# Analgesic efficacy of ultrasound guided erector spinae plane block in pediatric patients undergoing aortic coarctectomy

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**Abstract**

Objectives: This study aims to compare the efficacy of analgesia and any side effects of U/S guided Erector Spinae Plane block versus fentanyl usage in pediatric patients undergoing aortic coarctectomy.

Design: This randomized, controlled, double blinded study was carried out in Cairo University Hospital after approval of ethics and Research Committee of Anesthesia Department, Faculty of Medicine, Cairo University.

Settings: The research was carried out in pediatric cardiothoracic theatre at Cairo University's Abu El Reesh Pediatric Hospital

Participants: The patients were included in the study according to these criteria: age 3-12 months, American society of Anesthesia (ASA) II-III, scheduled to undergo aortic coarctectomy operation with left Lateral thoracotomy incision.

Interventions: Patients were randomly assigned to one of 2 groups: group S (n=14): the study group which received ESPB, Group C (n=14): the control group which receive no intervention.

Measurements and Results: ESBP reduced intraoperative consumption of fentanyl in children undergoing aortic coarctectomy compared to standard care. Furthermore, children in the ESBP group showed better hemodynamic profile with lower heart rate and blood pressure.

Conclusion: In aortic coarctectomy procedures, ultrasound-guided ESPB provided superior perioperative analgesia and better hemodynamic profile compared to standard care.

**Keywords:** *Erector – Spinea – Block – Pediatric – Aortic - Coarctectomy – Ultrasound - Analgesia.*

## INTRODUCTION

In the last 20 years, the use of extremely potent opioids for paediatric cardiac anaesthesia has grown in common. (1, 2) In addition to the essential benefit of hemodynamic stabilisation, high-dose opioid-based anaesthetic procedures can reduce the stress reaction, but they can also cause over sedation, respiratory depression, and the need for extended mechanical ventilation following surgeries. (2, 3)

Interrupting pain signals through peri-neural injection of local anesthetics have been known to reduce stress response, decrease opioid requirements, and improve postoperative pain control. (4, 5)

With the widespread use of US in regional anesthesia, newer techniques are being introduced and their relative indications are pioneered. Erector Spinae Plane Block (ESPB) is one of those techniques, which was described for the first time in 2016 by Forero et al, as a new ultrasound-guided method for treating thoracic neuropathic pain. (6)

It gained popularity because it is both simpler and easier to perform than other regional procedures such as thoracic paravertebral and thoracic epidural blocks. (6) It leads to effective postoperative analgesia when performed at T 4-5 level for breast and thoracic surgery, and T 7 level for abdominal surgeries. Spread of local anaesthetic following ESB in the cephalic and caudal directions can lead to analgesia from C7 to L2-3. (7, 8)

The use of the erector spinae plane Block (ESPB) block in the thoracic region in pediatric population is not adequately investigated; with most of the available data performed in sternotomy and no randomized controlled trials are available in children undergoing thoracotomy. (9-13)

This study aimed to determine the analgesic efficacy of U/S guided Erector Spinae Plane block compared to standard of care in children undergoing aortic coarctectomy.

## PATIENTS AND METHODS

This randomized, controlled, double blinded study was carried out in Cairo University Hospital after approval of ethics and Research Committee of Anesthesia Department, Faculty of Medicine, Cairo University (Code: MD-213-2019/28.12.2019) and obtaining informed consent from patients' parents or legal guardians; And was registered at clinical trial (NCT04128540).

A computer random number generator was used to achieve randomization. A research assistant who was not included in the study inserted patient codes into pre - numbered sealed opaque envelopes. An anesthesiologist who is experienced in performing the ESPB was responsible for opening the envelope and performing the block and was not involved in further management of the patient nor collection of the data. Anesthetic management and data collection were performed by the attending anesthesiologists who were blinded to the group assignment.

The patients were included in the study according to these criteria: age 3-12 months, American society of Anesthesia (ASA) II-III, scheduled to undergo aortic coarctectomy operation with left Lateral thoracotomy incision. The exclusion criteria were, patient guardian refusal, preoperative artificial ventilation, preoperative inotropic medication infusion, surgery with a midline sternotomy incision, anatomic abnormalities at site of injection, skin lesions or wounds at site of proposed needle insertion, allergy to any of the medications under study, any type of coagulopathy.

Patients with failed block (received 2 fentanyl boluses within 30 minutes after skin incision); patients who were not extubated within 2 hours postoperatively, and patients who had surgical issues (cardiopulmonary bypass, prolonged cross clamping … etc.) were considered as dropouts and their envelope was reused in the next patient.

Preoperative medication included intramuscular atropine 0.02 mg/kg and midazolam 0.2 mg/kg. Perioperative monitoring, including continuous ECG (GE-Datex Ohmeda 5 leads ECG cable), pulse oximetry (GE-Datex Ohmeda paediatric finger $SpO_2$ sensor), and non-invasive arterial blood pressure (GE-Datex Ohmeda NIBP cuff, children double tube with bag was started as soon as the patient arrived in the operating room.

Sevoflurane 5% in 50% $O_2$ was used to induce anaesthesia, followed by the placement of a peripheral intravenous (IV) cannula and the IV administration of fentanyl (1mcg/kg). After lack of consciousness, IV atracurium 0.5 mg/kg was used to facilitate oral endotracheal intubation; a capnogram was used to track end-tidal $CO_2$; and muscle relaxation was sustained by atracurium infusion in a dosage of 0.5 mg/kg/h. Participants were mechanically ventilated using a pressure-controlled mode, I: E ratio of 1:2, a peak inspiratory pressure (PIP) was settled to deliver a tidal volume of 6-8 ml/kg, and a respiratory rate of 20 to 35 cycles per minute aiming end-tidal $CO_2$ levels 30-40 mmHg. Sevoflurane concentration was adjusted to have bispectral index at 40-60. Nasopharyngeal temperature probe, central venous catheter and arterial cannula were inserted.

All patients received fentanyl infusion at a dose of ($0.5\ \mu g \cdot kg^{-1} \cdot h^{-1}$) (14, 15). Then, the patient's position was shifted from supine to lateral with the left side up.

Patients were randomly assigned to one of 2 groups: group S (n=14): the study group which received ESPB, Group C (n=14): the control group which receive no intervention.

The block was performed using a 25G echogenic needle guided by S-Nerve Ultrasound System P07576, USA with SL Ax/6-13 MHz linear high frequency transducer.

Block technique:

- In the right lateral decubitus position, a unilateral block was done, and each patient was turned on his or her side such that the blocked side was the uppermost.
- The bed was raised so that the needle, probe, and ultrasound screen could both be seen in full line-of-sight with limited head movement.
- A Strict sterile procedure was used, including skin sterilisation of the needle entry site with povidone iodine.
- The spinous process of T3 was identified by palpating the spinous process of C7 and counting down from there.

- A high-frequency 12 MHz linear ultrasound transducer was positioned 3 cm lateral to the T3 spinous process, which corresponds to the T2 transverse process, in a longitudinal orientation.
- Three muscles were defined superior to the hyperechoic transverse process: trapezius (uppermost), rhomboids major (middle), and erector spinae (lowermost).
- A 25 G needle was implanted in a caudal–cephalic direction, until the tip became deep to the erector spinae muscle, using an in-plane method.
- The correct needle tip position was tested by injecting 2 mL of normal saline into the fascial plane between the erector spinae muscle and the transverse process and visualising its linear spread (i.e., hydro-dissection) in the fascial plane.
- A 0.4 ml/kg (bupivacaine 0.25 percent and lidocaine 1 percent solution) (16) was infused at this site visualising the linear LA spread (hydro-dissection) in the fascial plane between the erector spinae muscle and the transverse process.
- The block was considered a failed block if the patient required more than two boluses of fentanyl during the first 30 minutes of the skin incision and the case was excluded from the study.

Hemodynamic and pain management

After 10 minutes, skin incision was initiated, and rescue analgesia in the form of a bolus of (Fentanyl 0.5mcg/kg) was administered to patients in either groups if their systolic blood pressure or heart rate was elevated by more than 20% from baseline (as measured 5 minutes after intubation). But, if SBP decreased more than 20% from baseline readings, intravenous fluids (10ml/kg) were given, and if not responding, calcium gluconate (30mg/kg) was given. Furthermore, if HR decreased more than 20% from baseline readings, atropine (0.01mg/kg) was given.

Ten minutes before aortic cross clamping, heparin in a dose of (100 IU/kg) was given, guided by ACT (more than 150 seconds). (17) After aortic cross clamping, if systolic blood pressure was elevated more than 20% from baseline (as mentioned before), one fentanyl bolus was given. After 2 minutes, if SBP was still rising, Sodium nitroprusside infusion was started at a dose of 0.3mcg/kg/min and increased according to the response to be stopped one minute before aortic de-clamping. Furthermore, sodium bicarbonate (2mleq/kg) was administered to all patients, just before aortic de-clamping to counteract reperfusion acidosis. (18)

After aortic de-clamping, if systolic blood pressure decreased (more than 20% from pre-cross clamping readings), IV fluids were given (in case of hypovolemia) and if not responding, vasopressors or inotropes were started (according to the haemodynamics and cardiac contractility). Furthermore, heparin was reversed by giving protamine sulfate (1mg/kg). Finally, Atracurium and fentanyl infusion were stopped 15 minutes before skin closure; reversal of neuromuscular blockade, patient recovery and extubation followed the local protocols. All surgeries in this study were carried out by the same physician in order to keep the time of the operation consistent.

Pain was assessed by the pediatric observational 10-point scale "Face, Leg, Activity, Cry, Consolability (FLACC) pain score. (Table 1); And if the patient's FLACC score equal or more than 4, morphine IV (0.1mg /kg) was used as rescue analgesia. Patients also received paracetamol in a dose of 15 mg/ kg IV every 6 h as a component of multimodal analgesia.

**Table (1): Face, Legs, Activity, Cry, Consolability (FLACC) Scale (19)**

| | 0 | 1 | 2 |
|---|---|---|---|
| **Face** | No particular expression or smile | Occasional grimace or frown, withdrawn, disinterested | Frequent to constant frown, clenched jaw, quivering chin |
| **Legs** | Normal position or relaxed | Uneasy, restlessness, tense | Kicking or legs drawn up |
| **Activity** | Lying quietly, normal position, moves easily | Squirming, shifting back and forth, tense | Arched, rigid, or jerking |
| **Cry** | No cry<br>(awake or sleep) | Moans or whimpers, occasional complaint | Crying steadily, screams or sobs, frequent complaints |
| **Consolability** | Content, relaxed | Reassured by occasional touching, hugging, distractible | Difficult to console or comfort |

Outcomes

Primary outcome: The total dose of intraoperative fentanyl boluses.

Secondary outcomes:

- FLACC score at 30 min, 60 min, 2 hours, 4 hours and 8 hours postoperatively.
- Hemodynamic data including HR and SBP at the following intervals; (T1; baseline reading 5 min after intubation, T2; after skin incision, T3; after rib retraction, T4; after aortic clamping, T5; after aortic declamping and T6; immediately after skin closure,30 min, 60 min, 2 hours, 4 hours and 8 hours postoperatively).
- The need for direct vasodilator (sodium nitroprusside) and its total consumption during the operation.
- Total consumption of morphine during the 1st 8 h post operatively.
- Time (in minutes) to 1st rescue analgesia (morphine) post operatively (defined as the elapsed time between stoppage of fentanyl infusion and a FLACC score ⩾4.
- The incidence of complications, postoperative vomiting, hematoma formation, itching, local anesthetic toxicity.

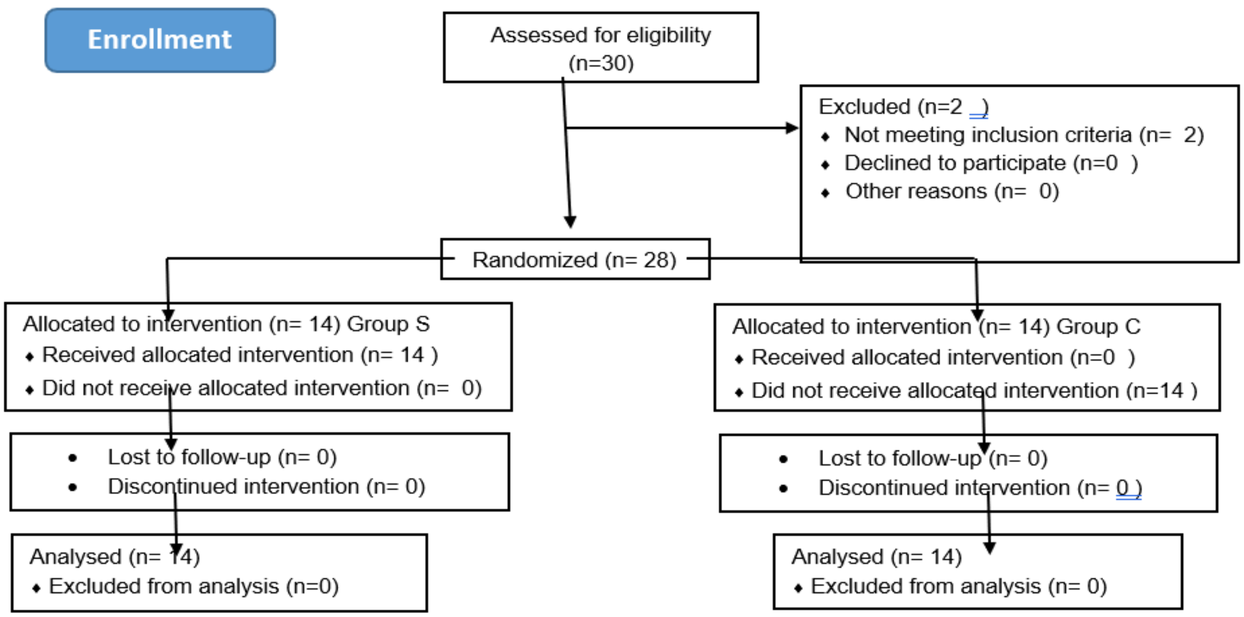
Statistical analysis and sample size calculation

Our primary outcome is the total dose intraoperative fentanyl boluses. In a pilot study on 10 patients, we reported that none of the studied cases in the intervention arm required fentanyl bolus versus mean doses of 1.0±0.41 among control group, then sample size calculation revealed very small number of cases (2 in each group) using G. Power Software version 3.1.9.4, we calculated a sample size that based on effect size of 10.14 .A convenient sample of 28 cases were retrieved as all cases who met eligibility criteria were recruited during study period.

Data were fed to the computer and analyzed using IBM SPSS Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. Qualitative data were described using number and percent. Quantitative data were described using median (minimum and maximum, IQR) and mean, standard deviation for non-normally & normally distributed data after testing normality using Kolmogrov-Smirnov test.

Significance of the obtained results was judged at the (0.05) level. Categorical data were analyzed using the Chi-squared test. Continuous data were analyzed sing unpaired student t test or Mann-Whitney U test according to normality of the data. Analysis of variance (ANOVA) test for repeated measures was used to compare the repeated measures with post- Hoc test Tukey and Boneferroni test. Freidmann test was used to compare more than 2 studied periods with post Hoc test Wilcoxon signed rank test.

**(Figure 1): CONSORT flow diagram.**




## Results

Thirty patients were screened for eligibility; two patients were excluded from the study due to change in the surgical decision. Twenty-eight patients were randomly allocated into either the ESPB group or the control group and were available for the final analysis. The subject distribution and allocation is outlined in the CONSORT flow diagram (Figure 1).

The demographic data of the patients were comparable between both groups. (Table 2)

**Table (2): socio-demographic characteristics of the studied groups**

| | Group S N=14 | Group C N=14 | P-value |
|---|---|---|---|
| **Age/months** | 5.64±2.13 | 5.43±1.74 | 0.773 |
| **Sex** <br> **Male** <br> **Female** | <br> 8(57.1) <br> 6(42.9) | <br> 9(64.3) <br> 5(35.7) | 0.699 |
| **Weight /kg** | 6.21±1.66 | 6.36±1.28 | 0.801 |
| **Height /cm** | 60.29±5.97 | 57.93±4.08 | 0.234 |

All the group C children required rescue intraoperative fentanyl boluses, whereas rescue was not required in the group S children; And the total dose of intraoperative fentanyl boluses in group S (0±0mcg) was significantly reduced in contrast to group C (10.71±2.97mcg) (p <0.001). (Table 3)

Also, only less than 30 % of children in group S required morphine in the 1st 8 hours postoperatively, unlike all children in group C. The total dose of postoperative morphine in group S (0-0.8mg) was significantly lower compared to group C (0.6-1.5mg) ($p < 0.001$). (Table 3)

It was noteworthy that the time duration to the 1st rescue analgesic requirement was significantly longer in group S pointing out an improved analgesic cover of ESPB. (Table 3)

**Table (3): Comparison of analgesic consumption between studied groups and change during follow up. Parameters described as median (min-max) (Interquartile range) and mean ±SD**

| | Group S N=14 | Group C N=14 | P value |
|---|---|---|---|
| **Total dose of intra-op fentanyl boluses (mcg)** | 0.0±0.0 | 10.71±2.97 | <0.001* |
| **Time to 1st rescue analgesia (h)** | 0(0-8) (0-4) | 1(0.5-1.0) (0.5-1.0) | 0.04* |
| **Total dose of morphine in the 1st 8 hours post-op (mg)** | 0.0(0.0-0.8) (0.0-0.7) | 0.80(0.6-1.5) (0.675-0.80) | 0.001* |
| **Number of cases required intra-op fentanyl boluses (%)** | 0 | 14(100%) | <0.001* |
| **Number of cases required morphine** | 4(28.6%) | 14(100%) | <0.001* |
| **Total dose of Na nitroprusside (mic) 0.3mcg/kg/min (almost 15 min)** | 0 | 0 | |

According to the hemodynamics, there was a statistical significance decrease in both heart rate and systolic blood pressure readings in group S when compared to group C. (Figure 2&3)

It was noteworthy that heart rate and systolic blood pressure trends were generally maintained all through the whole operation in group S. But in group C, heart rate was significantly increased (after skin incision, rib retraction, aortic cross clamping and also postoperatively) in relation to the baseline readings (Figure 2); and there was a marked swinging in systolic blood pressure (Marked increase after skin incision and marked decrease after aortic de-clamping) (Figure3).

**Figure (2):** line graph showing heart rate change. Parameters described as mean ±SD. (*statistically significant difference between group S& C, # statistically significant difference between baseline and every reading among group S & $: statistically significant difference between baseline and every reading among group C).

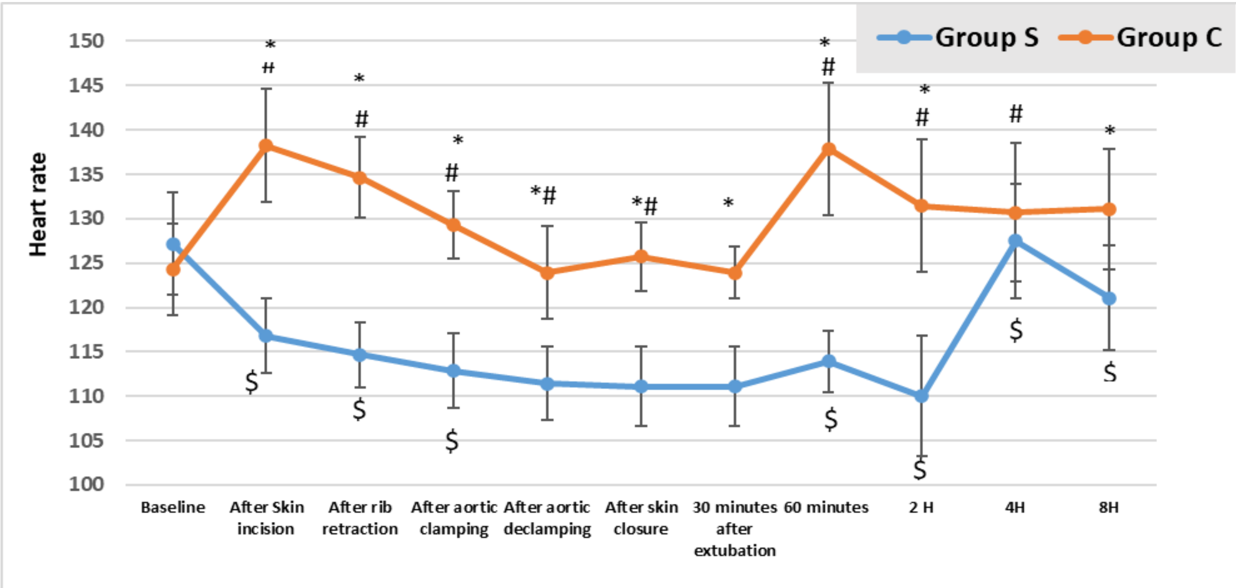
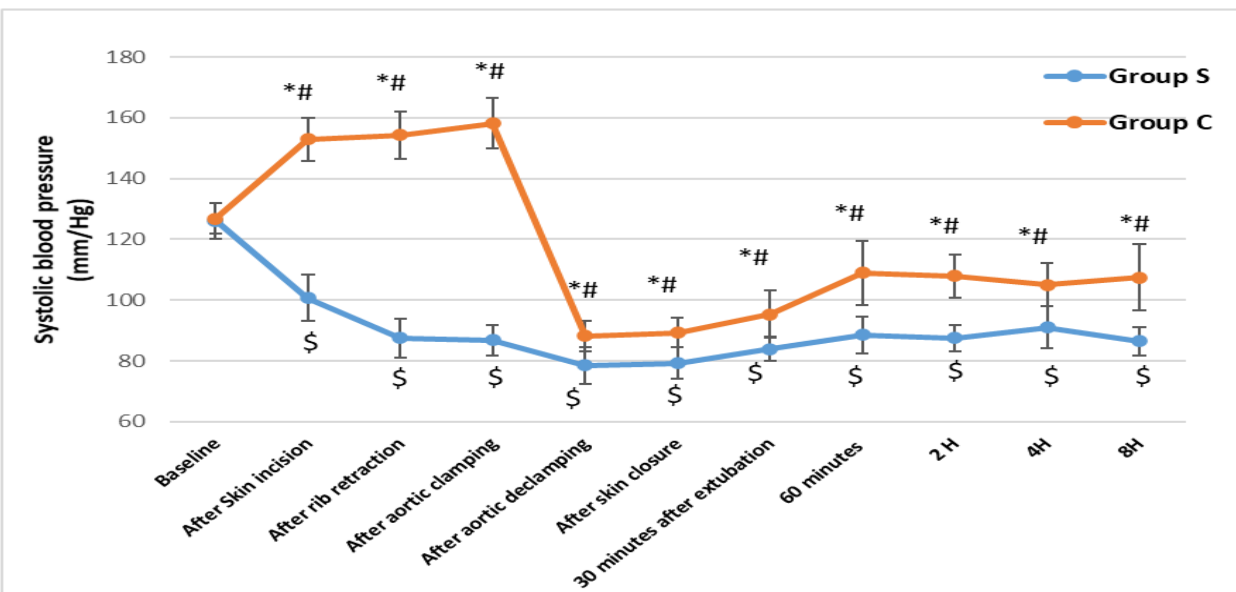



**Figure (3):** line graph showing systolic blood pressure change. Parameters described as mean ±SD. (*statistically significant difference between group S& C, # statistically significant difference between baseline and every reading among group S & $: statistically significant difference between baseline and every reading among group C).




Group S demonstrated significantly lower FLACC score until 4 hours post extubation in comparison to group C. (Table 4).

**Table (4): comparison of FLACC score between studied groups and change during follow up. Parameters described as median (min-max), (Interquartile range).**

| FLACC score | Group S N=14 | Group C N=14 | P value |
|---|---|---|---|
| **30 minutes post-operative** | 2(1.0-3.0) (1.0-3.0) | 4.0(2.0-7.0) (3.0-5.0) | <0.001* |
| **60 minutes post-operative** | 2(1.0-3.0) (2.0-3.0) | 7.0(2.0-8.0) (3.0-8.0) | <0.001* |
| **2h post-operative** | 2(1.0-3.0) (1.0-3.0) | 3.0(1.0-4.0) (3.0-4.0) | 0.018* |
| **4h post-operative** | 3.0(1.0-6.0) (2.0-4.0) | 4.0(2.0) (3.0-5.0) | 0.024* |
| **8h post-operative** | 3.0(1.0-5.0) (1.0-3.0) | 3.0(1.0-7.0) (2.0-3.0) | 0.885 |

According to the postoperative complications (vomiting, itching, hematoma and L.A. toxicity), we did not report any complications in both groups.

## Discussion

We report that ESBP reduced intraoperative consumption of fentanyl in children undergoing aortic coarctectomy compared to standard care. Furthermore, children in the ESBP group showed better hemodynamic profile with lower heart rate and blood pressure compared to the control group.

Injection of LA into the erector spinae plane causes clinical and radiologic proof of distribution that extends at least 3 vertebral levels cranially and 4 levels caudally from the injection site. (20) These findings were confirmed by radiologic imaging in a cadaver model. (6) The local anesthetic penetrates anteriorly through the inter-transverse connective tissue, gaining indirect access to the paravertebral space where it can potentially block the dorsal and ventral rami of the spinal nerves (6) and, possibly, sympathetic nerve fibers. (8)

We used a dose of 0.4 ml/kg (bupivacaine 0.25 percent and lidocaine 1 percent solution) in our patients; this dose was previously suggested by Hernandez MA et al. for inguinal hernia repair in preterm infants. (16)

We used a single shot technique in our patients. As the erector spinae fascia runs from the nuchal fascia cranially to the sacrum caudally, the medication distributes in a craniocaudal pattern, explaining how single-shot ESPB may cover numerous dermatomal levels with the advantage of the avoidance of catheter-related complications (leak, kinking, migration, hematoma and bruising). (6, 21)

The available literature for the use of ESPB in children undergoing thoracotomy is sparse. However, few case reports by John Hagen (22) and colleagues showed that children who received the block did not require intraoperative opioids and this is consistent with our results. The block did not show superior intraoperative analgesic profile in children undergoing sternotomy for open heart surgery compared to standard of care (23, 24) However, the postoperative analgesia was similar to our findings. It should be mentioned that open heart surgery differs from aortic coarcetectomy in duration, incision, age, and the presence of cardiopylmonary bypass.

In our patients, administration of ESPB was associated with better haemodynamic profile which is a vital objective during aortic coarctectomy operations

Aortic coarctectomy is characterized by great variation in hemodynamics which can affect the success rate, morbidity and mortality. Furthermore, perioperative pain management in this age group is usually challenging and it is desirable to avoid the hazards of systemic analgesic drugs; therefore, regional anesthetic techniques represents a favorable choice. Our findings introduce ESPB as a simple and effective technique for perioperative analgesia which is less time-consuming and has fewer complications than other regional anesthetic techniques such as thoracic epidural, paravertebral blocks, and intercostal nerve blocks.

This study has some limitations; it was performed in a single center, including special young age group performing one type of surgical incision; furthermore, we used one dose in a single shot approach. Future studies are warranted to evaluate continuous infusion protocols, other doses, additives, and other procedures.

## Conclusion

In aortic coarctectomy procedures, ultrasound-guided ESPB provided superior perioperative analgesia and better hemodynamic profile compared to standard care.

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