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Surgical Outcomes of Percutaneous Laser Disc Decompression in Lumbar Disc Herniation: Six Years' Experience from Hungary's Largest Neurosurgical Center

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Abstract

Objective: Percutaneous Laser Disc Decompression (PLDD) is a minimally invasive, non-open surgical technique, which uses laser energy to vaporize the nucleus pulposus in a percutaneous way. This technique has been used for over 30 years, but the safety and efficacy of PLDD is still often a concern of both physicians and patients. Some authors even go so far as to doubt that it has benefits at all. Our goal with this retrospective study was to add our clinical experience to this debate.

Patients and Methods: We retrospectively reviewed the data of 141 patients, who had undergone percutaneous laser disc decompression between 2013 and 2017 at the National Institute of Clinical Neurosciences in Hungary. All patients were operated by the same surgeon, according to the same protocol. The demographic and clinical data of the patients were analyzed. Of the demographic data, we used age and sex for the analyses. Clinical data included the levels of the lesion, the number of days from the onset of the symptoms to the intervention, the number of days spent in hospital directly related to the intervention, the frequency and nature of (intra- and postoperative) complications and their management and the frequency of cases when re-operation or any further intervention became necessary because of the failure of PLDD to completely resolve the symptoms. To judge immediate outcome, we used the original Macnab criteria. Short- and long-term VAS scores were also analyzed. The effect of the previously mentioned factors on VAS scores was also analyzed.

Results: The data of altogether 141 patients were analyzed. Of them, 58 were male (41%) and 83 were female (59%). The mean age was 49.43 years. In 81.89% of the cases, L4-5 and L5-S1 segments were affected. In 15 cases, multiple segments were affected. Classification according to the Macnab criteria was possible in 130 cases. The immediate outcome was excellent in 73 cases (56.2%), good in 15 cases (11.5%), fair in 5 cases (3.9%) and poor in 37 cases (28.5%). The recurrence rate was 15%. All complications, observed in 2.1% of the cases, were reversible. Significant improvement of the VAS scores was observed at the 6-week postoperative follow-up, which did not improve further by the 6-month follow-up. The 30% to 63% of those showing significant improvement maintained the excellent outcome for at least 2 years. Neither the demographic variables, nor time from the onset to symptoms and PLDD, nor time from the diagnosis to PLDD, nor the applied amount of energy had a significant effect on the VAS scores.

Conclusion: Our findings, therefore, corroborate the results of other studies and support the idea that PLDD is a safe, efficient and virtually complication-free method for the treatment for lumbar disc herniation, regardless of age and sex, if the patient met the selection criteria. We propose that this method is a logical next minimally invasive surgical step if at least one month's conservative treatment fails.

Keywords: Percutaneous laser disc decompression; Surgical treatment; Long-term outcome; Prognosis; Minimally invasive

Abbreviations

IDET: Intradiscal Electrothermal Therapy; FDA: Food and Drug Administration; LDH: Lumbar Disc Herniation; PLDD: Percutaneous Laser Disc Decompression PLA2: Phospholipase A2; PGE2: Prostaglandin E2; VAS: Visual Analogue Scale

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Introduction

Back pain is the second most frequent cause of admission to the hospital after upper respiratory tract infection [1]. Lumbar disc herniation is the most common cause of the lumbosacral radicular syndrome [2]. Some patients may recover by physiotherapy if started within 6 months of the onset of the symptoms, but the condition often evolves into a severe and debilitating state. For a long time, open surgery and spinal instrumentation were the conventional treatment methods of discogenic pain [2]. Today, a wider range of minimally invasive (percutaneous) procedures are at the surgeon's disposal, such as facet joint corticosteroid injection, medial branch blocks, intradiscal corticosteroid injection, Intradiscal Electrothermal Therapy (IDET), epidural steroid injection, trigger point injection, adhesiolysis, nucleoplasty and Percutaneous Laser Disc Decompression (PLDD) [3]. These procedures are safer, less time-consuming and a shorter hospital stay is needed. They also enable faster recovery and cause less scarring [4]. This latter aspect is important as scar formation after lumbar disc herniation surgery often leads to activity-related pain [5]. PLDD is a minimally invasive, non-open surgical technique, which uses laser energy to vaporize the nucleus pulposus in a percutaneous way [6]. It was introduced into clinical practice in 1986 by Choy et al. [3]. The absorption of the energy leads to vaporization of the water content of the nucleus pulposus, leading to a change in its protein structure, which causes a decrease in intradiscal pressure [7]. Choy et al. have demonstrated that a small decrease in intradiscal volume results in a substantial reduction in intradiscal pressure [8]. It can be hypothesized that the decompressive effects of PLDD reduce the activity of the sensory fibers of the outer annulus, decreasing pain sensation this way [9]. By 2002, over 35,000 such interventions had been performed worldwide [10]. PLDD has several advantages compared to open spinal surgery. Damage to the surrounding soft tissues is minimal, which results in lesser postoperative pain and only minor structural disruption [11]. Furthermore, several studies have shown that PLDD has good clinical efficacy in the treatment of Lumbar Disc Herniation (LDH) [8]. In addition to treating nerve root compression like other minimally invasive techniques, PLDD also reduced the inflammatory factors with the generation of heat by laser irradiation [12,13]. This is an important observation because radiculopathy has been attributed to the excessive production of chemical factors such as Phospholipase A2 (PLA2) and Prostaglandin E2 (PGE2) in the vicinity of the degenerative discs [14]. However, the safety and efficacy of PLDD is still often a concern of both physicians and patients [8,15], and Schenk et al. [13], in their review, concluded that there is not enough scientific evidence for the potential benefits of PLDD. In other words, the technique is still somewhat controversial. Our retrospective overview of pre- and postoperative data of a relatively large number of selected cases done according to the same protocol and by the same surgeon between 2013 and 2017 is an addition to the debate. We sought to describe the patient population to help future patient selection, and we sought to determine the surgical success of PLDD intervention in terms of resolving the patients' symptoms and the necessity of further procedures or lack thereof. Our goal was to help patient selection with our data and to further our knowledge on the safety and efficacy of this procedure.

Material and Methods

A retrospective database analysis was conducted, that included all patients who had been treated for LDH with laser discectomy at the National Institute of Clinical Neurosciences, Hungary between 2013 and 2017. All procedures were performed by the same surgeon, under the same circumstances and according to the same methodology, and with standardized inclusion criteria.

Inclusion and exclusion criteria

The inclusion criteria included contained disc herniation (≤ 3 mm) as demonstrated by Magnetic Resonance Imaging (MRI), persistent pain referring to one or more nerve roots for more than 4 weeks, positive Lasegue's sign [16], lack of paresis and/or vegetative symptoms, and symptoms refractory to at least one month of conservative treatment. Exclusion criteria included the cauda equina syndrome, paresis or plegia, spondylolisthesis, spinal stenosis, previous open surgery at the indicated disc level and pregnancy. Ruptured or extra-large contained discs were also excluded.

Surgical technique

The procedures were performed under local anesthesia, after sedative-analgesic premedication. C-arm fluoroscopy guidance (AP and lateral views) was used to target the appropriate disc. DIOMAX 1550 nm diode laser (KLS Martin, Germany) and a 400 μm bare fiber and PLDD introducer kit with an 18 G needle were used. The needle was placed inside the nucleus pulposus and parallel to the end plates by means of a posterolateral approach under sterile conditions. Laser power was 6 W to 8 W, the exposure time was 500 ms and the pause was 1s. During the procedure, anteroposterior and lateral lumbosacral plain X-rays were obtained in all patients to verify the level of PLDD (Figure 1). We applied an average of approximately 1200 J energy in total per procedure.

Analyzed data

The demographic and clinical data of the patients were analyzed. Of the demographic data, we used age and sex for the analyses. Clinical data included the levels of the lesion, the time from the onset, the number of days spent in hospital directly related to the intervention, the frequency and nature of (intra- and postoperative) complications and their management and the frequency of cases when re-operation or any further intervention became necessary because of the failure of PLDD to completely resolve the symptoms. To judge immediate outcome, we classified the patients according to the original Macnab criteria (at the six-week follow up) [17]. We also had short- and long-term subjective pain assessment data at our disposal. As a routine procedure, pain was assessed in these cases preoperatively, and six weeks and six months postoperatively with a Visual Analog Scale (VAS), where 0 represented complete lack of pain and 10 intolerable pain. These data were also analyzed. VAS scores were available separately for low back pain and pain related

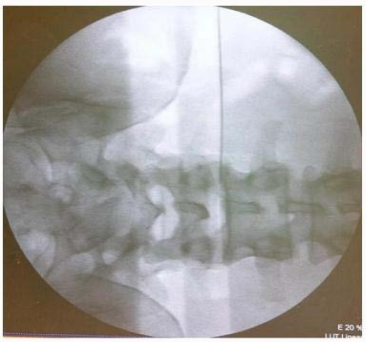

Figure 1: Positional verification with X-ray (anteroposterior view).

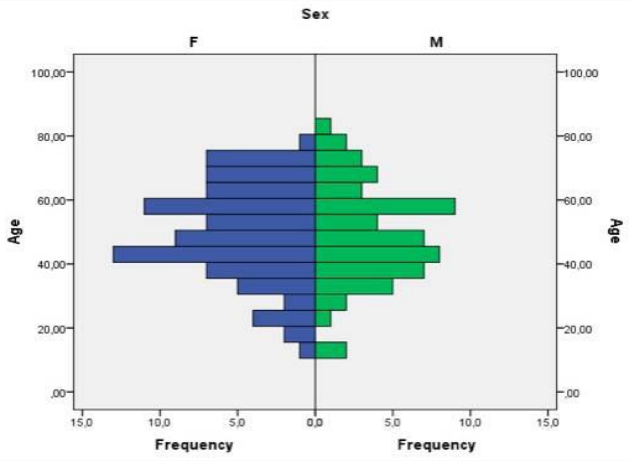

Figure 2: The distribution of the patients' ages by sex.

to the radicular syndrome. Therefore, for each patient, two sets of scores were available for three time points. At six months post op., an average of the scores of the two kinds of pain were calculated for each patient, and those cases where the average score turned out to be below 3.5, were designated for further follow-up to see how long this favourable outcome could last. Pain being the most important and most debilitating consequence of lumbar disc herniation, this parameter is an especially important one. Of the 141 surgeries, 5 were performed in 2013, 19 in 2014, 20 in 2015, 41 in 2016 and 52 in 2017. Thus, for the present analysis, we had 6 years' follow-up data from 5 cases, 5 years' data from 19 cases, 4 years' data from 20 cases, 3 years' data from 41 cases and 2 years' data from 52 cases.

Statistical methods

The data were analyzed in SPSS 22.0 (IBM, USA). Hypothesis tests were applied to VAS scores, and the rest of the variables were interpreted in a descriptive manner. For the continuous variables, we calculated means and standard deviation, and for the categorical variables, frequencies were calculated. As for the analysis of the VAS scores, first, a regression analysis was conducted to test if the demographic variables and time from the onset to symptoms and PLDD, time from the diagnosis to PLDD or the applied amount of energy had a significant effect on either set of the VAS scores. ANOVA with post-hoc analysis was also conducted to compare VAS scores by time of recording. Data analysis was conducted by an independent data analyst who had not been involved with the surgeries and had no previous contact with our team (see Acknowledgements).

Results

Demographic and preoperative clinical parameters

The data of altogether 141 patients were analyzed. Of them, 58 were male (41%) and 83 were female (59%). The mean age was 49.43 years (13 to 81 years, SD: 15.41). The distribution of age was normal in both sexes (Shapiro-Wilk p>0.05). The distribution of ages by sex is shown in Figure 2. The distributions clearly indicate a peak between 40 and 60 years of age. Females were affected slightly (but not significantly) more frequently. An average of 629.41 days (30 to 5400 days, SD: 943.69) passed between the start of the symptoms and PLDD. An average of 70.39 days (1 to 1800 days, SD: 164.36) passed between the diagnosis and PLDD. The prevalence of previous microdiscectomy in another segment was 6% (9 patients). The patients spent an average of 2.14 days in hospital related to PLDD (1 to 15 days, SD: 1.22). The distribution of the affected segments (levels of intervention) is given in Table 1. The preoperative VAS scores are given together with the postoperative scores under 6.2.1.

Postoperative data

Immediate outcome: Classification according to the Macnab criteria was possible in 130 cases (92% of all cases). The outcome was excellent in 73 cases (56.2%), good in 15 cases (11.5%), fair in 5 cases (3.9%) and poor in 37 cases (28.5%).

Visual analog scale: Table 2 Descriptive statistics of the VAS scores. Back: Scores for back pain; Radicular: Scores for pain related to the radicular syndrome. PRE: Preoperative scores; POST6W: Scores 6 weeks after PLDD; POST 6M: Scores 6 months after PLDD. The regression analysis indicated that neither of the demographic variables, nor time from the onset to symptoms and PLDD, nor time from the diagnosis to PLDD, nor the applied amount of energy had a significant effect on either set of the VAS scores, therefore these factors were not taken into consideration for the hypothesis tests. The hypothesis tests (ANOVA with Tukey's HSD) revealed the same pattern for both types of pain: The difference was significant between the preoperative status and the six-week assessment (p<0.000 for both types of pain), but the scores did not improve significantly by the 6 month assessment. A graphical illustration is given in Figure 3.

Table 3 summarizes the follow-up of VAS scores. From 2013 on, the number of PLDDs performed in our institute progressively increased. Drastic improvement in self-reported pain (VAS<3.5) was observed in 40% to 55% of the cases. The ratio was quite stable regardless of which year the procedure was performed in and the number of procedures performed in that year. As also seen in the table, the longer-term success in maintaining VAS<3.5 was more

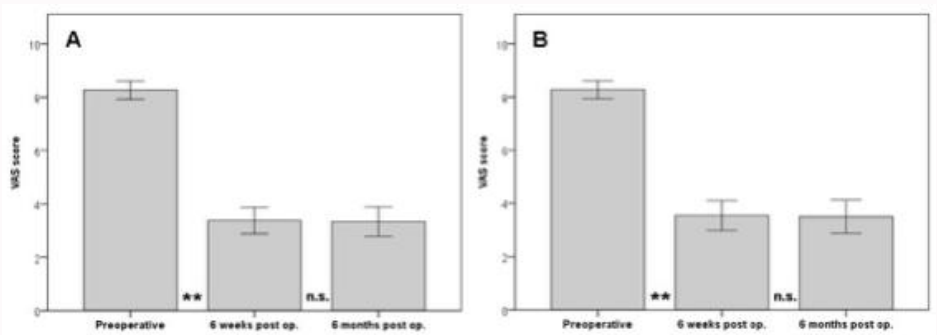

Figure 3: VAS scores A) Back pain. B) Radicular pain.
**Indicates significant difference; n.s. indicates non-significant difference

Table 1: Distribution of the affected segments in the studied patient population (n=138). Data of 3 patients were lost. In the majority of the cases, the segments L3-S1 were affected.

Segments	Number	Percentage
L3-4	10	7.25%
L4-5	79	57.25%
L5-S1	34	24.64%
L2-3 and L3-4	2	1.45%
L2-3 and L4-5	1	0.72%
L3-4 and L4-5	6	4.35%
L3-4 and L5-S1	1	0.72%
L4-5 and L5-S1	5	3.62%

Table 2: Descriptive statistics of the VAS scores. Back: Scores for back pain; Radicular: Scores for pain related to the radicular syndrome. PRE: Preoperative scores; POST6W: Scores 6 weeks after PLDD; POST 6M: Scores 6 months after PLDD.

		Back	Radicular
PRE	Mean	8.27	8.28
	SD	2.045	1.973
POST6W	Mean	3.37	3.55
	SD	2.888	3.225
POST6W	Mean	3.34	3.5
	SD	3.098	3.445

variable, the percentage spans from 30% to 63% (not counting 2013 where the low number of cases clearly has a distorting effect). Of all the analyzed patients who underwent PLDD (N=137, see below), 35 still report VAS<3.5, which means that the ratio of patients with at least 2 years of significant maintained improvement is 25.5%. In other words, one quarter of the patients profited significantly from the intervention considering a longer period. In 55 patients, PLDD brought no significant pain relief. In these cases, the average pre-procedure VAS score was 8.3 for back pain and 8.2 for radicular pain. The average VAS scores were 4.8 and 5.8 at six weeks, which increased to 5.8 and 6.9 at six months (back pain and radicular pain, respectively). Twenty-one of these patients needed open spine surgery, and another 21 required steroid injections after PLDD. Of these 55 patients, 25 were female and 21 were male, with a mean age of 47 years. Immediate and complete pain relief we observed in 38 patients (26.9%).

Complications, reoperation: Discitis occurred in 2 (1.5%) patients, probably due to thermal injury. Conservative treatment resolved this complication in both cases. In 1 case (0.75%) a temporary difficulty of urination developed, which required the insertion of a catheter, but later it resolved spontaneously. PLDD had to be repeated in 11 patients (7.8%) because of the recurrence of the same symptoms or symptoms in other dermatomes. The repeated procedures were performed in another segment or on the contra lateral side of the previously operated segment. In four further cases, recurrence was addressed by other techniques. Thus, the total recurrence rate was 10.63%. As previously mentioned, a total of 21 (~15%) patients had to undergo open spine microsurgical discectomy after PLDD. Also 21 (~15%) patients required steroid injection after PLDD. In these cases, the symptom of the patients was related to the previously affected segment. No death, cord damage or nerve damage occurred. As only a statistically non-meaningful number of multisegmental cases (n=15, 10.6%) were included in this study, multisegmentality was not included as a factor in the statistical analyses. However, we note that these cases did not differ from the rest either in surgical outcomes or complications.

Discussion

The results of our study are quite similar to the findings of other groups, but also somewhat different. Our results agree with most of the studies in that neither sex nor age appears to influence the surgical outcomes in PLDD. As the water content of Nucleus Pulposus (NP) decreases with age and PLDD is based on the concept that the intervertebral disc is a water-filled balloon, it is usually believed that PLDD is more effective in younger patients than in older patients. Ren et al. [11] made continuous follow-up results over 3 years of PLDD for LDH to identify the relationship between PLDD efficacy and age. They found that the efficacy of treatment with PLDD is fairly good for both selected younger and older patients. Our results support this conclusion. We add that even a long time since the onset of symptoms does not appear to be a factor that compromises outcomes, as long as the patient still falls within de inclusion criteria and does not meet any of the exclusion criteria. Regarding the surgical outcomes, we summarize our findings in relation to similar studies as follows. Tassi et al. reported good or excellent outcome of 84% according to the Macnab criteria [18]. Choy et al. [15] reported that such a high percentage, 89% in the study in question, could be maintained over as long as 17 years. Menchetti et al. reported that 68% of their patients had managed to maintain excellent outcome as per the Macnab criteria by the 5th year of follow-up [19]. Gronemeyer et al. observed patients in a 3 ± 2-year period and found that only 43% of the patients remained completely pain-free, which - while the authors do not refer to the Macnab criteria directly - implies excellent outcome [12]. Our results indicate 67.7% good or excellent immediate outcome, which a median of 60% of the patients could maintain for at least two years. As for the complication rates, we had three cases where complication occurred, discitis in two cases, and urination difficulty in one case. This means a 2.1% complication rate, which is higher than the 0.4% rate reported by Choy et al. [15], but the complications were only temporary and reversible in all three cases. Menchetti et al. in their multicentric study also found only mild and reversible complications [19]. Erbas et al. [5] reported that 12.7% of their 197 patients (9 female and 16 male) needed microsurgical discectomy after PLDD, which is in line with our finding of 15%. In contrast to the study of Gronemeyer et al. [12], who reported that 15.5% of their patients experienced no pain

Table 3: A summary of the follow-up of VAS scores (N=137). *Missing: in the case of five patients, we could not retrieve VAS data.

Year	Total(N)	<3.5 at 6 m (N)	% of total	Years Since op.	<3.5 (N) 2019	% of 6m	Missing*
2007	52	25	48.08	2	15	60	0
2006	41	20	48.78	3	6	30	0
2005	20	11	55	4	7	63.64	0
2004	19	10	-52.63	5	5	50	0
2003	5	2	40	6	2	100	0

relief at all after PLDD, we found no such cases. All of our patients experienced at least temporary pain relief (which was complete relief in 26.9% of our patients), as indicated by their VAS scores, even those in whom this relief never reached the statistically significant extent. Regarding the VAS scores, the study of Menchetti et al. [19] was the only one of the bigger studies to combine the Macnab criteria with VAS scores. They reported that in those patients who managed to maintain the excellent outcome, the average VAS score was 3.4, almost exactly the same as what we found at the six-month follow-up and after two years in a quarter of our patient population. While we have only our results and those of the Menchetti group to draw conclusions from, it appears safe to assume that 3.5 on the 10 point VAS score is an achievable long-term goal with PLDD. Our findings, therefore, corroborate the results of other studies and support the idea that PLDD is a safe, efficient and virtually complication-free method for the treatment for lumbar disc herniation, regardless of age and sex. We propose that this method is a logical next minimally invasive surgical step if at least one month's conservative treatment fails. Care must be taken, though, that the technique is used only in selected cases, according to the well-established eligibility criteria. However, it must be seen that the outcomes are still variable. All studies on PLDD suggest that the intervention yields high immediate success in 60% to 80% of the patients, and a considerable percentage of those patients remain symptom-free in the long run. In contrast, there is always a therapy-resistant fraction, and the remaining patients profit from PLDD to variable degrees. It is this latter patient population because of whom further studies are needed so that we can enhance our eligibility criteria and offer this otherwise efficient and minimally invasive therapy to the highest number of those in need of it. Furthermore, while we measure pain and functionality as indicators of surgical success, we know strikingly little about how this intervention influences our patients' quality of life, while the instruments for such studies do exist, such as the Oswestry Disability Index or the SF-36 health survey [20-22].

Conclusion

Based on our experience, our present findings and data published in the literature, we highly recommend PLDD as a first minimally invasive surgical choice for lumbar disc herniation, but we propose that there are aspects that still need to be explored. Of such aspects, we consider the long-term maintenance of the favourable outcomes, the reasons behind failure, and effects on patients' quality of life the most important ones.

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