Inc., Chicago, Illinois, USA). A P-value of less than 0.05 was considered statistically significant.

3. RESULTS

A total of 165 patients (104 females and 61 males) were enrolled in this study with a mean age of 52.1±15.0 years and 63% of the patients were females. Ninety patients (54.5%) with LDH undergone conventional open microdiscectomy and the remaining 75 patients undergone PLDD. The demographic and surgical characteristics of the subjects are summarized in table 1.

According to table 1, 78 (47.3%) patients were diagnosed with a LDH at the level of L4-L5. The mean duration (days) of suffering from severe symptoms prior to the surgery was lower in the open discectomy group, however, the difference was not statistically significant (P=0.12). We observed intra-/post- operation complications in a total of 6 patients. In the PLDD group, 1 (1.3%) patient suffered from temporary paresis of the lower limb and 1 (1.3%) patient had wet tap during the intervention. In the open discectomy group, 1 (1.1%) patient had cerebrospinal fluid (CSF) leak, 1 (1.1%) patient had deep vein thrombosis (DVT), and 2 (2.2%) patients suffered from wound infections at the post-operative course. The intra-group and inter-group comparisons of the outcome measurements are shown in table 2.

According to table 2 and fig 2, the baseline pain intensity was significantly lower among patients in the PLDD group (P<0.001). The mean level of VAS has significantly reduced during the course of our study in both the PLDD and open discectomy groups (P<0.001and P<0.001, respectively). At the final follow-up, there was no statistically significant difference in the level of VAS between the groups.

Our findings showed that the baseline quality of life was significantly lower among those who underwent open surgery comparing to the PLDD group (Fig 3). The score of SF-36 of the patients in both groups significantly improved over the 6 months follow-up of the study (P<0.001and P<0.001, respectively). The inter-group analysis showed no significant difference in the score of SF36 at 2 months post-operation between the groups (P=0.353). However, the mean SF36 score of the open discectomy group was significantly higher than the PLDD group at 6 months post operation (P=0.001).

At the baseline, the functional ability of patients in the surgical group was significantly lower than the PLDD group (P<0.001, Table 2). In both groups, the ODI scores significantly decreased from pre-operation to the 6-months post-operation (P<0.001 and P<0.001, respectively). At 2 months post-operation, the inter-group analysis showed no significant difference in ODI scores between the groups (P=0.50). However, the mean ODI score of the patients who underwent open discectomy was significantly lower than the PLDD group at 6 months follow-up (P=0.001, Fig 4).

4. DISCUSSION

The evolution of various minimally invasive spinal surgeries has provided more feasible choices for both patients and surgeons (Singh et al, 2015). Alternative to the open discectomy, PLDD has shown to be a competent technique (McMillan et al., 2004, Tassi et al., 2004) and is now being the choice of treatment for many surgeons.

In the current study, we retrospectively reported and compared the outcomes of patients with single-level protruded discs who underwent two different interventions for a duration of 6 months. The results showed that the clinical outcomes of both interventions are satisfactory and comparable. Our results also showed a low rate of complications for both procedures.

Based on the guidelines of our institute, cases with more severe presentations are assigned to the open discectomy surgery. Although (Brouwer et al., 2017) argued that PLDD might be more effective among those with acute or subacute symptoms, it is reported by (Peul et al., 2007), a longer duration of symptoms is a risk factor for poor clinical outcomes among those who undergo open microdiscectomy surgery. Therefore, subjects suffering from more severe pain intensity in a shorter timeframe were assigned to open discectomy group by the surgeons.

Patients in both groups showed a significant decline in the severity of pain during the course of our study measured by VAS. In the open microdiscectomy group, the pain intensity was decreased in 2 months and 6 months follow-ups. However, in the PLDD group, there was no significant improvement between 2- and 6-month follow-ups. Therefore, it could be argued that PLDD might decrease the pain severity in short-term and has less impact on pain intensity in longer follow-ups. These findings are not in accordance with the previous study (Brouwer et al., 2017) which has reported slightly lower VAS measures in the surgery group after 8 weeks and 26 weeks.

We also measured the quality of life of the subjects at baseline, 2 months and 6 months post-procedure, via the SF36 questionnaire. At the 2-months follow-up, both techniques achieved relatively similar results, nevertheless, we observed a decline in the SF36 score of the PLDD group at the 6-month follow-up which was statistically different from the open discectomy group. Our results

-in line with the results of a previous study (Brouwer et al., 2017)- could indicate that PLDD might affect the quality of life of the LDH patients more prominently in the short-term.

The disability caused by the LDH was assessed by the ODI and the results revealed that in both groups there was a successful decline in the index. Our study showed that although at 2 months follow-up the mean level score of ODI was relatively similar in both groups, PLDD failed to reduce the disability severity, further at the 6-month follow-up. This again could demonstrate that decreasing the disability is more eminent in the short-term for PLDD. These findings are in consistency with the previous study (Brouwer et al., 2017) which measured the disability with Roland Morris Disability Questionnaire at 8 weeks and 26 weeks. Although the main clinical outcome measures are different, the more efficient short-term results in the PLDD group of our study have been mentioned in the study conducted by (Ren et al., 2017) which revealed that LDH patients improved significantly in a short time after the PLDD.

In summary, our study showed that patients in the PLDD group reached the final outcome in VAS earlier at 2 months compared to the open group; however, the final outcomes in SF36 and ODI measures were statistically significant between the two groups and showed the superiority of open surgery in comparison to PLDD. This issue can be further highlighted considering that patients in the open surgery group had more severe symptoms at the baseline comparing to those who underwent PLDD.

The mechanism of pain reduction in microsurgery and PLDD might be different. Laser irradiation reduces a small amount of nucleus pulposus in the pathologic disc by vaporization, resulting in an immediate reduction of the intradiscal pressure, and withdrawal of disk compression on the nerve root (Choy, Altman, 1995). Additionally, PLDD reduces the inflammatory chemicals produced from the degenerative discs by laser heat generation (Saifuddin et al., 1999). Therefore, these mechanisms could make PLDD an acceptable method for the treatment of the small hydrated protruded discs with a higher intradiscal pressure. On the other hand, the microsurgery targets the mechanical compression of the bulged fragment of the disc regardless of its size, and following the resection of the fragment and irrigations, the inflammatory condition will subside (Brouwer et al., 2015).

Limitations

Due to the retrospective nature of our report, this study has several limitations such as lack of post-operative morphological assessment of disc and surrounding structures via MRI, relatively small sample size, and a short timeframe for patients' follow-up. More importantly, the non-randomized patient selection method and thereby baseline imbalance and a disparity in the proportion of the groups are other limitations of our study worth mentioning. Therefore, further prospective studies and controlled trials need to be performed in order to compare the clinical outcomes of the interventions more precisely.

CONCLUSION

In conclusion, our report showed that although patients with more severe symptoms had undergone open microsurgery, both methods significantly improved the clinical outcomes including pain intensity, quality of life, and functional status of the patients with protruded disc herniation.

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TABLES

Table 1. Demographic and surgery-related characteristics of the patients.

Groups, (n)		**PLDD (75)**	**Open (90)**
Age, mean (SD)		54.5 (16.5)	50.1 (13.4)
Female, n (%)		47 (62.7)	57 (63.3)
BMI, mean (SD)		27.4 (4.8)	26.8 (5.0)
Duration of symptoms prior to the intervention, mean (SD)		101.8 (67.3)	82.0 (71.8)
Surgery level, n (%)	**L2-L3**	1 (1.3)	4 (4.4)
	L3-L4	11 (14.7)	18 (20)
	L4-L5	42 (56.0)	36 (40)
	L5-S1	21 (28.0)	32 (35.6)
Post-operative complication, n (%)		2 (2.7)	4 (4.4)

Table 2. Outcome measures at different timepoints.

Outcome	**VAS ***			**SF36 ***			**ODI ***		
Time	**Base**	**2 m**	**6 m**	**Base**	**2 m**	**6 m**	**Base**	**2 m**	**6 m**
PLDD	4.9 (1.7)	1.9 (1.6)	1.8 (1.3)	50.1 (9.3)	84.6 (6.1)	80.2 (9.9)	49.5 (9.1)	15.6 (5.0)	19.8 (8.6)
Open	7.3 (2.1)	2.7 (1.8)	1.7 (1.0)	40.3 (12.9)	83.7 (5.5)	84.4 (4.6)	59.8 (12.6)	16.1 (5.2)	15.4 (3.7)
P-value	<0.001	0.004	0.808	<0.001	0.353	0.001	<0.001	0.50	<0.001

VAS, visual analogue scale; SF36, 36-item short form health survey; ODI, Oswestry disability index; Data are presented as mean (SD).

(*): The course of change within each group was statistically significant.

FIGURE LEGENDS

Figure 1. T2-weighted MRI of a 31-year-old male with L5-S1 herniated disc who underwent PLDD. Left: sagittal plane, Right: axial plane.

Figure 2. Comparison of visual analog scale (VAS) between the two groups. (*) represents a statistically significant difference between the groups.

Figure 3. Comparison of 36-item short form health survey (SF36) between the two groups. (*) represents a statistically significant difference between the groups.

Figure 4. Comparison of Oswestry disability index (ODI) between the two groups. (*) represents a statistically significant difference between the groups.

FIGURES

Figure 1

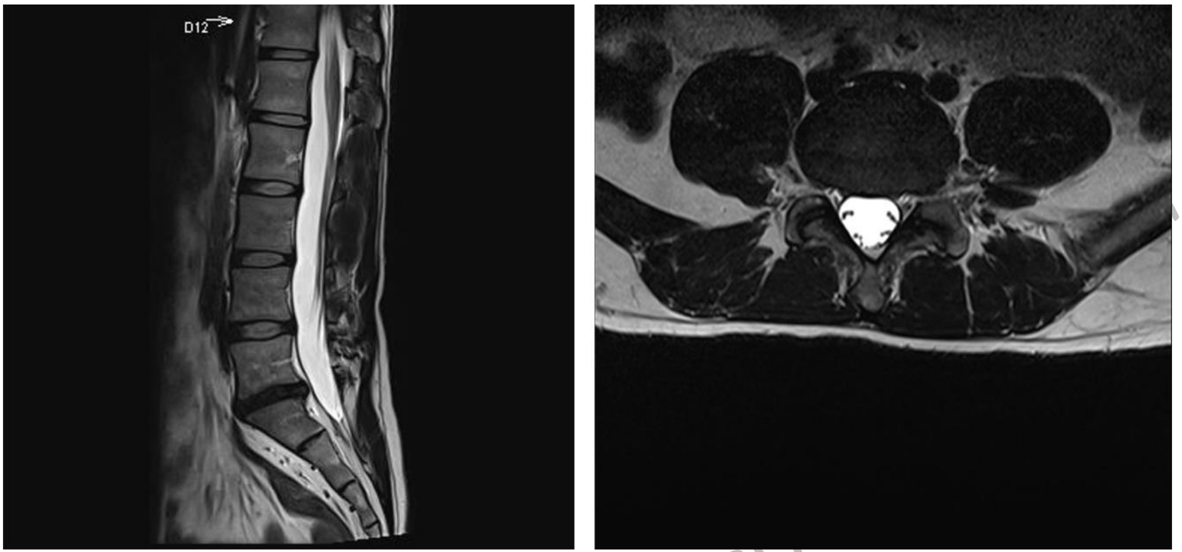

Figure 2

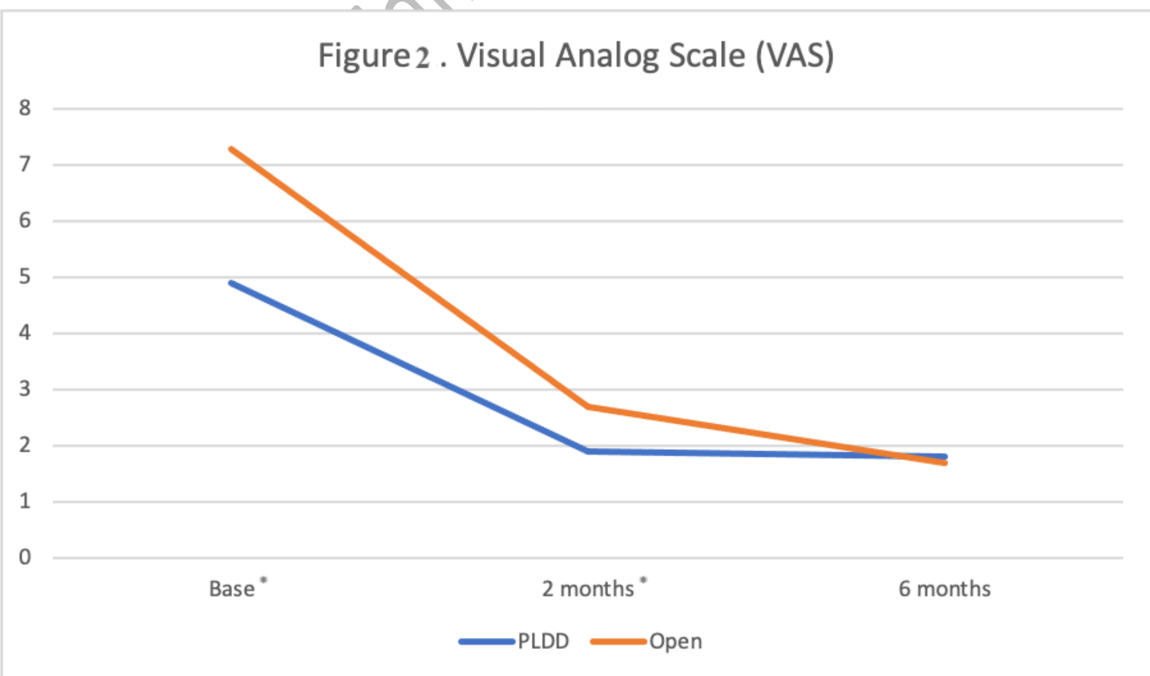

Figure 2 . Visual Analog Scale (VAS)

Figure 3

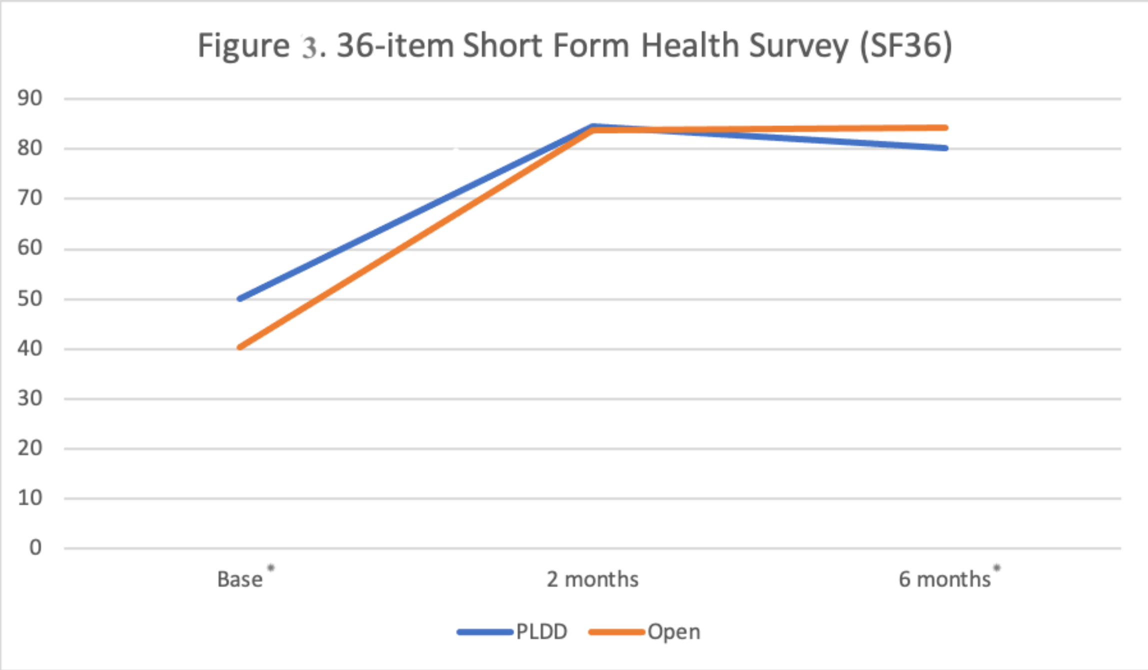

Figure 4