# Efficacy of Erector Spinae Plane Block after Trunk Surgery:
# A Stratified Randomized Observer-Blinded Comparative Study

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*Objective*: Although epidural anesthesia and paravertebral blocks are routinely administered to achieve postoperative analgesia after trunk surgery, the use of anticoagulant therapy has increased the number of cases in which these procedures are contraindicated. The efficacy of erector spinae plane block (ESPB), an alternative method of postoperative analgesia, has been reported following trunk surgery. This study aimed to determine the analgesic effect of this procedure over a 48-h period following abdominal, breast, and spinal surgery.

*Methods*: This stratified randomized, observer-blinded comparative study enrolled patients aged ≥20 years who underwent abdominal, breast, or spinal surgery at Juntendo University Shizuoka Hospital between June 20, 2018 and February 7, 2019. Patients were divided into the ESPB and non-ESPB groups. Numerical rating scale (NRS) scores, which were used to assess pain 0, 3, 6, 12, 24, and 48 h after surgery, were compared between both groups. The occurrence of adverse events was recorded.

*Results*: The analysis included 51 and 59 patients from the ESPB and non-ESPB groups, respectively. NRS scores were significantly lower in the ESPB group than in the non-ESPB group during the 48-h postoperative period. One patient in each group complained of nausea. Numbness of the extremities or an itching sensation of the skin were not observed in any patient.

*Conclusions*: ESPB significantly reduced NRS scores during the initial 48-h postoperative period without major complications. Our findings indicate the utility of the ESPB for postoperative analgesia after trunk surgery.

*Key words*: erector spinae plane block (ESPB), paravertebral block, epidural anesthesia, trunk surgery, postoperative analgesia

## Introduction

The provision of adequate analgesia at the early postoperative stage is essential not only for maintaining the patient's quality of life but also for reducing postoperative complications. Although epidural anesthesia provides good analgesia following trunk surgery, the recent rise in the use of anticoagulant therapy has resulted in an increase in the number of patients with contraindications for epidural anesthesia.

In recent years, numerous studies, accompanied by the development of ultrasonic devices, have enabled a safe peripheral nerve block procedure. Various peripheral nerve blocks, such as paravertebral, pectoral nerve, transversus abdominis plane, and rectus sheath blocks, have been used to achieve postoperative analgesia following trunk surgery.

The paravertebral block can exert an analgesic effect comparable to that of epidural anesthesia and is often used as a substitute for it. However, the procedure is relatively difficult and is dependent on

the operator's skill. Furthermore, epidural anesthesia and the paravertebral block are associated with the same level of risk in patients receiving anticoagulant therapy, according to the American Society of Regional Anesthesiology guidelines[1] for regional anesthesia and nerve block in patients undergoing antithrombotic therapy. Thus, these procedures cannot be performed in patients requiring anticoagulant therapy or those with coagulation disorders.

In 2016, Forero *et al*. reported that erector spinae plane block (ESPB) is an effective analgesic method for chronic chest pain. Since then, it has been used to provide analgesia during trunk surgery at several institutions[2]. This method is reportedly effective for postoperative analgesia following mastectomy[3)-6)], respiratory surgery[7) 8)], spinal surgery[9)-11)], urological surgery[12) 13)], and abdominal surgery[14)-17)], and in cases of rib fracture[18)].

ESPB is expected to be effective in any surgery of the abdomen, chest, and back, provided that the target spinal nerve level is appropriately selected. Furthermore, the presence of anticoagulant therapy or coagulation disorder does not affect implementation, since the ESPB is not a deep block, unlike epidural anesthesia or the paravertebral block. Thus, we aimed to evaluate the analgesic effect on total trunk surgery by the trend of NRS at 48-h postoperatively for three different trunk surgeries.

In this study, we hypothesized that ESPB would provide effective postoperative analgesia for overall trunk surgery. We performed ESPB in patients undergoing laparoscopic colorectal cancer surgery, breast cancer surgery, and spinal surgery to determine its analgesic efficacy throughout the initial 48-h postoperative period.

## Methods

### 1. Study design and population

This study was performed in a stratified randomized, observer-blinded, comparative fashion. Participants were randomized and stratified by sex and age, which were considered to affect postoperative pain.

The study enrolled patients aged ≥20 years who underwent laparoscopic colorectal cancer surgery, breast cancer surgery, or spinal (thoracic vertebrae and lumbar spine) surgery under general anesthesia at Juntendo University Shizuoka Hospital between June 20, 2018 and February 7, 2019. The exclusion criteria were as follows: (1) patients undergoing cervical spine surgery, (2) presence of skin lesions at the intended site of puncture site that rendered needle insertion unsuitable, (3) history of allergy to local anesthetics, and (4) patients undergoing emergency surgery in whom the procedure was considered dangerous.

The patients were randomized into two groups; one group received ESPB (ESPB group) and the other group did not receive ESPB (non-ESPB group). Patient randomization was performed according to a balanced randomization schedule (1: 1 ratio) by generating a random stratified allocation table. A researcher who was not involved in the clinical treatment assigned and allocated the participants. The intention-to-treat analysis method was used.

Written informed consent was obtained from all patients prior to study participation. This study was approved by the ethics committee of our hospital and was registered with the University Hospital Medical Information Network (UMIN: 000033056) on June 19, 2018. This report adheres to the Consolidated Standards of Reporting Trials statement (2010)[19)].

### 2. Anesthesia application

All patients underwent general monitoring for non-invasive blood pressure measurement, electrocardiography, and oxygen saturation measurement after entering the operating theater. Anesthesia induction was achieved by the administration of propofol (2 mg/kg), fentanyl (2 µg/kg), and rocuronium (1 mg/kg), followed by tracheal intubation. Thereafter, the ESPB group underwent surgery after ESPB, while the non-ESPB group underwent surgery without ESPB. During surgery, anesthesia was maintained with sevoflurane, desflurane, rocuronium, remifentanil, and fentanyl. All patients were administered dexamethasone (4.4 mg) intraoperatively for the prophylactic treatment of postoperative nausea and vomiting.

### 3. Block interventions

Patients undergoing breast cancer surgery were placed in the lateral position with the affected side facing upward. Patients undergoing colorectal

cancer surgery were placed in the left lateral position, and those undergoing spinal surgery were placed in the prone position.

After positioning the patient, the operator stood on his/her dorsal side and placed an ultrasonic diagnostic device (S-nerve; FUJIFILM SonoSite Inc., WA, USA) on the ventral side. A linear probe (6-15 Hz) was used to acquire an image parallel to the spine to visualize the target vertebral body. Subsequently, the linear probe was rotated by 90° and moved approximately 3 cm outward to confirm the junction between the transverse process and rib. The operator inserted a needle inward from the outer side and injected a bolus dose of local anesthetic (20 ml of 0.25% levobupivacaine per side) into the undersurface of the erector spinae muscle, targeting the junction of the transverse process and rib. The puncture for administering the local anesthetic was made in the cranial direction from T5 in participants undergoing breast cancer surgery and in the cranial direction from T10 in those undergoing colorectal cancer surgery. The local anesthetic was administered in the cranial direction from the spinal level at the lower end of the surgical site in participants undergoing thoracic spine surgery and in the caudal direction from T12 in those undergoing lumbar spine surgery. The local anesthetic was administered unilaterally in patients undergoing breast cancer surgery and bilaterally in those undergoing colorectal cancer or spinal surgery.

## 4. Pain evaluation

The first numerical rating scale (NRS) scores for pain were measured by observers who were not involved in the randomization process after the patients had recovered from general anesthesia and shifted to the recovery room. NRS scores at rest and during movement were measured again at 3, 6, 12, 24, and 48 h after surgery. The NRS comprised an 11-point scale ranging from 0 to 10: 0 was designated as the "absence of pain" and 10 as the "worst pain imaginable."

## 5. Postoperative analgesia

All patients enrolled in this study received intravenous patient-controlled analgesia with fentanyl (fentanyl: 20 µg/ml, continuous infusion: 1 ml/h, rescue dose: 1 ml/push, lockout time: 10 min) after surgery.

## 6. Outcome measures

The primary outcome was NRS scores at rest and during movement, which were measured 0, 3, 6, 12, 24, and 48 h after surgery. The presence or absence of nausea or vomiting, itching, and numbness of the limbs were recorded as secondary outcomes.

## 7. Sample Size Calculation and Statistical Analysis

We assumed that the mean difference in the NRS score at rest between the two groups was 1.0 and the standard deviation of the score in each group was 2.0. We determined that a minimum of 128 participants was needed to detect this difference with 80% statistical power with a two-tailed 5% significance level.

The continuous demographic variables are presented as mean ± standard deviation or median (interquartile range) and categorical variables are presented as numbers and percentages. The continuous demographic variables were compared using the independent two-sample t-test or Wilcoxon rank-sum test and percentages were compared using the chi-squared test. The inter-group comparison of NRS scores (i.e., the repeated measures) was performed using a two-way repeated measures multivariate analysis of variance. NRS scores obtained for up to 48 h after surgery were included in this analysis and the overall group differences across all time points were compared. The occurrence of each adverse event was tabulated for the safety analysis, and the two groups' frequencies were compared using Fisher's exact test.

The significance level was set to 5%, and a 95% confidence interval (CI) was used for all tests and estimations. Explanatory subgroup analysis analyses were also performed for each site of the breast, colon and rectum, and spine, similar to the primary analysis.

All analyses were performed using JMP Pro 14.3.0 for Macintosh (SAS Institute Inc, NC, USA) or SAS software for Windows.

## Results

During the study period, 128 participants met the inclusion criteria. Of them, 114 participants were

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                        │  Assessed for eligibility │
                        │        (n=128)           │
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                                  │───────▶│ Excluded (n=14)                   │
                                  │        │ ・change operation procedure (n=5) │
                                  │        │ ・Declined to participate (n=9)    │
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                        │       Randomized         │
                        │        (n=114)           │
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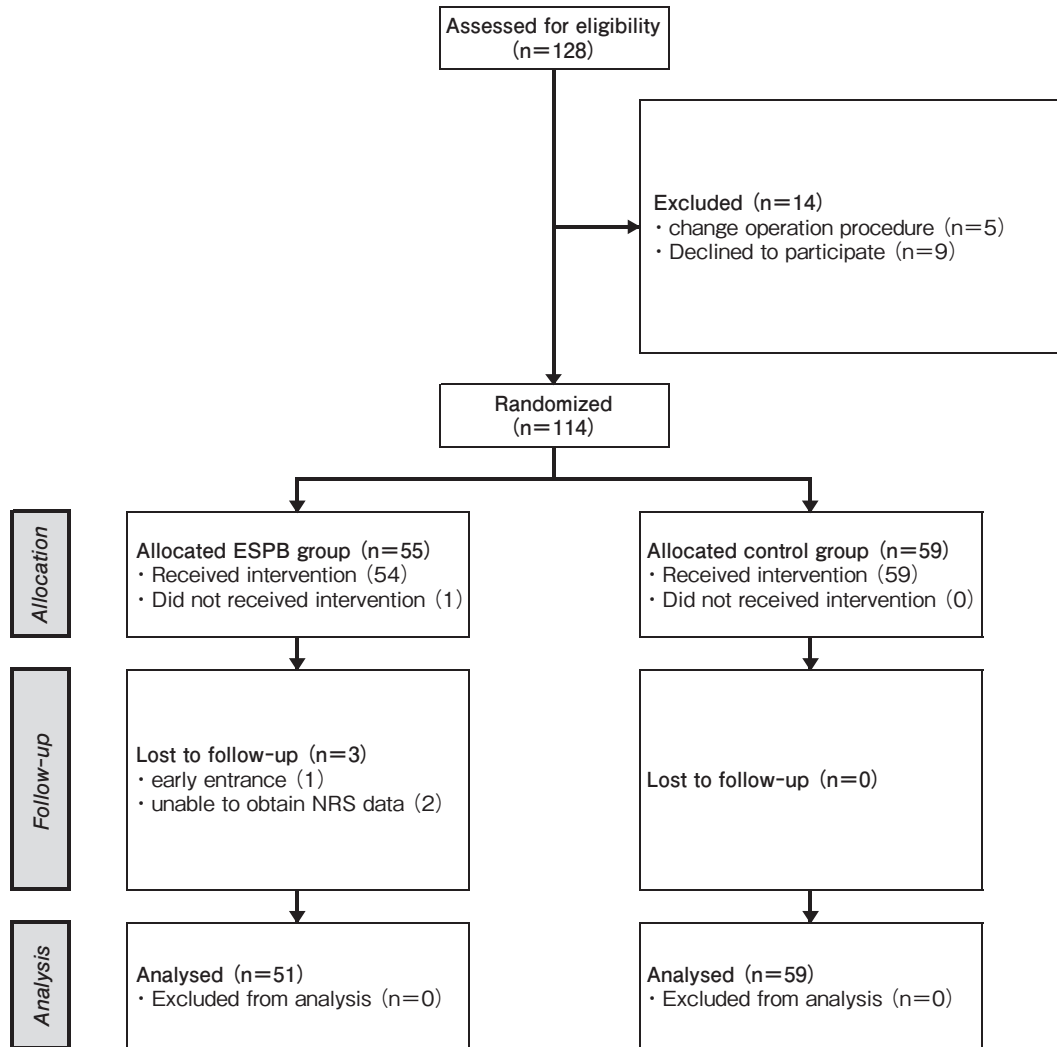| | |
|---|---|
| *Allocation* | **Allocated ESPB group (n=55)**<br>・Received intervention (54)<br>・Did not received intervention (1) | **Allocated control group (n=59)**<br>・Received intervention (59)<br>・Did not received intervention (0) |
| *Follow-up* | **Lost to follow-up (n=3)**<br>・early entrance (1)<br>・unable to obtain NRS data (2) | **Lost to follow-up (n=0)** |
| *Analysis* | **Analysed (n=51)**<br>・Excluded from analysis (n=0) | **Analysed (n=59)**<br>・Excluded from analysis (n=0) |

**Figure**-1  CONSORT flow diagram

randomized; thus, 55 participants were assigned to the ESPB group and 59 were assigned to the non-ESPB group. Fifty-four of the 55 participants in the ESPB group underwent ESPB, except for one participant in whom ESPB was discontinued due to procedural difficulties. Three participants were lost to follow-up (one participant was discharged early, while the NRS data could not be obtained in two participants). Hence, the remaining 51 participants were analyzed. All the 59 participants in the non-ESPB group were included in the analysis (Figure-1).

No significant differences were observed between the patient characteristics of the two groups (Table-1).

The overall NRS score for 48 hours after surgery was significantly lower in the ESPB group than that in the non-ESPB group (Figure-2).

Subgroup analysis of the analgesic effects for the three types of surgeries investigated in this study indicated that the total 48-h NRS scores reduced significantly following breast cancer surgery and spinal surgery, even on individual analysis, while no significant difference was observed following laparoscopic colon cancer resection (Figure-3).

The incidence of adverse events (secondary outcomes) was as follows: one patient in each group complained of nausea, but there were no complications of numbness of the extremities or an itching sensation of the skin in either of the groups (Table-2).

## Discussion

In our study, the ESPB was used for postoperative analgesia following abdominal, back, and breast surgery. NRS scores during the initial 48-h

Table-1　Patient demographic characteristics

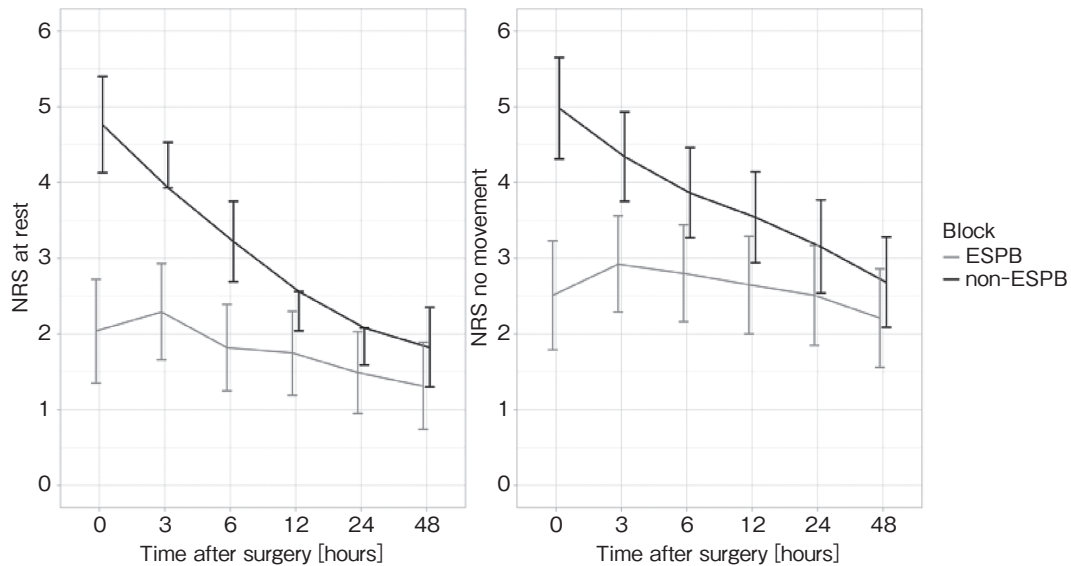|  | ESPB group (n=51) | Non-ESPB group (n=59) |
|---|---|---|
| Age [mean, SD] | 69.0 (1.68) | 67.1 (1.56) |
| Sex [n, %] |  |  |
| 　Male | 15 (29.4) | 23 (39.0) |
| 　Female | 36 (70.6) | 36 (61.0) |
| Height [mean, SD] | 155.6 (1.30) | 157.8 (1.21) |
| Weight [mean, SD] | 56.9 (1.75) | 58.8 (1.62) |
| Surgical site [n, %] |  |  |
| 　Breast | 21 (41.2) | 20 (33.9) |
| 　Colon and rectum | 12 (23.5) | 18 (30.5) |
| 　Spine | 18 (35.3) | 21 (35.6) |
| Surgery duration (min.) [mean, SD] | 168 (10.9) | 188 (10.1) |
| Anesthesia duration (min.) [mean, SD] | 238 (12.1) | 252 (11.3) |

ESPB: Erector Spinae Plane Block



Figure-2　Numerical rating scale scores at rest and during movement within the initial 48-h postoperative period
NRS: numerical rating scale

postoperative period were significantly lower in the ESPB group compared to the non-ESPB group. Few studies have reported a reduction in NRS scores following administration of the ESPB at various time points after surgery. However, no study has demonstrated that the use of ESPB reduced NRS scores throughout the initial 48-h postoperative period and provided effective analgesia.

Furthermore, we targeted the back (spinal surgery), abdomen (laparoscopic colorectal cancer surgery), and chest (breast surgery) to investigate the analgesic effect of ESPB on the entire trunk compared to conventional peripheral nerve blocks. The present results suggest that ESPB has analgesic effects on the entire trunk.

Based on these results, this study demonstrated the analgesic efficacy of the ESPB during the postoperative period, which could be contribute to multimodal analgesia in patients without good indication for epidural anesthesia or the paravertebral block.

To date, the studies focusing on the ESPB have failed to elucidate the mechanism underlying the
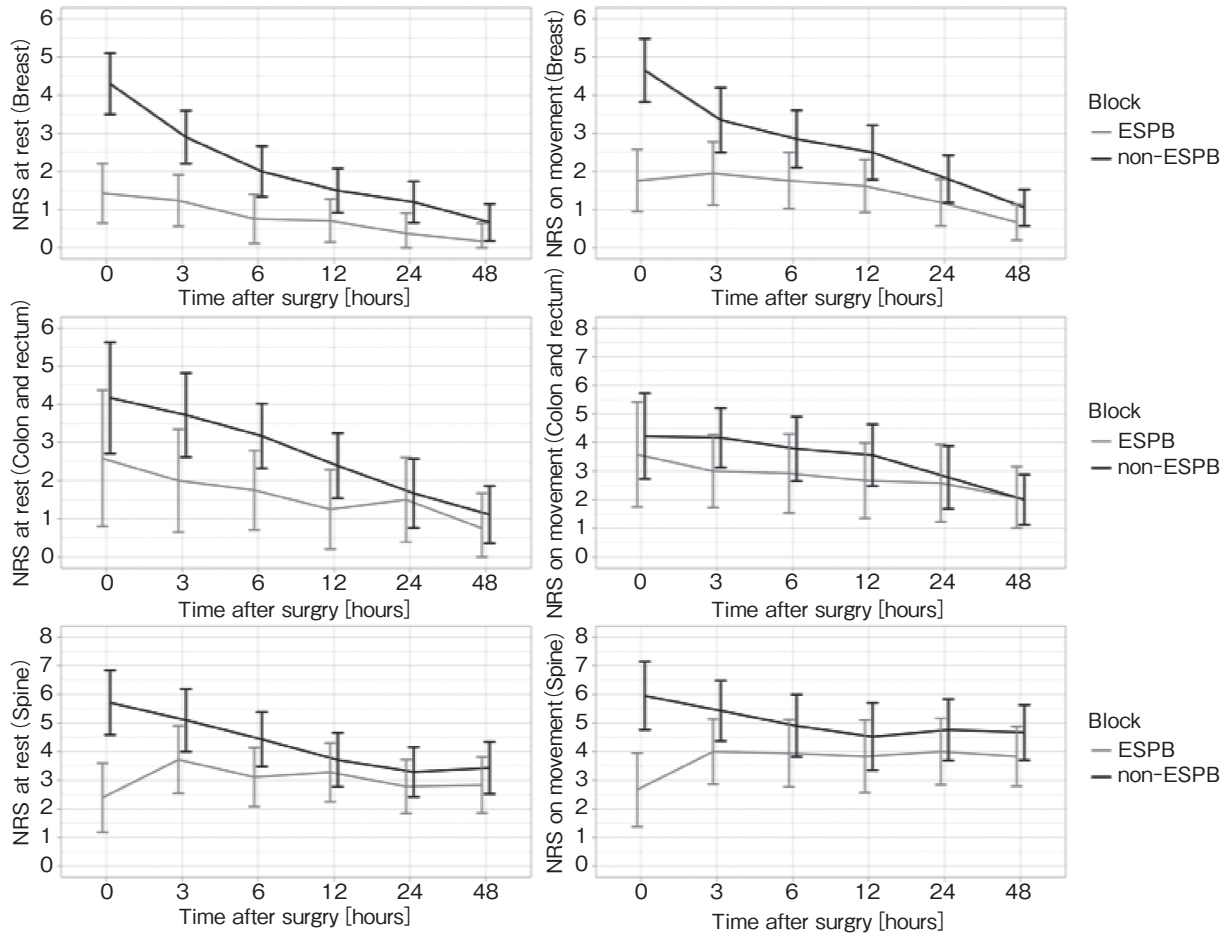
**Figure-3** Subgroup presentation of numerical rating scale scores at rest and during movement within the initial 48-h postoperative periodn
NRS: numerical rating scale

**Table-2** Number of adverse events in the ESPB and non-ESPB groups

| | FSPB group (n=51) | Non-ESPB group (n=59) | p-value |
|---|---|---|---|
| PONV | 1 | 1 | >0.99 |
| numbness of extremities | 0 | 0 | >0.99 |
| itching | 0 | 0 | >0.99 |

ESPB: Erector Spinae Plane Block, PONV: postoperative nausea and vomiting

onset of the analgesic effect, although multiple anatomical studies have investigated this aspect. Some studies reported that local anesthetics spread through the costotransverse foramina and connective tissues to the paravertebral or epiretinal space[20)  21)], resulting in the blockade of the dorsal and ventricular rami, while others reported that local anesthetics did not spread to the paravertebral and epidural spaces[22)]. Some studies have reported

a sort of intermediate effect, i.e., the local anesthetic solution does not consistently spread to the paravertebral or epidural space and that this mechanism of onset is unstable[23) 24)]. The results of this study showed that overall, effective analgesia was obtained in the trunk region. Thus, it can be assumed that the local anesthetic solution spread to the paravertebral or epidural space, which resulted in the blockade of not only the dorsal rami, but also the ventral rami or multiple intercostal nerves.

We ascertained the following target puncture levels for the ESPB that corresponded to each surgical wound in our study protocol: from T5 for breast surgery, from T10 for abdominal surgery, and from T12 for lumbar spine surgery. The selection, dose, concentration, and puncture level of the local anesthetics were determined by using previous reports on the spread of drug solutions in the ESPB and case reports of patients who were managed with the ESPB as reference. However,

further research is required to determine the appropriate puncture sites and concentration and dose of local anesthetics.

Epidural anesthesia may cause complications, such as epidural hematoma, epidural abscess, and nerve injury. A paravertebral block may also cause complications, such as pneumothorax and/or vascular puncture near the pleura. In contrast, the target puncture site for the ESPB is the transverse process, which is far from any critical structures, such as the pleura, central nervous system, and large blood vessels, and is easily recognized by diagnostic ultrasound devices. Therefore, the likelihood of major complications is expected to be extremely low, especially in patients with bleeding tendencies. In fact, pneumothorax was reported as the only significant complication for the ESPB to our best knowledge [25]. Thus, the ESPB is a safer procedure compared to the epidural anesthesia and paravertebral block procedures.

The present subgroup analysis did not show any analgesic effect for laparoscopic colon cancer resection. ESPB injects local anesthetic into the inferior surface of the erector spinae muscle, it is markedly effective for the dorsal rami and may be effective but insufficient for the ventricular rami. In the case of spinal surgery, ESPB was markedly effective. In the case of breast surgery, the local anesthetic was effective because it was distributed from the injection site to the intercostal space, but in the case of abdominal surgery, the area requiring analgesia was large, and distribution to the intercostal space alone may have been insufficient.

Our study has several limitations. First, we were unable to confirm the range of effects in the participants or examine the success and/or failure of the block procedure because ESPB was performed after the induction of general anesthesia in this study. Second, this was an observer-blinded comparative study, in which no placebo treatment (sham block) was administered to the non-ESPB group. Thus, we cannot exclude the possibility that this could have biased the maintenance of anesthesia during surgery by the attending anesthesiologists. Third, this study did not compare the effects of ESPB with those of epidural anesthesia and paravertebral blocks. Thus, further studies are needed to determine the equivalency of the effects of these procedures.

ESPB significantly reduced NRS scores for postoperative pain after trunk surgery throughout the 48-h postoperative period. Unlike conventional epidural anesthesia or paravertebral block, ESPB can be performed in patients receiving anticoagulant therapy or in patients with coagulation disorders and may reduce the rate of serious complications. Our findings suggest that ESPB may be useful for providing perioperative analgesia in all types of trunk surgery.

## Conclusions

ESPB significantly reduced the NRS scores for postoperative pain after trunk surgery throughout the 48-h postoperative period. Our findings indicate that ESPB is a useful means of perioperative analgesia for overall trunk surgery.

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## Author contributions

Study conception and design: M.K
Drafting of the article: T.O
Analysis and interpretation of data: N.Y
Data acquisition: S.S and K.K

## Conflicting interest statement

The authors declare that there is no conflict of interest.

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