Retrospective Study

The Safety and Outcome of Erector Spinae Plane Block in Patients Using Antiplatelets, Anticoagulants, or Peripheral Vasodilators

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Background: The erector spinae plane block (ESPB) is used in various clinical situations with good to excellent analgesic effectiveness. The ESPB can be performed safely even in patients with altered hemostasis. However, the safety of ESPB in patients being treated with antiplatelets and anticoagulants is based on limited clinical data, mostly from single case series.

Objectives: The primary endpoint of this study was to identify any complications related to a thoracic or lumbar ESPB in patients using an antiplatelet, an anticoagulant, or a peripheral vasodilator without any preprocedure or postprocedure time interval. The secondary endpoint was to compare the clinical efficacy of ESPB in ischemic and nonischemic groups.

Study Design: Retrospective study.

Setting: The pain clinic of a tertiary university hospital.

Methods: After careful reviewing of medical records, if patients were taking medications with antiplatelet, anticoagulant, or peripheral vasodilator properties, or combinations of these medications due to ischemic disease, they were assigned to the ischemic group. If patients were taking only a peripheral vasodilator due to cervical or lumbar spinal stenosis but did not have any ischemic disease, they were assigned to the nonischemic group. Right- or left-sided unilateral ultrasound-guided ESPB was performed depending on the patient's pain location.

Results: There were only 2 patients who developed an adverse event: one each in the ischemic (1/103, 0.9%) and the nonischemic groups (1/149, 0.7%). These complications were irrespective to hematoma or bleeding. The post-ESPB Numeric Rating Scale scores for pain were significantly higher in the ischemic group than the nonischemic group at all measured time points ($P < 0.001$). However, there were no significant differences between the groups in the number of patients who experienced a ≥ 50% reduction in Numeric Rating Scale scores or in those who required spinal surgery due to inadequate ESPB efficacy.

Limitation: The actual incidence of complications might be underestimated since this study did not include any unreported complications due to its retrospective data collection.

Conclusion: In our study, ESPB had a complication rate less than 1% which was irrespective of bleeding. Hematoma or bleeding did not occur in either group. The ischemic group demonstrated lower clinical efficacy with ESPB than the nonischemic group.

Key words: Anticoagulant, antiplatelet, bleeding, complication, erector spinae plane block, hematoma

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In accordance with an increased incidence of ischemic cardiac or cerebrovascular disease (1), the prophylactic or therapeutic use of an antiplatelet or anticoagulant medication is common among patients with chronic spinal pain. If patients taking an anticoagulant medication should receive various spinal

procedures, potential complications, including bleeding or hematoma formation, need to be considered. Current guidelines recommend having a specific time interval from the last dose taken to the intervention depending on the antiplatelet or anticoagulant medication (2). The guideline suggested by the European Society of Regional Anesthesia recommends specific time intervals both pre and post neuraxial and deep nerve blocks because of their high bleeding risk (2). However, superficial nerve blocks do not require any time interval before and after the procedure (2).

Since the introduction of erector spinae plane block (ESPB) in 2016, it has been used in various clinical situations with good to excellent analgesic efficacy (3-8). Our previous studies demonstrated that ESPB at T2 is effective in achieving a successful outcome and sympatholytic effect in patients with cervical radiculopathy (9,10). Compared to the neuraxial technique, an ESPB is technically easier to perform and is safer. Moreover, an ESPB in patients being treated with anticoagulant or antiplatelet medication has minimal or no bleeding risk (11,12). An ESPB can be performed safely even in patients with altered hemostasis with an abnormal activated partial thromboplastin time or prolonged international normalized ratio (13).

According to the guideline published by the European Society of Regional Anesthesia, ESPB is classified as a superficial nerve block that does not require any preprocedure or postprocedure time interval (2). However, in contrast to a thoracic or cervical ESPB, the fascial plane of a lumbar ESPB is deeply located and requires a more cautious approach. Accordingly, a lumbar ESPB requires more technical expertise than a cervical or thoracic ESPB (14). Therefore, the safety of a lumbar ESPB in patients taking antiplatelet or anticoagulant medication without any preprocedure or postprocedure time interval needed to be studied. Moreover, the safety of an ESPB in patients treated with antiplatelet and anticoagulants is based on limited clinical data, mostly from single case series (13).

Previous study reported that advanced age, diabetes mellitus, a history of cerebrovascular disorder, and ischemic heart disease were associated with lumbar spinal stenosis with peripheral arterial disease (15). Patients with spinal stenosis combined with peripheral artery disease had a lower improvement in quality of life than patients with lumbar spinal stenosis who did not have peripheral artery disease (15). Therefore, the effectiveness of an ESPB in patients with spinal stenosis and ischemic disease has the potential to be low.

The primary endpoint of our study was to identify any complications related to a thoracic or lumbar ESPB in patients using an antiplatelet, an anticoagulant, or a peripheral vasodilator without any preprocedure or postprocedure time interval. The secondary endpoint was to compare the clinical efficacy of ESPB in ischemic and nonischemic groups.

Methods

Patients

This retrospective study was approved by our institutional review board (2024-11-012), which waived the need for informed patient consent. From February 2022 through May 2024, 312 consecutive patients who received a thoracic or lumbar ESPB at least twice for pain improvement were reviewed and evaluated for suitability for inclusion in our study. Only patients who were followed up regularly for at least 2 months were included. If medical records included only one or 2 missing data, they were included for analysis. However, 60 incomplete medical records with more than 3 missing data were excluded, such as demographic data, location of the ESPB, type of ischemic disease, comorbidity, antithrombotic medication, laboratory coagulation data, any post ESPB complications, or the clinical outcome at the 2-month follow-up. Finally, the medical records of 252 patients were included in the final analysis.

The records of patients who received an ESPB who were using an antiplatelet, an anticoagulant, or a peripheral vasodilator were retrieved using Clinical Data Warehouse v 2.5 (CDW, Planit Healthcare) using the key words "erector spinae plane block and antiplatelet, anticoagulant, or peripheral vasodilator."

Patient Assignment

If a patient was taking an antiplatelet (clopidogrel, cilostazol, or triflusal [not USFDA approved]), an anticoagulant (apixaban, edoxaban, rivaroxaban, or warfarin), a peripheral vasodilator (limaprost [not USFDA approved] or beraprost [not USFDA approved]), or combinations of these medications due to ischemic heart, cerebral, or vascular disease, the patient was assigned to the ischemic group. If a patient was only taking a peripheral vasodilator due to cervical or lumbar spinal stenosis but did not have any ischemic disease, the patient was assigned to the nonischemic group.

Data Collection

Patient data collected included age, gender, pain

disease requiring an ESPB, number and location of the ESPB, type of ischemic disease, comorbidity, antithrombotic medication, laboratory coagulation data, any post ESPB complications, and the clinical outcome at the 2-month follow-up.

Antiplatelet, Anticoagulant or Peripheral Vasodilator Medication

All patients included in our study continued taking aspirin, antiplatelet, anticoagulant, or peripheral vasodilator pre and post the ESPB. Types and combinations of the medications were identified by medical record review.

ESPB Procedure

A right- or left-sided unilateral L3 or L4 ESPB was performed depending on the location of the back and radiating leg pain. If a patient reported neck or arm pain due to cervical spinal stenosis or disc herniation, a thoracic ESPB at T2 was performed. The patient was placed prone. A curved low-frequency probe or a linear high-frequency probe (GE HealthCare, Logiq S8) were used in the lumbar and thoracic region, respectively.

Moving a probe from the midline to the lateral side of the lumbar or thoracic spine, the spinous process, lamina, and transverse process were identified. Once confirmed, an 80 mm, 22G ultrasound needle (B. Braun, Stimuplex® Ultra 360®) was inserted in the plane in a cephalocaudal direction. Twenty mL of 0.2% ropivacaine was injected subsequent to contact with the transverse process. Following this injection, the linear spread of local anesthetics beneath the erector spinae muscle was confirmed. All images of the ultrasound-guided ESPB were recorded and digitally transmitted and saved in a picture archiving and communication system.

Adverse Events

The primary outcome of this study was to identify adverse events in relation to an ultrasound-guided ESPB. Included adverse events—hematoma formation, local anesthetic systemic toxicity, leg numbness, and injection site pain lasting more than 3 days—were identified through medical record review.

Outcome Evaluation

The Numeric Rating Scale (NRS-11) was used to evaluate the patients' pain levels. These data were obtained preblock, and at postblock 2 weeks, 4 weeks, and 8 weeks. The patients whose NRS-11 score was reduced by > 50% and patients who received spinal surgery due to low efficacy of the ESPB adminstered were compared.

Statistics

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 ischemic and nonischemic groups. Categorical variables were reported as the number of patients (%) and compared using Pearson's χ^2 test or Fisher's exact test. A P value < 0.05 was considered statistically significant. Statistical calculations were made using IBM SPSS Statistics 20 (IBM Corporation).

Results

The electronic medical records of 312 patients were reviewed after excluding 60 patients. Excluded patients had insufficient medical records. According to the presence or absence of major organ ischemic disease, patients were assigned into either the ischemic group (n = 103) or the nonischemic group (n = 149) (Fig. 1).

The ischemic group had more men ($P <$ 0.001) and more frequently received ESPBs than the nonischemic group ($P < 0.05$). The most common pain causes in the ischemic and nonischemic groups were lumbar foraminal stenosis and lumbar disc herniation, respectively ($P < 0.001$). Ischemic heart disease (67/103, 65%) was the most common disease in the ischemic group patients. The number of patients who had severe major organ disease other than an ischemic disease was higher in the ischemic group (26/103, 25.2%) than the nonischemic group (8/149, 5.3%) ($P <$ 0.001, Table 1). The most commonly used medication in the ischemic group was

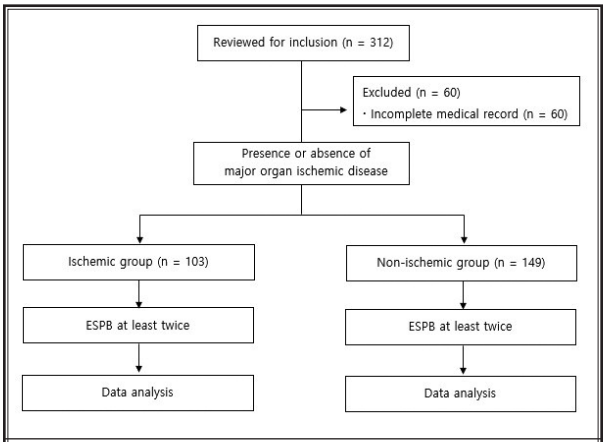

Fig. 1. *Flow chart of the study.*

aspirin along with an antiplatelet or an anticoagulant or a peripheral vasodilator (Table 2). The ischemic group patients had lower platelet counts than the non-ischemic group patients (167.2 ± 61.5 vs 204.5 ± 67.4, $P < 0.001$). However, prothrombin time was similar between the groups (Table 3).

Post-ESPB adverse events were rare in both groups. Each group only had one patient who had an adverse event (Table 4). Two patients developed a complication, but they were not due to a hematoma or bleeding.

The post ESPB NRS-11 scores were significantly higher in the ischemic group at all measured time points ($P < 0.001$). However, there were no significant differences between the groups in the number of patients who experienced a ≥ 50% reduction in NRS scores or in those who required spinal surgery due to inadequate ESPB efficacy. (Table 5).

Discussion

In our study, the overall complication rate was less than 1% in patients receiving an ultrasound-guided ESPB using a 22G needle without stopping an antiplatelet or anticoagulant in both groups of ESPB. Although all patients were using either an antiplatelet or an anticoagulant before and after their ESPB in the ischemic group, and ischemic group patients had significantly lower platelet counts, no hematomata occurred. Two patients developed a complication—one, injection site pain, the other, leg numbness. Neither complication was due to bleeding.

Our results are in accordance with previous reports which demonstrated minimal or no risk of bleeding after an ESPB (11,12). Rectal sheath block, a fascial plane injection performed in the abdomen, demonstrated a complication rate of 2.4%. However, most of the complications were from an extrarectus sheath injection. Vascular injury or hematoma formation was found only in 0.2% (16).

The ESPB procedure, which is easy to be performed under ultrasound guidance, has been reported to be a safe procedure with a low complication rate (3). Even patients with altered hemostasis and patients undergoing cardiac surgery who are receiving either an anticoagulant or an antiplatelet did not have any post ESPB bleeding or hematoma formation (12,13). The block target of ESPB, deep in the erector spinae muscle and superficial to the transverse process, is dis-

Table 1. *Patient demographic data*.

	Ischemic Group (n = 103)	Nonischemic Group (n = 149)	*P* Value
Age (years)	72.3 ± 8.0	70.5 ± 8.4	0.092
Gender (men)	58 (56.3)	45 (30.2)	< 0.001
Pain disease requiring ESPB			< 0.001
Lumbar central stenosis	1 (1.0)	1 (0.7)	
Lumbar foraminal stenosis	30 (29.1)	44 (29.5)	
Lumbar disc herniation	20 (19.4)	52 (34.9)	
Lumbar spondylolisthesis	15 (14.6)	24 (16.1)	
Cervical foraminal stenosis	12 (11.7)	5 (3.4)	
Cervical spondylotic myelopathy	1 (1.0)	0 (0)	
Cervical disc herniation	3 (2.9)	2 (1.3)	
Postherpetic neuralgia	8 (7.8)	0 (0)	
Postlaminectomy pain syndrome	13 (12.6)	21 (14.1)	
Number of ESPBs	3.1 ± 2.5	2.5 ± 1.2	0.045
Region of ESPBs			<0.001
Thoracic	22 (21.4)	6 (4.0)	
Lumbar	81 (78.6)	143 (96.0)	
Types of ischemic diseases			
Ischemic heart disease	67 (65)	0 (0)	
Ischemic cerebral disease	28 (27.2)	0 (0)	
Peripheral vascular disease	5 (4.9)	0 (0)	
Ischemic heart disease with ischemic cerebral disease	2 (1.9)	0 (0)	
Ischemic heart disease with peripheral vascular disease	1 (0.9)	0 (0)	
Incidence of comorbidity (%)	26 (25.2)	8 (5.3)	<0.001

Values are mean ± SD or number of patients (%). ESPB: erector spinae plane block
Included diseases for comorbidity were abdominal aortic aneurysm, aortic valve insufficiency, lung disease (bronchiectasis, chronic obstructive pulmonary disease, lung cancer), cerebral aneurysm, cholangiocarcinoma, chronic renal failure, heart failure, and lymphoma.

tant from a major vessel, the spinal canal, and the epidural space (3,12,17). The compressibility of the puncture site, any nearby large blood vessel, and the presence of the neuraxial structure are important factors to minimize bleeding risk (2). Because of its good analgesic efficacy and its relative safety (3-6,13), an ESPB could be a good alternative option if patients had an altered hemostasis, impaired coagulation, or were taking antiplatelet treatment.

Table 2. *Types of medicated antiplatelet, anticoagulant, or peripheral vasodilator without discontinuation before and after erector spinae plane block in the ischemic and nonischemic groups.*

	Ischemic Group (n = 103)	Nonischemic Group (n = 149)
Aspirin only	14 (13.6)	0
Aspirin with antiplatelet or anticoagulant or peripheral vasodilator	34 (33.0)	0
Peripheral vasodilator with antiplatelet or anticoagulant	10 (9.7)	0
Antiplatelet with anticoagulant	2 (1.9)	0
Antiplatelet only	26 (25.2)	0
Anticoagulant only	17 (16.5)	0
Peripheral vasodilator only	0 (0)	148 (99)

Values are number of patients (%). Included antiplatelets and anticoagulants in the ischemic group are P2Y12 receptor inhibitors (clopidogrel, cilostazol, and trifusal) and direct oral anticoagulants (apixan, edoxaban, rivaroxaban, and warfarin), respectively. Included peripheral vasodilators are limaprost and beraprost. The patients in the nonischemic group took a peripheral vasodilator due to spinal stenosis of the cervical or lumbar region.

Table 3. *Laboratory coagulation data.*

	Ischemic Group (n = 103)	Nonischemic Group (n = 149)	*P* Value
Platelet count (103/μL)	167.2 ± 61.5	204.5 ± 67.4	< 0.001
Prothrombin time (INR)	1.09 ± 1.06	0.95 ± 0.07	0.285
Prothrombin time (second)	11.27 ± 1.06	10.98 ± 0.74	0.064

Values are mean ± SD. INR: international normalized ratio

Table 4. *Adverse events of real-time ultrasound-guided erector spinae plane block.*

	Ischemic Group (n = 103)	Nonischemic Group (n = 149)
Hematoma formation	0 (0)	0 (0)
Local anesthetic systemic toxicity	0 (0)	0 (0)
Leg numbness	0 (0)	1 (0.9)
Injection site pain lastingmore than 3 days	1 (0.9)	0 (0)

Values are number of patients (%)

In contrast to the regional anesthesia required in the operating room, a broader spectrum of interventional and pain procedures exists with variable targets and objectives. From low-risk peripheral nerve blocks to high-risk invasive procedures—including vertebral augmentation, spinal cord stimulation lead placement, deep visceral block, and spine interventions—variable pain procedures require more procedure-specific and patient-specific guidelines (18).

ESPB could be categorized into low risk procedures according to the American Society of Regional Anesthesia and Pain Medicine guideline. However, if patients have a high risk for bleeding—such as old age, a history of bleeding tendency, concurrent uses of anticoagulants/antiplatelets, liver or advanced renal diseases—they should be treated as intermediate-risk procedures (18).

P2Y12 receptor inhibitors are used commonly in combination with aspirin and dual antiplatelet therapy to minimize any thrombotic events for acute coronary syndromes and in patients who undergo a coronary intervention. Clopidogrel, the most commonly used medication in our study, has several limitations, including a lack of response in 4%–30% of patients, its susceptibility to drug-drug interactions, and genetic polymorphism (2).

In our study, the ischemic and nonischemic groups used limaprost as concomitant and sole medications, respectively. Limaprost, an analogue of prostaglandin E1 with a strong vasodilatory action and an antiplatelet activity, increases blood flow to the spinal nerve roots in patients with spinal stenosis, thereby creating an analgesic effect (19-23). When limaprost was used concomitantly with antithrombotics, a higher than usual daily dose, and the first week after drug initiation, the risk of bleeding increased by 1.5-fold in periods of limaprost exposure (24). In spite of this increased risk, a previous study reported no complication related with bleeding when limaprost was used continuously in patients receiving a transforaminal epidural injection (19). In our study, the ischemic group also used limaprost as a concomitant treatment with an antiplatelet, however, no bleeding complications occurred.

Table 5. *Clinical outcomes*.

	Ischemic Group (n = 103)	Nonischemic Group (n = 149)	*P* Value
NRS-11 0 week	5.8 ± 0.7	5.1 ± 0.7	< 0.001
NRS-11 2 weeks	3.8 ± 1.4	3.1 ± 1.2	< 0.001
NRS-11 4 weeks	3.7 ± 1.5	2.7 ± 1.5	< 0.001
NRS-11 8 weeks	3.7 ± 1.6	2.6 ± 1.5	< 0.001
NRS-11 reduction > 50%	46 (44.7)	85 (57.0)	0.056
Spinal surgery due to a lack of efficacy of ESPB	8 (7.7)	7 (4.7)	0.418

Values are mean ± SD or number of patients (%). ESPB: erector spinae plane block; NRS-11: Numeric Rating Scale

The ischemic group had a lower clinical efficacy with their ESPB than the nonischemic group.

Most of the patients in the ischemic group had ischemic heart or cerebral disease. In addition, ischemic group patients had severe comorbidities other than ischemic heart or cerebral disease. Previous studies have reported that combined comorbidity was associated with poor outcomes in patients with lumbar spinal stenosis who received surgical treatment (25,26). Also, patients with spinal stenosis combined with peripheral artery disease had less improvement in their quality of life compared to patients with lumbar spinal stenosis who did not have peripheral artery disease. Older age, diabetes mellitus, cerebrovascular disorder, and ischemic heart disease are useful predictors of lumbar spinal stenosis with peripheral arterial disease (15).

Limitations

Our study has several limitations. First, the actual incidence of complications might be underestimated since this study did not include any unreported complications due to its retrospective collection of data. Second, minor vascular injuries, which are easy to miss, and local superficial bleeding and bruising were not evaluated. Third, this study was performed only in an Asian population who generally have a lower body mass index than the Western population, thereby limiting the study's generalization. Fourth, a larger sample size is needed with a population with an already known low risk.

Conclusions

In conclusion, ESPB performed with 22G ultrasound-guided needle had a complication rate less than 1% which were not due to bleeding. Hematoma or bleeding did not occur in either group. The ischemic group had a lower clinical efficacy with their ESPB than the nonischemic group.

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