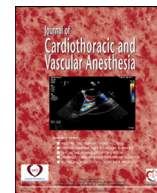




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Original Article

Efficacy of Bilateral Erector Spinae Plane Block in Management of Acute Postoperative Surgical Pain After Pediatric Cardiac Surgeries Through a Midline Sternotomy

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Objective: Regional analgesia continues to evolve with the introduction of ultrasound-guided fascial plane blocks. Erector spinae plane block (ESPB) is a novel technique gaining recent acceptability as a perioperative modality of analgesia in various thoracic and abdominal surgeries. However, literature on the use of ESPB in pediatric cardiac surgery is limited.

Design: A prospective, randomized, single-blind, comparative study.

Setting: Single-institution tertiary referral cardiac center.

Participants: Eighty children with acyanotic congenital heart disease undergoing cardiac surgery through midline sternotomy.

Interventions: The subjects were allocated randomly into 2 groups: ESPB (group B, n = 40) received ultrasound-guided bilateral ESPB at the level of T₃ transverse process and control (group C, n = 40) receiving no block.

Measurements and Main Results: The postoperative pain was assessed using Modified Objective Pain Scores (MOPS) which were evaluated at 0, 1, 2, 4, 6, 8, 10, and 12 hours after extubation. Group B demonstrated significantly reduced MOPS as compared with group C until the 10th postoperative hour (p < 0.0001), with comparable MOPS at the 12th hour. The consumption of postoperative rescue fentanyl was also significantly less in group B in comparison to group C (p < 0.0001) with a longer duration to first rescue dose requirement in group B. In addition, the group B showed lower postoperative sedation scores and intensive care unit stay in contrast to group C.

Conclusion: Ultrasound-guided bilateral ESPB presents a simple, innovative, reliable, and effective postoperative analgesic modality for pediatric cardiac surgeries contemplated through a midline sternotomy.

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Key Words: bilateral erector spinae plane block; midline sternotomy; modified objective pain score; postoperative pain; pediatric cardiac surgery; ultrasound-guided

THE EVOLUTION of regional analgesic modalities and increasing ultrasound use has resulted in the widespread application of regional techniques for perioperative analgesia in the pediatric population.¹ Despite an encouraging literature on the use of

novel fascial plane blocks for thoracotomy, regional analgesic approaches for cardiac surgery through a midline sternotomy are largely limited to paravertebral, intercostal, and neuraxial blocks.² However, the technical difficulty, resultant hypotension, and the possibility of epidural hematoma after heparinization³ has prompted the evaluation of emerging regional analgesic techniques for pediatric cardiac surgical subsets.

The literature on the fascial plane blocks such as serratus anterior plane block⁴ and pectoral nerves block⁵ fails to suggest

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adequate analgesia for surgery through a midline sternotomy considering a limited spread of drug, even if given bilaterally.⁶ The recently introduced ultrasound-guided interfascial plane block, bilateral erector spinae plane block (ESPB), at the level of T₃ transverse process is a viable option for management of postoperative pain after midline sternotomy.⁷

The ESPB has been traditionally described for the management of acute and chronic thoracic pain⁸. However, a bilateral ESPB is expected to provide an analgesic cover spanning the entire thorax at the desired dermatomes including the midline, which could prove beneficial for cardiac surgery through midline sternotomy. The present study was designed to test the hypothesis that the administration of bilateral ESPB with ropivacaine 0.2% would improve postoperative analgesia after pediatric cardiac surgery. The requirement of additional rescue analgesic medication and adverse events associated with ESPB also were studied.

Patients and Methods

The study was approved by the institute ethics committee (IECPG-434/16.10.2017) and registered at ctri.nic.in (CTRI/2018/02/011763). The study protocol was explained to the parents of participants with a written informed consent obtained from the parent and assent procured from the participant children of appropriate age. This randomized, comparative, observer-blinded study was performed with initial recruitment of 100 children with an American Society of Anesthesiologists physical status class I and II undergoing cardiac surgical procedures through midline sternotomy (Fig 1). The patients with preoperative ejection fraction <35%, low-cardiac-output syndrome, recurrent ventricular arrhythmias, preoperative inotropic support, allergic to the amide type of local anesthetics (LA), requiring intubation for more than 3 hours or re-exploration, and requiring redo or emergency

surgery were excluded from the study. The enrolled children were subsequently randomized into 2 groups using a computer generated random number table: group B receiving bilateral ESPB with 0.2% ropivacaine and group C without any intervention. The postoperative pain was managed with rescue intravenous (IV) fentanyl. Both the groups received IV acetaminophen 15 mg/kg every 8 hours as a component of multimodal analgesia.

A routine preoperative assessment was performed for all the patients. Premedication in the form of 1 mg/kg promethazine syrup was administered, 1 hour before shifting to the operating room. Standard American Society of Anesthesiologists monitoring was instituted and the children were anesthetized as per institutional protocol. The protocol constituted an induction with sevoflurane in oxygen 50% and air, peripheral IV cannulation of appropriate size followed by IV midazolam, 0.05 to 0.1 mg/kg, fentanyl, 1 to 2 µg/kg, and rocuronium, 0.6 mg/kg, to facilitate endotracheal intubation. Femoral arterial access was established for intra-arterial pressure monitoring. Central venous catheter was inserted in the right internal jugular vein for central venous pressure monitoring in addition to the temperature, end-tidal carbon dioxide, and near infrared spectroscopy monitoring. Anesthesia was maintained with sevoflurane (0.9-2%) in 50% oxygen in air mixture and supplemental boluses of 0.1 mg/kg of atracurium, with the hemodynamics maintained within 20% of the baseline.

Ultrasound-Guided ESPB

The ESPB was performed with the child in a right lateral decubitus position under aseptic precautions. A high frequency (6-13 MHz) linear ultrasound transducer (Sonosite Inc, Bothell WA) was placed in a longitudinal orientation over the T₃ transverse process lateral to the spinous process. After identifying the muscles (trapezius, rhomboid major, and erector spinae)

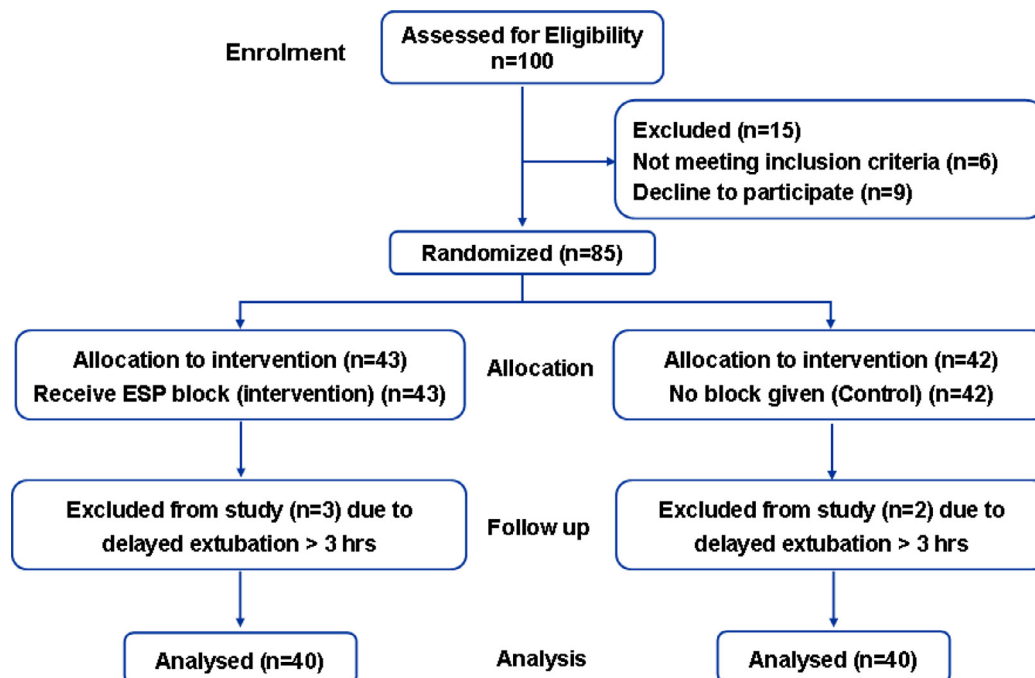


Fig 1. Consort flow diagram.

above the hyperechoic transverse process image, a 5-cm 22-gauge Stimuplex A block needle (B. Braun, Melsungen, Germany) was inserted in-plane in a cephalo-caudad direction. The endpoint was defined as the needle pointing to the tip of transverse process piercing the erector spinae muscle. The LA was deposited at this position, close to the costotransverse foramen. The needle tip position was confirmed by hydrolocation with 0.5 to 1 mL of 1% lidocaine indicating linear fluid spread lifting the fascial plane between the transverse process and erector spinae muscle. After careful negative aspiration, 1.5 mg/kg of 0.2% ropivacaine was administered under ultrasound guidance (Fig 2). The process was repeated with injection of 1.5 mg/kg of 0.2% ropivacaine on the contralateral side adding up to a cumulative dose of 3 mg/kg ropivacaine.

Following sternotomy, adequate heparinization was achieved with a resultant activated clotting time >480 seconds before the initiation of cardiopulmonary bypass in both the groups. After a satisfactory surgical correction, the patient was weaned off cardiopulmonary bypass followed by protamine administration. The patients were transferred to the intensive care unit (ICU) after completion of the procedure.

Postoperative ICU Management and Postoperative Pain Assessment

The electrocardiogram, invasive blood pressure, respiratory rate, and pulse oximetry (Spo₂) were monitored and recorded throughout the postoperative period. The study subjects were extubated within 2 to 3 hours postoperatively once they fulfilled the extubation criteria (conscious, hemodynamically stable, (peak inspiratory pressure) PIP <20 cmH₂O above positive end-expiratory pressure (PEEP), no neuromuscular blockade, and normal arterial blood gas analysis). Postoperative pain assessment was performed using Modified Objective Pain Score (MOPS)⁹ at 0, 1, 2, 4, 6, 8, 10, and 12 hours post extubation. Acetaminophen, 15 mg/kg, IV, every 8 hours was administered in both the groups. A rescue analgesic fentanyl, 0.5 to 1 µg/kg, was administered when the MOPS score was ≥4 at rest. Postoperative adverse effects such as nausea,

vomiting, cardiac arrhythmia, and complications such as LA toxicity, and vascular puncture were recorded and treated.

Statistical Analysis

Primary and Secondary Endpoints

MOPS at 0, 1, 2, 4, 6, 8, 10, and 12 hours post extubation constituted the primary endpoints. The secondary endpoints included intraoperative fentanyl requirement, extubation time, time to first rescue analgesic requirement, postoperative cumulative fentanyl requirement up to 12 hours, Ramsay sedation score¹⁰, ICU stay, and incidence of adverse events.

Sample Size Calculation

Considering the scarcity of literature that directly compares the effectiveness of ultrasound-guided ESPB with control group for postoperative analgesia in pediatric cardiac surgery, a pilot study was contemplated to assist in sample size estimation. Hence, based on the preliminary study of MOPS (2.9 ± 0.41 in ESPB group and 3.2 ± 0.42 in the control group), an estimated sample size of 40 children in each group was required to a study power of 90% ($\alpha = 0.05$).

The continuous variables were presented as mean with standard deviation and categorical data were presented as numbers and percentages. The normality was tested using Shapiro-Wilk test. The Chi-square test or Fisher exact test was used to establish the association between qualitative parameters. The Student t test was employed to observe the difference in quantitative variables between the groups. The data were processed using STATA software, version 14 (Stata Corp LP, College Station, TX). A p value < 0.05 was considered to be statistically significant.

Results

One hundred children were initially recruited. Fifteen children were excluded at the enrolment level and 5 children were excluded at follow-up level owing to delayed extubation (>3

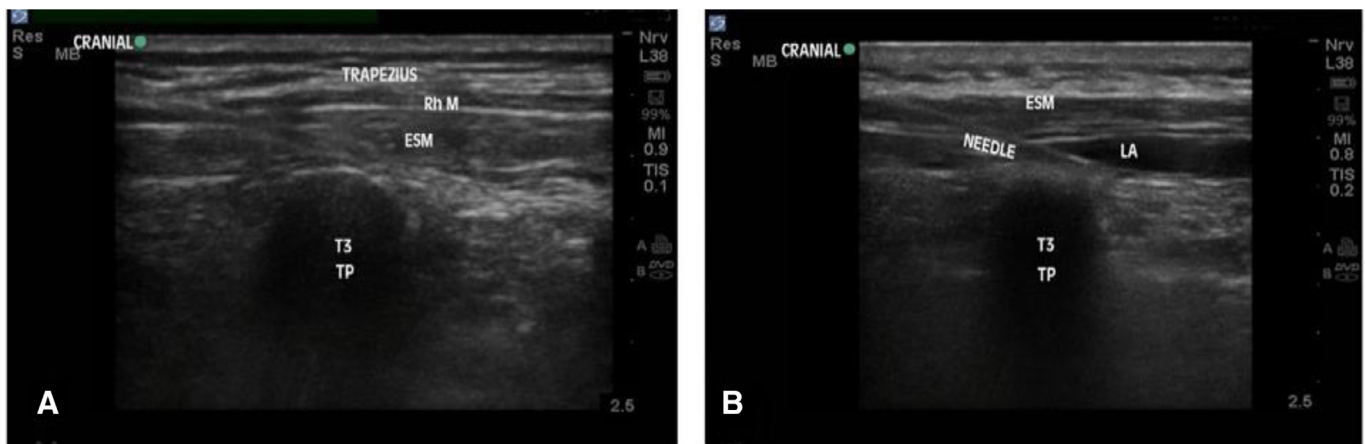


Fig 2. Ultrasound-guided erector spinae plane block. (A) Demonstrating hyperechoic T3 transverse process and above it the trapezius, rhomboid major, and erector spinae muscle from superficial to deep. (B) Needle pointing the muscle plane between T3 transverse process and erector spinae muscle and local anesthetic separating the fascial plane. ESM, erector spinae muscle; LA, local anesthetic; Rh M, rhomboid major muscle; TP, transverse process.

Table 1
Demographic Data, Surgical Procedures, and Intraoperative Variables

Variable	Group B: ESP Block (n = 40) (Mean ± SD)	Group C: No Block (n = 40) (Mean ± SD)	p Value
Age (mo)	28.43 ± 21.50	29.83 ± 24.07	0.813
Weight (Kg)	10.81 ± 5.51	9.47 ± 4.86	0.252
Sex (male/female)	22/18	23/17	0.82
Duration of surgery (min)	77.30 ± 9.98	79.86 ± 10.31	0.331
Surgical Procedures			0.478
ASD closure	25	28	
VSD closure	15	12	
Cardiopulmonary bypass time (min)	37.4 ± 4.45	39.7 ± 7.96	0.172
Aortic cross-clamp time (min)	19.1 ± 4.70	20.2 ± 5.06	0.387

Abbreviations: ASD, atrial septal defect; ESP, erector spinae plane; SD, standard deviation; VSD, ventricular septal defect.

hours), hence 80 children were analyzed in this study. The subject distribution and allocation is outlined in the CONSORT flow diagram (Fig 1). The groups B and C were comparable with regards to the demographic and surgical data (Table 1).

The trends of MOPS are depicted in Figure 3 with group B demonstrating significantly lower MOPS until 10 hours post extubation in comparison to group C ($p < 0.0001$) with no significant difference between the MOPS at the 12th hour (Table 2). The intraoperative fentanyl requirement and extubation time was comparable in both the groups.

All the group C children required postoperative rescue fentanyl, whereas rescue was required in 28 children in group B. The postoperative fentanyl dose in group B ($1.08 \pm 0.91 \mu\text{g}/\text{kg}$) was significantly reduced in contrast to the group C ($5.52 \pm 3.27 \mu\text{g}/\text{kg}$) ($p < 0.0001$) (Table 3). It was noteworthy that the time duration to the first rescue analgesic dose requirement was significantly longer in group B pointing out an improved analgesic cover of ESPB (Table 3).

The postoperative sedation score was also significantly higher in group C (3 ± 0.58) as compared with group B (2.3 ± 0.46) ($p < 0.0001$). Postoperative ICU stay was significantly less in group B (10.7 ± 1.87 hours) as compared with group C (14.16 ± 2.26 hours) ($p < 0.0001$) (Table 3).

Five children in group B and 8 children in group C had postoperative vomiting, respectively. Two children in group B and 3 children in group C demonstrated an increased temperature up to 38.7°C postoperatively, which subsided within 6 hours (Table 4). No complication related to the bilateral ESPB technique and LA administration was discovered.

Discussion

This prospective, randomized, controlled study was conducted to evaluate bilateral ESPB for the management of postoperative pain after pediatric cardiac surgery performed through a midline sternotomy. Bilateral ESPB was effective in relieving the post-sternotomy pain with a longer duration of analgesia in terms of reduced requirement of rescue postoperative analgesics

as compared with the control group. This finding in absence of any noteworthy complications adds to the applicability as an opioid-sparing postoperative analgesic regimen to facilitate early recovery after pediatric cardiac surgery.

With an increasing emphasis on enhanced recovery after cardiac surgery and improved safety profile of newer LA agents such as ropivacaine, regional analgesia-centered pain management is gaining popularity. Tirota et al.,¹¹ observed lower morphine requirement following a continuous incisional LA infusion in their study on pediatric patients undergoing cardiac surgery. However, the current sophisticated ultrasound-guided regional analgesic modalities present promising pain management with single shot injection without major complications.

The administration of ESPB anesthetizes the dorsal and ventral rami of the spinal nerve roots, which results in profound analgesia of the ipsilateral hemithorax. In addition, the drug spreads in a craniocaudal fashion as the erector spinae fascia extends from the nuchal fascia cranially to the sacrum caudally, explaining the ability of single-shot ESPB to cover multiple dermatomal levels.^{8,12} The index study elucidated that a bilateral performance of ESPB at the level of T₃ transverse process could account for sound analgesic adjuvant for pain emanating from a sternotomy incision. Moreover, the dose of ropivacaine employed in the present study is in accordance with the recent literature evaluating fascial plane blocks in pediatrics.¹³⁻¹⁵

ESPB has been increasingly utilized by the modern day perioperative physician in the pediatric cohort. Hernandez MA et al.,¹⁶ performed a single-shot ESPB at the level of T₁ transverse process in a 3-year-old child undergoing a giant paraspinous lipoma resection. The block demonstrated excellent perioperative pain control over the T₂ to T₈ dermatomes while ensuring hemodynamic stability. Another successful report on the use of continuous ESPB in a 3-year-old child with the hypoplastic left heart syndrome for thoracoscopic diaphragm plication demonstrated excellent postoperative analgesic coverage and recovery.¹⁷ Muñoz et al.¹⁸ performed ultrasound-guided single-shot ESPB in a 7-year-old child with 11th rib tumor and reported a satisfactory postoperative analgesia.

However, the mechanism and extent of the drug spread has been debated. Pooling of the data from a pilot study⁷ indicates that injection of 20 mL (0.3 mL/kg) of LA into the erector spinae plane produces clinical and radiologic evidence of spread that extends at least 3 vertebral levels cranially and 4 levels caudally from the site of injection. Radiologic imaging in a cadaver model substantiated these findings.⁸ Moreover, the potential spread to epidural and paravertebral space and involvement of dorsal and ventral rami prompted the authors to conduct a bilateral ESPB for ensuring extensive analgesic cover, thereby avoiding catheter-related problems encountered in previous studies.¹⁹

There were a few limitations of the study. First, the sample size was relatively small. Second, despite the favorable pain scores, the inability to assess the dermatomal sensory blockade considering the age of subjects posed an impediment to successful establishment of a proposed sternal analgesia.

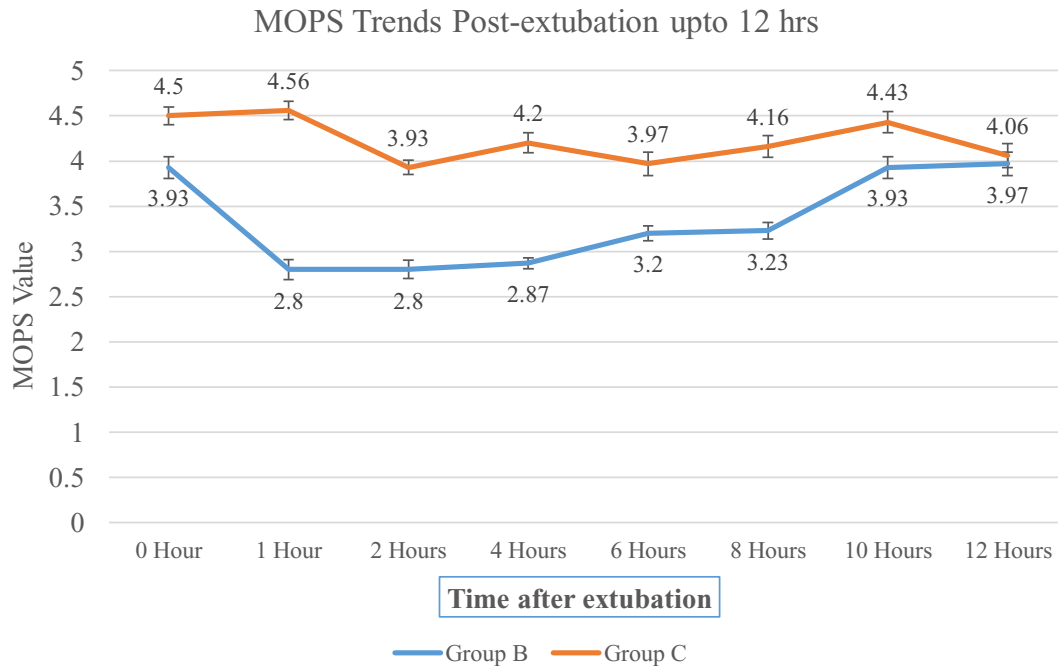


Fig 3. Modified Objective Pain Score (MOPS) trends in both the group postextubation up to 12 hours. Group B, erector spinae plane block group; Group C, no block group.

Table 2
Comparison of MOPS Postextubation at Various Intervals up to 12 Hours

Time After Extubation	Group B: ESP Block (Mean ± SD)	Group C: No Block (Mean ± SD)	p Value
0 Hour (immediately after extubation)	3.93 ± 0.63	4.5 ± 0.57	0.0006
1 Hour	2.8 ± 0.61	4.56 ± 0.56	<0.0001
2 Hours	2.8 ± 0.55	3.93 ± 0.45	<0.0001
4 Hours	2.87 ± 0.34	4.2 ± 0.61	<0.0001
6 Hours	3.2 ± 0.48	3.97 ± 0.71	<0.0001
8 Hours	3.23 ± 0.50	4.16 ± 0.64	<0.0001
10 Hours	3.93 ± 0.69	4.43 ± 0.67	0.0065
12 Hours	3.97 ± 0.71	4.06 ± 0.73	0.5973

Abbreviations: ESP, erector spinae plane; MOPS, Modified Objective Pain Score; SD, standard deviation.

Table 3
Secondary Outcome and Their Comparison Between Groups

Secondary Outcome	Group B: ESP Block (Mean ± SD)	Group C: No Block (Mean ± SD)	p Value
Intraoperative fentanyl consumption ($\mu\text{g}/\text{kg}$)	10.45 ± 3.23	11.46 ± 2.06	0.1004
Extubation time (min)	45.36 ± 5.48	47.23 ± 5.80	0.1423
Time to first rescue analgesia (measured after extubation) (h)	4.5 ± 0.62	1.8 ± 0.53	<0.0001
Postoperative fentanyl consumption from postextubation up to 12 hour ($\mu\text{g}/\text{kg}$)	1.08 ± 0.91	5.52 ± 3.27	<0.0001
Ramsay sedation score	2.3 ± 0.46	3 ± 0.58	<0.0001
ICU stay (h)	10.7 ± 1.87	14.16 ± 2.26	<0.0001

Abbreviations: ESP, erector spinae plane; ICU, intensive care unit; SD, standard deviation.

Moreover, the technique mandated a bilateral administration of the block, which could attribute to an elevated risk of LA systemic toxicity. In addition, these pediatric regional analgesic blocks are usually performed in the anesthetized patients hence, analgesic benefits must be carefully weighed against

the potential risks. The lack of concrete evidence-based recommendations on drug dosages compounds the problem furthermore. Third, the incorporation of cost benefit analysis incurred by reduced ICU stay could have added incremental value to the study.

Table 4
Adverse Effects in the ICU 12 Hours Postoperatively

Adverse Effects	Group B (ESP Block) (n = 40)	Group C (No Block) (n = 40)	p Value
None	33 (82.5%)	29 (72.5%)	0.700
Vomiting	5 (12.5%)	8 (20%)	0.588
Fever	2 (5%)	3 (7.5%)	0.775
Pruritus,	-	-	-
Bradycardia	-	-	-
Hypotension	-	-	-
Respiratory depression	-	-	-

NOTE. Value are presented as number (percentage).

Abbreviations: ESP, erector spinae plane; ICU, intensive care unit.

Conclusion

Ultrasound-guided bilateral ESPB demonstrated excellent postoperative analgesia with reduced requirement of rescue analgesics after midline sternotomy in the pediatric cardiac surgical cohort. The ESPB promises to be a simple, effective, and a safer regional analgesic technique considering easy visualization of sonographic targets and a distant site of injection from the neuraxis, pleura, and major vascular structures. The study adds a new dimension to the existing literature on the application of ESPB in the cardiac surgical arena.

Acknowledgments

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Declaration of Competing Interest

The authors declare no conflicts of interest.

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