

Comparison of ultrasound-guided erector spinae plane block versus transmuscular quadratus lumborum block for postoperative analgesia after caesarean delivery: A prospective randomized non-inferiority clinical trial

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Abstract

Background and Aims: Regional techniques are a part of multimodal analgesia following cesarean delivery. Cesarean delivery warrants a regional technique, which can provide somatic and visceral analgesia-like quadratus lumborum block (QLB) and erector spinae plane block (ESPB). In this study, we investigated the non-inferiority of ESPB at T12 and transmuscular-QLB (TQLB) at L2-L3 for postoperative analgesia in cesarean delivery.

Material and Methods: In this prospective, randomized, non-inferiority trial, 124 patients undergoing cesarean delivery were enrolled to receive bilateral TQLB or ESPB with 20 mL of 0.25% ropivacaine on each side. All patients received prophylactic acetaminophen and ketorolac for 2 days. Our primary objective was to compare the total tramadol consumption in the first 48 h between the two groups. Secondary objectives were to compare cumulative tramadol consumption, postoperative Numeric Rating Scale (NRS) score at rest, and with movement at various time points, the time for first rescue analgesic requirement, development of complications related to the block, and patient satisfaction with analgesia between the two groups.

Results: The total tramadol consumption in 48 h (47.3 ± 34.9 mg in ESPB and 50.9 ± 38.7 mg in TQLB), duration of first rescue analgesic (22.8 ± 15.8 h in ESPB and 22.7 ± 15.6 h in TQLB), and patient satisfaction were similar between the two groups. Both groups had similar pain scores except at rest at 6 h and on movement at 4 h, 6 h, and 36 h, whereas the ESPB group had lower NRS scores ($P < 0.05$).

Conclusion: The analgesic effect of bilateral ESPB at T12 was non-inferior to that of bilateral TQLB post-caesarean delivery.

Keywords: Analgesia, cesarean, pain management, postoperative

Key Message:

What is already known about the topic: Cesarean delivery warrants a regional analgesia technique which can provide somatic and visceral analgesia postoperatively. While quadratus lumborum block (QLB) is a well-established technique for cesarean delivery there are very few comparative studies on erector spinae plane block (ESPB) in cesarean delivery. In the studies comparing ESPB for other lower abdominal procedures, it has been given at T9 only.

What new information this study adds: The analgesic effect of bilateral ESPB at T12 was non-inferior to that of bilateral TQLB performed at L2-L3 with the same volume post-caesarean delivery and can be an important addition to multimodal analgesia protocols after cesarean delivery.

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Introduction

Regional techniques are popular as a part of multimodal analgesia following cesarean delivery.^[1] Postoperative analgesia after cesarean delivery warrants a regional technique, which can provide somatic and visceral analgesia from bilateral T10–L1 nerves.^[2] A coverage from bilateral lateral and anterior cutaneous branches of T12-L1 for the Pfannenstiel skin incision, bilateral T10-L1 for abdominal muscles, and bilateral T10-L1 uterine innervation via the preganglionic and postganglionic sympathetic fibers of the inferior hypogastric plexus is required [Figure 1]. Blocking of the somatic pain can be obtained with transversus abdominis plane (TAP) block, transversalis fascia plane block (TFPB), ilioinguinal and iliohypogastric nerve blocks, and wound infiltration.^[3]

Transmuscular quadratus lumborum block (TQLB), also known as anterior QLB or QL3, has been shown to provide analgesia superior to other regional techniques available for lower abdominal procedures, as it provides somatic and visceral pain relief.^[4-6] However, QLB is a deeper block with potential for hematomas.^[7]

Erector spinae plane block (ESPB) is a superficial, and technically simpler block also postulated to provide somatic and visceral pain relief.^[8] There are very few comparative studies on ESPB in cesarean delivery and even when ESPB has been administered for other lower abdominal procedures it has been given at T9.^[9-12]

We hypothesized that the ESPB administered at T12 might provide analgesia as effective as that of TQLB after cesarean

delivery. This study was designed to investigate whether the analgesic effect of ESPB at T12 is non-inferior to that of TQLB at L2-L3 for cesarean delivery, in accordance with the Consolidated Standards of Reporting Trials statement.^[13]

Material and Methods

This trial was a prospective, single-center, non-inferiority randomized clinical trial. Ethical approval for this study was provided by Saveetha Medical College and Hospital institutional review board. The trial was registered with the Clinical Trials Registry of India (CTRI/2022/02/040404) in February 2022. Between February 2022 and June 2022, we enrolled 122 primigravidae parturients who were scheduled for elective cesarean delivery via a Pfannenstiel incision under spinal anesthesia, with the American Society of Anesthesiologists physical status II, aged between 18 and 40 years old, weighing between 50 and 70 kg, and full-term singleton pregnancy. Exclusion criteria were coagulopathy, localized infection, allergy to study medication, uncontrolled anxiety or other psychiatric disorders, daily use of opioid analgesics, a disorder in communication, patient refusal, body mass index ≥ 40 kg/m², and known fetal abnormalities.

A single investigator assessed the parturient for eligibility, obtained written informed consent, and educated participants about the Numeric Rating Scale (NRS) and rescue analgesia during the preanesthetic interview on the day before surgery. The NRS score was used to determine the pain level on a scale 0 to 10, in which 0 represents no pain and 10 represents the worst pain imaginable. The patients were randomly

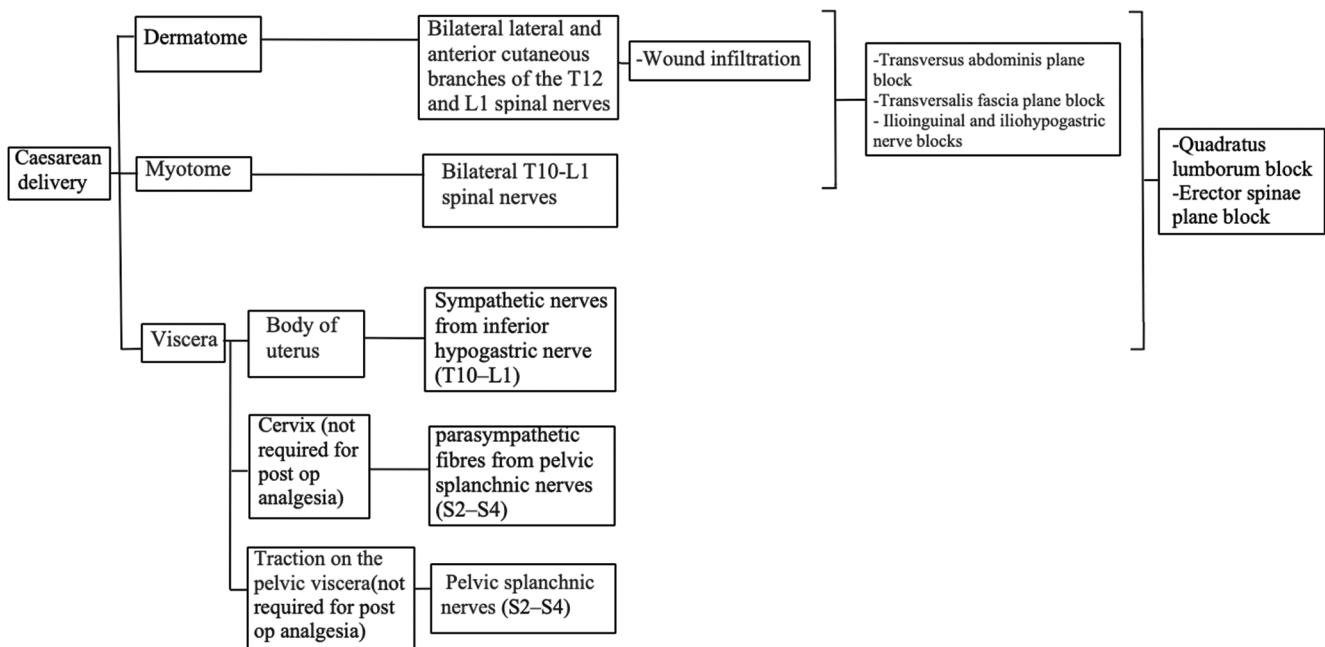


Figure 1: Innervation for post-operative analgesia for cesarean delivery and sensory coverage of the regional techniques

assigned to two equal groups (bilateral TQLB or a bilateral ESPB) using a computer-generated random number program, and allocation concealment was performed using a serially numbered opaque sealed envelope technique. Envelopes containing group allocation were opened by the primary investigator after the administration of spinal anesthesia and attaining a sensory level of T6 or higher. Neither the study subjects nor the outcome assessors knew the study group. The primary investigator, who had experience with more than 100 TQLB and ESP blocks, respectively, performed the block. The outcome data were recorded by a blinded investigator who visited the patient for 48 h postoperatively.

All parturients received oral pantoprazole 40 mg and metoclopramide 10 mg on the day of surgery. In the operation theater after the measurement of baseline heart rate, blood pressure, and saturation, an 18G intravenous (IV) cannula was inserted and intravenous fluids were started. Subarachnoid block was administered using a 25-gauge Quincke spinal needle with 10 mg hyperbaric bupivacaine (2.0 mL, 0.5%) to achieve a level of T4-T6 as assessed by the loss of sensation to a cold spirit swab. The surgical procedure was executed in a routine manner. If the upper sensory level was below T6 after 20 min; this was considered a failed spinal, and the patient would have been excluded from the study. If there were intraoperative complications that could lead to the prolongation of the surgical duration or there was early regression of spinal level, which could lead to perception of pain, opioid supplementation, or general anesthesia with propofol was administered as appropriate, and the patient was excluded from the study. If the newborn required intensive care, patients were excluded as it could lead to anxiety and error in reporting pain.

At the end of the surgery, with routine monitoring, and under aseptic precautions, the patients were given either TQLB or ESPB bilaterally. Hydrodissection was performed with 1–2 mL of saline and then both groups received 0.25% ropivacaine (20 mL) on each side, 40 ml after negative aspiration.

For TQLB, after turning the patients laterally, a 1-5 MHz, 5 mm curvilinear array transducer (GE LOGIQ e, Wauwatosa, WI, USA) was placed transversely on both flanks at the horizontal level of L2-3. The ultrasound transducer was adjusted until the “Shamrock sign” formed by the quadratus lumborum (QL) muscle, psoas major, and erector spinae was visualized. A 23G 90 mm Quincke–Babcock needle was inserted in-plane from posteriorly. Local anesthetic was injected in the plane between the QL muscle and psoas major and confirmed by visualizing the local anesthetic spreading in a linear pattern between the muscles.

Subsequently, TQLB was repeated on the opposite side after repositioning the patient.

For ESPB, the patient was positioned in the right lateral position (for a right-handed investigator and vice versa for a left-handed investigator) and a 4-12 MHz, 5 mm linear array transducer (GE LOGIQ e, Wauwatosa, WI, USA) was used. The T12 spinous process was identified using ultrasound by starting sagittally at the lumbosacral gap and moving upward counting the spinous process till T12. Once located, the probe was moved laterally from spinous process approximately 3 cm until the transverse process was identified. A 23G 90 mm Quincke–Babcock needle was inserted in the cranial–caudal direction in-plane to contact the transverse process. Local anesthetic was injected in the interfascial plane between the erector spinae muscle and the transverse process and confirmed by visualizing the local anesthetic spreading in a linear pattern between the muscle and the bony acoustic shadows of the transverse process.

The patients were shifted to the postoperative care unit and monitored over a period of 48 h. The duration of surgery (time from the start of skin incision to the end of skin closure) was recorded. Postoperatively, all patients received standard analgesia (acetaminophen, starting with 1 g IV infusion at the conclusion of the block and every 8 h, and ketorolac 30 mg IV every 12 h for 2 days) and rescue analgesia with slow intravenous tramadol 50 mg was administered by a nurse each time when NRS \geq 4.

The data were collected at predetermined time intervals of 2, 4, 6, 12, 24, 36, and 48 h post-cesarean delivery. The severity of pain at rest and on movement (hip flexion and coughing) was assessed using an 11-point numerical rating scale (0 = no pain and 10 = the worst possible pain). The “time for first analgesic requirement” was noted when the patient first complained of pain and tramadol was given, considering the time of completion of the block procedure as “Time 0.” The cumulative and total consumption of tramadol in 48 h was calculated for each patient. The subjects were monitored for any complications associated with the block such as vessel puncture, bowel perforation, and quadriceps weakness. Patient satisfaction with postoperative analgesia was assessed at 48 h postoperatively using a 5-point scale (1 = very unsatisfied, 2 = unsatisfied, 3 = fair, 4 = satisfied, and 5 = very satisfied).

The primary outcome was to compare the total tramadol consumption in the first 48 h between the two groups, and the secondary outcomes were to compare the cumulative tramadol consumption, postoperative NRS score at rest and with movement at 2, 4, 6, 12, 24, 36 and 48 h postoperatively,

the time for first rescue analgesic requirement, development of complications related to block, and the patient satisfaction with analgesia between the two groups.

According to an Indian study by Jadon *et al.*^[6] in 2021, the standard deviation of the total dosage of tramadol in QLB was 0.35 mg with an effect size of 0.57. Considering a non-inferiority margin of 30% and an expected difference of 10%, with a power of 80%, and an alpha error of 5%, the calculated sample size was 52 in each group. Considering a dropout of 20%, the required sample size will be 62 in each group.

Statistical analysis

The data were recorded on a standardized data collection sheet, entered using the Microsoft Excel spreadsheet, and analyzed using the Statistical Package for the Social Sciences (SPSS) version 20.0 (SPSS Inc., Chicago, IL, USA). The normality of the data was determined using the Kolmogorov–Smirnov test. Continuous data are expressed as mean and standard deviation (SD) or median and interquartile range (IQR) and categorical data are expressed as frequency and percentages. Statistical comparisons between the groups were made using Student's *t*-test for normally distributed continuous variables, Mann–Whitney *U* test for non-normally distributed continuous variables, Chi-square test or Fisher's exact test, or Kruskal–Wallis test for categorical data. A *P* value of < 0.05 was considered statistically significant.

Results

Figure 2 shows the flowchart of the study. We enrolled 124 patients, and 4 patients in both groups were excluded, due to conversion to general anesthesia following prolonged duration and opioid supplementation intraoperatively. Two newborns in each group were shifted to the neonatal intensive care unit (ICU) for observation and the mothers were excluded. Accordingly, we analyzed 56 patients in both groups.

There was no difference between groups in terms of demographic data or operative data [Table 1]. As shown in Table 2 and Figure 3a, there was no significant difference in the mean cumulative and total tramadol consumption in the 48 h after surgery; the mean \pm SD of total tramadol consumption at 48 h was 47.3 ± 34.9 mg in ESPB and 50.9 ± 38.7 mg in TQLB; the difference in means was 3.6 (95% confidence interval [CI]: 10.2–17.4) mg; *P* value = 0.61).

The NRS score was significantly lower in ESPB than TQLB at rest at 6 h and on movement at 4 h, 6 h, and 36 h. However, there was no statistically significant difference in the NRS score at other times [Figure 3b, 3c].

There were no significant differences between the two groups in the time to the first rescue analgesic requirement (22.8 ± 15.8 h in ESPB and 22.7 ± 15.6 h in TQLB; *P* = 0.96). Parents' responses yielded similar satisfaction scores between the two groups (*P* value = 0.05) but four patients (two patients in the ESPB group and two patients in the TQLB group) were unsatisfied with analgesia [Table 2]. No block-related complications were observed in either group.

Discussion

This non-inferiority trial found that ESPB at T12 was non-inferior to TQLB for postoperative analgesia after cesarean delivery in terms of opioid requirement postoperatively during the first 48 h. These findings are supported by a recent study, which compared single-shot ESPB at T9 with TQLB for cesarean delivery and reported no significant differences between the two blocks in terms of pain scores or opioid consumption.^[9]

The NRS scores were similar between ESPB and TQLB, except at 4 h, 6 h, and 36 h, where ESPB had significantly lower scores. However, the maximum NRS score difference between groups was 0.45 during these times. So, although the differences were statistically significant, it is likely that the differences were clinically irrelevant, especially in the setting of multimodal therapy. Other studies also concluded that both these blocks individually provided a significant reduction in postoperative opioid requirement and pain scores in cesarean delivery.^[3,5,6,10-12,14]

The time to first rescue analgesic requirement was similar between both the groups (22.8 ± 15.8 h in ESPB and 22.7 ± 15.6 h in TQLB). A meta-analysis concluded that QLB is effective for approximately 12 h but not 24 h in cesarean delivery.^[5] Most studies and case reports have observed a duration of 12–24 h for ESPB and up to 48 h for QLB for various surgeries.^[10,12] These differences can be attributed to the fact that conventionally ESPB is given at a higher thoracic level and would not be sufficient for coverage of the surgical procedure.

Opioids can be added as additive agents to bupivacaine. However, this could have led to adverse effects such as itching,

Table 1: Demographic and operative data according to groups

	ESPB (n=56)	TQLB (n=56)
Age (years)	26.4 \pm 3.8	26.4 \pm 3.7
Height (cm)	156 \pm 6	157 \pm 5
Body weight (kg)	69.9 \pm 12.8	71.4 \pm 10.6
Duration of surgery (min)	81.0 \pm 20.4	79.0 \pm 19.4

Data are mean \pm standard deviation. ESPB=Erector spinae plane block, TQLB=Transmuscular quadratus lumborum block

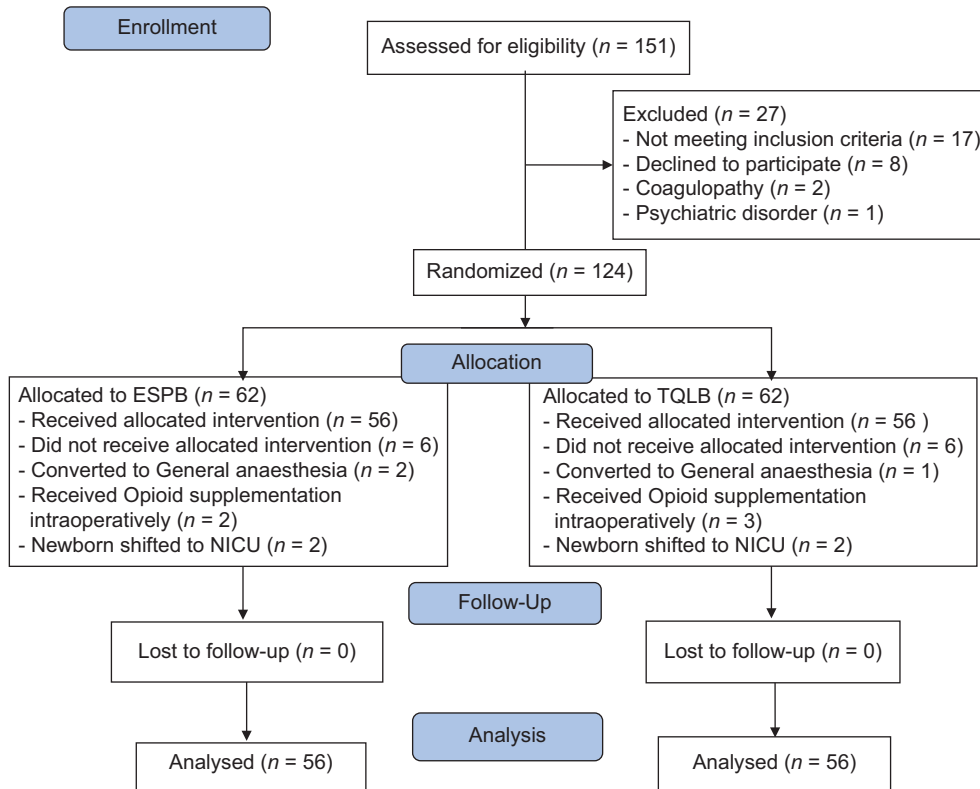


Figure 2: CONSORT flowchart diagram of the study population. ICU = intensive care unit, ESPB = erector spinae plane block, TQLB = transmuscular quadratus lumborum block

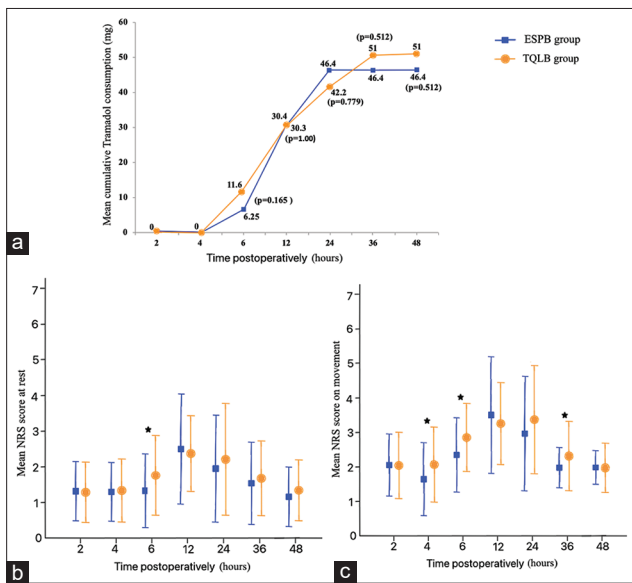


Figure 3: (a). Mean cumulative tramadol consumption. (b). Mean NRS score at rest between ESPB and TQLB. (c). Mean NRS score on movement between ESPB and TQLB. NRS = numeric rating scale, ESPB = erector spinae plane block, TQLB = transmuscular quadratus lumborum block

nausea, vomiting, and urinary retention.^[15] In addition to circumventing the adverse effects, we avoided opioids to demonstrate the difference between the two blocks distinctly and analyze their efficacy after general anesthesia because intrathecal opioids may improve postoperative analgesia. It has

been shown that when administered before general anesthesia, ESPB can significantly reduce the dosage of general anesthetic agents and shorten the emergence time.^[14]

Complications such as needle trauma in terms of unintentional puncture of the viscera and large blood vessels are associated with blind methods and negligible with ultrasound.^[7] QLB is a deeper block with the potential for hematomas in anticoagulated patients, hence, the need to follow the waiting period after anticoagulants and antiplatelets. However, ESPB is a superficial and technically simpler fascial plane block, and it does not necessitate the changing of the position twice.^[7] There have been reports of quadriceps weakness after TQLB due to proximity between the block site and the lumbar plexus. This can be prevented by avoiding the puncture of the psoas major muscle.^[16] Following ESPB, there is possibility of drug spread in the areas where the lumbar nerves enter the psoas muscle. This might present a problem with ambulation.^[17] Motor weakness in the lower extremities probably follows the administration of a high concentration and volume of local anesthetic.^[10,18,19] However, in our study, no adverse effects were noted with either type of block.

Both groups yielded similar satisfaction scores with respect to analgesia. QLB is proposed to provide analgesia due to the spread of the local anesthetic along the thoracolumbar

fascia (TLF) and the endothoracic fascia into the paravertebral space of T7–L1 dermatomes [Figure 4]. This could lead to visceral analgesia from the spread of anesthetics to the celiac ganglion or sympathetic trunk via the splanchnic nerve. An additional mechanism of action could be due to local anesthetic action on the network of sympathetic neurons, mechanoreceptors, and pain receptors contained in the superficial layer of the TLF.^[20] We have chosen TQLB for the optimal point of needle insertion, as it provides better analgesia due to a definitive endpoint and consistent drug spread.^[21]

Magnetic resonance imaging and cadaveric data showed that following an ESPB, the injectate spreads anterior to the transverse process through the costovertebral foramen spreading to the paravertebral (which contains the origin of the dorsal and ventral rami and the sympathetic chain),

intercostal, foraminal, and partially epidural space and also in the areas where the lumbar nerves enter the psoas muscle [Figure 4].^[17] This leads to the blockage of both visceral and somatic nerve fibers, which provide excellent analgesia comparable to paravertebral block or lumbar plexus block.^[22] Although a few studies contradict that ESPB cannot be an alternative to paravertebral block due to its limited spread, the patients in our study had good analgesic coverage with ESPB.^[23]

Although the craniocaudal spread of ESPB is more limited in the lumbar region when compared to the thoracic region due to the arrangement and thickness of lumbar musculature, significant contrast spread was observed even when a local anesthetic was deposited at lower lumbar levels.^[17,24] A meta-analysis revealed an additional reduction in opioid consumption when ESPB was performed at the vertebral

Table 2: Outcome variables according to groups

	ESPB (n=56)	TQLB (n=56)	P	Estimated treatment effect
Total tramadol consumption in 48 h (mg)	47.3±34.9	50.9±38.7	0.61	3.6 (-10.2 to 17.4) ^a
First rescue analgesia (h)	22.8±15.8	22.7±15.6	0.96	0.1 (-5.78 to 5.98) ^a
Patient satisfaction with analgesia at the end of 48 h ^b	4.00 (2-5)	4.00 (2-5)	0.06	0.00004 (-0.00003 to 0.00003) ^c

Data are mean ± standard deviation or median (range). ^aDifference in means of the two groups (95% confidence interval). ^bAssessed using a 5-point scale (0=very unsatisfied, 2=unsatisfied, 3=fair, 4=satisfied and 5=very satisfied). ^cApproximated median of the difference between the 2 groups (95% nonparametric confidence interval). ESPB=erector spinae plane block, TQLB=transmuscular quadratus lumborum block

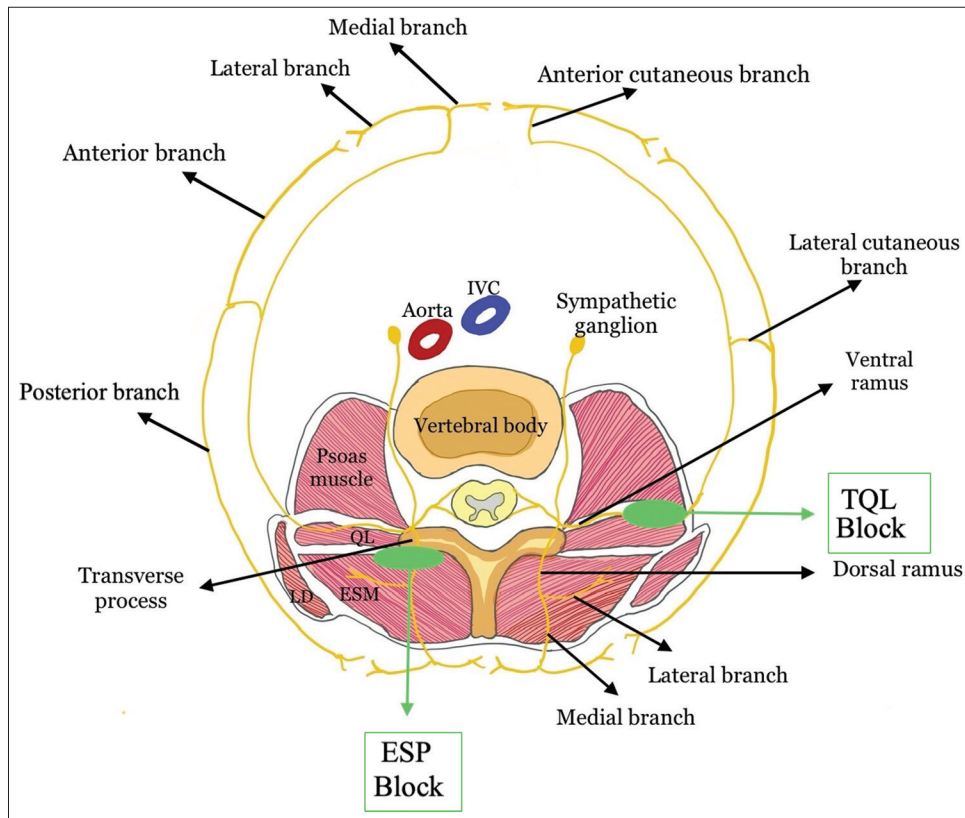


Figure 4: Depiction of the plane of injection and mechanism of action of QLB and ESPB. ESM = erector spinae muscle, QL = quadratus lumborum muscle, LD = latissimus dorsi muscle, IVC = inferior vena cava, ESP = erector spinae plane, TQLB = transmuscular quadratus lumborum

level of incision/operation than at the fixed thoracic/lumbar level.^[25] Hence, we have chosen T12 as we need coverage from bilateral T10-L1 level for the analgesia post-cesarean delivery with a Pfannenstiel incision.^[26] The authors also observed that for the in-plane approach to ESPB, the direction of the needle should be from the cephalad to the caudad end. This ensures the direction of spread of local anesthetic caudally toward the dermatomes required for analgesia for cesarean delivery. This is in accordance with the fact that LA spread in lumbar ESPB is mainly cephalad and reduced caudally.^[27]

We performed both blocks after the surgery with the patient lateral and still under the effects of spinal anesthesia. We opted against performing the block before surgery because the ultrasonographic anatomy may be less clear with the gravid uterus and it would be uncomfortable for the patient and technically difficult. During the study, we observed that lateral positioning might constitute a hindrance to the use of both blocks as it can be time-limiting and challenging. However, both blocks may be beneficial in cases with demonstrated adverse effects of opioids such as pruritus, or to avoid its ill effects such as urinary retention.^[15] In ESPB given outside the current study, it has been observed by the authors that ESPB is technically more challenging and time-consuming compared to QLB in obese patients due to the increased depth of the location of the transverse process.

The study also had a few limitations. Because sensory dermal testing could not be performed as the block was given following a subarachnoid block, we were neither able to evaluate the occurrence of cases of failed, inadequate, or functioning block till the onset of pain nor compare the dermatomal spread between the two blocks. Tramadol can have variable metabolism and efficacy depending on cytochrome P-450 enzyme 2D6 activity levels; however, we used tramadol due to institutional preferences. There was a lack of comparison to the standard of care using intrathecal or epidural opioids due to institutional preferences. The baseline quadriceps strength was not tested. This was a single-blinded study where the primary investigator administered the block, but to maintain the superiority of data collection the outcome assessor was blinded to the allotment.

We recommend that further investigation should focus on confirming the reproducibility of the block and determining the extent of analgesia that can be achieved by the use of catheters or adjuvants such as dexamethasone. Also, the influence of analgesic interventions on patient-reported outcomes such as mother–child bonding, breastfeeding ability, time to ambulate, and return to activities of daily living should be considered in future studies.

Conclusion

In this study, the total opioid consumption in 48 h, the duration of the first rescue analgesic requirement, and patient satisfaction were similar between the two groups. Both groups had similar pain scores except at 4, 6, and 36 h where the ESPB group had a minimally lower NRS score. In conclusion, we found that the analgesic effect of bilateral ESPB at T12 was non-inferior to that of bilateral QLB performed with the same volume post-cesarean delivery.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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