Randomized Trial

Endoscopic Epidural Laser Decompression Versus Transforaminal Epiduroscopic Laser Annuloplasty for Lumbar Disc Herniation: A Prospective, Randomized Trial

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Background: Lumbar radicular pain often results from lumbar disc herniation, spinal stenosis, or degenerative spondylolisthesis. Minimally invasive disc decompression procedures, such as nucleoannuloplasty or epiduroscopic neural decompression by laser, have been devised to treat such pain.

Objective: The short-term outcomes of disc decompression by endoscopic epidural laser decompression (EELD) or transforaminal epiduroscopic laser annuloplasty (TELA) were compared in patients with lumbar radicular pain due to disc herniation.

Study Design: A randomized, prospective trial.

Setting: The Department of Anesthesiology and Pain Medicine at Spine Health Wooridul Hospital in Daegu, Korea.

Methods: A total of 97 patients were enrolled in this study; 48 patients underwent EELD and 49 underwent TELA. The pain relief was evaluated at baseline and at 1, 3, and 6 months post-procedure via the numeric rating scale (NRS). The Oswestry Disability Index (ODI) was recorded at baseline and at the final follow-up. Postoperative wound pain was assessed over a 24-hour period. Complications and side effects were also recorded, as were operative times (from local anesthetic infiltration at entry sites to suturing of skin).

Results: At post-treatment months 1, 3, and 6 the mean pain scores of patients were significantly lower (relative to pre-treatment baseline) regardless of the procedure used. However, the mean pain scores did not differ significantly by procedure (EELD vs TELA). As well, the number of patients who obtained relief from their pain and needed analgesics was not statistically significant. The irrigation volume was significantly higher in the TELA group. Two patients undergoing TELA procedures experienced headache during the procedures; however, no serious complications such as bleeding, dural/neural injuries, or infection were recorded for either group.

Limitation: The observed significant reductions in pain (from baseline) lacked secondary outcome substantiation and given the mid follow-up period, no long-term follow-up results were monitored.

Conclusion: Both EELD and TELA provide similar outcomes and are reasonable treatment options for carefully selected patients with lower back or radicular pain.

Key words: Epiduroscopy, laser, annuloplasty, disc, herniation, TELA

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Lumbar radicular pain is a common accompaniment of lumbar disc herniation, spinal stenosis, and degenerative spondylolisthesis. Disc herniation typically presents as radicular pain radiating from the back into the leg along dermatomes of the affected nerve roots. In addition to the pain inflicted by nerve root compression, a severe inflammatory response to herniated nucleus pulposus may ensue. Epidural

corticosteroid injections (interlaminar, transforaminal, or caudal) are thus effective for this type of pain (1-4). In prior studies, brief to moderate periods of pain relief have been achieved in 55 – 84% of patients through this strategy (5,6).

For patients with pain refractory to epidural corticosteroids, other modes of treatment are available, including minimally invasive options for disc decompression (7-10). Major advantages of such techniques (versus open surgery) include better preservation of spinal architecture, less tissue destruction, and lower procedure-related risk.

Endoscopic discectomy with thermal annuloplasty is a notable procedure of this type. Using a bipolar radiofrequency probe, Tsou et al (11) have also devised a technique for postero-lateral transforaminal selective endoscopic discectomy and thermal annuloplasty. Cheng et al (12) consider this method safe and effective in treating carefully selected patient subsets with discogenic lumbar back pain, conferring better clinical results in instances of single-level involvement.

Endoscopic epidural laser decompression (EELD) similarly permits herniated disc ablation by laser or forceps, gaining entry at the sacral hiatus. This procedure is typically accomplished by a holmium: yttrium-aluminum-garnet (Ho: YAG) laser (13,14). A number of articles on EELD have been published to date (9,10,15), indicating significantly improved measures of pain (i.e., visual analog scale and Oswestry Disability Index [ODI]) in patients with herniated intervertebral disc (HIVD)-related low back pain and radiculopathy (9). In patients (n = 93) subjected to epiduroscopy-guided Ho:YAG laser intervention for chronic back and leg pain syndrome, Ruetten et al (14) recorded positive postoperative follow-up results in 45.9%. Transforaminal epiduroscopic laser annuloplasty (TELA) is another recent development enabling simultaneous disc decompression and thermal annuloplasty. While differing in mode of exit, TELA affords direct decompression of HIVD by laser or forceps, destruction of ingrown nerve, and annular modification via a 1414-nm neodymium: yttrium-aluminum-garnet (Nd: YAG) side-firing laser.

To our knowledge, there are no published comparisons of EELD or TELA in the context of herniated disc decompression. This study was conducted to evaluate the short-term results thereof, assessing the therapeutic success of each procedure.

Methods

A total of 97 patients were enrolled in this randomized, prospective study. Our institutional review board approved the study protocol, with all of the patients offering signed informed consent. In this longitudinal, cohort-controlled study the patients were divided into 2 groups, EENL or TELA, depending on the mode of application of the treatment.

Inclusion criteria were single-level, low back pain and/or radicular pain, clear evidence of HIVD on spinal magnetic resonance imaging (MRI), and lumbar radicular pain and/or back pain which had not responded to traditional treatments (pharmacotherapy and physical therapy) within the previous 4 weeks. The data that were collected included patient age, gender, duration of pain, and nature of symptoms (location of pain). Exclusion criteria were as follows: low back pain elicited by pressure on paraspinal muscles, foraminal or extraforaminal HIVD on cross-sectional MR images, spondylolisthesis, pain due to infection, bleeding tendency, and Tarlov cyst.

EELD Procedure

EELD was performed with the patients in the prone position under local anesthesia (1% lidocaine). Through skin incisions (5 – 10 mm) at the sacral hiatus, 17-gauge Tuohy needles were inserted into the sacrum, inserting guide wires and dilators in turn. A steerable 3.0 mm video-guided catheter (VGC) incorporating epiduroscopes and a Ho:YAG laser with end-firing fiber (VersaPulse P20, Lumenis®, Yokneam, Israel) were then introduced (Fig. 1). Lateral imaging views (Fig. 2), generated via C-arm fluoroscopy and epiduroscopy, helped verify VCG positioning (in the ventral epidural space) and tip placement (at the inferior-most aspects of the targeted disc, encompassing the posterior longitudinal ligament [PLL]). Contrast of 1 ~ 2 mL was injected to obtain a ventral epidurogram, which showed the outline of the pathology. Adhesiolysis (done initially) allowed anatomic visualization and localization of pathology (Fig. 3). Bulging PLLs were subsequently reduced using a Ho:YAG laser set at 2.5 W (0.5 J, 5 Hz). Once the VGC had penetrated the HIVD below the PLL (through holes in the PLL), decompression of the herniated discs was undertaken by the Ho:YAG laser set at 8 W (0.8 J, 10 Hz). Ruptured discs were later decompressed, upon epiduroscopic confirmation of nerve root decompression. At completion, the VGC was removed, and an incision at the sacral hiatus was sutured. In the absence of complaints, the patients were transferred to the recovery room.

TELA Procedure

TELA was likewise performed with the patients

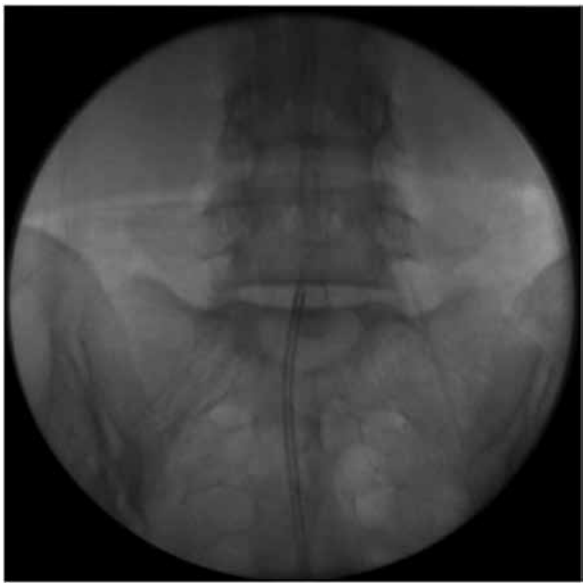

Fig. 1. *Steerable 3.0 mm VGC incorporating epiduroscopes and Ho:YAG laser with end-firing fiber were then introduced (AP view).*

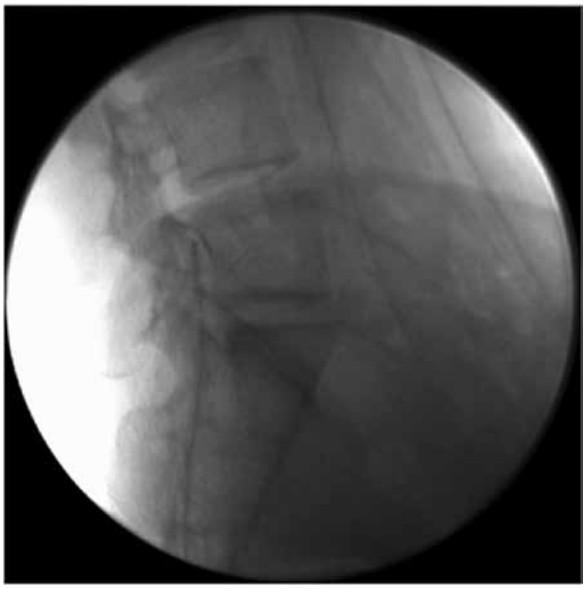

Fig. 2. *Lateral imaging views helped verify VCG positioning (in ventral epidural space) and tip placement.*

in the prone postition under local anesthesia. Prior to the procedure, the point of entry (usually 12 – 14 cm in spinal midline) was determined by measuring from the midline on MRI. A conventional posterolateral approach on the side of pathology was used. Presumptive skin entry and needle track was infiltrated with 1% lidocaine, then a 15-gauge spinal needle was inserted just lateral to the superior articular pillar (SAP) toward the targets level. After the SAP was touched with the needle, the needle slipped down the SAP toward the ventral epidural space. Confirmed needle placement in the anterior epidural space, as shown in anteroposterior (AP) and lateral radiographic views, was followed by guide wire insertion and incision (0.7 cm) of overlying skin. Both cannula and soft tissue dilator were then inserted along the guide wire into the ventral epidural space, under continuous fluoroscopic monitoring (AP and lateral views). Once cannula was placed, an epiduroscope (needle view CH, outer diameter 3.4 mm) was introduced, carrying a Nd:YAG laser with side-firing fiber. C-arm fluoroscopy yielded images in lateral view, verifying epiduroscopic position in the ventral epidural space and confirming the appropriate locations near the targeted disc (Fig. 4A, 4B). Any neural injury, such as dual puncture or traversing or exiting nerve injury was checked through the epiduroscopic views. Epidural fat and transforaminal ligament were first removed (via

Fig. 3. *Epiduroscopic view allowed anatomic visualization and localization of pathology.*

forceps) to ensure anatomic visualization (Fig. 5). Bulging PLLs again were reduced via the Nd:YAG laser with side-firing fiber side, set at 2.5 W (0.5 J, 5 Hz). Once the laser-tip had entered the HIVD below the PLL (through

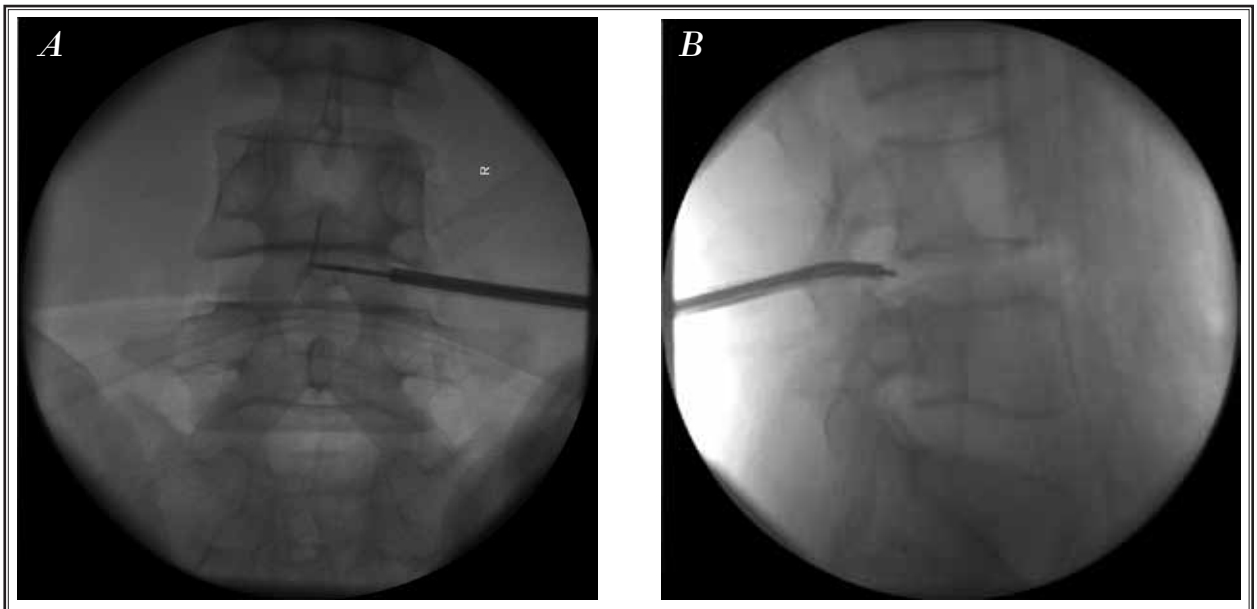

Fig. 4. *C-arm fluoroscopy yielded images in lateral view, verifying epiduroscopic position in the ventral epidural space and confirming the appropriate locations near the targeted disc in AP view(A) and lateral view(B).*

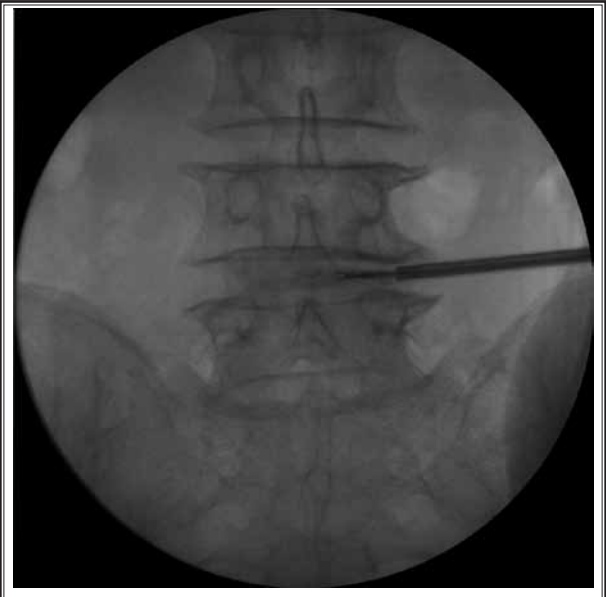

Fig. 5. *Epidural fat and transforaminal ligament were first removed (via forceps) to ensure anatomic visualization.*

holes in the PLL), Nd:YAG laser decompression of the herniated disc took place, with the unit set at 8 W (0.8 J, 10 Hz) (Fig. 6A, 6B). The ruptured disc was eventually decompressed, given epiduroscopic confirmation of nerve root decompression. The steps taken at the procedural completion were the same as those of EELD.

The operative site was irrigated with solutions of antibiotics and normal saline, delivered through the inserted cannula during all procedures. Afterwards, the patients were observed for neurologic deficits or other procedure-related problems and were typically discharged on the same day or within 24 hours.

The main outcome parameter was pain scores determined by the numeric rating scale (NRS). The patients were evaluated at pre-treatment baselines and at post-treatment months 1, 3, and 6. The ODI was recorded at baseline and at the final follow-up. Postoperative wound pain was assessed over a 24-hour period. For mild pain, nonsteroidal anti-inflammatory drugs (NSAIDs) alone were given. NSAIDs plus opioids were prescribed for pain of moderate (5 – 10 mg/day) or severe (10 – 20 mg/day) intensity. Complications and side effects were also recorded, as were the operative times (from local anesthetic infiltration at entry sites to suturing of skin).

Independent t-test and analysis of variance (ANOVA) were used to analyze the collected data, equating statistical significance with type I error rates of < 0.05. All computations relied on standard software SPSS Version 23.0 (IBM Corporation, Armonk, NY). The sample size of 97 was specified in advance to provide 90%

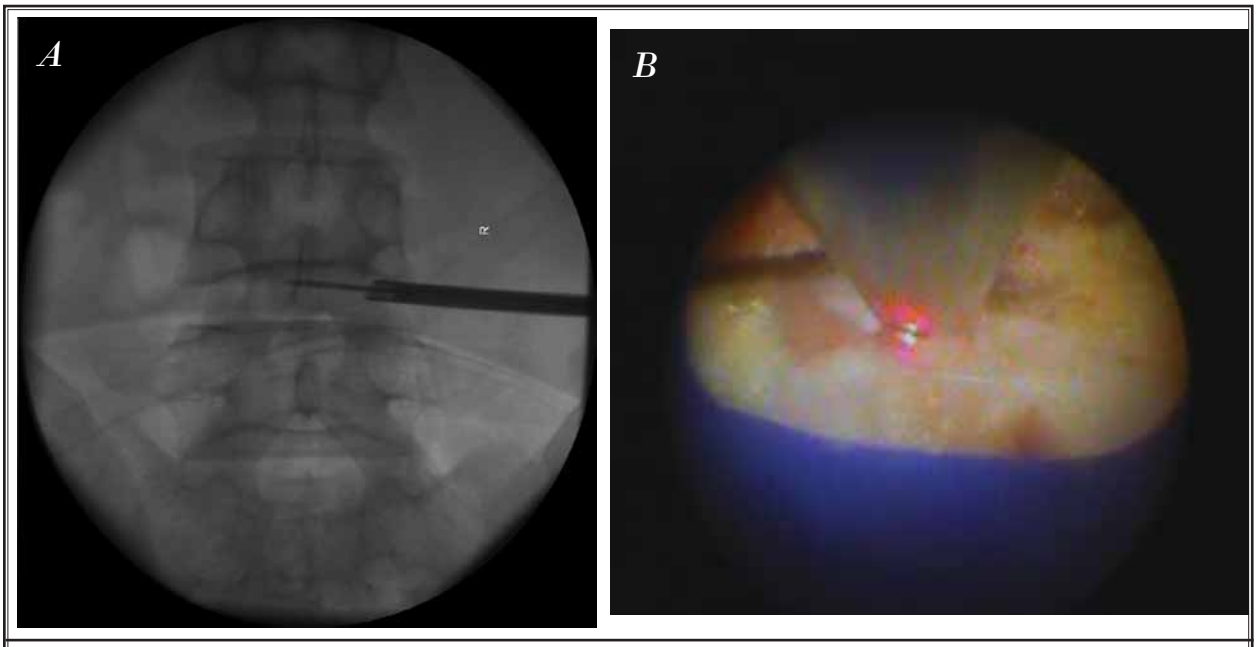

Fig. 6. *Nd:YAG laser decompression of herniated disc took place; C-arm view (A) and endoscopic view (B).*

power to detect a difference in the amount of change in pain scores between treatments of at least 2.8.

Results

Each of the 97 patients studied was grouped according to procedure (EELD vs TELA). A summary of patient characteristics, herniation levels, and pain locations is provided in Table 1. The mean post-treatment pain scores at months 1, 3, and 6 were significantly lower ($P = 0.000$) in each group (Table 2), although the between-group differences were not significant (Table 3). The ODI score was statistically and significantly decreased compared with baseline (Table 4).

As well, the number of patients who obtained relief from their pain and needed analgesics was not statistically significant (Table 5, 6). The irrigation volume was significantly higher in the TELA group (Table 7). Two patients undergoing TELA procedures experienced headache during the procedures; however, no serious complications such as bleeding, dural/neural injuries, or infection were recorded for either group.

Discussion

The outcomes of this study indicate that significant pain relief is achievable by either EELD or TELA, with comparable results, corroborating previous data

Table 1. *Patient Characteristics*

n = 97	EELD (n = 48)	TELA (n = 49)
Age (yrs)	49.8 ± 14.2	49.4 ±16.8
Gender (M:F)	26 : 22	27 : 22
Level		
L3-4	3	3
L4-5	16	19
L5-S1	29	27
Pain Duration (months)	38.9 ≥ 3.9	18.2 ≥ 8.2

EELD = endoscopic epidural neural laser decompression, TELA = transforaminal epiduroscopic laser annuloplasty

Table 2. *Changes of NRS Score*

Group (n = 97)	Pre-treat	Post 1 month	Post 3 months	Post 6 months	*P*-value
EELD (n = 48)	7.6 (0.8)	3.2 (1.5)*	2.8 (1.1)*	2.5 (1.1)	0.000
TELA (n = 49)	7.3 (0.8)	3.1 (1.2)*	3.1 (1.2)*	2.7 (1.1)	0.000

EELD = endoscopic epidural neural laser decompression, TELA = transforaminal epiduroscopic laser annuloplasty

Table 3. *Comparison of the NRS scores between the EELD and TELA groups.*

Follow-up	EELD (n = 48)	TELA (n = 49)	*P*-value
Pre-treat	7.3 (0.8)	7.6 (0.8)	0.060
Post 1 Month	3.1 (1.2)	3.3 (1.5)	0.559
Post 3 Months	3.1 (1.1)	2.8 (1.1)	0.336
Post 6 Months	2.8 (1.1)	2.5 (1.1)	0.211

EELD = endoscopic epidural neural laser decompression, TELA = transforaminal epiduroscopic laser annuloplasty

Table 4. *Changes of the ODI between the EELD and TELA groups.*

Group	Pre-treat	Post 6 months	*P*-value
EENL (n = 48)	52.4 ± 20.6	28.6 ± 16.6	0.000
TELA (n = 49)	52.7 ± 21.4	27.8 ± 18.7	0.000
P-value	0.624	0.789	

EELD = endoscopic epidural neural laser decompression, TELA = transforaminal epiduroscopic laser annuloplasty

Table 5. *The number of patients who obtained the percentage improvement of pain at post-procedure 3 months.*

Follow-up	NRS	Procedure		*P*-value
		EELD (n = 48)	TELA (n = 49)	
1 Month	NRS < 50%	11 (22.9%)	13 (26.5%)	0.929
	NRS ≥ 50%	36 (77.1%)	37 (73.5%)	
3 Months	NRS < 50%	10 (20.8%)	6 (12.2%)	0.254
	NRS ≥ 50%	38 (79.2%)	43 (87.8%)	
6 Months	NRS < 50%	8 (16.7%)	3 (6.1%)	0.102
	NRS ≥ 50%	40 (83.3%)	46 (93.9%)	

EELD = endoscopic epidural neural laser decompression, TELA = transforaminal epiduroscopic laser annuloplasty

Table 6. *The number of patients who needed analgesics (post-procedure 24 hours).*

	Pain (24 hrs)		
	Mild	Moderate	Severe
EELD (n = 48)	42	3	3
TELA (n = 49)	43	4	2

EELD = endoscopic epidural neural laser decompression, TELA = transforaminal epiduroscopic laser annuloplasty

Table 7. *Operation time and irrigation solution volume between the EELD and TELA groups.*

n = 97	EELD (n = 48)	TELA (n = 49)	*P*-value
Operation Time (min)	44.6 ± 11.0	44.6 ± 9.3 (40–210)	0.728
Irrigation Volume (mL)	110.2 ± 57.5	1041.7 ± 444.2 (500–2000)	0.000

EELD = endoscopic epidural neural laser decompression, TELA = transforaminal epiduroscopic laser annuloplasty

(9,12,16). To further clarify, both EELD and TELA served well in terms of ablating/cauterizing disc material or annular tears.

The 2100-nm Ho:YAG used in our EELD procedure is capable of tissue destruction through direct contact, regardless of the exposure duration or beam intensity (17,18). However, thermal injury of neural structures is preventable by limiting disc ablation to areas between the posterior longitudinal ligament and the posterior annulus. In the TELA procedures, a 1414-nm Nd:Yag laser was used to ablate. Introduced earlier than the Ho:YAG laser, this unit is not intended for deep tissue penetration. Nonetheless, shallow tissue damage is feasible by adjusting its wave length to that of the Ho:YAG laser (19). Advantages of the Nd:YAG laser include easier control, less manufacturing expense, and efficacy equivalent to a holmium laser (20,21). In in vivo porcine and human cadaveric models, the 1414-nm Nd:YAG laser was also proven effective and safe under spinal epiduroscope guidance (22).

Of note, the need for analgesics did not differ significantly by group. In the TELA procedures, working cannulas penetrate muscle, thereby producing muscle pain; in EELD, sacral bone may be stricken when channeling through sacral hiatus, resulting in bone pain—hence the comparable outcomes. On the other hand, EELD was prohibitive in Tarlov cyst in the event of a sacral area Tarlov cyst or occlusion/block of the sacral hiatus.

Although the procedural times likewise did not differ by group, the irrigation volumes were significantly different. Irrigation solution was essential for adequate endoscopic views. In TELA procedures, it was instilled by active pressure pumps (rather than gravity), resulting in higher volumes, whereas assistants manually injected the solution in EELD procedures, limiting the volume to 100 – 200 mL. This volume, being substantially less than that used for TELA, was not fully withdrawn from the

epidural space and the potential for insufficient removal of the herniated disc was a concern. Unfortunately, magnitudes of disc herniation were not examined here. Also worth mentioning, 2 of our patients complained of headaches during TELA procedures, raising the question of a proclivity with TELA (vs EELD). We guessed that the high irrigation volume or speed could be increase the intracranial pressure (ICP). This increased ICP may be the cause of the headache. However, instilled irrigation solution was routinely retained in EELD procedures, boosting epidural pressure to create a risk of headache. The pressure utilized (50 mL/min) for irrigation during TELA may thus provide a better explanation for the related episodes of headache.

An acknowledged limitation of our study is that the significant pain reductions achieved (from baseline) lacked secondary outcome substantiation. The follow-up period was short (< 6 months), unaccompanied by mid- or long-term follow-up results. Additionally, the numbers of patients was small. In the present study, foraminal or extraforaminal HIVD were excluded. During EENL procedure, we could not easily place epiduroscopy and could not distinguish the herniated disc and nerve root. A new product is needed.

Conclusion

In summary, our findings suggest that EELD and TELA are both reasonable treatment options for carefully selected patients with lower back pain and radicular pain of disc origin, providing similar outcomes.

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