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Original Article

Is trans-sacral endoscopic laser decompression truly effective? Clinical and functional assessment of a single spine center

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ABSTRACT

Background: Herniated nucleus pulposus (HNP), without causing significant neurological deficit, is a more frequently occurring disease of the spine affecting the activities of daily living with chronic back pain and sometimes progressing to produce significant functional deficit. Trans-sacral epiduroscopic laser decompression (SELD) is being increasingly used as a treatment modality for these conditions and has been shown to give effective results. We present the clinical outcomes of the patients undergoing SELD in our institute for HNP.

Methods: A retrospective study of 411 patients who underwent SELD for lumbar disc herniation was done, analyzing the clinical outcomes by measuring visual analog scale (VAS) scores for leg pain and back pain, Oswestry Disability Index (ODI) score, and Short form health survey (SF -36) scores and followed up for 6 months.

Results: A total of 195 males and 216 females underwent SELD, with a mean age of 33.2 ± 0.9 years and a mean follow-up period of 7 ± 1.6 months. VAS scores for back pain and leg pain improved significantly from 6.9 ± 0.5 and 6.6 ± 0.6 preoperatively to 1.1 ± 0.5 ($P > 0.05$) and 0.4 ± 0.5 ($P > 0.05$) at 6 months. ODI score decreased from 28.2 ± 1.7 to 9.4 ± 1.7 at 6 months from the intervention ($P < 0.05$). SF-36 showed significant improvement in overall categories through 6 months of follow-up. Twenty-four patients had dural punctures, and four patients needed blood patches but recovered without any complications. One patient had aggravation of the disc herniation post-procedure, and was managed by endoscopic discectomy.

Conclusion: SELD is a safe, accurate, and effective procedure in treating symptomatic lumbar disc herniation with excellent clinical outcomes and effective pain relief with minimal damage to paraspinal muscles with an easier learning curve, reproducible results, and high safety index.

Keywords: Holmium: Yttrium-aluminium-garnet laser, Lumbar back pain, Minimally invasive, Trans-sacral epiduroscopic laser decompression, Visual analog scale score

INTRODUCTION

Epiduroscopy is a percutaneous minimally invasive procedure used for various diagnostic and therapeutic purposes in the lumbosacral area. It involves the use of a flexible epiduroscope entering epidural space through sacral hiatus for various indications such as epidural drug delivery, epidural catheter placement and diagnosis, adhesiolysis, laser decompression of disc herniation, and spinal cord stimulation electrode implants. The concept of epiduroscopy was introduced

in 1931 and was first used for diagnosing epidural lesions such as disc herniation, venous congestion, and neuritis.[20] The first flexible fiberglass endoscope was developed in 1958,[22] which led to the development of the currently used epiduroscope along with the use of scope and laser for various applications used in current times. United States Food and Drug Administration (US-FDA) in 1996 approved Myelotec Myeloscopy (Myelotec, Inc., Great Neck, NY), which visualizes the epidural pathology through a scope introduced through sacral hiatus. Eventually, the sacral epiduroscopic laser decompression (SELD) technique was developed using fiber optics, light source, and laser technology for treating various lumbosacral pathology. The procedure of epiduroscopy was described in three generations. The first generation used a blind technique where the lumbar pathologies were addressed under fluoroscopy guidance, which had no precision and relied on mechanical and chemical adhesiolysis, such as percutaneous epidural neuroplasty (PEN).[21] The second generation included the percutaneous epidural balloon neuroplasty (PEBN), which included a steerable catheter with an inflatable balloon tip used for mechanical adhesiolysis, also with those of the PEN technique, which showed better outcomes.[12] At present, a third-generation technique is used wherein a steerable catheter with two lumens through which a scope is introduced and the pathological lesion is reached precisely under video guidance. Furthermore, the laser system is used to ablate the pathological lesion which is passed through the second lumen.

In the early 2000s, SELD saw extensive applications in various pathologies such as adhesions, spinal stenosis, soft and hard disc herniations, chronic back pain, and failed back syndrome.[3,4,6,7,9,10,16,18,19] The use of lasers for direct decompression of the ruptured annulus works by vaporizing the bulging disc, adhesiolysis of structures around the nerve root, cauterization of sinovertebral nerve, and saline irrigation of inflammation.[13-15,23] Thus, the true indication for SELD was narrowed down to soft disc herniation.[17]

Very few papers have published the clinical outcomes of SELD used in the treatment of soft disc herniations. We reviewed the clinical outcomes of patients treated with SELD for lumbar disc herniation in a single institute.

MATERIALS AND METHODS

The design was a retrospective analysis of the data collected routinely and was conducted in accordance with the Declaration of Helsinki, and a government owned public Institutional Review Board waiver was given.

The study was an analysis of patients who underwent trans-SELD for lumbar disc herniation between July 2019 and September 2022 in the institute. Three spine surgeons of the institute performed all the procedures. The three surgeons and their teams did preoperative and postoperative clinical and radiological measurements as a part of their routine follow-up. All patients satisfying the inclusion criteria were included in the study.

The inclusion criteria were as follows:

1. Persistent low back pain with/without radicular pain in leg not responding to adequate conservative treatment
2. Concurrent magnetic resonance imaging (MRI) confirms features of mild-to-moderated soft disc herniation.

The exclusion criteria were as follows:

1. Severe motor weakness (Medical Research Council grade 3 or less)
2. Hard disc
3. Foraminal disc herniation
4. Severe spinal stenosis (Grade B) or instability
5. Infection
6. Bleeding diathesis/history of epidural hematoma (EDH)
7. Anatomical abnormalities of lumbosacral region
8. Previous history of lumbar surgery
9. Multilevel procedure
10. Insufficient/incomplete follow-up of 6 months.

Clinical data such as age, gender, diagnosis, operating level, and complications were noted. Clinical outcomes were measured using a visual analog scale (VAS) for leg pain and back pain, Oswestry disability index (ODI), and SF-36 score. A preoperative MRI of the lumbar spine was done to confirm the diagnosis. Analyses were performed using the Statistical Package for the Social Sciences software for Windows (version 25, 2007, IBM Corporation, Armonk, New York, United States). Data presented as Mean ± Standard deviation or Median (25^{th}–75^{th} quartile) or frequency (percentage). The normality of data was assessed using the Shapiro–Wilk test. As the data were not normally distributed, change in parameter postoperation was assessed using the Friedman test for repeated measures after adjusting for Bonferroni correction. Change in SF-36 was assessed using the Wilcoxon sign-rank test for patient outcomes. $P < 0.05$ was considered to be statistically significant.

Procedure

Instruments

A video-guided catheter of 3.3 mm (Myelotec) with two lumens, 1.15 mm for epiduroscope, and 1.75 mm for instruments was used [Figure 1]. 1 mm flexible epiduroscope, the flexible fiber of 550 μm diameter was used to pass holmium: yttrium-aluminium-garnet (Ho: YAG) laser of high quality, 2100 nm wavelength, and 0.4 mm penetration depth was used to provide adequate ablation of hydrated disc with negligible risk of thermal injury to neural structures along with continuous hydration.

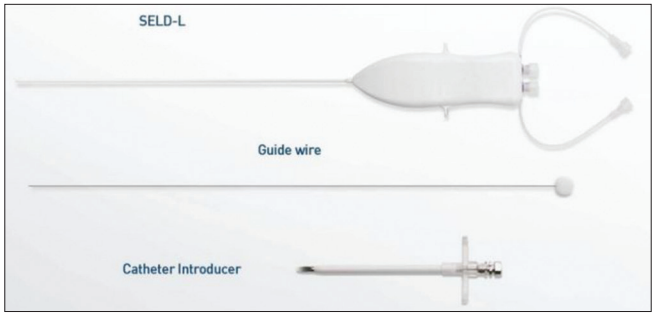

Figure 1: Sacral epiduroscopic laser decompression-L (SELD-L) with lumen dimensions.

Technique

After explaining the patient about the procedure and getting informed consent, the procedure is performed under local anesthesia using lidocaine over the sacral hiatus. The patient was positioned on a radiolucent table with a Wilson frame in the prone position; the bolsters were H shaped to decrease the intra-abdominal pressure and obliterate the lumbar lordosis. The patient is wide awake with continuous vitals monitoring communicating with the team regarding the pain responses.

A 5 mm stab incision was made on the sacral hiatus, and a trocar was introduced under fluoroscopic guidance to pierce the sacrococcygeal ligament, and the video-guided catheter was introduced into the ventral epidural space through the trocar. The position of the catheter in the ventral epidural space was verified using fluoroscopy, and then, the catheter was advanced along the ventral epidural space, steering it in lateral planes to reach the desired level and side under continuous anteroposterior and lateral plane monitoring of fluoroscopy, along with visual monitoring using the epiduroscope passed through 1 lumen of the catheter. Once the designed position is reached, the fiber of the Ho: YAG laser, which is in the second lumen, is advanced to the tip of the catheter, and the laser target area is illuminated green before it is used. The radio-opaque dye was introduced in the ventral epidural space, with the epidurogram showing the inability of the dye to pass beyond the pathological level due to the bulging posterior longitudinal ligament due to herniated nucleus pulposus and adhesions [Figure 2a]. Once confirmed, the laser is used to ablate and dehydrate the disc, causing it to shrink along with continuous saline irrigation, thus further reducing the risk of thermal injury and reducing bleeding due to hydrostatic pressure. Once the bulge visibly shrinks, the radio-opaque dye is passed to reconfirm the same which shows flattening of the bulge and free from beyond the pathological level [Figure 2b]. The sinuvertebral nerve and adhesiolysis of nearby nerve roots were cauterized [Figure 2c], and the inflammation was also irrigated [Figure 2d]. Steroid and saline irrigation was done finally before withdrawing the catheter, closure was done with adhesive glue, and dressing was done.

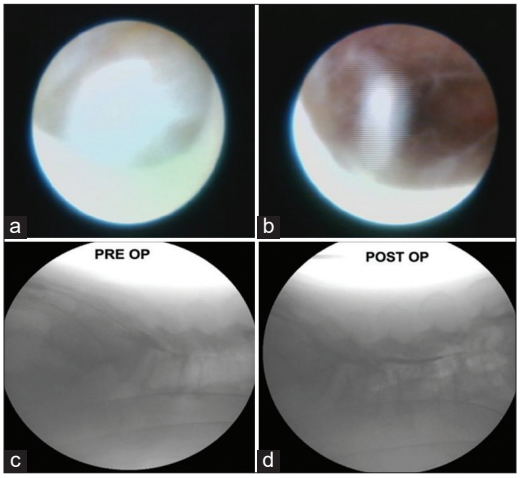

Figure 2: (a) Pre-procedure epiduroscope view (disc bulge in white), (b) post-procedure epiduroscope view (disc bulge cleared), (c) pre-procedure epidurogram, and (d) post-procedure epidurogram.

RESULTS

A total of 429 patients underwent SELD from July 2019 to September 2022. Eighteen patients were excluded from the study due to the short follow-up period and loss to follow-up leading to a total of 411 patients completing the study. There were 195 males and 216 females, mean age of 33.2 ± 0.9 with a mean follow-up period of 7 ± 1.6 months. The levels involved were L2–3 (56 cases, 13.6%), L3–4 (63 cases, 15.3%), L4–5 (169 cases, 41.2%), and L5–S1 (123 cases, 29.9%). The mean procedure time was 16.6 ± 7.1 min [Table 1].

Postoperative clinical parameters showed significant improvements with VAS back pain score improved significantly from 6.9 ± 0.5 preoperatively to 1.2 ± 0.5 at 3 months ($P < 0.05$) and to 1.1 ± 0.5 at 6 months ($P > 0.05$) [Table 2]. Similarly, the VAS leg pain score improved significantly from 6.6 ± 0.6 preoperatively to 0.5 ± 0.5 at 3 months ($P < 0.05$) and 0.4 ± 0.5 at 6 months ($P > 0.05$) [Table 3]. Preoperative mean ODI score decreased from 28.2 ± 1.7 to 9.4 ± 1.7 at 6 months from the intervention ($P < 0.05$) [Table 4]. SF-36 showed significant improvement across all the subcategories throughout follow-up till 6 months [Table 5]. The postoperative pain at the stab site was managed by oral analgesics, leading to early recovery, and all of the patients without complications were recovered to be able to discharged on postoperative day 1. Five patients had EDH-related symptoms manifesting as low back pain and numbness in the legs, with a VAS score of ≤3. Four of them were managed conservatively by observation, and one was washed out by epiduroscope. Twenty-four patients had a dural puncture during the procedure, 20 of which were observed for 2 days with bed rest and minimal mobilization, including bathroom and seated eating. Four patients were managed with a blood patch, and all had excellent outcomes.

Table 1: Demography.

Characteristics	Mean±SD	Minimum–Maximum
Age (years)	33.2±0.9	19–61
	Frequency	**Percentage**
Gender		
Males	195	47.4
Females	216	52.6
Level		
L2–L3	56	13.6
L3–L4	63	15.3
L4–L5	169	41.2
L5–S1	123	29.9

SD: Standard deviation

Table 2: VAS back pain.

	Mean±SD	Minimum–Maximum	*P*-value in comparison to the previous time point
Preoperative	6.9±0.5	6–8	---
Day 1	3.5±0.6	2–5	0.001
Day 7	2.9±0.8	1–4	0.001
1 month	1.2±0.5	0–2	0.001
3 months	1.2±0.5	0–2	0.999
6 months	1.1±0.5	0–2	0.999

P-value derived using the Friedman Test for repeated measures after adjusting for Bonferroni correction. SD: Standard deviation, VAS: Visual analog scale

Table 3: VAS leg pain.

	Mean±SD	Minimum–Maximum	*P*-value in comparison to the previous time point
Preoperative	6.6 ± 0.6	6–8	---
Day 1	2.6 ± 0.8	2–6	0.001
Day 7	2.4 ± 0.6	1–3	0.001
1 month	1 ± 0.5	0–2	0.001
3 months	0.5 ± 0.5	0–1	0.001
6 months	0.4 ± 0.5	0–1	0.999

P-value derived using the Friedman Test for repeated measures after adjusting for Bonferroni correction. SD: Standard deviation, VAS: Visual analog scale

One patient had aggravation of the disc herniation post-procedure, and was managed by endoscopic discectomy with excellent outcomes. No infections or worsening of neurology were noted.

DISCUSSION

Lasers have been used as early as 1984 for disc ablation and reduced disc size with excellent clinical outcomes first documented by Ascher and Heppner[1] using carbon dioxide and Nd lasers. At present, Ho: YAG lasers work on the principle of the vaporizing effect of hydrated disc as the water absorbs the energy of wavelength of 2000 nm, and Ho: YAG wavelength is close to it with a pulse duration of 350 μs with <0.4 mm fluid absorption thus providing a safe and effective ablation with minimal thermal damage.[11,16,18]

Table 4: ODI.

	Mean±SD	Minimum–Maximum	*P*-value in comparison to the previous time point
Preoperative	28.2±1.7	26–35	---
Day 1	26.4±1.4	24–30	0.001
Day 7	22.2±1.6	18–26	0.001
1 month	15±1.6	12–18	0.001
3 months	12.4±1.1	10–18	0.001
6 months	9.4±1.7	6–13	0.001

P-value derived using the Friedman Test for repeated measures after adjusting for Bonferroni correction. ODI: Oswestry disability index, SD: Standard deviation

The US-FDA approved epiduroscopy in 1996, after which there was significant development till reaching the current day SELD technique and saw applications not just in soft disc herniations but also spinal stenosis, spinal cysts, chronic back pain, adhesions, and failed back syndrome.[2,4,6,8,10,14,16,19] However, considering the principle of laser above explained, the use of SELD can be justified in its use for ablation of soft disc herniation as more permanent, and the other effects of mechanical adhesiolysis or drugs used concurrently are transient.[5,15,17]

The authors consider the third-generation video-guided laser ablation to have a distinct advantage over the preceding generations, whereas, in the first generation, PEN had a blind technique and relied only on fluoroscopy and mechanical and chemical adhesiolysis. The second-generation PEBN, though it had a steerable catheter, relied on mechanical clearance of adhesions with the aid of a balloon, but stenosis always had the chance of recoil as it was just pushed, not cleared. The third-generation SELD has the greatest benefit of early and more permanent resolution of the pain due to its precision of location due to video guidance and the effectiveness of ablation due to laser ablation of the lesion. The second distinct advantage seems to be slowing down and sometimes halting the progress of the disease, which is truer in younger patients. The annular protein, after laser firing, denatures and forms a thicker, firmer band, thus tightening and converting to a tough band, preventing more herniation of the nucleus pulposus.

Lee *et al.*,[17] in 2016, studied a total of 250 patients who underwent SELD for lower back pain and radiculopathy by

Table 5: SF-36 score.

	Preoperative		6 months postoperative		*P*-value
	Mean±SD	Minimum–Maximum	Mean±SD	Minimum–Maximum	
Physical health	16.3±4	5–20	100±0	100–100	0.001
Role physical	0±0	0–0	100±0	100–100	0.001
General Health	0±0	0–0	100±0	100–100	0.001
Bodily pain	26.3±5.8	15–40	83.9±2.5	80–90	0.001
Emotional well-being	37.2±3.2	32–44	93.2±1.8	92–96	0.001
Role emotional	28±6.4	25–50	100±0	100–100	0.001
Energy vitality	27.3±6.1	22–45	100±0	100–100	0.001
Social function	23.3±6.7	15–35	95.1±8.9	75–100	0.001
Health change	0–25	0–25	100±0	100±0	0.001

P-value derived using Wilcoxon sign-rank test. SD: Standard deviation

definitive neural compression documented on MRI using Ho: YAG laser and measured the clinical outcomes. They noted a significant improvement in VAS scores of leg pain from 7.1 to 3.6 and back pain from 5.9 to 4.1 at 2 weeks and 2.6 and 2.7, respectively, at 3 months. ODI scores improved from 50 to 19 at 2 weeks and 12 at 3 months, and a significant reduction in the size of herniation in postoperative MRI scans. They suggested SELD as an effective treatment modality for patients with symptomatic lumbar disc herniations.

Son *et al.*,[23] 2020, published a study where 82 patients underwent one level SELD for symptomatic lumbar disc herniation and did a 6 month follow-up. They noticed a significant improvement in VAS leg pain and back pain from 5.43 ± 1.73 and 6.10 ± 1.67 to 2.8 ± 1.43 and 3.58 ± 2.08 at their final follow-up; the success rate was 58.5% according to Odom's criteria. They noted no significant surgery-related complications, and 17% of the patients needed additional procedures during follow-up. They concluded that SELD has less favorable clinical outcomes in treating lumbar disc herniation and suggested further studies with a larger cohort, as the findings were not in line with other studies.

In our present study, five patients developed EDH, and four were managed conservatively due to the size of the hematoma. Of the 24 dural punctures encountered, most of them were during the early part of the study, where the experience was limited and as the surgeons got familiar with the procedure, these reduced drastically. Furthermore, we noted that ten of them had ventral filum terminale, five had central wide filum terminale, and nine had perineural cysts, leading to an increased risk of dural puncture [Figure 3]. The authors suggest initiation of saline irrigation as soon as the sacro-coccygeal ligament is crossed which, in turn, helps create a path for advancement of the catheter the virtue of hydro dissection.

The authors emphasize the limitations of the technique, including the smaller field of view through epiduroscope and poor picture quality in the closed epidural space, thus

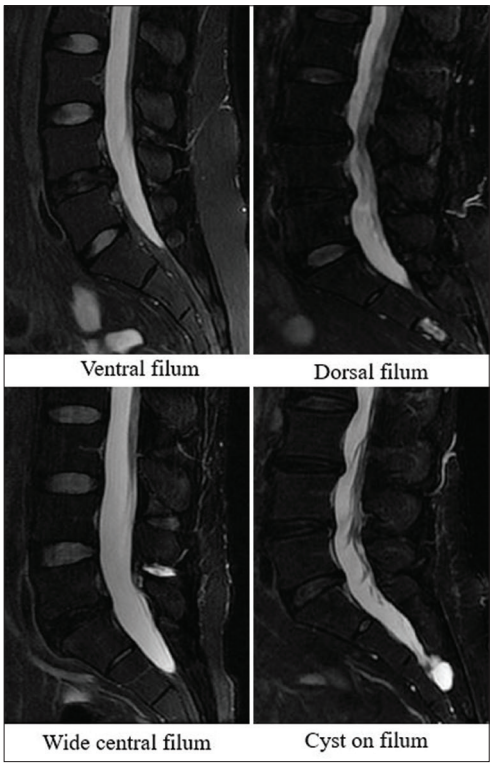

Figure 3: Variants of filum terminale.

decreasing the visibility and restricting the ablating ability. The improvements in video quality and wider-angle optics will address this. Second, there is a limitation in the amount of disc tissue that can be ablated due to the penetration of the laser, which, in the future, may be overcome by side firing laser with better penetration. The study had a few limitations. The study was retrospective; hence, all the variables were not under control. The post-procedure MRI was not done routinely as there was a clinical improvement and was cost effective. Future studies with larger sample sizes and with post procedure MRI to document the sizes in disc would be suggested.

CONCLUSION

SELD is a safe, accurate, and effective procedure in treating symptomatic lumbar disc herniation with excellent clinical outcomes and effective pain relief with minimal damage to paraspinal muscles with an easier learning curve, reproducible results, and a high safety index.

Ethical approval

The Institutional Review Board has waived the ethical approval for this study as it is a retrospective study.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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