



ORIGINAL INVESTIGATION

Evaluation of ultrasound-guided bilateral low thoracic erector spinae plane block for postoperative analgesia in cesarean delivery patients: a prospective, randomized, controlled clinical trial

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KEYWORDS

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Abstract

Background: Erector spinae plane block (ESPB) is a recently described block. In many reports, ESPB has been reported to provide effective postoperative analgesia in patients undergoing cesarean delivery (CD). Herein, we compared the effectiveness of ESPB and control group in postoperative analgesia in patients undergoing CD under spinal anesthesia.

Methods: This assessor-blinded, prospective, randomized, efficiency study was conducted in the postoperative recovery room and ward at a tertiary university hospital. Eighty-six patients ASA II–III were recruited. Following exclusion, 80 patients were randomized into two equal groups (block and control group). Standard multimodal analgesia was performed in the control group while ESPB block was performed in the intervention (ESPB) group. Opioid consumption was measured and pain intensity between groups was compared using Numeric Rating Scores (NRS).

Results: NRS was lower in Group ESPB at 3rd and 6th hours. There was no difference between NRS scores at other hours. Opioid consumption was lower in Group ESPB.

Conclusion: When added to multimodal analgesia, bilateral ultrasound guided low thoracic ESPB leads to improve the quality of analgesia in the first 24 hours in patients undergoing CD.

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Introduction

First described for the treatment of chronic neuropathic pain, erector spinae plane block (ESPB) is a regional anesthesia technique indicated for chronic pain as well as postoperative pain control for many surgeries.^{1,2} While this technique has been used for postoperative analgesia in many surgical procedures from the cervical vertebra surgery to lower extremity surgery, randomized controlled studies on its effectiveness, in many indications, have yet to be performed.³

Cesarean delivery (CD) is the most commonly performed obstetric surgery, and dealing with CD-associated postoperative pain is important for both patient satisfaction and early mobility.⁴ Pain following CD is not only from somatic and visceral sources due to skin and uterine incisions but also from visceral pain caused by uterine cramping.^{5,6} In order to manage this complicated sources of pain, opioids and nonsteroidal analgesic agents are used as well as neuraxial techniques such as epidural analgesia plus transversus abdominis plane block, ilioinguinal, and iliohypogastric blocks, and more recently described interfascial plane blocks such as quadratus lumborum blocks.^{6–8}

While the use of ESPB as part of multimodal analgesia for CD has been previously reported, to our knowledge, no randomized controlled study has been published.^{9–11} In this randomized controlled study, the effect of bilateral low thoracic ESPB on the postoperative analgesia requirements and pain density in CD patients were evaluated.

Methods

Study design

This randomized, controlled, prospective, assessor-blinded study was performed according to the Declaration of Helsinki principles between October 2019 and December 2019. The study was approved by the local ethics committee (Antalya Training and Research Hospital Clinical Ethical Board SBU Antalya SUAM:2019-20/11) and registered with clinicaltrials.gov (NCT04118413). All patients gave written informed consent to be included in the study and for use of their data for research purposes.

American Society of Anesthesiologists (ASA) physical status II–III patients aged 18–45 years due to undergo CD with spinal anesthesia were recruited to the study. Patients with psychiatric or neurological disease that would affect pain perception, morbid obese patients, those undergoing general anesthesia or having failed spinal anesthesia, those with local infection at site of ESPB or spinal anesthesia, those with a history of vertebral surgery, and those with coagulation disorders or use of analgesia previous to surgery were excluded.

Patients were randomized in the operating room using sequentially numbered opaque sealed envelopes¹² into ESPB group or control group. Randomization was performed by one of the authors for all patients (M.U.). Randomization ID of patients was used for all data collection and follow-up. Medical personnel collecting data and conducting follow-up were blinded to the group of the patient. The anesthesiologist (H.A.) performing the block did not play any role in

the collection of postoperative data or its analysis and was therefore blinded. In the control group, all anesthesia and analgesia techniques were identical except for application of ESPB.

Management of surgical anesthesia

The same anesthesia management regime was used in all patients. Intravenous (IV) line was placed in the preoperative room and 7 mL.kg⁻¹.h⁻¹ of normal saline was commenced. Without sedoanalgesia, patients were placed in the sitting position and through midline approach a 26G spinal needle was inserted and spinal anesthesia was performed using 2–2.3 mL 0.5% heavy bupivacaine. No additional agent was administered in any patient for spinal anesthesia. Surgery commenced when Pinprick demonstrated the spinal block had reached the level of T10 vertebra. No local anesthetic was used by the surgical team.

Application of ESPB

All blocks were performed immediately after surgery in the lateral position. Local anesthetic for skin or subcutaneous tissue was not used as the spinal anesthesia effect had not worn off. ESPB was performed under sterile conditions using ultrasound guidance of a high frequency linear transducer. T11 vertebra was identified, and the transducer was placed 3 cm lateral to the spinous process in the parasagittal plane. Following identification of erector spinae muscles and the transverse process a 21G 10-cm needle (Stimuplex A, B Braun, Melsungen, Germany) was inserted using an out-of-plane approach. The tip of the needle was placed into the fascial plane on the deep (anterior) aspect of erector spinae muscle. The location of the needle tip was confirmed by visible fluid spread lifting erector spinae muscle off the bony shadow of the transverse process on ultrasonographic imaging. A total of 20 mL consisting of 10 mL bupivacaine 0.5%, 5 mL lidocaine 2% and 5 mL normal saline was applied to the interfascial plane. The procedure was repeated for the opposite side.

Standard postoperative analgesia protocol and measurements of pain

Following ESPB, patients were transferred to the recovery room and 1 g IV paracetamol was given, and the dose repeated every 8 hours for the first 24 hours. A patient-controlled analgesia that included 0.5 mg.mL⁻¹ of morphine with no basal infusion, 1 mg bolus and 20-minute lock out time was commenced before the patient was transferred to the ward. The numeric rating scale (NRS) was used for measurement of postoperative pain at intervals (1st, 6th, 12th, and 24th hours) for 24 hours. NRS is a one-dimensional measure of pain intensity in adults. The NRS is a segmented numeric version of the visual analog scale in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of the patient's pain. The 11-point numeric scale ranges from "0" representing one pain extreme (e.g., no pain) to "10" representing the other pain extreme (e.g., "pain as bad as you can imagine" or "worst

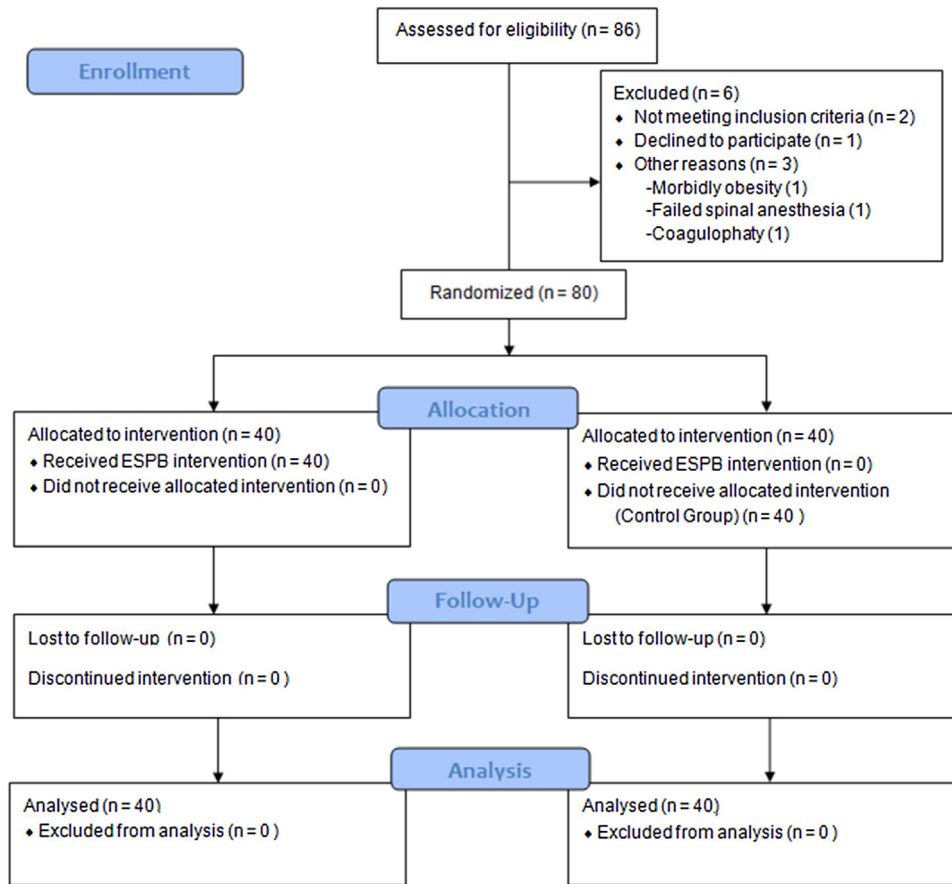


Figure 1 Flow diagram of study.

pain imaginable’). Cumulative morphine consumption at 3rd, 6th, 12th, and 24th hours were noted.

Outcome measures

The primary outcome was opioid consumption via PCA within the first 24 hours. The secondary outcome was NRS scores during rest (NRS-rest) and movement/coughing (NRS-dynamic). Also, nausea/vomiting within the first 24 hours was also measured.

Sample size and statistical analyses

A pilot study of 10 patients per group was performed, demonstration morphine consumption as 3.9 ± 1.9 mg in the ESPB and 5.6 ± 2.2 mg in the control group. With an alpha of 0.05, beta of 0.10 and power of 0.95, the number of participants required for the study was calculated as 38 for each group. Forty patients were included considering the risk of possible dropouts. Statistical analysis was performed using SPSS 16.0 (SPSS, Chicago, IL, USA). Normality of data was determined using the Kolmogorov-Smirnov test. Continuous variables were expressed as mean \pm standard deviation, and median (25th–75th percentiles). For continuous variables with equal variance, univariate analysis was performed using a 2-sample independent *t*-test. For data without normal distribution, Mann-Whitney U test was

used. Chi² test was used for ratio comparison. Categorical variables (ASA, gender, etc.) were compared using Fisher exact test. Kaplan-Meier analysis was used for first analgesia requirement time and distribution was compared using Breslow generalized Wilcoxon test. A *p*-value of <0.05 was considered statistically significant. Bonferroni correction was used for analysis of NRS scores, statistical significance was adjusted to $p < 0.01$, due to measurements from 5 time points.

Results

Of 86 patients recruited for the study, 80 were included. Reasons for exclusion are shown in the CONSORT diagram (Fig. 1). There was no statistical difference between the groups regarding age, gender, ASA physical status, height and weight, as well as surgical times (Table 1).

Morphine consumption during the first 24 hours was statistically significantly less in the ESPB group (4.02 ± 2 mg vs. 6.02 ± 2.23 mg, $p < 0.001$). Cumulative morphine requirements at 3rd, 6th, and 12th hours were also less in ESPB group when compared to control group ($p < 0.001$) (Table 2). The cumulative opioid requirement of both groups and its hourly distribution is shown in Figure 2.

When NRS scores were compared between groups, NRS-at rest and NRS-dynamic scores were lower in ESPB group at 3rd and 6th hours ($p < 0.001$). Pain scores at 1st, 12th, and 24th

Table 1 Patient demographics, surgical times and statistical evaluation.

	ESPB (n = 40)	Control (n = 40)	<i>p</i>
Age (year)	29.02 ± 4.44	30.6 ± 5.34	0.154
Height (cm)	161.8 ± 5.58	161.2 ± 3.99	0.581
Weight (kg)	75.47 ± 13.28	78.47 ± 9.80	0.253
ASA II/III	31/9	29/11	0.605
Surgical time (min)	54.50 ± 11.25	57.25 ± 9.75	0.246

Data are expressed as mean ± standard deviation or number. *p* values were italicized.

Table 2 Comparison of postoperative opioid consumption between control and ESPB groups.

Cumulative Morphine consumption (mg)	ESPB (n = 40)	Control (n = 40)	<i>p</i>
3 h	0 (0–0)	1 (0–2)	<0.001
6 h	0 (0–2)	2 (1–2)	<0.001
12 h	4 (2–5)	5.5 (4–7)	<0.001
24 h	4 (3–5)	6 (4–8)	<0.001

Data are expressed as median (percentiles 25–75). *p* values were italicized and *p*-values that are written in bold represent statistical significance.

Table 3 Average NRS scores during the first 24 h.

NRS-at rest	ESPB (n = 40)	Control (n = 40)	<i>p</i>
1 st hour	0 (0–2)	1.5 (0–2)	0.343
3rd hour	2 (2–3)	3 (3–4)	<0.001
6th hour	3 (3–4)	4 (4–5)	<0.001
12th hour	2 (2–3)	2 (2–3)	0.231
24th hour	1.5 (0–2)	2 (0–2)	0.191
NRS-Dynamic			
1st hour	0 (0–3)	2 (0–3)	0.115
3rd hour	2 (2–4)	3 (3–5)	<0.001
6th hour	3 (3–5)	4 (4–5)	<0.001
12th hour	2 (2–3)	2 (2–4)	0.345
24th hour	2 (1–3)	2 (1–3)	0.106

Data are expressed as median (percentiles 25–75). *p* values were italicized and *p* values that are written in bold represent statistical significance.

hours were not significantly different between the groups (Table 3). Nausea and vomiting were observed in 9 patients in the control group and 7 patients in the ESPB group. Three patients per group required ondansetron. The time for the first opioid requirement was 6.9 ± 3.17 hours (median: 6 h) for the ESPB group and 3.72 ± 1.92 hours (median: 3 h) for the control group ($p < 0.001$) (Fig. 3).

Discussion

Our study has shown that bilateral low thoracic ESPB performed after CD decreases 24-h opioid requirement and increases the time to first analgesia requirement NRS scores were within acceptable limits in each group but statistically significantly lower at 3rd and 6th hours in the ESPB group.

Postoperative pain in CD has both visceral and somatic components. Blockage of visceral fibers can be obtained through blocking of the lateral and anterior cutaneous branches of the T12 and L1 spinal nerves. This can be obtained with transversus abdominis plane (TAP) block,

transversalis fascia plane block (TFPB), ilioinguinal and iliohypogastric nerve blocks, and quadratus lumborum block (QLB).^{7,8,13} While these techniques are theoretically only effective on somatic pain, posterior spread to the thoracolumbar nerve roots in QLB and blockage of the deep branches of the intercostal nerves in other blocks lead to partial blockage of visceral fibers too therefore blocking parietal and incisional pain.^{13–15} The most important pathway for the transmission of visceral pain is via pathways as high as the celiac plexus. The celiac plexus receives its primary innervations from the greater, lesser, and least splanchnic nerves that arise from T5 to T12 nerve roots. Also, exteriorization of the uterus may lead to traction on the pelvic viscera, and pain in this region can be conveyed via the pelvic splanchnic nerves (S2, 3, 4 nerve roots).¹⁶

ESPB is a recent peri-paravertebral block that is reported as a regional anesthesia method effective on both somatic and visceral pain.^{17,18} Although anatomic, radiologic, and clinical cases suggest that the local anesthetic of ESPB reaches not only the ventral and dorsal nerves but the sympathetic chain as well, this topic is still controversial.^{19–21} In

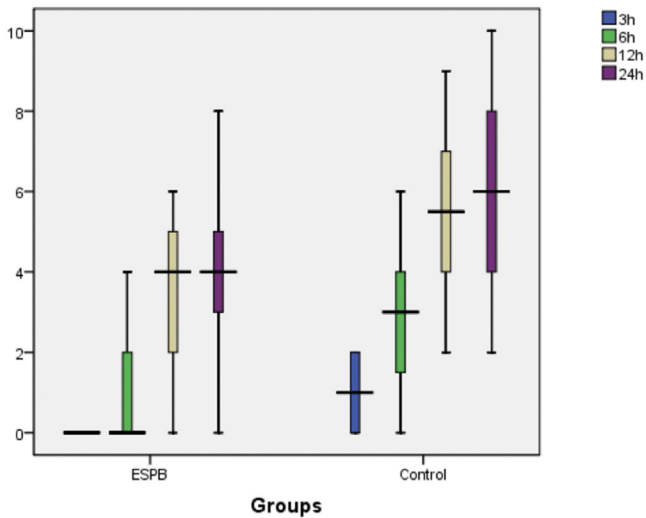


Figure 2 Morphine consumption of patients at 3rd, 6th, 12th and 24th h according to groups. Minimum, first quartile, median, third quartile and maximum are shown.

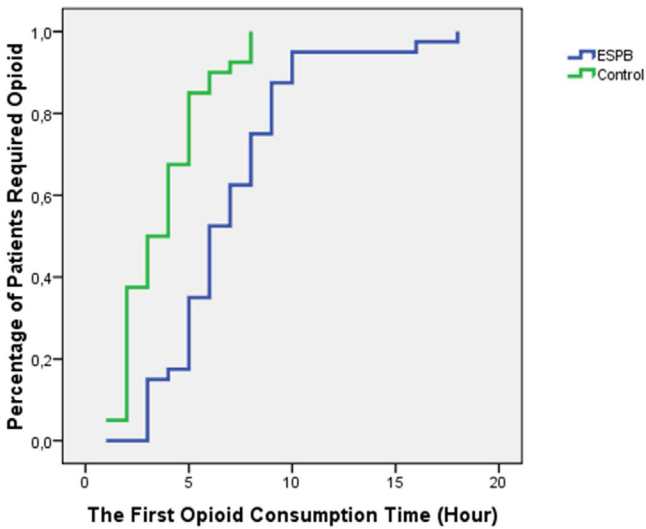


Figure 3 Kaplan-Meier Analysis of the first opioid requirements of patients.

lieu of anatomic data, ESPB is thought to be a useful method for postoperative analgesia following CD. The first report of ESPB in CD was by Altinpulluk et al. with more reports following.^{10,11,22,23} While ESPB is generally considered safe, lower extremity motor block following ESPB for CD has been reported as a complication/unintended event.²⁴ All cases demonstrate that ESPB decreases analgesia requirements and lowers NRS scores in CD.

Our study supports and substantiates literature findings previously reported. In Pfannenstiell incisions, blockage of the T12–L1 dermatome is important for management of cutaneous pain. We performed all ESPB from T11. When the anatomy of the lower thoracic vertebral area is examined, it is observed that the superior costovertebral ligament does not exist inferior to the T11–T12 spaces. Therefore, it is possible that local anesthetic will spread uncontrolled to the paravertebral area and lead to motor weakness.^{24–27} It is for

the same reason that we avoided higher concentrations and used 0.25% of bupivacaine.

It is possible that analgesia requirements may have been delayed in both groups as the sensorial block of spinal anesthesia lasts 2–3 hours and therefore pain due to uterine contractions may have not been felt by participants. In studies of postoperative pain in patients undergoing CD under general anesthesia, the measure of timing of the first opioid requirement is not feasible due to uterine contractions observed during the first hours.¹³ Considering that the first analgesia requirement of most patients in the ESPB group was after the 6th hour, we can safely say that our results demonstrate that ESPB has an effect on visceral pain.

In addition to bupivacaine, we could have added an opioid agent when performing spinal anesthesia as an additive agent. However, this could have led to adverse effects such as itching, nausea, and vomiting. However, in a study designed to compare two regional anesthesia techniques, the addition of intrathecal opioid may increase postoperative analgesia quality and therefore more prominently demonstrate the difference between two different blocks.⁶ There is still a requirement for comparison of ESPB to other peri-paravertebral blocks such as QLB. Even though the comparison of a peri-paravertebral block and an abdominal wall block is debatable, the requirement for comparison of ESPB and TAP/II–IH blocks still exists. Peri-paravertebral blocks such as ESPB and QLB are comparatively long to perform due to positioning and needling time. Studies need to compare both analgesic efficacy as well as application time, safety, pharmacokinetics, and effect time.

ESPB performed using higher volume of local anesthetic may have been more effective on CD related somatic and visceral pain, however, this may have led to an increase in complications related to the local anesthetic. The effect of higher concentrations of local anesthetic on visceral and somatic pain in ESPB applications is still a point for discussion that requires comparative studies. Also, we could have extended the effect of neuraxial analgesia by including intrathecal morphine. However, had intrathecal morphine been used, the differences between the ESPB and control groups would be different in the first 24 hours. It might be more difficult to detect the differences between the two groups and the intrathecal opioid could have shadowed the effect of ESPB.

Our study has some limitations. This is a randomized controlled study, and all blocks were performed after completion of surgery while patients were still under the effect of spinal anesthesia. A sham group, in place of or in addition to a control group, using a small volume of normal saline applied instead of local anesthetic for ESPB would have increased the quality of methodology of our study. This means the patient could have also been blinded in our study. Comparative studies comparing the analgesic effects of ESPB and other interfascial blocks could have also been planned. Another limitation is the lack of dermatome and quadrant analysis of sensorial blockage. However, in our study design, the intersection of ESPB and spinal anesthesia would make the analysis of this data difficult. We also believe that evaluating only the cutaneous sensory effect of ESPB which also has effect on somatic and visceral pain would have led to misinformation regarding the results. ESPB could have been applied one hour before spinal anesthesia or after the effect

of spinal anesthesia has subsided. This would have allowed us to perform sensorial analysis. However, both applications would have several aspects open to discussion. Another limitation is that patients may have used PCA to treat any preexisting non-operative pain, leading to incorrect data. In order to minimize this, we educated the participants of this study to not use morphine for these purposes. Further studies would be required to evaluate this inference.

Conclusion

Our study has demonstrated that ultrasound-guided bilateral low thoracic ESPB, when added to multimodal analgesia, significantly decreased the first 24-h analgesia requirement and, therefore, improved the quality of analgesia. We believe that ESPB will soon take its place among other interfascial plane blocks as a frequently used block in the postoperative analgesia of CD without the use of intrathecal opioids.

Ethical approval

All procedures involving human participants were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Conflicts of interest

The authors declare no conflicts of interest.

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