Retrospective Analysis

The Catheter Tip Position and Effects of Percutaneous Epidural Neuroplasty in Patients with Lumbar Disc Disease During 6-Months of Follow-up

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Disclaimer: This study was supported by the Teun Teun Research Foundation and no external funding was received. Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 03-02-2014
Revised manuscript received: 04-20-2014
Accepted for publication: 04-25-2014

Free full manuscript: www.painphysicianjournal.com

Background: Percutaneous epidural neuroplasty (PEN) is a minimally invasive intervention designed to treat neck, back, and low back pain. The efficacy of lumbar PEN has been relatively well investigated, but clinical effectiveness according to catheter position has not yet been established.

Objective: The purpose of this study was to compare clinical outcomes between the ventral and dorsal positions of the catheter tip during lumbar PEN procedures using a retrospective review series.

Methods: A total of 303 patients with back pain from single-level lumbar disc disease with and without radiculopathy were included in this study. In all patients, an attempt was made to place the catheter tip in the ventral position to maximize theoretical clinical improvement; however, several catheters failed to reach the desired position. Patients were assigned to 2 groups after lumbar PEN procedures were completed: those with catheters in the ventral position (Ventral group) and those with catheters in the dorsal position (Dorsal group). Clinical outcomes were assessed according to the Visual Analog Scale (VAS) score for back pain and leg pain at 0, 1, 3, and 6 months after treatment.

Results: The only demographic difference observed between the 2 groups (Ventral and Dorsal groups) was an elongated symptom duration in the Dorsal group compared to the Ventral group (16.1 vs. 9.4 months, P = 0.013). The VAS (back) scores during the follow-up period (1, 3, and 6 months) were similar between the 2 groups. In one area of the VAS scoring (leg), the Ventral group showed a similar effect at postoperative one month compared to the Dorsal group, but significantly improved at postoperative 3 and 6 months (1.3 and 0.9 in ventral group, and 1.9 and 1.4 in dorsal group, respectively; P = 0.002 and 0.010). Odom's criteria were also significantly improved over 6 months in the Ventral group compared to the Dorsal group.

Limitations: This study was a retrospective analysis with a relatively short follow-up duration was not a randomized, controlled study. Therefore, the clinical effects of the catheter position could be confounded by other variables.

Conclusion: In this short-term follow-up study, the effects of lumbar PEN on VAS scores were different according to the position of the catheter tip in patients with single-level lumbar disc herniation. Better outcomes in the Ventral group may have been achieved by more localized treatment with a selective block in the epidural space closer to the dorsal root ganglion and ventral aspect of the nerve root.

Key words: Lumbar disc disease, pain management, percutaneous epidural neuroplasty, catheter position, dorsal, ventral

Pain Physician 2014; 17:E599-E608

Low back pain is a common medical and social problem. It is estimated that approximately 80% of all people will experience low back pain at some period during their lifetime, and approximately 18% of the population is experiencing low back pain at any given moment (1-3). Disc degeneration is a degenerative process related to aging, and most individuals are asymptomatic. However, pathologic degeneration can be a major cause of pain and disability (1). Radiculopathy is pain that occurs along the dermatome of a nerve due to inflammation or other irritation of the nerve root at its connection to the spinal column. Surgical discectomy is regarded as an effective treatment for lumbosacral radicular pain caused by a corroborative disc herniation that is recalcitrant to less invasive treatment (4-7). Unfortunately, postlaminectomy syndrome is known to put stress on the lumbar spinal root, and indeed, the scar tissue formed around the nerve roots may irritate them and cause continuous neuropathic pain. Moreover, adhesions formed postoperatively following spine surgery may also result in chronic inflammation and nerve root irritation.

As a minimally invasive therapy, percutaneous epidural neuroplasty (PEN) is a catheter procedure in which the catheter is placed directly into the lesion site compromising the nerve root. It has been used in refractory chronic low back pain or following failed back surgery syndrome (8-14). The goal of PEN is to ameliorate aberrant adhesions, which can physically prevent the direct application of drugs around the nerves, and to deliver medication to the targeted site (15-18). Hence, PEN may be effective in pain reduction and functional improvement in patients with chronic lower back or leg pain due to lumbar disc herniation (LDH) (19). As a result, numerous studies have attempted to analyze the effectiveness of PEN among patients with LDH. In the clinical setting, the catheter for PEN could be placed in the ventral or dorsal portion of the spinal canal. From an anatomical standpoint, drug delivery to the ventral side of the spinal canal could improve the effectiveness of PEN. However, to our knowledge, there has been no clinical study of the effects of the position of the drug delivery site in lumbar PEN for LDH. The purpose of this study was to determine whether the clinical outcomes of PEN are affected by catheter position and to evaluate the effectiveness and safety of lumbar PEN in single-level LDH.

Methods

Patients

This single-center, retrospective review series was conducted from June 2012 to December 2012 after obtaining institutional review board approval. A total of 303 patients with single lumbar disc disease were included in this study. Inclusion criteria for this study were back pain with and without radicular pain, LDH confirmed by magnetic resonance imaging (MRI), and a visual analogue scale (VAS, 0 – 10) score of 5 or more after receiving appropriate conservative treatment for at least 4 weeks in the form of medication and/or physiotherapy. Exclusion criteria were lack of correlation between radicular symptoms and the level of disc herniation on MRI, prior spinal surgery, clinical signs of spinal cord compression, bleeding disorders, instability, spondylolisthesis, spinal canal stenosis, ossification of a longitudinal ligament, and other traumatic injuries, as well as associated somatic, psychiatric, or underlying systemic disease. All patients were treated with lumbar PEN using a Racz catheter. An initial attempt was made to place the catheter tip in the ventral position in order to maximize the theoretical clinical improvement; however, this was not successful in all patients. Patients were assigned to one of 2 groups after the lumbar PEN procedure was complete: a ventral-positioned catheter tip group (Ventral group) or a dorsal-positioned catheter tip group (Dorsal group).

Surgical Procedures

Lumbar PEN was performed under fluoroscopy in a sterile operating room with monitoring equipment for blood pressure, pulse rate, and pulse oximetry. Fluoroscopy was adjusted over the lumbosacral area such that a caudal approach could be used for both the anteroposterior and lateral views. After appropriate positioning of the fluoroscopy, the needle insertion area was determined around the sacral hiatus and was injected with local anesthetics. An RK needle (RK needle, Epimed International, Inc.) was introduced into the caudal epidural space under fluoroscopic guidance. Once the needle placement was confirmed to be in the epidural space, a lumbar epidurogram was performed using approximately 5 mL of a non-iodinated contrast agent (IOBRIX, ACCUZEN, Seoul, Korea). Identification of the filling defects was attained by examining the contrast agent flow. We confirmed that there was no intravas-

cular or subarachnoid placement of the needle; if such malpositioning occurred, the needle was repositioned. After appropriate confirmation of the epidurography, a Racz catheter was advanced through the RK needle to the area of the filling defect or the site of pathology, as determined by MRI. Adhesiolysis was then carried out, and the final positioning was intended to be in the lateral or ventral epidural space. Following the positioning of the catheter, at least 3 mL of contrast agent was injected. If there was no subarachnoid, intravascular, or other extra-epidural filling and satisfactory filling was obtained in the epidural and targeted regions, 6 mL of 0.2% preservative-free ropivacaine containing 1,500 units of hyaluronidase and 4 mL of 40% triamcinolone acetate were injected. However, in some cases, the desired final position in the ventral epidural space was not achieved and the catheter was instead placed in the dorsal portion after several tries. Depending on the final catheter position, all patients were assigned to one of 2 groups after the lumbar PEN procedures were completed: a ventral-positioned catheter tip group (Ventral group, Fig. 1A) and a dorsal-positioned catheter tip group (Dorsal group, Fig. 1B). One hour following the procedure, 6 mL of 10% sodium chloride solution was subsequently infused over 30 minutes in the recovery room under monitoring. The intravenous line and epidural catheter were removed and the patient was discharged if all parameters were satisfactory. The first follow-up was performed one week following the procedure. During these periods, all participants received nonsteroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants of equal doses to reduce procedure-related pain.

Clinical Assessment

All patients completed 6 months of follow-up, consisting of a medical interview with a physician and pain assessment by a pain-specialized nurse. Both examiners were blinded to the patients' group assignments. VAS (score range: 0 to 10, with 0 reflecting no pain) scores

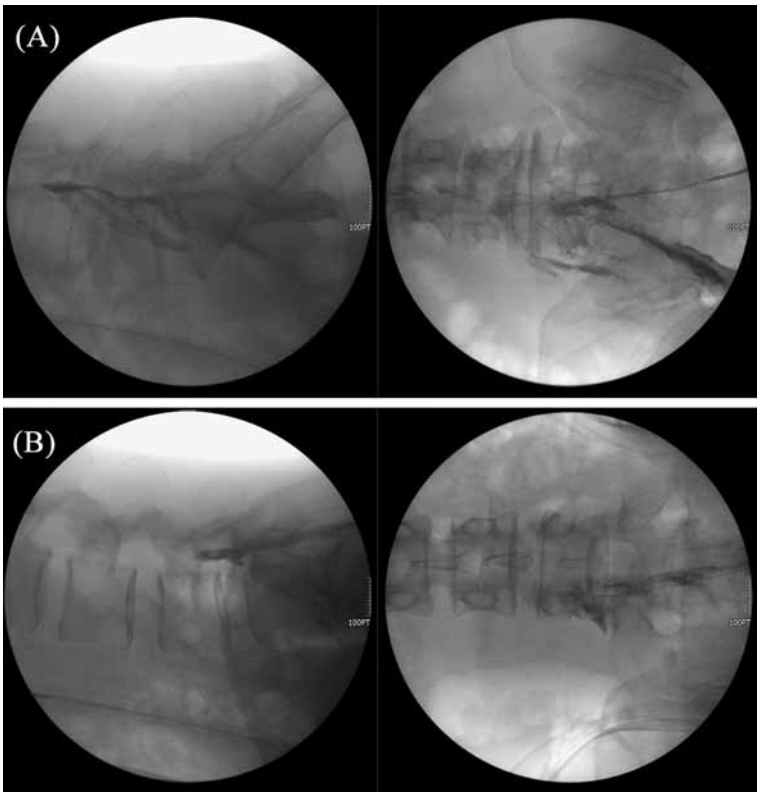

Fig. 1. *Epidurography pattern of lumbar PEN with a ventral-positioned catheter (A): more localized selective block in the epidural space closer to the dorsal root ganglion and ventral aspect of the nerve root and a dorsal-positioned catheter; (B): diffuse non-selective block in the epidural space closer to the dorsal aspect of the spinal canal.*

for back pain (VAS back) and leg pain (VAS leg), as well as Odom's criteria, which rates outcomes as excellent, good, fair, or poor, were used to evaluate the clinical effectiveness of PEN in terms of pain reduction and functional improvement at pretreatment and 1, 3, and 6 months after PEN. All patients were asked to give their answers considering the average severity of their symptoms over the week prior to their visit. Successful pain relief was described as a 50% or more reduction in VAS score, and good or excellent results in Odom's criteria were considered to be reflective of "good" outcomes. We used Student's t-test and the chi-square test to compare clinical outcomes according to the catheter position after lumbar PEN. All statistical analyses were performed using SPSS software version (SPSS Inc., Chicago, IL, USA), and statistical significance was defined as $P < 0.05$.

Results

Demographics

The demographic data of the patients are summarized in Table 1 and Fig. 2. All lumbar PEN procedures were performed in 303 patients with single-level lumbar disc disease. The catheter tip was positioned in the ventral portion in 204 cases (Ventral group) and in the dorsal portion in 99 cases (Dorsal group). The average age, gender ratio, height, and weight between the 2 groups were 48.4 years, 52.9% male, 164.6 cm, and 62.1 kg in the Ventral group, and 50.4 years, 60.6% male, 165.9 cm, and 64.9 kg in the Dorsal group ($P = 0.153$, 0.209, 0.155, and 0.236, respectively). Symptom duration was significantly different between the groups. The Dorsal group had an elongated symptom duration with 16.1 ± 30.9 months compared to 9.4 ± 15.7 months in the Ventral group ($P = 0.013$). The level of disc dis-

Table 1. *Demographic data of patients who underwent lumbar PEN according to catheter position.*

		Ventral	Dorsal	*P*-value
Age (years)		48.4 ± 11.7	50.4 ± 11.0	0.153
Sex (male)		52.9%	60.6%	0.209
Weight (kg)		62.1 ± 15.8	64.9 ± 16.2	0.155
Weight (cm)		164.6 ± 9.3	165.9 ± 8.3	0.236
Symptom duration (months)		9.4 ± 15.7	16.1 ± 30.9	0.013
Disc Level	L2/3	8	4	0.999
	L3/4	21	10	
	L4/5	106	52	
	L5/S1	69	33	
Total		204	99	

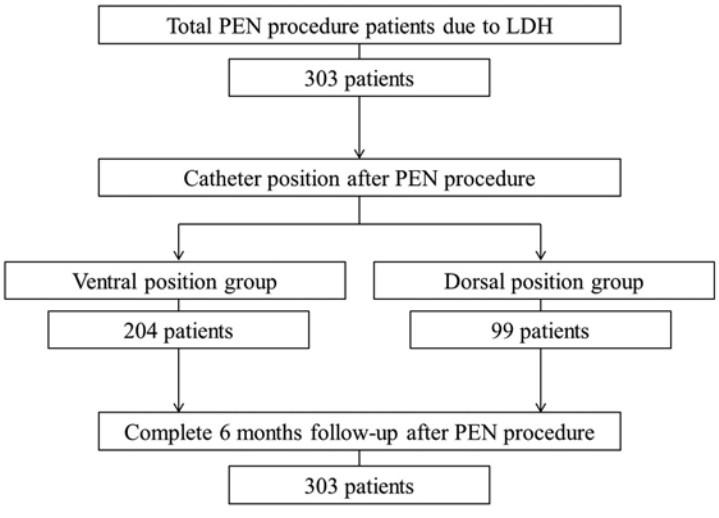

Fig. 2. *Flowchart of the groups according to the final catheter position after PEN due to LDH.*

placement involvement was not different between the groups (8 cases at L2/3, 21 cases at L3/4, 106 cases at L4/5, and 69 cases at L5/S1 in the Ventral group; and 4 cases at L2/3, 10 cases at L3/4, 52 cases at L4/5, and 33 cases at L5/S1 in the Dorsal group; $P = 0.999$).

Clinical Results

The clinical results are summarized in Figs. 3 – 5. Mean VAS (back) scores for the Ventral and Dorsal groups, respectively, were 6.35 and 6.21 ($P = 0.451$) preoperatively, 2.33 and 2.12 ($P = 0.369$) after one month, 1.46 and 1.48 ($P = 0.899$) after 3 months, and 0.90 and 1.24 ($P = 0.071$) after 6 months of follow-up (all $P < 0.001$ compared to preoperative status, Fig. 2). Mean VAS (leg) scores for the Ventral and Dorsal groups, respectively, were 4.74 and 5.03 ($P = 0.201$) preoperatively, 1.75 and 2.12 ($P = 0.073$) after one month, 1.29 and 1.94 ($P = 0.002$) after 3 months, and 0.90 and 1.39 ($P = 0.010$)

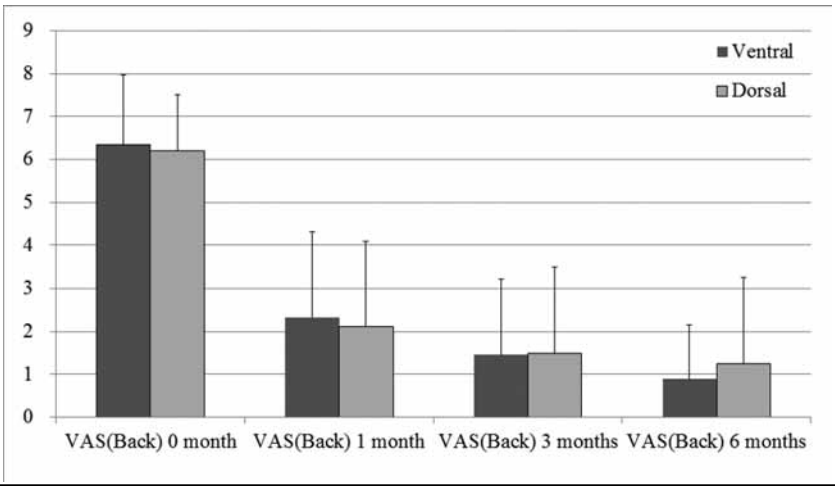

Fig. 3. *Comparison of VAS (back) scores between those with lumbar PEN with a ventral-positioned and a dorsal-positioned catheter pre-procedure and at 1, 3, and 6 months after treatment; no statistical differences were observed during the follow-up period.*

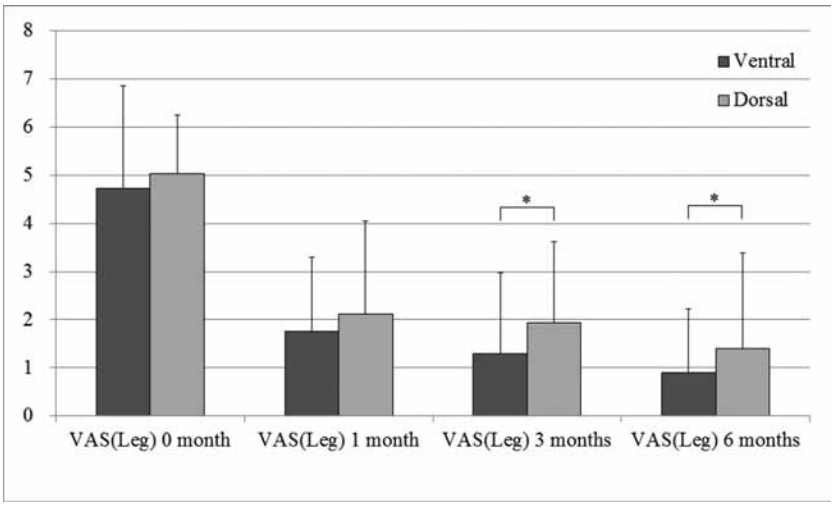

Fig. 4. *Comparison of VAS (leg) scores between those with lumbar PEN with a ventral-positioned and a dorsal-positioned catheter pre-procedure and at 1, 3, and 6 months after treatment; * statistically significant differences were observed at 3 (P = 0.002) and 6 months (P = 0.010) after treatment.*

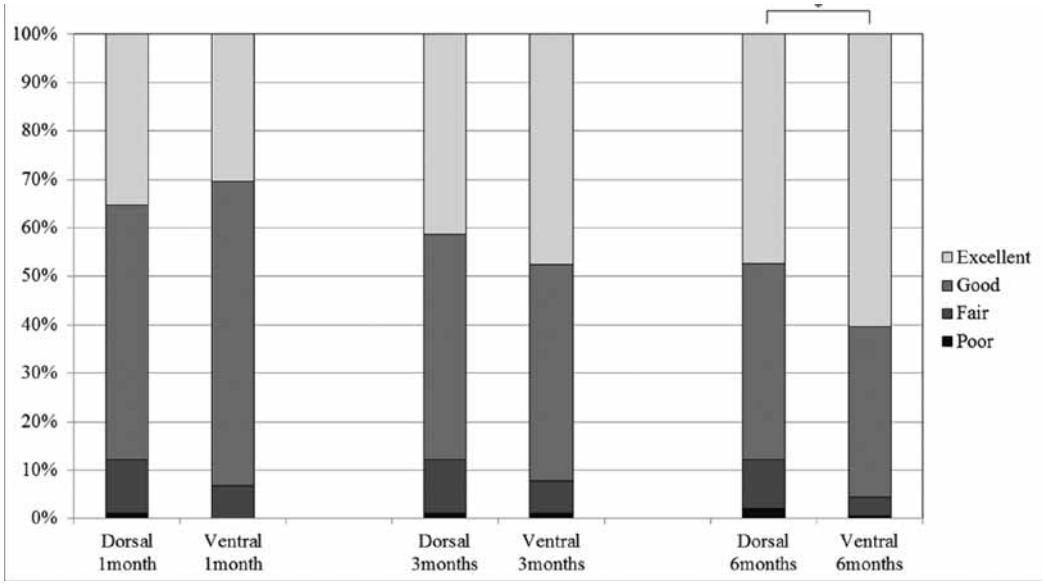

Fig. 5. *Comparison of Odom's criteria between those with lumbar PEN with a ventral-positioned and a dorsal-positioned catheter pre-procedure and at 1, 3, and 6 months after treatment; * statistically significant difference in composition was observed at 6 months (P = 0.041) after treatment.*

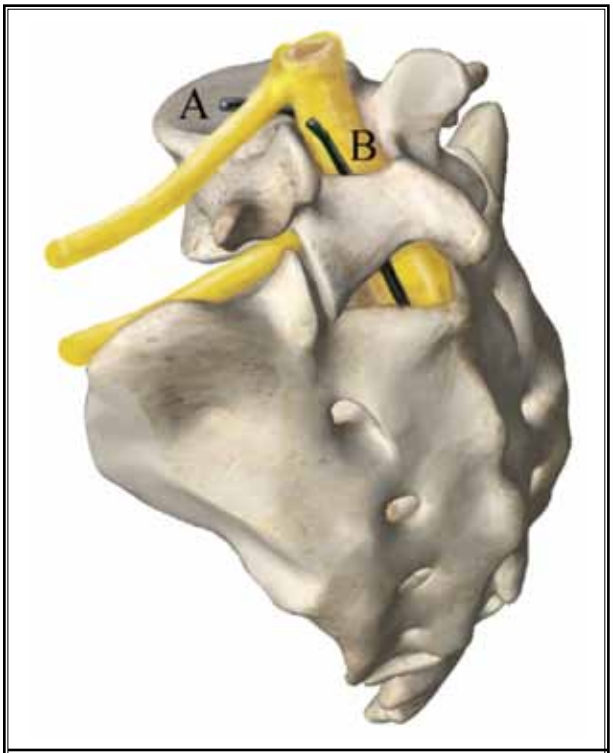

Fig. 6. *The illustration demonstrates more ventral and more localized drug delivery in lumbar PEN with a ventral catheter position (A) compared to a dorsal catheter position (B) when using epidural catheter (this illustration was created using 3D4Medical's Essential Anatomy app for the iPad).*

after 6 months of follow-up (all $P < 0.001$ compared to preoperative status, Fig. 3). VAS (back) scores were not significantly different between the 2 groups during the 6-month follow-up period. VAS (leg) scores were similar at one month after the procedure, but were significantly lowered in the Ventral group compared to the Dorsal group at 3 and 6 months of follow-up. Odom's criteria at one and 3 months of follow-up were also not significantly different in the proportions of excellent, good, fair, and poor scores. Odom's criteria at 6 months of follow-up were significantly different between the 2 groups ($P = 0.041$, Fig. 6).

Discussion

PEN has been used to treat intractable chronic pain that is not responsive to conservative management, and has been shown to have excellent clinical efficacy (20). PEN has been shown to be more effective compared to not only physical therapy, but also to caudal epidural steroid injections for the treatment of chronic lower back and leg pain, because it eliminates adhesions and fibrous tissue that might prevent the spread of injected medications into the specific lesion site with the placement of the catheter tip within the target areas (14,21). Consequently, the application of an adequate concentration of steroids or other solution to the appropriate target area could improve outcomes (11). Hence, PEN is usually performed in patients for whom conservative

treatment and conventional injections have failed. In considering the anatomy, drug delivery to the ventral side of the spinal canal could improve the effectiveness of PEN. However, to our knowledge, there has been no clinical study examining the effects of the position of the drug delivery site in PEN. As a result, this study was conducted to determine whether the clinical outcomes of PEN are affected by the catheter position and to evaluate the effectiveness and safety of lumbar PEN in single-level LDH.

Anatomically, spinal nerves sprout from the ventral portion of the thecal sac and travel out of the spinal canal directly to its ventral and lateral aspects. If medication is injected to treat nerve pathology, the effects of therapy might be maximized by targeting the ventral side of the thecal sac. As a result, the physicians in our clinics attempted to position the catheter to the ventral portion of the thecal sac. However, the desired position could not always be achieved. The PEN catheter could be placed in the ventral or dorsal portion of the spinal canal. As our results indicate, the ventral position was utilized in 67.3% (204 of 303) of cases and the dorsal position was utilized in 33.7% (99 of 303) of cases. Unfortunately, there were no clinical data related this topic, so we could not compare the ventral rate to those achieved in other clinical settings. We postulate that differing results from other studies may be due to different catheter positioning.

Although there are no related data regarding catheter positions in PEN, there are some interesting similar studies. The PEN procedure is considered to be more effective than epidural steroid injection (ESI) (13,14,22). A randomized controlled trial comparing percutaneous adhesiolysis in chronic function-limiting, recalcitrant low back pain in post-lumbar surgery syndrome demonstrated effectiveness in 73% of the patients at 12 months of follow-up (14). Another randomized controlled trial showed that percutaneous adhesiolysis utilizing local anesthetic, steroids, and hypertonic sodium chloride solution may be effective in patients with chronic, function-limiting low back and lower extremity pain with spinal stenosis with significant pain relief in 76% of patients (10). Significant improvement with at least 50% relief of pain and improvement in functional status in 82% of patients was illustrated at the 2-year follow-up visit in the intervention group compared to 5% in the control group receiving caudal epidural injections in another study (22). We think that the superior effect of PEN compared to ESI was secondary to a more localized selective block in the epidural space placed closer to the dorsal root ganglion and the ventral aspect of the nerve root (Fig. 6). Indeed, a previous study by Huston (23) examining ESI compared the cervical interlaminar versus transforaminal approaches. This study reviewed the efficacy, complications, side effects, and techniques for interlaminar and transforaminal cervical ESI, and reported that cervical transforaminal ESI is more effective than interlaminar ESI based upon the accurate delivery of medication to the site of pathology, stressing the need for future prospective, randomized, controlled studies.

In the present study, different clinical results were observed in the Ventral and Dorsal groups. VAS (back) scores at 6 months after the procedure showed similar effects between the groups, but the Ventral group showed significant improvement in VAS (leg) scores at postoperative 3 and 6 months (VAS [leg] scores at one month were similar between the groups). Odom's criteria at 6 months were also significantly improved in the Ventral group compared to the Dorsal group. These results could have been derived from anatomical differences, with a more localized and selective block closer to the dorsal root ganglion and ventral aspect of the nerve root.

In the demographic data, interesting results were observed. Our intention in all cases was to position the catheter in the lateral and ventral epidural space. Unfortunately, in 99 cases (33.7%), ventral positioning was not obtained and the catheter was placed instead in the dorsal position after several trials. The demographic data, including age, gender, weight, height, and disc level, were not different between the groups, but the symptom duration was significantly different between the groups. The symptom duration of the Ventral group was 9.4 ± 15.7 months, but this duration was elongated to 16.1 ± 30.9 months in the Dorsal group (P = 0.013). We hypothesize that the different symptom duration between the 2 groups may be derived from microadhesions in the epidural space. Despite no definitive evidence of microadhesions in the epidural space near degenerated discs, there is often indirect evidence of microadhesions. In the mouse model of acute noncompressive disc herniation, nucleus pulposus results in elevation of epidural IL-6, TNF- α, IFN- γ, and macrophages (24,25). This model may prove useful in the study of the biochemical processes by which NP {sp} induces inflammation-induced nerve root irritation and radiculopathic pain. Similarly, symptom duration may correlate with microadhesions in human models, as suggested by our study.

There are several limitations to the present study. First, this study was a retrospective analysis with a relatively short follow-up duration. Second, this study was not a randomized, controlled study. Therefore, the clinical effects of the catheter position could be confounded by other variables. Indeed, whether replication of pain during catheter placement is correlated with either ventral placement or with superior outcomes compared to lack of replication of pain remains unclear. In the clinical setting, the patient in whom the catheter was positioned in a ventral position typically experienced more pain immediately postprocedural when compared to those who had the catheter positioned in a dorsal position. However, the clinical results were more improved than other when the catheter was placed ventrally. More studies are warranted to better appreciate the benefits of dorsal versus ventral catheter placement in the future.

Despite these limitations, we gleaned important clinical information. This study supports PEN as a potential treatment strategy for patients with single-level LDH. The study further suggests that more localized treatment with a selective block in the epidural space closer to the dorsal root ganglion and ventral aspect of the nerve root is strongly correlated with clinical results up until 6 months.

Conclusion

The effects of lumbar PEN on VAS scores differed according to the position of the catheter tip in patients with single-level LDH. Better outcomes with the Dorsal group may have been achieved via more localized treatment with a selective block in the epidural space closer to the dorsal root ganglion and ventral aspect of the nerve root.

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