

Prospective Evaluation

e Clinical Effectiveness and Prognostic Indicators of Parasagittal Interlaminar Epidural Injection

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Background: Interlaminar epidural steroid injection (ESI) is a well-established intervention to improve radicular leg pain. However, few studies have demonstrated the prognostic factors for interlaminar ESI.

Objective: To investigate the clinical effectiveness and prognostic indicators of parasagittal interlaminar ESI during a 2-week follow-up.

Study Design: Prospective evaluation.

Setting: An interventional pain management practice in South Korea.

Methods: After Institutional Review Board approval, parasagittal interlaminar ESI under fluoroscopic guidance was performed in 55 patients with central spinal stenosis. The numerical rating scale (NRS) and the Oswestry Disability Index (ODI) (%) were used to evaluate clinical efficacy and prognostic indicators. To determine the prognostic indicators, treatment outcomes were classified as successful (decreased NRS \geq 50%, decreased ODI \geq 40%) and unsuccessful (decreased NRS < 50%, decreased ODI < 40%) results.

Results: Parasagittal interlaminar ESI significantly improved the NRS and ODI (%) scores after 2 weeks compared to those measured pretreatment. Paresthesia provocation ($P = 0.006$) was a significant prognostic factor on the NRS, whereas the Beck Depression Inventory (BDI) score ($P = 0.007$), paresthesia provocation ($P = 0.035$), and epidurography finding ($P = 0.038$) were significant on the ODI (%) score between patients with successful and unsuccessful outcomes.

Limitations: We included the method of parasagittal interlaminar ESI only, therefore, direct comparison with other techniques was not available.

Conclusion: Parasagittal interlaminar ESI significantly improved the NRS and ODI (%) scores. Paresthesia provocation was a prognostic indicator on the NRS and ODI (%) scores, and BDI scores and epidurography findings were prognostic indicators for the ODI (%) score.

Key words: Parasagittal interlaminar epidural steroid injection, spinal stenosis, radicular leg pain, prognostic indicator, paresthesia provocation, epidurography, Beck Depression Inventory

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Epidural steroid injection (ESI) is a frequently performed intervention to improve low back and radicular leg pain which are commonly observed in patients with intervertebral disc disease or spinal canal stenosis (1,2).

The transforaminal, interlaminar, and caudal approaches are the techniques used to deliver the medica-

tion to the epidural space (3,4). Many pain physicians prefer transforaminal epidural injections because a high concentration of medication can be delivered to the anterior epidural space, and several studies have shown improved short-term outcomes in patients with radicular leg pain due to lumbar disc disease and spinal stenosis (5,6). However, these advantages should

be reconsidered due to the risk of steroid entering into the vascular (1,7-9) and intervertebral disc spaces when using the transforaminal technique (10,11).

The interlaminar technique has demonstrated lower incidence of intravascular and intradiscal injection rates compared to transforaminal ESI (10,12). Interlaminar ESI is performed through a parasagittal or midline approach, and parasagittal ESI results in greater anterior epidural spread and more effective pain relief compared to those of midline ESI (13,14). In addition, parasagittal ESI is technically less challenging with equivalent pain relief and functional improvement compared to transforaminal ESI (15).

We have observed in our clinical practice that ESI is a good therapeutic option without pain recurrence for long periods in some patients; however, ESI has a very limited or failed response to improve symptoms in other patients. In addition, the evidence for ESI is highly variable, ranging from intermediate to strong in various reports. Many factors including psychological, lumbar spine magnetic resonance imaging (MRI) findings, epidural flow pattern of contrast, and provocation of concordant pressure may have contributed such variations in the ESI evidence (2,3,13,16).

We have observed some patients with a subjective sensation of painful paresthesia during injection into the epidural space. Concordant pain provocation is subjective pain that is distributed the same as the patient's baseline pain, whereas discordant pain means dissimilar in quality and distribution. Candido et al (17) and Sinofsky et al (2) demonstrated that concordant pain provocation during a lumbar epidural injection correlates with pain relief and is a good prognostic indicator. However, McCormick et al (18) showed that concordant pain provocation does not predict pain relief during lumbar transforaminal ESI. Therefore, it is uncertain whether concordant or discordant pain provocation during interlaminar or transforaminal ESI is a prognostic indicator.

The purpose of this study was to evaluate the effectiveness of parasagittal interlaminar ESI for treating chronic low back pain and leg pain in patients with spinal stenosis. This study also investigated various factors influencing clinical outcome of parasagittal interlaminar ESI in patients with spinal stenosis.

METHODS

This study was approved by the ethics committee of our institution. We explained the benefits, risks, and goals of this study and obtained written informed

consent from all patients. Sixty patients who received fluoroscopically guided parasagittal interlaminar ESI from September 2014 to September 2015 were enrolled in this study. These patients had chronic low back or leg pain for at least 3 months duration due to central spinal stenosis. They showed a minimal response to conservative therapy, including medications and physical therapy.

We excluded those patients with pregnancy; laboratory findings suggesting infection, inflammation or coagulopathy; and allergy to contrast dye, steroids, or local anesthetics. Patients who had received ESI or back surgery in the previous 6 months were excluded. We included patients who had stopped taking anticoagulants for the required time before interlaminar ESI. Among the 60 patients, 5 were excluded due to refusal to participate in this study. Finally, 55 patients were enrolled and 55 cases of parasagittal interlaminar ESI were analyzed.

The diagnosis of central lumbar spinal stenosis was confirmed by clinical characteristics and a radiological evaluation including MRI.

Data Collection

We obtained clinical data including age, gender, duration of symptoms, predominant symptoms (axial pain vs. leg pain), severity of neurogenic intermittent claudication (NIC), and degree of depression. Depression was assessed by the Korean version of the Beck Depression Inventory (BDI). The BDI is a standardized questionnaire to assess cognitive, affective, and somatic symptoms of depression (19). All data were obtained before performing ESI.

Data about anterior epidural spreading and presence of concordant pain provocation were obtained during fluoroscopically guided parasagittal interlaminar ESI. We observed the epidural spread pattern after a 2 mL injection of contrast material, confirmed anterior epidural spread with a lateral view, and asked the patients if they had any concordant pain provocation or not. The patients were asked if the pain was in the same distribution as their original pain (concordant) or dissimilar or absent in both quality and location.

Clinical Evaluation of Efficacy

We used the numerical rating scale (NRS) as well as the Korean version of the Oswestry Disability Index (ODI) to evaluate clinical effectiveness in terms of reducing pain and functional improvement at pretreatment and 2 weeks after the ESI series. ESI was performed

twice with a 2 week interval before the final treatment outcome evaluation with the NRS and ODI. All patients reported average severity of their symptoms over the previous one week. A score of 0 on the NRS represents no pain, and a score of 10 represents the worst pain imaginable. The Korean version of the ODI (0 – 50) was used to assess functional improvement. This test has satisfactory reliability with a test-retest correlation reliability of 0.9333 (20). ODI (%) was obtained using the scores provided from 10 sections by each patient.

Successful pain relief and functional improvement was defined as a 50% or more reduction in the NRS and 40% or more reduction in the ODI (%) scores, respectively. Unsuccessful pain relief and functional improvement was defined as less than 50% reduction in the NRS and less than 40% reduction in the ODI (%) score. No improvement or aggravated previous symptoms were also defined as an unsuccessful outcome.

Injection Technique

A single pain physician performed all ESIs to minimize variability in placing the needle and to provide more homogenous conditions. Injection level and side were determined by the main symptoms of the patient and the level of stenosis shown by MRI. ESI was per-

formed at the lower level in cases of stenosis affecting more than one level. For example, ESI was performed at L5-S1 in patients with spinal stenosis at L4-5 and L5-S1.

Patients were prepared and draped in a sterile fashion in a prone position. The left or right superior border of the inferior lamina was marked at the desired level. The overlying skin was infiltrated with 1% lidocaine and a 21 gauge Tuohy needle (Taechang Industrial Co., Kongju, Korea) was inserted until the needle reached the superior border of the inferior lamina. If the bony contact was made with the superior border of the inferior lamina, loss of resistance technique was used to ensure entry into the epidural space. A lateral fluoroscopic image was obtained when loss of resistance was felt using air to confirm that the needle was positioned within the posterior border of the spinal canal. After checking the needle position, 2 mL of contrast dye was injected and confirmed the epidural injection using an anteroposterior and lateral fluoroscopic image (Fig. 1A, B). If the proper epidural contrast pattern in accordance with the painful side of the patient was shown, we assessed the presence of anterior epidural spread in a lateral view. After assessing the epidural spread pattern, we injected the therapeu-

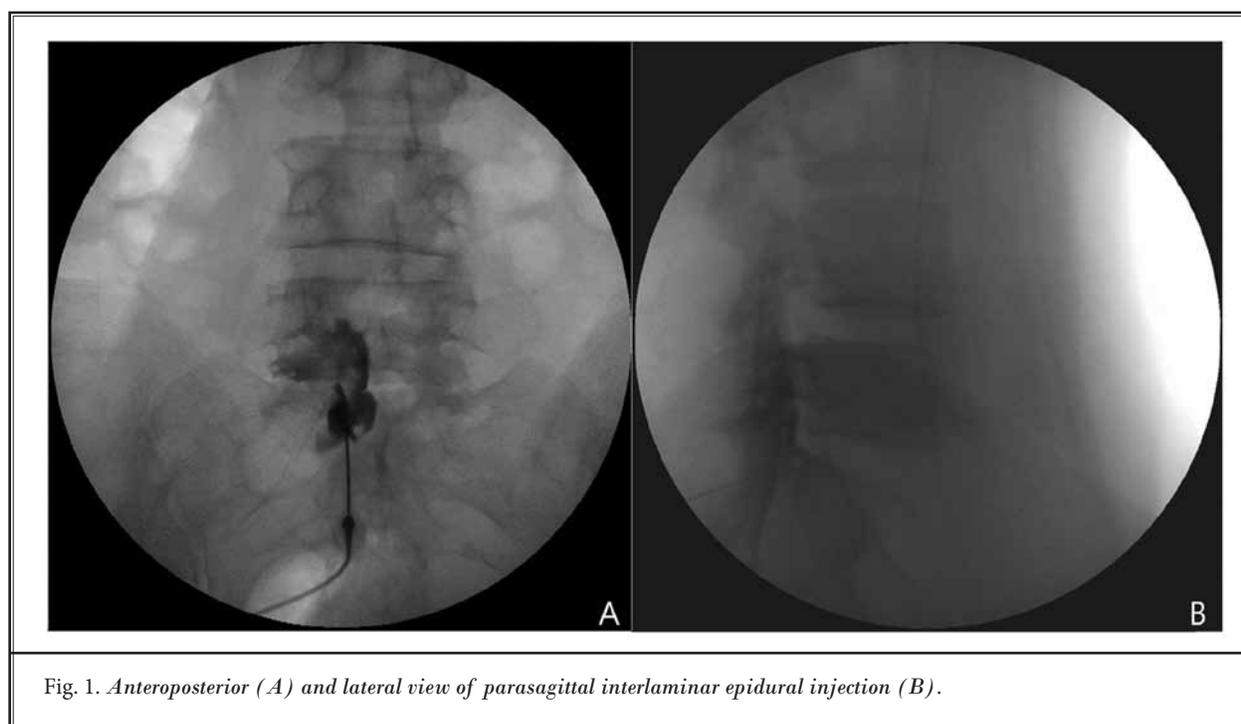


Fig. 1. Anteroposterior (A) and lateral view of parasagittal interlaminar epidural injection (B).

tic medication consisting of 5.0 mg dexamethasone and 3 mL 0.2% ropivacaine. Immediately after the injection, the patient was asked if they experienced any pain during the injection and if the pain was similar or dissimilar to their original pain.

Statistical Analysis

The sample size for this study was 55 patients. The primary measure for clinical efficacy of the epidural injection was changes in the self-reported NRS and ODI (%) scores. We also analyzed various prognostic factors influencing clinical outcome (successful vs. unsuccessful treatment). The independent Student's t-test was used to compare the continuous variable of pain (NRS, and ODI [%] scores). To assess prognostic indicators of ESI, the following characteristics were compared between patients with successful and unsuccessful treatment outcomes on the NRS and ODI (%) using the chi-square test: gender distribution, duration of symptoms (3 – 6 months vs. > 6 month), predominant symptom (axial pain vs. leg pain), severity of claudication, BDI score, type of provocation (concordant vs. discordant or absent), and presence of anterior epidural spread. Age was also compared between successful and unsuccessful treatment outcomes on NRS and ODI (%) with Student's t-test. All statistical analyses were performed using SPSS ver. 12.0 (SPSS Inc., Chicago, IL, USA). The results were considered statistically significant if the *P* value was less than 0.05.

RESULTS

We enrolled 55 patients with central spinal stenosis, and 55 cases of parasagittal interlaminar ESI were analyzed. According to the painful side of spinal stenosis, 33 cases of parasagittal ESI were performed on the right side and the remaining 22 cases on the left side. Thirty-four cases of parasagittal ESI were performed at L5-S1, 20 cases at L4-5, and one case at L3-4.

ESI significantly improved the NRS and ODI (%) scores 2 weeks after treatment compared to those measured pretreatment (Table 1).

Among the 55 patients, 37 (67.2 %) and 31 (54.3%) patients showed successful treatment out-

comes based on the NRS and ODI (%) scores at 2 weeks post-treatment.

When parasagittal interlaminar ESI was performed under fluoroscopic guidance, 38 patients (69%) experienced concordant paresthesia provocation and 49 patients (89%) demonstrated anterior epidural spread confirmed based on lateral fluoroscopic image (Tables 2 and 3).

Among the clinical (age, gender, pain duration, predominant symptom, severity of NIC, Beck Depression Inventory, and paresthesia provocation) and epidurography findings analyzed between patients with successful and unsuccessful outcomes, only paresthesia provocation (*P* = 0.006) showed statistical significance on the NRS, whereas the BDI score (*P* = 0.007), paresthesia provocation (*P* = 0.035), and epidurography findings (*P* = 0.038) showed statistical significance on the ODI (%) scores between patients with successful and unsuccessful outcomes (Tables 2 and 3).

DISCUSSION

ESI has been used for decades to treat radicular leg pain from spinal stenosis, herniated discs, and other disc-related spinal radiculopathies. In this study, we evaluated the clinical effectiveness of parasagittal interlaminar ESI and identified the prognostic factors for successful ESI. As many previous reports have demonstrated, ESI has short-term benefits (12,21-23). Therefore, we evaluated the short-term outcome (2 weeks) using the self-reported NRS and ODI (%) scores.

Overall, we observed significant improvement on the NRS and ODI (%) scores at 2 weeks after ESI. Approximately 67% and 54% of patients demonstrated successful results based on the NRS and ODI (%) scores, respectively, 2 weeks after treatment. Hashemi et al (13) reported successful results of parasagittal interlaminar ESI and effective pain relief (NRS < 3) and improved disability (ODI < 20%) were observed in 76.5% and 78% of patients compared to those after midline ESI, respectively. Sinofsky et al (2) also demonstrated the clinical effectiveness of interlaminar parasagittal ESI and reported that 38% of patients showed greater than a 75% pain reduction.

Table 1. Comparison of pain and functional disability between pre- and post-treatment.

	Pretreatment (n = 55)	2 Weeks Post-treatment (n = 55)	<i>P</i>
NRS	6.1 ± 1.4	3.0 ± 1.7	< 0.001*
ODI (%)	40.8 ± 15.4	25.6 ± 13.8	< 0.001*

Significant difference was found between pretreatment and 2 weeks. NRS: Numeric Rating Scale, ODI: Oswestry Disability Index

Our study demonstrated that concordant paresthesia provocation occurred in 69% of patients and was a prognostic indicator on the NRS and ODI (%) scores. Candido et al (17) suggested that concordant pain provocation during interlaminar ESI is associated with

better and longer pain relief at follow-up.

Paresthesia provocation is also observed during needle-nerve contact, however, paresthesia provocation experienced during injection of medication is distinct from needle-nerve contact induced paresthesia. The

Table 2. Comparison of clinical and epidurography findings between patients with successful and unsuccessful outcomes in numeric rating scale.

		2 weeks post-treatment		
		Successful (n = 37)	Unsuccessful (n = 18)	P
Age		60.9 ± 15.0	62.4 ± 9.0	0.092
Gender	Male	18	5	0.141
	Female	19	13	
Pain Duration	3 ~ 6 month	22	15	0.077
	> 6 month	15	3	
Predominant symptom	Axial pain	3	5	0.052
	Leg pain	34	13	
Neurogenic intermittent claudication	Severe	19	8	0.631
	Mild	18	10	
Beck Depression Inventory	< 14	20	5	0.066
	14 ~ 63	17	13	
Paresthesia provocation	Concordant	30	8	0.006*
	Disconcordant or absent	7	10	
Epidurography	Anterior spread	34	15	0.339
	Posterior spread	3	3	

Values are mean ± SD or number of patients. Successful pain reduction was defined as 50% or more reduction of numeric rating scale. Severe or mild neurogenic intermittent claudication was defined according to walking distance; severe claudication was defined walking ≤ 200 m and mild > 200 m.

Table 3. Comparison of clinical and epidurography findings between patients with successful and unsuccessful outcomes in Oswestry Disability Index (%).

		2 weeks post-treatment		
		Successful (n = 31)	Unsuccessful (n = 24)	P
Age		60.6 ± 15.2	62.5 ± 10.6	0.111
Gender	Male	14	9	0.568
	Female	17	15	
Pain Duration	3 ~ 6 month	19	18	0.283
	> 6 month	12	6	
Predominant symptom	Axial pain	3	5	0.245
	Leg pain	28	19	
Neurogenic intermittent claudication	Severe	14	13	0.508
	Mild	17	11	
BDI score	< 14	19	6	0.007*
	14 ~ 63	12	18	
Paresthesia provocation	Concordant	25	13	0.035*
	Disconcordant or absent	6	11	
Epidurography	Anterior spreading	30	19	0.038*
	Posterior spreading	1	5	

Values are mean ± SD or number of patients. Successful pain reduction was defined as 40% or more reduction of Oswestry Disability Index. Severe or mild neurogenic intermittent claudication was defined according to walking distance; severe claudication was defined walking ≤ 200 m and mild > 200 m.

incidence of neurological complications after ESI is exceedingly low. The reproduction of daily and typical pain during interlaminar ESI may indicate proper delivery of medication to the target, thus increasing the possibility of improved pain resolution and decreased disability.

According to our data, BDI scores and epidurography findings were prognostic indicators on ODI (%). Patients with lower BDI scores (< 14) and epidurography with anterior spread demonstrated more favorable outcomes. Thirty (54%) patients had BDI scores higher than 14; therefore, more than half of the patients were depressed, which is commonly observed in patients with chronic lower back pain (24) and is associated with a poorer surgical outcome of spinal stenosis surgery (25,26).

Candido et al (27) reported that parasagittal interlaminar ESI is superior to transforaminal ESI in demonstrating anterior epidural spread. Among the 49 patients (89%) who showed anterior epidural spread in our study, 30 patients (61%) demonstrated successful results based on ODI (%) score.

Anatomically, the ventral epidural space is closer to the posterior intervertebral disc space and nerve roots, which is a known pathological site for lumbar radiculopathy and it contains abundant pain substances (3-6,13,15,16). In this study, we only included patients with central spinal stenosis, therefore, a more complex mechanism applies to the development of clinical presentation. NIC is usually observed in central type stenosis, and results from mechanical compression of the nerve root, and the artery and vein surrounding the nerve root, provoking venous congestion or arterial ischemia of the nerve root (28). Although injecting steroid medication into the ventral epidural space has some limitation to resolve venous congestion or arterial ischemia around the nerve root, more patients (61%) demonstrated successful result based on the ODI (%) score compared to those who received medication in the posterior epidural space (16%). Gupta et al (29) concluded that ventral epidural spread of a contrast agent is associated with significantly improved visual analog scale (VAS) scores compared to those of a comparative group. In addition, transforaminal ESI results in lower VAS compared to those following paramedian or midline ESI, however, ventral epidural spread was nearly equal with that of paramedian ESI (29).

Transforaminal ESI is a commonly performed technique to deliver medication into the ventral epidural space, while avoiding dural puncture, vascular injection, and segmental nerve injury. However, numerous studies

have reported complications due to transforaminal ESI, including paraplegia, quadriplegia, and intradiscal injection (7,8,10,11), which should not be ignored.

There are several limitations of this study. First, we only included the method of parasagittal interlaminar ESI, therefore, direct comparison with other techniques including transforaminal or midline ESI was not available. In this study, we focused on identifying the prognostic indicator of ESI rather than a direct comparison with another technique. In addition, we included patients with central type stenosis who visited our pain clinic most commonly. According to Manchikanti et al (30) transforaminal ESI shows level III evidence for short-term improvement only, whereas caudal and interlaminar epidural injections have level II evidence for long-term efficacy in patients with lumbar central type spinal stenosis. Moreover, it was difficult to perform midline ESI, which is inferior to transforaminal or parasagittal ESI, in patients who complain of severe pain and disability (3,5,6,13).

Second, the follow-up period after ESI was relatively short, however, we were able to more effectively restrict factors that could affect therapeutic outcomes of ESI.

Third, we studied a small number of patients, therefore, we could not conduct a multivariate analysis to identify predictors of successful and unsuccessful results.

CONCLUSION

In this study, we investigated the clinical effectiveness of parasagittal ESI based on NRS and ODI (%) score, and identified possible prognostic factors. Parasagittal ESI demonstrated significant improvement on the NRS and ODI (%) after 2 weeks compared to scores assessed pretreatment. Among the 55 patients, 37 (67.2 %) and 31 (54.3%) patients showed successful treatment outcome based on the NRS and ODI (%) 2 weeks post-treatment, respectively.

Paresthesia provocation was a prognostic indicator in terms of the NRS and ODI (%), and the BDI scores and epidurography findings were prognostic indicators in terms of the ODI (%).

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