Randomized Trial

Randomized Controlled Study of Percutaneous Epidural Neuroplasty Using Racz Catheter and Epidural Steroid Injection in Cervical Disc Disease

Guy Yeul Ji, MD[1], Chang Hyun Oh, MD, PhD[2], Keun Su Won, MD, PhD[3], In Bo Han, MD, PhD[3], Yoon Ha, MD, PhD[1], Dong Ah Shin, MD, PhD[1], and Keung Nyun Kim, MD, PhD[1]

From: [1]Department of Neurosurgery, Spine and Spinal Cord Research Institute, Yonsei University College of Medicine, Seoul, Korea; [2]Department of Neurosurgery, Guro Teun Teun Hospital, Seoul, Korea; [3]Department of Neurosurgery, CHA University, Bundang CHA Medical Center, Sungnam, Korea

Address Correspondence: Dong Ah Shin, MD, PhD, Department of Neurosurgery, Yonsei University College of Medicine 50, Yonsei-ro, Seodaemun-gu, Seoul 120-752, Korea E-mail: shindongah@me.com

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Background: The efficacy of lumbar percutaneous epidural neuroplasty (PEN) as a minimally invasive technique has been relatively well investigated, but the clinical effectiveness of cervical PEN (C-PEN) has yet to be established.

Objective: The purpose of this study was to compare clinical outcomes between C-PEN and cervical epidural steroid injection (C-ESI).

Study Design: Randomized control study.

Setting: University hospital center.

Methods: Eighty patients with neck pain from single level cervical disease with and without radiculopathy were included in this study. Patients were randomly assigned into 2 groups: C-PEN or C-ESI. Clinical outcomes were assessed according to Neck Disability Index (NDI) score and Visual Analog Scale (VAS) score for arm pain until 12 months after treatment.

Results: All C-PEN and C-ESI groups showed better NDI recovery and greater reduction in VAS score at postoperative 6 months ($P < 0.001$). The C-PEN group demonstrated better NDI score at postoperative 6 months than the C-ESI group ($P = 0.014$), while there were no differences at 2, 4, and 12 months. Additionally, the C-PEN group showed lower VAS scores at all follow-up intervals compared to the C-ESI group ($P < 0.050$). Symptom relief was sustained for a significantly longer duration in the C-PEN group than in the C-ESI group (23.4 vs. 20.5 weeks, $P < 0.001$).

Limitations: The follow-up period was relatively short with a small sample size, and the grade of cervical disc disease, root compression, and disc degeneration grade were could not considered in this study.

Conclusions: C-PEN was superior to C-ESI in terms of better NDI recovery (at 6 months) and greater reduction in VAS score (until 12 months) in treating single level cervical disc herniation. Better outcomes with C-PEN may have been achieved via a more localized selective block in the epidural space closer to the dorsal root ganglion and ventral aspect of the nerve root.

Key words: Cervical, cervical disc disease, pain management, percutaneous epidural neuroplasty, percutaneous adhesiolysis, epidural steroid injection

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Neck pain is common in the general population, it is disabling, and it is costly. The lifetime prevalence of neck pain has been reported to range from 26% to 71%, with 12-month prevalence estimates ranging from 30% to 50% (1-5). Neck and upper extremity pain as well as headaches may stem from a number of structures including cervical intervertebral discs, cervical facet joints, atlanto-axial

and atlanto-occipital joints, ligaments, fascia, muscles, and nerve root dura capable of transmitting pain (5). In a study by Yin and Bogduk (6), the prevalence of discogenic pain among the study's patients was 16%, the prevalence of zygapophysial joint pain was 55%, and the prevalence of lateral atlanto-axial joint pain was 9%. Yet most causes of neck pain involve multiple pathologies, as various studies have demonstrated. In such studies, discogenic pain without zygapophysial joint pain was observed in 20% of the patients with neck pain, whereas both a symptomatic disc and a symptomatic zygapophysial joint were identified in the same segment in 41% of patients (6,7). In cervical radicular pain, however, it is assumed that mechanical compression, nerve root irritation, and/or neurotoxicity are involved (8-11).

Various treatment modalities, including cervical epidural steroid injections (ESI) (1,5,12-14), physiotherapy and a cervical collar (15), surgical treatment (16), as well as percutaneous cervical nucleoplasty (17), have been used to treat cervical radicular pain, and all of these treatment options have been shown to produce moderate to good clinical results. Among these treatments, ESI is commonly performed to manage chronic neck pain (1,12,13). Cervical ESI has been used to treat radicular pain from herniated discs, spinal stenosis, chemical discs, chronic pain secondary to post-cervical surgery syndrome, and chronic neck pain of discogenic origin (5). However, evidence for the use of cervical ESI has been the subject of some debate, and at best has shown only moderate success in managing cervical radiculopathy (with motor or sensory disturbance). No evidence is available for its use in the management of axial neck pain, post-surgery syndrome, or discogenic pain (5,12,13,18).

Cervical percutaneous epidural neuroplasty (PEN) was derived from lumbar PEN and has been applied as a treatment option for cervical disc herniation (19-22). PEN is considered to be more effective than non-selective ESI, owing not only to adhesiolysis, but also to a more localized selective block in the epidural space closer to the dorsal root ganglion and ventral aspect of the nerve root. However, to the best of the present authors' knowledge, studies have yet to compare the effectiveness of PEN and ESI for the treatment of cervical disc herniation. Herein, this randomized controlled study was performed to compare the clinical outcomes of cervical PEN and ESI for the treatment of single level cervical disc herniation.

Methods

Patients

This clinical trial was designed as a single center, randomized, single-blind, and comparative controlled clinical trial, and was conducted from April 2011 to January 2012 after gaining institutional review board approval. A total of 80 patients with single cervical disc disease were included in this study, and they were randomly assigned to either of 2 treatment groups: the cervical PEN (C-PEN) (40 cases) or cervical ESI (C-ESI) (40 cases) group. Inclusion criteria for this study were patients exhibiting symptoms of axial neck pain with or without unilateral radicular pain, cervical disc herniations with concordant radicular pain confirmed by magnetic resonance imaging (MRI), and a visual analogue scale (VAS, 0 – 10) score of 6 or more after receiving appropriate conservative treatment for at least 4 weeks in the form of medication and/or physiotherapy. Exclusion criteria were patients exhibiting a lack of correlation between radicular symptoms and the level of disc herniation on MRI, zygapophysial joint pain, prior spinal surgery, clinical signs of spinal cord compression, bleeding tendency, instability, spondylolisthesis, spinal canal stenosis, ossification of a longitudinal ligament and other traumatic injuries, as well as associated somatic, psychiatric disease, or an underlying systemic disease.

Surgical Procedures

Cervical PEN was performed as previously described by Viesca et al (20). The patient was placed in the prone position on a fluoroscopic table and an 18-gauge puncture needle (RX Epidural Needles - Coudé®, Epimed International Inc.) was placed at vertebral level C7-T1 or T1-T2 under local anesthesia and advanced to the cervical epidural space using the loss of resistance technique (23). Epidurography was performed to confirm the filling defects and the needle position, and a specialized epidural catheter (VERSA-KATH®, Epimed International Inc.) was placed directly into the herniated disc level under fluoroscopic control. Next, 2 to 3 mL of a non-ionic contrast (IOBRIX®, ACCUZEN, Seoul, Korea) was injected. After confirming the proper position of the catheter tip, hyaluronidase in preservative-free normal saline was injected (Fig. 1A). An additional small amount of dye was injected to check for analysis of adhesion, and then 5 mL of a mixture of 0.2% ropivacaine plus 5 mg of dexamethasone was administered slowly.

C-ESI was performed through the needle entry at

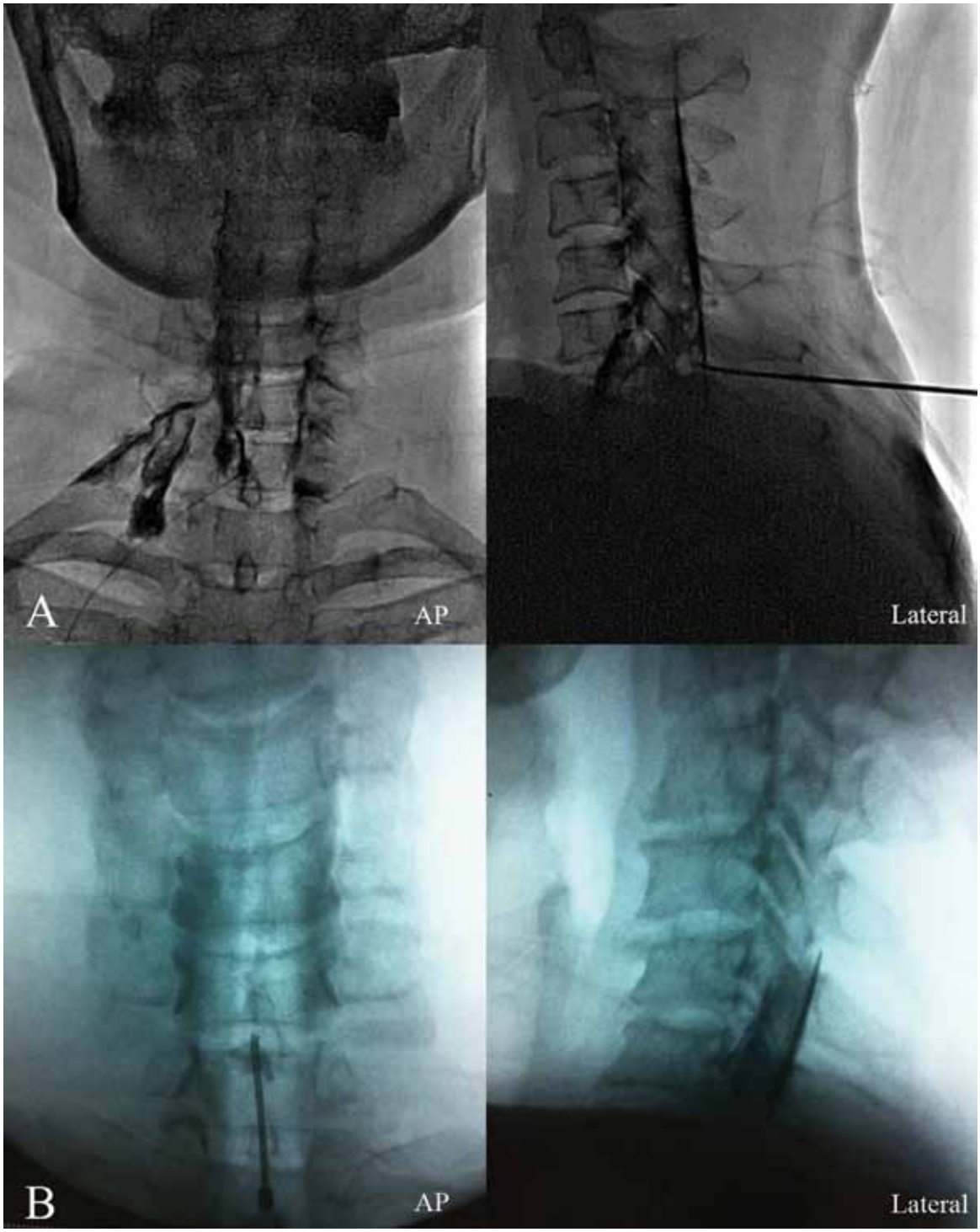

Fig. 1. *(A) Epidurography pattern of cervical percutaneous epidural neuroplasty: More localized selective block in the epidural space closer to the dorsal root ganglion and ventral aspect of the nerve root. This case showed the diffusion of contrast dye to nerve root with dorsal aspect of epidural space. (B) Epidurography pattern of cervical epidural steroid injection: bilaterally diffuse non-selective block in the epidural space closer to the dorsal aspect of the spinal canal.*

the C7-T1 level with patients in the prone position on a fluoroscopic table (Fig. 1B). A spinal needle was placed into the "straight line" of the spinous processes using the loss of resistance technique under lateral fluoroscopic guidance. After the needle was in place, 3 to 5 mL of a non-ionic contrast was injected to perform an epidurogram, and then, 5 mL of a mixture of 0.2% ropivacaine plus 5 mg of dexamethasone was administered slowly.

During the all procedures, cervical loculation was prevented by flexion rotation of the neck. The loculation of contrast in a small area was avoided, because this can significantly increase the pressure in the epidural space, and can compromise the already tenuous arterial blood supply to the spinal cord (23,24). The patients were educated about a neural flossing exercise to increase its effectiveness (23).

Clinical Assessment

All patients completed 6 months of follow-up, consisting of a medical interview with a physician and pain assessment by a pain-specialist nurse. Both were blinded to the patients' group assignments. Neck disability index (NDI) score was determined for each patient using a self-administrated questionnaire, which has been shown to be reliable, valid, and sensitive. NDI was used to measure neck-related disabilities, including pain intensity and headache, as well as the ability to perform activities including personal care, lifting, reading, concentrating, working, driving, sleeping, and participating in recreational activities (25). NDI was score calculated as the summation of scores for each of the 10 items above, which ranged from 0 (no activity limitation) to 5 (major activity limitation). In addition, outcomes in relation to arm pain were evaluated using VAS (arm) that ranged from 0 (no pain) to 10 (worst pain imaginable), from which the patient selected the number most representative of their pain. The evaluation was performed before the procedure, and at 2, 4, 6, and 12 months postoperatively.

Statistical Analysis

We used Student's t-test and the chi-square test to compare clinical outcomes of C-PEN and C-ESI. 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. Both the C-PEN group and C-ESI group were composed of 40 patients (20 men and 20 women). Average age, height, and weight were 56.7 years old, 163.4 cm, and 65.9 kg in the C-PEN group,

Table 1. *Demographic data of patients who underwent either PEN or ESI for cervical disc disease.*

	Cervical PEN Group	Cervical ESI Group	*P*-value
Male/Female	20/20	20/20	1.000
Age (years)	56.7 ± 10.5 [35 – 88]	53.5 ± 7.6 [42 – 76]	0.123
Height (cm)	163.4 ± 7.5 [152 – 176]	162.5 ± 6.0 [151 – 177]	0.556
Weight (kg)	65.9 ± 8.4 [51 – 84]	66.7 ± 8.7 [52 – 82]	0.675
Symptom Duration (week)	10.7 ± 4.8 [0.4 – 17.6]	10.8 ± 5.0 [0.4 – 10.8]	0.927
Symptom Characteristics			
Posterior Neck Pain (PNP)	20	14	0.175
PNP + Radiculopathy	20	26	
Lesion Level			0.844
C3/4	5	7	
C4/5	10	10	
C5/6	14	12	
C6/7	9	7	
C7/T1	2	4	
Neck Disability Index	27.6 ± 3.5 [21 – 34]	27.9 ± 3.8 [21 – 36]	0.715
Visual Analog Scale (Arm)	7.8 ± 1.1 [6 – 10]	7.8 ± 1.0 [6 – 11]	1.000

Data are reported as Mean ± Standard deviation [Minimum – Maximum]

and 53.5 years old, 162.5 cm, and 66.7 kg in the C-ESI group (P = 0.123, 0.556, 0.675, respectively). Symptom duration was not statistically different between the 2 groups (10.7 weeks in the C-PEN group vs. 10.8 weeks in the C-ESI group, P = 0.927), and preoperative symptoms were similar (20 cases with only posterior neck pain [PNP] and 20 cases with PNP + radiculopathy among the C-PEN group; 14 cases with only PNP and 26 cases with PNP + radiculopathy among the C-ESI group [P = 0.175]). The involved level of disc displacement was also not different between the 2 groups (5 cases at C3/4, 10 cases at C4/5, 14 cases at C5/6, 9 cases at C6/7, and 2 cases at C7/T1 in the C-PEN group; and 7 cases at C3/4, 10 cases at C4/5, 12 cases at C5/6, 7 cases at C6/7, and 4 cases at C7/T1 in the C-ESI group; P = 0.844). Follow-up was completed at 6 months, except for 7 patients (3 patients in C-PEN group and 4 patients in C-ESI group) who had not completed follow-up at 12 months.

Clinical Results

The clinical results are summarized in Figs. 2 and 3. Mean NDI scores for the C-PEN and C-ESI groups, respectively, were 27.6 and 27.9 (P = 0.715) preoperatively, 13.0 and 13.6 (P = 0.237) after 2 months, 11.6 and 12.6 (P = 0.142) after 4 months, 11.0 and 13.3 (P = 0.014) after 6 months, and 13.0 and 13.7 (P = 0.372) after 12 months of follow-up (all P < 0.001 compared to preoperative status, Fig. 2A). Mean VAS (arm) scores for the C-PEN and C-ESI groups, respectively, were 7.8 and 7.8 (P = 1.000) preoperatively, 3.2 and 3.7 (P = 0.019) after 2 months, 2.6 and 3.3 (P = 0.019) after 4 months, 2.7 and 3.5 (P = 0.033) after 6 months, and 3.1 and 3.6

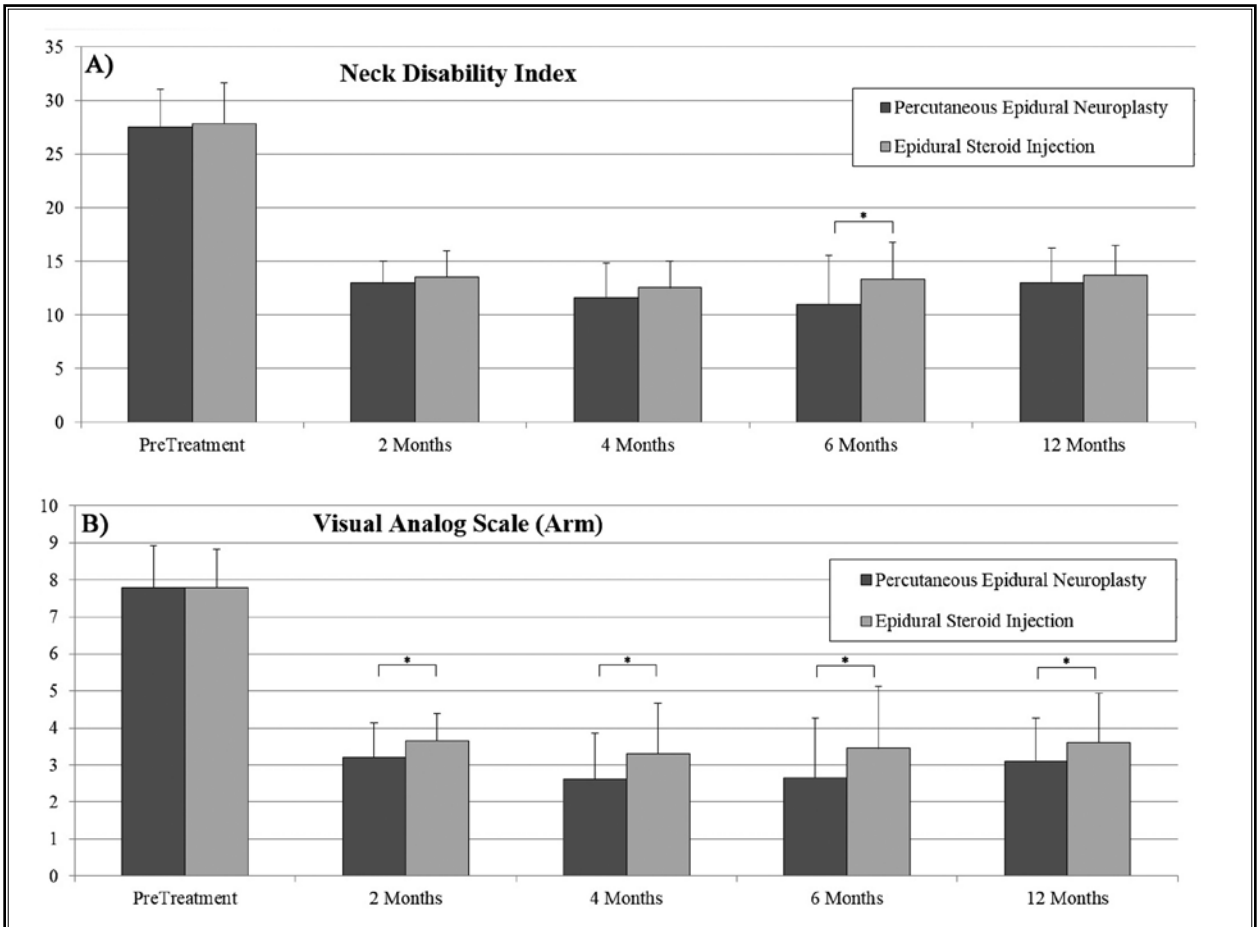

*Fig. 2. (A) Comparison of NDI score between cervical PEN and ESI checked before the procedure and at 2, 4, 6, and 12 months after treatment: * A statistical difference (P < 0.05) was observed only at 6 months after treatment. (B) Comparison of VAS (arm) score between cervical PEN and ESI checked before the procedure until 12 months after treatment: * A statistical difference (P < 0.05) was observed for all follow-up periods.*

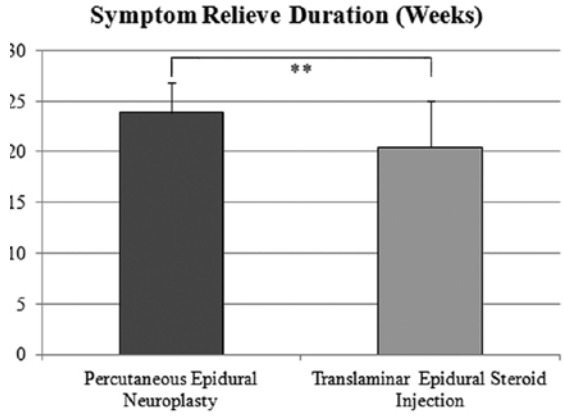

Fig. 3. *The duration of symptom relief (tolerable pain without limitations in daily activities) was longer in the cervical PEN group compared to the cervical ESI group, ** $P < 0.001$.*

($P = 0.046$) after 12 months of follow-up (all $P < 0.001$ compared to preoperative status, Fig. 2B). NDI score was only significantly different between the C-PEN and C-ESI groups at postoperative 6 months, while VAS (arm) scores were uniformly lower in the C-PEN group at all follow-up periods up to 12 months. Symptom relief was sustained for a significantly longer duration in the C-PEN group than in the C-ESI group (23.4 weeks vs. 20.5 weeks, $P < 0.001$). No complications were noted in either group.

Discussion

Epidural steroid injections have been commonly used in conservative treatment for neck pain and/or radiculopathy. Epidural injections have been utilized to deliver anti-inflammatory medicine in an effort to decrease inflammation at nerve roots, and provide satisfactory pain relief of a permanent or temporary nature for several months. In the literature, pathophysiologic and observational studies support the use of C-ESI in the management of cervical disc herniation and spondylotic stenosis (14). However, according to a systemic review by Benyamin et al (5), the indications for the use of this treatment in managing chronic neck and upper extremity pain are based on Level II-1 evidence (evidence obtained from well-designed controlled trials without randomization)

C-ESI may be administered via translaminar or transforaminal approaches. Translaminar injection is relatively easy to perform, but is administered as a non-selective procedure into the epidural space. A transforaminal approach allows for a diagnostic block to identify the affected level, providing useful information for future surgery in the event it becomes necessary. Good evidence supports the use of cervical transforaminal ESI, and reliable pain relief has been demonstrated for up to one year or longer in some studies (27). However, the complications are well known, and some of them can be devastating. Most complications of cervical transforaminal ESI, including headaches, transient neurologic deficits, hypersensitivity reaction, vasovagal reaction, or incident of transient global amnesia, are generally transient (28). Some patients, however, may experience more serious adverse events, consisting of vertebrobasilar brain infarcts, cervical spinal cord infarcts, spinal anesthesias, transient ischemic attacks, seizures, spinal cord edemas, brainstem edema with herniation or with reversible ischemic neurologic deficit, cortical blindness due to air embolus, cervical epidural hematoma, paraspinal hematoma, or peripheral neurapraxia (29). Hence, pain physicians urge caution before proceeding with cervical transforaminal ESI.

Recently, C-PEN, derived from lumbar PEN, has been applied as a treatment option for cervical disc herniation (19-21). Recent decades have seen tremendous progress in the understanding of neural pathways and the type and extent of tissue involvement in back pain (20). This in turn has stimulated the development of new treatment techniques for epidural decompressive neuroplasty or lysis of adhesions. It is natural for connective tissue or any kind of tissue to form fibrous tissue as part of the process that takes place after disruption of intact milieu, and tissues surrounding neural structures behave in the same fashion (20). Nerve roots can become entrapped by scar tissue and subjected to continuous pressure. Kuslich et al (30) concluded that pain at a nerve root entrapped by scar tissue might be associated with fixation of the affected nerve root, thus making it more susceptible to tension and compression. In the presence of scar tissue, changes in neural tissues can occur that can present as neck pain or radiculopathy (30). Not only postoperative scars (gross scar) but also spontaneous perineural adhesion (microscopic adhesion) may play a role in pain generation (31). The indications for C-PEN are broad and included cervicalgia or cervical radiculopathy of any of the following origins: failed neck surgery syndrome, cervical disc bulge with or without cervical radiculopathy, cervical radiculopathy of any other origin, epidural fibrosis, and spinal stenosis (20). Unfortunately, studies have yet

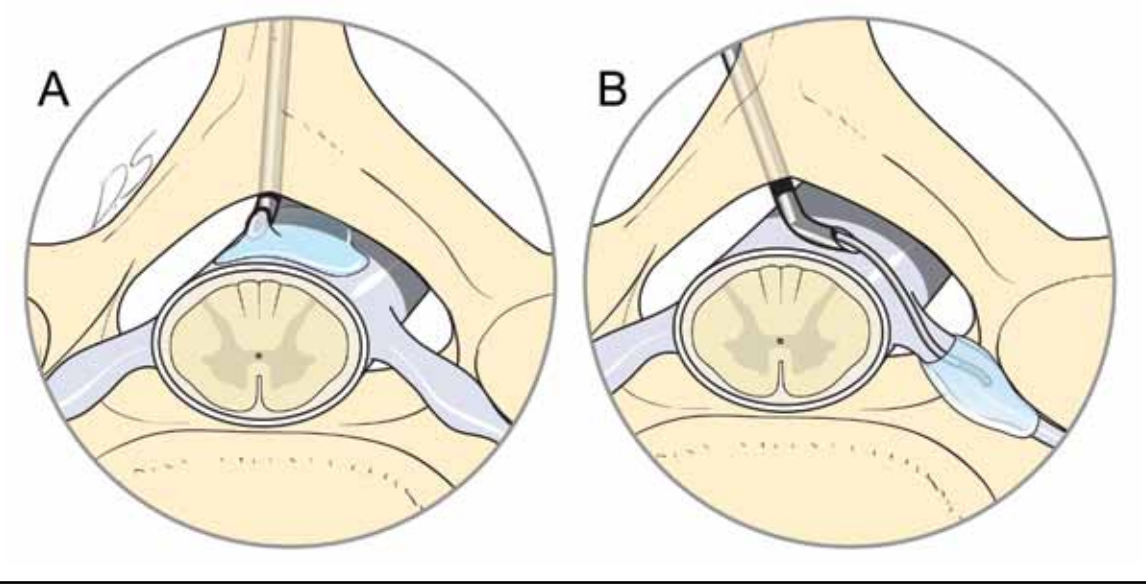

Fig. 4. *The illustration demonstrated more ventral and more localized drug delivery in cervical percutaneous epidural neuroplasty by using a Racz catheter. (A) Drug delivery usually localized to the dorsal side in cervical epidural steroid injections, but (B) the drug diffused from the dorsal to ventral side with the use of a Racz catheter in cervical percutaneous epidural neuroplasty.*

to demonstrate the efficacy of C-PEN in single level disc disease, and hence, as a randomized controlled study comparing clinical outcomes between C-PEN and cervical translaminar ESI in single level disc disease, the present study is quite meaningful.

The PEN procedure is considered to be more effective than ESI as it comprises a more localized selective block in the epidural space placed closer to the dorsal root ganglion and ventral aspect of the nerve root, between the nerve and the disc herniated particle where the micro-adhesion by the inflamed nerve was suspected (Fig. 4). The authors considered that microadhesion by discal irritation with inflamed nerve is present and this microadhesion could remove by mechanical adhesiolysis (catheter indwelling), chemical adhesiolysis (hyaluronidase), and hydrostatic adhesiolysis (radio-opaque dye and saline). We added this explanation. This aspect was discerned to be related with our clinical data for cervical PEN and ESI. In the present study, NDI and VAS (arm) scores for the C-PEN and C-ESI groups significantly improved from those preoperatively. Additionally, a statistical difference in NDI score between C-PEN and C-ESI was observed only at 6 months after treatment, while statistical differences in VAS (arm) scores between the 2 groups were observed for all follow-up periods up to 12 months after treatment. The more favorable results for C-PEN were discerned to have derived from the more anatomically localized selective block in the epidural space placed closer to the dorsal root ganglion and ventral aspect of the nerve root compared to ESI. As well, by more selective targeting of lesions, symptom relief was also maintained for a longer duration in the C-PEN group than in the C-ESI group. Although, no previous study has explicitly compared the effectiveness of C-PEN and C-ESI, similar results were observed in a previous study by Huston (14) which compared cervical interlaminar versus transforaminal ESI. This previous study reviewed the efficacy, complications, side-effects, and techniques for interlaminar and transforaminal C-ESIs, and reported that cervical transforaminal ESI was 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 interpreting the results of the present study, several limitations warrant consideration. First, the follow-up period was relatively short to examine the long-term effects of C-PEN and C-ESI. Second, this report comprised a relatively small sample size. As only patients with single level disc disease were included, grade of cervical disc disease, such as the degree of root compression by cervical disease or disc degeneration grade, was not evalu-

ated in this study. Indeed, all pain charts were collected by the pain-specialist nurse using the result of pain pattern, provocating and relieving factor, MRIs, but the discogenic pain was not definitively diagnosed without discography, which is an invasive technique with a high false positive rate. And C-PEN as the authors described does not exactly correspond to the terms of adhesiolysis, although we tried to treat the contrast filling defects. Despite these limitations, this study is the first to evaluate the efficacies of C-PEN and C-ESI among single level cervical disc disease patients as a comparative randomized control study. Additionally, the results of this study suggest the potential use of C-PEN as another treatment strategy in cervical disc disease. In the near future, larger-scale multi-center studies with longer follow-up durations are required to elucidate the true differences between C-PEN and C-ESI in patients with cervical disc degeneration, one study of which has been undertaken by our study group.

Conclusion

C-PEN in treating single level cervical disc herniation was superior to C-ESI in terms of better NDI recovery and greater reduction in VAS score. Better outcomes with C-PEN may have been achieved via a 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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