Randomized Trial

Comparison of the Low Back Pain Relief and Spread Level After Upper and Lower Lumbar Erector Spinae Plane Block

JiHee Hong, MD, PhD, JiHoon. Park, MD, PhD, Seungwon Lee, MD, and Jaeyun Lee, MD From: Department of Background: The erector spinae plane block (ESPB), which was introduced to manage the Anesthesiology and Pain thoracic pain, is an ultrasound-guided technique that is relatively easy, less invasive, and safer. In Medicine, Keimyung University spite of its technical ease and safety of ESPB, few studies have explored the analgesic efficacy and Dongsan Hospital, Daegu, South the exact spread level of injected local anesthetics. Korea Address Correspondence: Objectives: The purpose of this study is to compare the analgesic efficacy and spread level of the Ji H. Hong, MD, PhD upper and lower lumbar ESPBs. Department of Anesthesiology and Pain Medicine, Keimyung Study Design: Prospective, randomized design. University Dongsan Hospital 1035 Dalgubeol-daero, Dalseo-gu Daegu, 42601 South Korea **Setting:** The pain clinic of a tertiary university hospital. E-mail: swon13@daum.net Methods: This study included 84 patients with low back pain with or without leg pain who Disclaimer: There was no external funding in the preparation of this received lumbar ESPB at L2 (L2 ESPB group) or L4 (L4 ESPB group) using 10 mL of 0.2% ropivacaine manuscript. mixed with 10 mL of the contrast medium. After finishing 20 mL of the local anesthetic mixture injection, a fluoroscopic examination was performed to evaluate the spread level. Analgesic efficacy Conflict of interest: Each author was assessed using an 11-point Numeric Rating Scale (NRS-11) and a Back Pain Functional Scale. certifies that he or she, or a member of his or her immediate family, has no commercial Results: The number of patients who showed excellent-to-moderate low back pain relief was 35 association (i.e., consultancies, (83.3%) and 36 (78.5%) in the L2 and L4 ESPB groups, respectively. Significant reductions in pain stock ownership, equity interest, on the NRS-11 and improvements in disability were found in both groups. The total number of patent/licensing arrangements, vertebral segments to which the anesthetic drugs spread was significantly higher in the L2 ESPB etc.) that might pose a conflict of interest in connection with the group than in the L4 ESPB group (2.7 \pm 0.5 vs 2.0 \pm 0.2, P = 0.002). submitted manuscript. Limitations: The analgesic efficacy of lumbar ESPB was evaluated with only short-term outcomes. Manuscript received: 04-03-2023 Revised manuscript received: 04-06-2023 Conclusions: Both the L2 and L4 ESPB groups demonstrated a significant reduction in low back Accepted for publication: pain and improvement in disability. The L2 ESPB group demonstrated a significantly increased 05-16-2023 spread level compared to the L4 ESPB group. Free full manuscript: www.painphysicianjournal.com Key words: Erector spinae plane block, spread level, low back pain, analgesic efficacy Pain Physician 2023: 26:549-556 he erector spinae plane block (ESPB), which was effective management of thoracic neuropathic pain,

originally introduced to manage the thoracic pain with ESPB at the T5 level, is an ultrasoundguided technique that is relatively easy to perform, less invasive, and safer (1,2). In contrast to common neuraxial techniques, such as paravertebral or epidural injections, the ESPB targets an interfascial plane, which is far from the spinal cord, root, and pleura (2,3). In addition to the effective management of thoracic neuropathic pain, favorable clinical outcomes have also been reported in various clinical situations, such as thoracotomy, laparoscopic cholecystectomy, gastrectomy, mastectomy, and spinal surgery (3-8). The ESPB can be performed in the cervical, thoracic, and lumbar regions according to the location of pain origin. For the relief of chronic or acute low back pain, lumbar ESPB is a favored method (9,10). A few previous studies (11,12) have demonstrated the good analgesic efficacy of lumbar ESPB for acute pain control after lumbar spine surgery or hip arthroplasty. One retrospective study and 3 case reports (13-16) have shown good clinical outcomes of lumbar ESPB in patients with chronic low back pain due to degenerative spine disease or failed back surgery.

A previous case report (16) suggested that highvolume lumbar ESPB in selected cases would be a safe alternative, which has a similar effect to other interventional pain procedures. For the generalization of previous findings, a prospective randomized clinical trial is required.

The exact mechanism of action of ESPB remains unclear. A recent study (1,17) suggested that the analgesic effect of thoracic ESPB could be obtained by blocking the ventral and dorsal rami of the spinal nerves by passing the needle for injecting the local anesthetic through the costotransverse foramen. After performing lumbar ESPB at the L4, the injected agent was found to spread along the psoas muscle and in the intervertebral foramen, which possibly leads to an analgesic effect similar to the lumbar plexus block or transforaminal epidural injection (16). The study of the physical spread of the injected agent can be used to predict the clinical outcome and elucidate the possible mechanism of action of ESPB.

The size of the vertebra and the area of the fascial plane where the local anesthetic would spread is larger in the lumbar region than in the thoracic region (2). Possibly, the area of the fascial plane or anatomical barriers in the upper and lower lumbar regions where the injected local anesthetics diffuse might be different. However, there is no study comparing the analgesic efficacy and levels of physical spread of the local anesthetics in upper and lower lumbar ESPBs.

The primary endpoint of this study was to compare the analgesic efficacy of ESPB in low back pain when it was performed at the L2 or L4 using 20 mL of local anesthetics. The secondary endpoint of this study was to compare the spread level in the cranial and caudal directions in L2 and L4 ESPBs.

METHODS

Study Design

This prospective, single-center, randomized, parallel-armed study was approved by our institutional review board (2022-01-026-04). All study patients gave their written informed consent to participate in this

study. Before enrolling patients, this study was registered with clinical trials.gov (NCT 05487339, principal investigator: Ji H. Hong, date of registration: August 4, 2022). In total, 118 patients aged between 20 and 80 years who received L2 or L4 ESPB were enrolled, and 84 patients completed this study (August 12, 2022 to February 24, 2023) (Fig. 1).

Patient Selection

The inclusion criteria were as follows: 1) patients who have subacute or chronic low back pain with or without leg pain due to lumbar intervertebral disc herniation, foraminal stenosis, central stenosis, and spondylolisthesis, which have been confirmed via either lumbar computed tomography (CT) or magnetic resonance imaging (MRI); 2) patients who have the most severe level of spinal stenosis at L3-L4, which was confirmed via lumbar CT or MRI. If patients present with multiple discogenic or stenotic lesions, including at the L3-L4 level, those patients were also included. We selected patients with lesions at the L3-L4 level since the injected anesthetic agent could easily reach adjacent to a stenotic or discogenic level following L2 or L4 ESPB; 3) patients with an 11-point Numeric Rating Scale (NRS-11) score (18) of > 4 within the previous week since the screening day; 4) Back Pain Functional Scale (BPFS) < 45 (19); 5) duration of pain > one month; and 6) patients who can fully understand all items described in the BPFS. The exclusion criteria were as follows: 1) patients with a history of allergic reactions to local anesthetics and the contrast medium; 2) pregnancy; 3) spine deformity; 4) prior history of lumbar spine surgery; 5) no previous lumbar MRI or CT; 6) coagulation abnormality; 7) an incorrect level of ESPB; and 8) history of receiving injection therapy within one week before the study were excluded.

Randomization and Masking

In this study, the effects of L2 or L4 ESPB were compared after administering 20 mL of a local anesthetic mixture. Patients were assigned randomly to be in 1 of 2 groups receiving the same volume of local anesthetic at different spinal levels. According to a computer-generated randomization table, patients in the 2 groups received 20 mL of the 0.1% ropivacaine mixture at the L2 (L2 ESPB group) or 20 mL of the 0.1% ropivacaine mixture at the L4 (L4 ESPB group). A local anesthetic mixture was made using 10 mL of 0.2% ropivacaine mixed with 10 mL of the contrast medium. One member of the study group opened the sealed envelope and performed ESPB according to the assigned group. This physician was not blinded to the study group. However, all the patients, outcome investigators, and data analysts were blinded to the group assignment, and they were not involved in the ESPB procedure.

Assessment of Clinical Outcome

The severity of low back pain was evaluated using the 11-point NRS-11 (18) (0, no pain; 10 worst pain imaginable) before administering the ESPB, and then at 10 minutes, one week, 2 weeks, and 4 weeks after the ESPB. The BPFS (0, maximal disability; 60, no disability), was assessed before administering the ESPB and 4 weeks after the ESPB. The NRS-11 and BPFS were assessed by a physician who did not know the assigned patient group. The NRS-11 was obtained by asking "What was your average pain score over the past 24 hours?"

BPFS, which aims to assess disability in low back pain patients, was developed by Stratford et al (19) in 2000. It is a self-reporting

questionnaire consisting of 12 items that evaluate the patient's ability to perform physical activities. The 12 items present diverse domains (school, home activities, habits, bending, wearing shoes or socks, lifting an object from the ground, sleeping, sitting, standing, walking, climbing stairs, and driving). Each item is scaled on a 6-point Likert scale (range 0-5), with "0" meaning the inability to perform the action due to back pain and "5" indicating no difficulty at all (total score range 0-60). A validity and reliability study of BPFS was performed in 2022 (20). Before a patient was given the BPFS, the physician explained the BPFS questionnaire thoroughly and how to provide responses for each item.

Excellent relief of pain and disability was defined as a > 50% reduction in NRS-11 and a 30% increase in BPFS, respectively. Moderate relief of pain and disability was defined as a < 50% reduction of NRS-11 and a 30% increase in BPFS, respectively. When there were no changes in pain and disability, they were defined as poor relief of pain and disability.

During the 4 weeks of the study period, all patients received L2 or L4 ESPB twice at one-week intervals, irrespective of their pain relief, and they were strictly counseled not to receive any other injection therapy. They were given an acetaminophen (325 mg) and Tridol (37.5 mg) combination, aceclofenac 100 mg, and



pregabalin 25 mg for medication during the 4 weeks of the study period.

Technique for Ultrasound-Guided ESPB

One physician, who had experience with fluoroscopic- and ultrasound-guided injections of > 10 years, performed the L2 or L4 ESPB, according to the assigned group. Right- or left-sided lumbar ESPB was performed depending on the location of the back pain and the radiating leg pain. If a patient received on both sides of ESPB, only one side of the injection was included in the fluoroscopic analysis for determining the spread level. Patients were laid in a prone position for the performance of L2 or L4 ESPB. Using a curved lowfrequency probe (GE Healthcare, Logiq S8, Milwaukee, WI) enveloped in a sterile polyvinyl sheath containing ultrasound gel and oriented in the longitudinal position, the spinous process, the lamina, and the lumbar transverse process were scanned serially by moving the probe from the midline to the lateral side of the lumbar spine. For the confirmation of the L4 ESPB level, the spinous process of the L4 was first identified, and then the probe was moved to the lateral side until the appearance of the transverse process of the L4 vertebra. For the confirmation of the L2 ESPB level, the same method as followed for the L4 ESPB was applied. Once identified, a 100 mm, 23-G needle was inserted to touch the transverse process of the L2 or L4 vertebra and advanced in the plane from the caudal to the cranial direction. A local anesthetic mixture was injected subsequent to the contact with the transverse process. We confirmed the linear spread of the local anesthetic mixture beneath the ES muscle. After administering 20 mL of the local anesthetic mixture, a fluoroscopic examination was performed to confirm the final cranial and caudal spread levels. Lastly, we confirmed that the ultrasound-guided L2 or L4 ESPB was performed at the correct level. If the ESPB was performed at a different level than L2 or L4, those patients were excluded from this study.

Analysis of the Cranial and Caudal Spread Level

The spread level of ESPB was assessed using the saved fluoroscopic images in the Picture Archiving and Communication System (M6, INFINITT Healthcare, Seoul, Korea). One of the authors, who was not involved in fluoroscopic- or ultrasound-guided ESPB and was blinded to the patient group, analyzed the spread level. This physician had > 10 years of clinical experience in ultrasound- and fluoroscopic-guided injections.

The extent of the cranial and caudal spreads was assessed using anteroposterior images. After identifying the highest cranial and lowest caudal ESPB levels, the final cranial and caudal spread levels were assessed by counting all the segments covered by the contrast medium. For the L4 ESPB group, one segment of cranial and caudal spreads from the L4 was defined when the contrast medium was detected until the upper endplate of the L3 and the lower endplate of the L5, respectively. When the contrast medium was detected only reaching up to half the L3 or L5 body, it was defined as 0.5 seqments of the cranial or caudal spread. For the L2 ESPB groups, one segment of cranial and caudal spreads from the L2 was defined when the contrast medium was detected until the upper endplate of the L1 and the lower endplate of the L3, respectively. When the contrast medium was detected only reaching up to half the L1 or L3 body, it was defined as 0.5 segments of the cranial or caudal spread.

Statistics

A preliminary study for sample size calculation was performed. Assuming the mean differences in BPFS between the L2 and L4 ESPB groups as 5 \pm 7 and an α error level of 0.05, a β error level of 0.2, and a

dropout rate of 15%, 39 patients were required in each group with 80% power and a significance level of 5%.

The Kolmogorov-Smirnov test was used to examine the normal distribution. If it showed normal distribution, an independent Student's t test was used to compare the continuous variables (mean \pm SD). Categorical variables were reported as the number of patients (%) and compared using Pearson's chi-square test. A repeated measure of analysis of variance was used to analyze the changes in NRS-11 at multiple time points between the L2 and L4 ESPB groups (SPSS Software Version 20, Armonk, NY). A *P* value of < 0.05 was considered statistically significant.

RESULTS

A total of 118 patients were assessed for eligibility in this study; however, 18 were excluded since they refused to participate in it or satisfied other exclusion criteria. The remaining 100 patients were randomly allocated into the L2 or L4 ESPB group. Ten patients in the L2 ESPB group and 6 patients in the L4 ESPB group were excluded from data analysis due to follow-up loss and missing values (Fig. 1). The patient characteristics and reason for low back pain were similar between the groups (Table 1).

Primary Outcome

The number of patients who showed excellent-tomoderate pain relief was 35 (83.3%) and 36 (78.5%) in L2 and L4 ESPB groups, respectively (Table 2). During the study period, a significant reduction of NRS-11 was found in both groups of ESPB and the effect of time was statistically significant in the groups (P < 0.001, Fig. 2). There were no significant differences in the number of patients according to the degree of pain relief (P = 0.434, Table 2). NRS-11 changes did not show any significant effects for the group and time and group interaction (Fig. 2).

The number of patients who showed excellent-tomoderate improvement in disability was 35 (83.3%) and 29 (69.0%) in the L2 and L4 ESPB groups, respectively (Table 3). A significant increase in BPFS was found at 4 weeks after ESPB compared to before ESPB in both groups ($33.5 \pm 8.7 \text{ vs } 39.4 \pm 10.1$ in the L2 ESPB group, $31.3 \pm 9.9 \text{ vs } 37.9 \pm 11.0$ in the L4 ESPB group, *P* < 0.001; Fig. 3). There were no significant differences in the number of patients according to the improvement in disability and BPFS changes between the L2 and L4 ESPB groups (*P* = 0.233, Table 3, Fig. 3).

	L2 ESPB Group (n = 42)	L4 ESPB Group (n = 42)	P value
Age (y)	67.5 ± 10.2	62.9 ± 13.9	0.082
Gender (M/F)	17 (40.5)/25 (59.5)	18 (42.9)/24 (57.1)	0.999
Body Mass Index (kg/m²)	24.4 ± 3.3	24.7 ± 2.4	0.726
Duration of Low Back Pain	5.3 ± 5.5	6.7 ± 9.8	0.435
Side of Injection (R/L)	22 (52.4)/20 (47.6)	19 (45.2)/23 (54.8)	0.663
Diagnosis			0.780
Lumbar Intervertebral Disc Herniation	8 (19)	8 (19)	
Lumbar Foraminal Stenosis	14 (33.3)	16 (38.1)	
Lumbar Central Stenosis	16 (38.1)	12 (28.6)	
Lumbar Spondylolisthesis	4 (9.5)	6 (14.3)	

Table 1. Demographic data of the patients.

Values are mean ± SD or number of patients (%). ESPB: erector spinae plane block.

Secondary Outcome

The total number of vertebral segments in the cranial and caudal directions was significantly higher in the L2 ESPB group than in the L4 ESPB group (2.7 \pm 0.5 vs 2.0 \pm 0.2, *P* = 0.002, Table 4). The cranial and caudal spreads were more extensive in the L2 ESPB group than in the L4 ESPB group (*P* < 0.001, Table 4).

DISCUSSION

Lumbar ESPB, which was performed at the upper or lower lumbar region, demonstrated significant relief in low back pain. The number of patients showing excellent-to-moderate relief of pain was as much as 80% in both groups of ESPB. However, significant differences were not found in the NRS-11 changes between the L2 and L4 ESPB groups. Irrespective of the upper or lower lumbar region where the ESPB was performed, significant relief of low back pain was obtained. This relief of low back pain was also consistent with the improvement in disability, which showed a significant increase in BPFS 4 weeks after ESPB.

The proportion of patients showing excellent improvement in disability (> 30% increase in BPFS) was lower than that of showing excellent improvement in low back pain (> 50% reduction in NRS-11). In contrast to the changes in NRS-11, a longer duration observation period might be required to obtain significant changes in disability (21). In this study, we evaluated

Table 2. The number of patients showing pain relief according
to an 11-point numeric rating scale between the L2 and L4
ESPB groups.

	L2 ESPB Group (n = 42)	L4 ESPB Group (n = 42)	P value 0.434
Excellent (> 50% reduction)	25 (59.5)	19 (45.2)	
Moderate (< 50% reduction)	10 (23.8)	17 (33.3)	
Poor (no reduction)	7 (16.7)	9 (21.4)	

Values are number of patients (%). ESPB: erector spinae plane block. Excellent: > 50% reduction in the 11-point Numeric Rating Scale (NRS-11); Moderate: < 50% reduction in the NRS-11; Poor: no reduction in the NRS-11.



Fig. 2. Comparison of changes in the 11-point NRS-11 before ESPB, and at 10 minutes after ESPB, 1 week after ESPB, 2 weeks after ESPB, and 4 weeks after ESPB between the L2 and L4 ESPB groups. A higher score indicates a greater degree of pain. ESPB: erector spinae block; NRS-11: numeric rating scale.

Table 3. The number of patients showing improvement in disability according to the back pain functional scale between the L2 and L4 ESPB groups.

	L2 ESPB Group (n = 42)	L4 ESPB Group (n = 42)	P value 0.233
Excellent (> 30% increase)	14 (33.3)	9 (21.4)	
Moderate (< 30% increase)	21 (50.0)	20 (47.6)	
Poor (no increase)	7 (16.7)	13 (31.0)	

Values are number of patients (%). ESPB: erector spinae plane block. Excellent: > 30% increase in back pain functional scale (BPFS); Moderate: < 30% increase in BPFS; Poor: no increase in BPFS.



Table 4. The mean number of vertebral segments covered with the contrast medium during L2 or L4 ESPB.

	L2 ESPB Group (n = 42)	L4 ESPB Group (n = 42)	P value
Number of Segments with Cranial Spread	0.7 ± 0.4	0.2 ± 0.2	< 0.001
Number of Segments with Caudal Spread	1.0 ± 0.3	0.8 ± 0.2	< 0.001
Total Number of Segments	2.7 ± 0.5	2.0 ± 0.2	0.002

Values are mean ± SD. ESPB: erector spinae plane block.

the BPFS only 4 weeks after the ESPB, which is too short to observe significant changes in disability. A further clinical study is required with a longer study period to evaluate the changes in disability.

Several studies (12,22) have demonstrated the good analgesic efficacy of lumbar ESPB in patients with low back pain; however, these studies focused on patients with postoperative low back pain after lumbar disc surgery or acute back pain in the emergency department. This study included patients of subacute or chronic low back pain due to degenerative spine disease, which we encounter most commonly in the outpatient pain clinic, to validate the analgesic effect of lumbar ESPB. Clinical studies (14-16), demonstrating the good clinical effects of lumbar ESPB in patients with subacute and chronic low back pain, are not enough and most of them are case series.

The concept of injecting local anesthetics between the transverse process and the ES muscle is the same for lumbar and thoracic ESPBs. Lumbar ESPB is more challenging than the thoracic region since the injection point is deeper and more laterally located (2). Anatomically, the composition of the lumbar ES muscle is different from the thoracic ES muscle. From medial to lateral, the thoracic ES muscles are the semispinalis, longissimus, and iliocostalis muscles (3). In contrast to the thoracic area, the multifidus muscle becomes thick and prominent as it descends to the lumbosacral area and it adheres to the medial-dorsal side of the lumbosacral spinous process. In contrast to the thoracic region, the multifidus muscle needs to be considered as a part of the ES muscle in the lumbosacral area (2,3). The thoracic spine accompanies the paravertebral space, which provides an important route of action for the thoracic ESPB. However, the lumbar spine does not have any paravertebral space, and the psoas muscle is located anterior to the transverse process (9). The lumbar nerve root exits from the intervertebral foramen and is divided into dorsal and ventral rami. Along with the thoracic spine, the dorsal rami go posterior direction into the ES muscle; whereas, the ventral rami go anteriorly into the psoas muscle, and they become united to form the lumbosacral plexus within the psoas muscle (23). According to a previous cadaveric study (9,24), extensive dye distribution was found around the ES muscle and spread to the dorsal rami in all cadavers when L4 ESPB was performed using 20 mL of dye. However, the injected dye did not show any spread anteriorly into the dorsal root ganglion, ventral rami, or intervertebral foramen.

In this study, the total number of lumbar vertebral segments in the cranial-to-caudal direction was 2.7 and 2.0 segments in the L2 and L4 ESPB groups, respectively (Table 4). Increased spread level presents clinically relevant meaning since the analgesic or sensory block effect of ESPB depends on the cranial-to-caudal direction spread of local anesthetics extending several vertebral levels in the fascial plane (17). The L2 ESPB group demonstrated a significant distribution of injected anesthetic agent in the cranial-to-caudal distribution compared to the L4 ESPB group. Although, not statistically significant, the L2 ESPB group demonstrated a higher number of patients showing excellent relief of low back pain and disability.

When L4 ESPB was performed using 20 mL of methylene blue in a human cadaver, the craniocaudal spread was found between L2-L5 or L3-L5 (9,25). Moreover, the spread of the dye to the dorsal rami occurred in all cases; whereas, the spread to the ventral rami occurred in only 17% of cases (25). The injection volume used in the cadaver was the same as in the present study, but the injected solution (methylene blue) was different (24,25). In contrast to methylene blue, the contrast medium mixed with local anesthetics in this study has distinct characteristics due to its unique osmolality and viscosity (26). Therefore, such differences in injected material characteristics might lead to a different level of the craniocaudal spread. In addition, the spread of dye in a cadaveric model might have some differences due to reduced tissue tension and elasticity in the cadaver (2,9).

When ESPB was performed at the lower lumbar region, it demonstrated a more limited distribution of injectate in the cranial and caudal directions. The iliolumbar ligament has a passage from the transverse process of the L5 to the iliac crest, and it forms the thickened lower end of the thoracolumbar fascia. The presence of the iliolumbar ligament in the lower lumbar region provides a barrier, which limits further caudal spread (24). The ES muscle bellies become thicker in the lower lumbar region than in the upper region (24). The thinner muscle bellies in the upper lumbar region may permit a more extensive craniocaudal distribution than the lower lumbar region.

This study includes several limitations. First, we evaluated the analgesic efficacy of lumbar ESPB with only short-term outcomes. However, we could regulate other possible factors effectively that might have affected the clinical result of this study due to the short study period. Second, this study did not have any control group and included only 2 experimental groups. For the control group, ESPB needs to be performed with only normal saline, not including any local anesthetics. However, patients were reluctant to be injected with normal saline when it was explained. Third, we used BPFS for the assessment of physical disability. This scale does not include domains of psychosocial or quality of life; it includes only the domain of physical activity. Further study is required, which also evaluates the psychosocial aspects of ESPB.

CONCLUSIONS

Both the L2 and L4 ESPB groups demonstrated significant relief in low back pain and improvement in disability. The L2 ESPB group demonstrated a significantly increased spread level compared to the L4 ESPB group.

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