Prospective Study

Predictors of a Favorable Response to Erector Spinae Plane Block for Lumbosacral Radiculopathy

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Background: The erector spinae plane block (ESPB), which was introduced to manage the thoracic pain, is a technical easy and less invasive ultrasound-guided technique. Although the ESPB is used widely in various clinical situations, no studies have evaluated the association between the clinical outcomes of the ESPB and the numerical changes of the perfusion index (PI).

Objectives: The purpose of this study is to investigate the association between the clinical response following ESPB and other possible factors including the changes of PI.

Study design: Prospective, nonrandomized, and an open-label study.

Setting: The pain clinic of a tertiary university hospital.

Methods: This study included 91 patients of low back pain with degenerative spinal disease who received L4 ESPB using 20 mL of 0.2% ropivacaine. For the predication of clinical outcome, the PI was measured for 30 min at the blocked side subsequent to the ESPB. Various demographic data were also analyzed to predict the clinical outcomes.

Results: The PI of the responder group was higher value than that of the nonresponder group until 30 min but did not show any statistically significant differences. Multivariate logistic regression analysis revealed that the duration of pain (odds ratio [OR], 0.95; 95% CI, 0.90-1.00; $P = 0.043$), the right side injection (OR, 3.87; 95% CI, 1.42-10.55; $P = 0.008$), and the PI ratio of 1.5–3 at 10 min (OR, 3.79; 95% CI, 1.36-10.57; $P = 0.011$), were independent factors associated with successful outcomes.

Limitation: The responder and the nonresponders were categorized using only changes of the numeric rating scale. The categorization based on the changes of functional disability or quality of life was not used.

Conclusion: The right side injection, duration of pain less than 3 months, PI ratio of 1.5–3 at 10 min following the ESPB were associated with successful clinical outcomes.

Key words: Erector spinae plane block, perfusion index, numeric rating scale, low back pain

Trial registry number: Clinical trial registry information service (NCT05723367).

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The erector spinae plane block (ESPB) was first described in 2016 as an interfascial plane block for the management of thoracic neuropathic pain (1). Since then, numerous case reports and clinical studies have been published reporting good to excellent analgesic efficacy in various clinical situations (2-7). Moreover, this ESPB provides more safety compared to the neuraxial block. A reduced incidence of epidural hematoma, direct spinal cord injury, and central infection has been reported (8). Even patients of altered hemostasis, activated partial thromboplastin time ratio or international normalized ratio exceeding 1.5 times the normal value, could be managed with the ESPB safely (9).

For the performance of the ESPB, the erector spinae (ES) muscle just lateral to the spinous process should be identified under ultrasound guidance. Once identified, a needle is advanced through the ES muscle until the contact of the transverse process. Upon contact with the transverse process, local anesthetic is injected into this plane, making the ES interfascial plane (1,10). The suggested action mechanism of the ESPB is the block of the ventral and dorsal rami of the spinal nerves and sympathetic nerve fibers (2,11). The ESPB can be performed in the cervical, thoracic, and lumbar regions. Among them, lumbar ESPB has demonstrated good analgesic efficacy for acute pain control of lumbar spinal surgery or hip arthroplasty (12-15). Even chronic low back pain due to degenerative spinal disease or failed back surgery could be successfully managed with lumbar ESPB (16-20).

The perfusion index (PI) can reflect the perfusion status of the monitoring site using the calculated parameters obtained from the special pulse oximeter. The advantages of PI measurement are its simple procedure and noninvasiveness and its ability to provide more quantitative information about peripheral circulation (21). A previous study reported that the responder group (> 50% pain reduction) demonstrated a significantly higher PI ratio 5 min following the transforaminal epidural block (22). However, no studies have evaluated the association between the clinical outcomes of the ESPB and the numerical changes of PI.

Therefore, the purpose of this study is to investigate the association between the clinical response following ESPB in patients with lumbar degenerative spinal disease and numerical changes of PI. Also, we aimed to identify other possible factors predicting a successful or poor response subsequent to the ESPB.

Methods

Patients

This prospective, single group, and open label study was approved by our institutional review board (2023-01-025-02). The potential benefits and risks of this study were explained fully before patient enrollment, and they provided informed consent. This study was registered at clinical trials. gov (NCT 05723367) before patient inclusion.

Ninety–one patients aged between 20 and 80 years, who underwent ultrasound guided–L4 ESPB at the pain clinic were included. The inclusion criteria were as follows: 1) patients who have low back pain with or without leg pain due to foraminal stenosis, central stenosis, spondylolisthesis, and herniated disc disease; 2) patients with an 11-point numeric rating scale (NRS-11) (18) of > 4 within the previous week since the screening day; 3) with back pain functional scale (BPFS) < 45 (19); and 4) and duration of pain > one month.

The exclusion criteria were as follows: 1) patients with a history of allergic reactions to local anesthetics; 2) pregnancy; 3) with spine deformity; 4) with a history of lumbar spine surgery; 5) no previous lumbar magnetic resonance imaging or computed tomography; 6) coagulation abnormality; 7) peripheral arterial disease or who are taking any medication, which affects the peripheral circulation; and 8) who require bilateral lumbar ESPB.

L4 ESPB Under Ultrasound Guidance

One physician who had experiences of ultrasound guided injections for > 10 years performed this procedure. Right- or left-sided unilateral ESPB was performed depending on the location of the back and radiating leg pain. The patient was laid in a prone position for the performance of L4 ESPB. Using a curved low-frequency probe (GE Healthcare, Logiq S8, USA) in the longitudinal position enveloped in a sterile polyvinyl sheath containing an ultrasound gel, the spinous process, lamina, and L4 transverse process were confirmed serially moving a probe from the midline to the lateral side of the lumbar spine. Once identified, a 100 mm, 23 gauge needle was inserted in the plane from the cephalad to caudad direction. A 20 mL of 0.2% ropivacaine was injected subsequent to the contact of the transverse process. Following this injection, the linear spread of local anesthetics beneath the ES muscle was confirmed. For the evaluation of pain improvement, the NRS-11 (NRS-11, 0: no pain, 10: worst pain imaginable) was obtained before ESPB, at 30 min, 2 weeks, and 4 weeks after ESPB.

All included patients received ESPB twice. A second ESPB was performed at 2 weeks after the first injection. At 4 weeks after the first visit, the pain relief of patients was observed without any ESPB. The NRS-11 was measured by asking "What was your average pain score over the past 24 hours?"

To identify the possible factors related to the clinical outcome, patients were divided into responders and nonresponders. Responders were patients who showed improvement of pain > 50% (> 50% reduction of NRS-11). Nonresponders were patients who showed improvement of pain < 50% (< 50% reduction of NRS-11).

All demographic data including age, body mass index, diagnosis of spine, duration of pain, and side of injection were obtained by reviewing the electronic medical records and were further analyzed to predict successful outcomes. Specifically, the pain location was subdivided into back pain only, leg pain only, and back pain with leg pain.

Measurement of PI

The ambient temperature of the pain clinic was set 23–26°C for the proper evaluation of the changes of PI values. The ambient temperature was measured at a remote site from the heat generating equipment. One hour before the measurement of the changes of PI, all patients were educated to avoid smoking, alcohol intake, and severe exercise, which might affect the peripheral circulation. All patients were laid in bed for 10 min under an ambient room temperature before the measurement of the baseline PI using Masimo pulse oximetry (Masimo Corp, Irvine, CA, USA) sensor attached to the first toe. All PI values were measured at 2-min intervals until 30 min subsequent to the injection of local anesthetics in the blocked lower extremity using Masimo pulse oximeter sensors. The PI values were recorded automatically by the Masimo instrument configuration tool (Masimo Corp, Irvine, CA, USA) data extraction system.

Since the ESPB was performed twice, the PI was measured at each time of ESPB. Therefore, the mean value of PI measured during 2 ESPBs was used for the final analysis. During the period of measurement of PI values, patients were laid in bed in supine position with limited unnecessary movement.

The PI ratio was calculated as the ratio between the PI at a specific time point following a local anesthetic injection and the baseline PI. The specific time points when the PI ratio were obtained included 4, 10, 20, and 30 min after ESPB.

Statistical Analysis

The Kolmogorov-Smirnov test was used to examine normal distribution. If it showed normal distribution, an independent Student's t-test was used to compare the continuous variables between the responder and nonresponder groups. Categorical variables were reported as the number of patients (%) and compared using Pearson's chi square test or Fisher's exact test. An analysis of variance for repeated measures with post hoc pairwise comparisons using the Bonferroni test was used to compare the changes in PI ratio and NRS-11 at multiple time points between the responder and nonresponder groups. Univariate and multivariate analysis were performed to identify the possible outcomes of predictive factors associated with a successful response. Variables with *P*-values of < 0.1 on univariate logistic regression analysis were included in multivariate logistic regression analyses (IBM SPSS Statistics 20.0). A *P*-value of < 0.05 was considered statistically significant. The odds ratio (OR) and 95% CI for successful outcomes of lumbar ESPB were calculated by logistic regression analyses.

Results

A total of 102 patients were evaluated for eligibility in this study; however, 8 patients were excluded since they refused to participate or met other exclusion criteria. Three patients did not visit the pain clinic at the 4 week follow-up. The remaining 91 patients were allocated into the responder or nonresponder group based on the results of NRS-11 reduction (Fig. 1).

The patient demographic data were similar between the responder and nonresponder groups except the duration of pain and the side of injection. Significantly more patients were found when the duration of pain was < 3 months and the side of ESPB was right (*P* < 0.02, Table 1).

The PI was measured at 2-min intervals until 30 min and the baseline PI was similar between the responder and nonresponder groups. The PI of the responder group was higher than that of the nonresponder group until 30 min. However, it did not show any statistically significant differences (Fig. 2). Moreover, the PI ratio

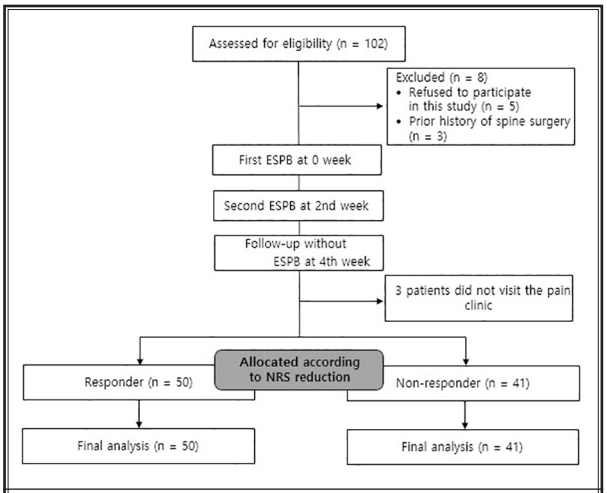

Fig. 1. *Flow chart of the study.*
NRS-11, numeric rating scale

Table 1. *Patient demographic and clinical data.*

	Responders (n = 50)	Nonresponders (n = 41)	Total (n = 91)	*P* value
Age (years)	65.0 ± 11.3	68.4 ± 12.9	66.6 ± 12.1	0.19
Gender (male)	22 (44)	14 (34.1)	36 (39.5)	0.393
Body mass index (kg/m^2)	23.7 ± 2.9	24.3 ± 4.2	23.9 ± 3.5	0.39
Diagnosis				0.46
Foraminal stenosis	22 (44)	15 (36.6)	37 (40.7)	
Central stenosis	3 (6)	1 (2.4)	4 (4.4)	
Spondylolisthesis	9 (18)	13 (31.7)	22 (24.2)	
Herniated disc disease	16 (32)	12 (29.3)	28 (30.8)	
Duration of pain				0.02
< 3 months	33 (66)	16 (39)	49 (53.8)	
3 – 12 months	14 (28.0)	16 (39)	30 (33)	
>12 months	3 (6.0)	9 (22)	12 (13.2)	
Spinal level				0.39
L3–4	0	1 (2.4)	1 (1.1)	
L4–5	28 (56.0)	18 (43.9)	46 (50.5)	
L5–S1	7 (14)	4 (9.8)	11 (12.1)	
L3–4–5	7 (14)	11 (26.8)	18 (19.8)	
L4–5–S1	8 (16)	7 (17.1)	15 (16.5)	
Injection side (left)	21 (42)	28 (68.3)	49 (53.8)	0.02

Values are mean ± SD or number of patients (%).

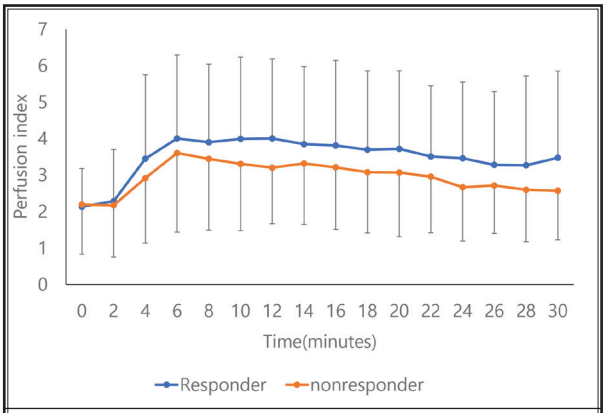

Fig. 2. *Changes of the perfusion index values at different time points in the responders and nonresponder groups.*

of the responder group was higher than that of the nonresponder group at 4, 10, 16, and 30 mins after ESPB, but did not show any statistically significant differences (Table 2). The NRS-11 of the responder group was significantly lower than that of the nonresponder group at second and fourth weeks ($P < 0.001$, Table 3).

Univariate logistic regression analysis showed that the right sided injection (OR, 2.97; 95% CI, 1.25–7.06; $P = 0.014$) and PI ratio of 1.5–3 at 10 min (OR, 2.75; 95% CI, 1.13–6.72; $P = 0.027$) were associated with successful outcomes. Multivariate logistic regression analysis revealed that the duration of pain (OR, 0.95; 95% CI, 0.90–1.00; $P = 0.043$), right sided injection (OR, 3.87; 95% CI, 1.42–10.55; $P = 0.008$), and PI ratio of 1.5–3 at 10 min (OR, 3.79; 95% CI, 1.36–10.57; $P = 0.011$, Table 4), were independent factors associated with successful outcomes.

Discussion

In this study, successful outcomes at 4 weeks after lumbar ESPB were achieved in 55% of patients with low back pain accompanying with or without leg pain. The duration of pain, injection side, and PI ratio of 1.5–3 at 10 min were independent factors associated with a successful response of lumbar ESPB.

Epidural injections with or without steroids have been the most commonly used interventions to treat lumbar radiculopathy. Caudal, interlaminar, and transforaminal epidural injections are commonly performed pain interventions. Among them, transforaminal injection is more advocated than the 2 other methods since the lower volume of injections can be applied near

Table 2. *Perfusion index (PI) ratio over time.*

PI ratio	Responders (n = 50)	Nonresponders (n = 41)	*P* value
T4	1.63 ± 0.66	1.51 ± 0.90	0.99
T10	1.94 ± 0.73	1.71 ± 0.93	0.76
T16	1.94 ± 0.73	1.79 ± 1.20	0.99
T30	1.67 ± 0.87	1.41 ± 0.88	0.68

T4; 4 min following the erector spinae plane block, T10; 10 min following the erector spinae plane block, T16; 16 min following the erector spinae plane block, T30; 30 min following the erector spinae plane block. PI ratio (PI at each time point/PI at T0)

Table 3. *Changes of numeric rating scale (NRS-11) over time.*

	Responders (n = 50)	Nonresponders (n = 41)	*P* value
Pain severity (NRS-11)			
T0	5.9 ± 0.6	5.7 ± 0.8	0.45
T30 min	4.6 ± 1.1	5.0 ± 1.1	0.33
T2 weeks	2.4 ± 0.9	4.8 ± 0.9	< 0.001
T4 weeks	2.1 ± 0.7	4.7 ± 0.9	< 0.001

T0; before treatment, T30 min; 30 min following the erector spinae plane block, T2weeks; 2 weeks following the erector spinae plane block, T4 weeks; 4 weeks following the erector spinae plane block.

Table 4. *Univariate and multivariate logistic regression analyses for predictive factors associated with a successful response after the lumbar erector spinae plane block.*

	Univariate Odds Ratio (95% CI)	*P* value	Multivariate Odds Ratio (95% CI)	*P* value
Age	0.98 (0.94 – 1.01)	0.191		
Body mass index	0.95 (0.84 – 1.07)	0.389		
Pre-injection symptom				
Back pain only	Reference			
Radiculopathy only	1.42 (0.18 – 11.0)	0.736		
Radiculopathy with back pain	1.05 (0.14 – 8.18)	0.963		
Pain duration (month)	0.96 (0.92 – 1.00)	0.05	0.95 (0.90 – 1.00)	0.043
Injection side (R)	2.97 (1.25 – 7.06)	0.014	3.87 (1.42 – 10.55)	0.008
Spinal disease type				
Foraminal stenosis	Reference			
Central stenosis	2.05 (0.19 – 21.59)	0.552		
Spondylolisthesis	0.47 (0.16 – 1.38)	0.171		
Herniated disc disease	0.91 (0.34 – 2.46)	0.851		
Perfusion index ratio at 10 min				
PI ratio < 1.5	Reference			
PI ratio 1.5–3	2.75 (1.13 – 6.72)	0.027	3.79 (1.36 – 10.57)	0.011
PI ratio > 3	2.44 (0.51–11.80)	0.266	1.21 (0.23 – 6.46)	0.826

the source of pain (25). However, procedure guidance using fluoroscopy or computed tomography, exposure to the radiation, and reported complications including spinal cord injury, paraplegia, and dural puncture make the need to find safer procedures (20,21). When lumbar ESPB is performed at the L4 level using high volumes of local anesthetics, it can result in a similar effect to the lumbar plexus block via an injected material spread toward the psoas muscle. Partially, it was known to spread into the neural foramen (11,27,28).

Successful outcome, the reduction of NRS-11 > 50%, was achieved in 55% of patients with low back pain. When low back pain was managed with epidural injection, a successful outcome was achieved in 67% of patients (29). The provocation of paresthesia was associated with successful outcomes (29). The proportion of successful outcomes with ESPB in this study was slightly lower than that of a previous study with epidural injection (29). Further study is required to clarify that lumbar ESPB has similar or better therapeutic effects in lumbosacral radiculopathy compared to those in other interventional pain procedures.

The ESPB has been used widely for the purpose of pain management in acute, subacute, and even chronic painful conditions. The ESPB, which was used during the postoperative low back pain after lumbar spinal surgery or back pain in the emergency department, explains its analgesic efficacy during the acute or subacute period (13,15,30,31). Also, the effectiveness of lumbar ESPB in patients with chronic low back pain

due to lumbar disc herniation or failed back surgery syndrome has been reported (16,18). This study demonstrated that short duration of pain was associated with a good response of lumbar ESPB. In accordance with the result of this study, short duration of symptom was an independent predictor of a good response to transforaminal epidural steroid injection for lumbar radiculopathy (32,33).

In this study, the location of pain was subdivided into back pain only, leg pain only, and back pain with leg pain. However, the location of original pain was not associated with successful outcomes of ESPB. In contrast to the result of this study, the cervical epidural steroid injection performed in the patient who presents a radicular pain only was associated with a successful treatment outcome (34).

The PI analyzes the peripheral blood circulation using the wave form obtained from photoplethysmography. Pulsatile and nonpulsatile signals comprise the PI, and they are a numerical value for the ratio between the pulsatile and nonpulsatile blood flow. Pulsatile flow is regulated by a vessel tension, preload, and vasoactive drug, whereas nonpulsatile flow is affected by a venous tension and body fluid volume (24,35-37). If a peripheral nerve block or neuraxial block was performed successfully, this could affect the sympathetic nerve activity, which results in increased peripheral blood flow with high proportion of pulsatile signal. Such a high proportion of pulsatile signal results in increased PI, which provides an objective method to predict peripheral nerve block success (36,38). The PI was an earlier, clearer and more sensitive measurement tool than the skin temperature increases and demonstrated quicker response after various interventions (21,35). In this study, the PI ratio at 10 min following ESPB was analyzed at a cut-off value of 1.5 to predict the clinical outcomes. The cut-off PI ratio of 1.5 was used since previous studies suggested that the PI ratio of 1.4 or 1.7 at 10 min demonstrated an excellent sensitivity and specificity to predict the peripheral block success (36,38). This study showed that the PI ratio of 1.5–3 at 10 min following ESPB was associated with successful outcomes. During 30 min of the PI measurement, the PI ratio was maintained over 1.5 in both the responder and nonresponder groups. However, it did not show any statistical differences. In contrast to the result of this study, the PI ratio at 5 min following lumbar transforaminal epidural injection demonstrated a significantly higher value in the responder group than in the nonresponder group (22). A higher PI ratio subsequent to the ESPB implies the success of block. Therefore, the PI ratio of 1.5–3 at 10 min following the block could be associated with an independent predictor of a successful response.

Limitations

This study includes several limitations. First, the PI was measured only in the blocked side of the extremity. Second, the responder and the nonresponder groups were categorized using only changes of NRS-11. The categorization based on the changes of functional disability or quality of life was not used. Third, the measurement period of 30 min was too short to predict the success of the block or any analgesic effects of ESPB. Fourth, the right side of injection of ESPB was associated with successful outcomes. However, it is uncertain why the right or left side of injection was associated the clinical response. Further study is required to clarify this point.

Conclusion

In conclusion, the right sided injection, the duration of pain less than 3 month, and the PI ratio of 1.5–3 min at 10 min following the ESPB were associated with successful clinical outcomes.

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