Comparison of ultrasound-guided thoracic erector spinae plane block versus paravertebral block for analgesia after pediatric cardiac surgery

Analgesia en cirugía cardíaca pediátrica: Comparación entre bloqueo erector espina y bloqueo paravertebral

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ABSTRACT

Background: In pediatric cardiac surgery, the use of multimodal analgesia, including a regional analgesic technique reduces opioid consumption and adverse effects. **Objective:** This study aimed to compare the effect of the ultrasound-guided bilateral thoracic erector spinae plane block (ESPB) and paravertebral block (PVB) on postoperative pain score and opioid consumption. **Methods:** This is a single center randomized, controlled, double-blinded, non-inferiority study. A total of 50 eligible pediatric patients, aged 2-10 years, scheduled for elective open cardiac surgery via median sternotomy were recruited. Bilateral ultrasound-guided thoracic ESPB at T4 was performed in patients included in the ESPB group and bilateral PVB was done in patients included in the PVB group by injecting 0.25% bupivacaine 0.4mL/kg on each side. The primary end point was fentanyl consumption during the first 24 h following extubation, while the secondary endpoints were postoperative modified objective pain score (MOPS), time needed to perform the block, intraoperative fentanyl consumption, time to the first analgesic request and the incidence of mechanical complications. **Results:** Both ESPB and PVB similarly reduced fentanyl consumption during the first 24 h following extubation and MOPS at all time points of measurement. Intraoperative fentanyl consumption and time to first analgesic request were similar in both ESPB and PVB group. The time needed to perform the block was significantly shorter in the ESPB group than the PVB group. Mechanical complications of needle advancement did not occur in any patients. **Conclusion:** In pediatric patients scheduled for open cardiac surgery via median sternotomy, ultrasound-guided bilateral thoracic ESPB is non-inferior to PVB in providing postoperative analgesia in terms of opioid consumption and pain score. Moreover, ESPB is easier and its performance requires a shorter period than PVB.

Key words: Cardiac surgery, pediatrics, erector spinae plane block, paravertebral block, ultrasound.

RESUMEN

Antecedentes: En cirugía cardíaca pediátrica, el uso de analgesia multimodal, incluida una técnica analgésica regional, reduce el consumo de opioides y los efectos adversos. **Objetivo:** Este estudio tuvo como objetivo comparar el efecto del bloqueo bilateral del plano del erector de la columna torácica (ESPB) guiado por ecografía y el bloqueo paravertebral (PVB) sobre la puntuación del dolor posoperatorio y el consumo de opiáceos. **Métodos:** Este es un estudio de no inferioridad, aleatorizado, controlado, doble ciego, en un solo centro. Se reclutó un total de 50 pacientes pediátricos entre 2 a 10 años, programados para cirugía cardíaca abierta electiva mediante esternotomía media. A los pacientes incluidos en el grupo BES se les realizó EL bloqueo bilateral guiado por ecografía en T4 y a los pacientes incluidos en el grupo BPV se les

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realizó bilateral mediante la inyección de bupivacaína al 0,25% 0,4 ml/kg en cada lado. El objetivo principal fue el consumo de fentanilo durante las primeras 24 h después de la extubación, mientras que los objetivos secundarios fueron el puntaje de dolor objetivo modificado (MOPS) posoperatorio, el tiempo necesario para realizar el bloqueo, el consumo de fentanilo intraoperatorio, el tiempo hasta la primera solicitud de analgésico y la incidencia de dolor mecánico. complicaciones

Palabras clave: Cirugía cardíaca, pediatría, bloqueo del plano del erector de la espina, bloqueo paravertebral, ultrasonido.

Introduction

Pain after cardiac surgery arises mainly from the site of sternotomy incision and to lesser extent from the sites of inserting the drainage tubes. The implementation of perioperative analgesia in pediatric patients undergoing cardiac surgery is challenging because they have unique anatomical characteristics and unpredictable hemodynamic response to pain and opioid analgesics. Traditionally, high-dose IV opioids were used to control pain after cardiac surgery, however this may cause hypotension, bradycardia, respiratory depression, delayed extubation and opioid habituation. In pediatric cardiac surgery, the use of multimodal analgesia, including a regional analgesic technique reduces opioid consumption and their adverse effects[1].

Paravertebral block (PVB) has gained more popularity than other regional analgesic techniques including caudal and epidural for perioperative analgesia in pediatric cardiac surgery[2]. Thoracic paravertebral block provides adequate postoperative analgesia with favorable adverse effects[3],[4]. The use of thoracic PVB in cardiac surgery is associated with decreased pain severity and opioid consumption in both adults[5],[6] and children[2],[7].

Erector spinae plane block (ESPB) is a relatively new facial plane block involving injecting local anesthetics between erector spinae muscle and transverse process[8]. Single shot ESPB provides good postoperative analgesia after many surgeries such as breast surgery[9] and thoracic surgery[10]. In cardiac surgery, few reports have demonstrated the analgesic efficacy of ESPB in both adults[11] and children[12].

The aim of this randomized controlled study was to compare the effect of ultrasound-guided bilateral thoracic ESPB and PVB on postoperative pain score and opioid consumption. Our hypothesis was that, ESPB would be non-inferior to PVB in providing postoperative analgesia in children scheduled for cardiac surgery via median sternotomy.

Methods

This single-center prospective, randomized, double-blinded, controlled, non-inferiority study was conducted in our institutional hospital from June 2020 to December 2021 after approval from Mansoura Faculty of Medicine Review Board on May 3, 2020 (IRB code: R.20.04.821). Pan African clinical trial registry approved the registration of this study on May 8, 2020 with unique ID PACTR202005904505939. A total of 50 eligible patients were enrolled. Children aged between 2 and 10 years with American Society of Anesthesiologists physical I & II scheduled for elective open cardiac surgery via median sternotomy

were recruited for the study. Informed written consent was signed from the patient legal guardian. Exclusion criteria were history of previous cardiac surgery, urgent surgery, unstable hemodynamics, presence of coagulopathy, neurological dysfunction, mechanically ventilated patient, allergy to study drugs, thoracic spine deformity and history of thoracic vertebrae trauma or surgery. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki with good clinical practice.

Randomization and blindness

Patients were randomly allocated to 2 equal groups using computer-generated random numbers before surgery. The patient group assignment was placed in a sealed opaque envelope that was opened at the morning of surgery by an anesthesia resident who was not involved in the study. Data collection was done by experienced nurses who were blind to the patient group allocation. Patients were equally allocated to either the PVB group or the ESPB block group.

Management of general anesthesia

The patient received intramuscular midazolam 0.1 mg/kg, ketamine 3 mg/kg and atropine sulphate 0.015 mg/kg in the preoperative area 15 min before the separation from their guardians. On arrival in the operating room, 5 lead electrocardiography and pulse oximetry were connected to the patient. Anesthesia was induced with intravenous injection of propofol 2 mg/kg, fentanyl 2 µg/kg and rocuronium 0.9 mg/kg to facilitate endotracheal intubation. Arterial and central venous catheters were inserted using the linear high frequency ultrasound transducer under complete sterilization. The patient was also monitored using capnography, urinary catheter and nasopharyngeal temperature probe. Anesthesia was maintained with 1%-2% isoflurane in 50% oxygen/air mixture, fentanyl 1µg/kg/h and rocuronium 0.3 mg/kg/h with administration of fentanyl 3 µg/kg/h increments if heart rate and mean arterial blood pressure rise above 20% from the baseline.

Technique of ultrasound-guided ESPB and PVB

Both ESPB and PVB were performed after the induction of anesthesia in a lateral position. We counted and identified the spinous processes of thoracic vertebrae from cranial to caudal to identify and mark the T4 spinous process. The skin area at the site of needle puncture and around T4 was sterilized with povidone-iodine and 70% isopropyl alcohol, and isolated with sterile drapes. The high-frequency linear transducer of ultrasonography was enclosed within a sterile sheath and placed in a
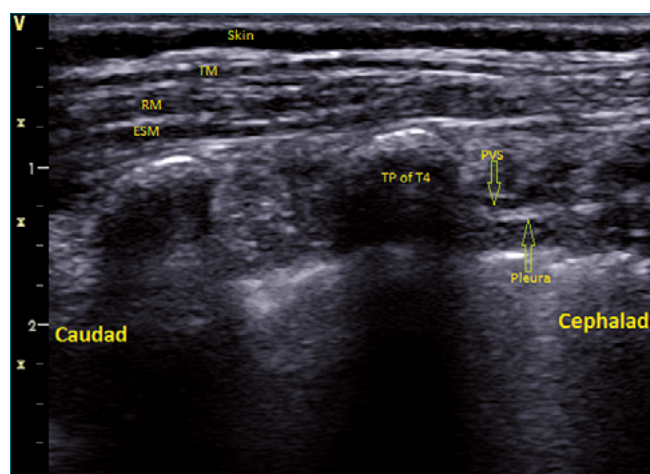
parasagittal position just lateral to T4 spinous process to view the erector spinae muscle, T4 transverse process, superior costotransverse ligament, paravertebral space and pleura (Figure 1). A 50 mm 22-gaug sonographic needle was inserted from cephalad to caudad direction in an in-plane technique aiming at T4 transverse process (ESPB) (Figure 2A) or the paravertebral space between T3 and T4 (PVB) (Figure 2B). In ESPB, the needle tip pierced trapezius, rhomboid major, and erector spinae muscle where the local anesthetic was injected just posterior to the T4 transverse process. In PVB, the needle tip was more deeply advanced between T3 and T4 transverse processes to penetrate the superior costotransverse ligament where the local anesthetic was injected in the paravertebral space just posterior to the pleura. Both ESPB and PVB performed bilaterally by injecting 0.4 mL/kg 0.25% bupivacaine on each side.

Intraoperative management

Standard median sternotomy incision was used for all surgeries. The patient received heparin 300-400 i.u/kg via the central venous catheter to increase the activated clotting time above 480 sec before instituting cardiopulmonary bypass. The pump flow was (100-150) mL/kg/min and patient temperature was maintained at (33-35) °C. After completion of the surgical repair of the cardiac anomaly and fulfilling the criteria of weaning from cardiopulmonary bypass (CPB), patient was separated from the bypass. At the end of surgery, the patient was transferred to the intensive care unit (ICU).

Postoperative management

In the ICU patient was monitored using the same intraoperative monitoring parameters. The patient was extubated within few hours once the criteria of extubation were fulfilled (adequate level of consciousness, good breathing parameters, hemodynamic stability on minimal or no inotropic, acceptable arterial blood gases and the absence of significant bleeding). The patients received intravenous paracetamol 15 mg/kg/8h.

Postoperative pain was assessed using 10 points Modified Objective Pain Score (MOPS).[13]

Fentanyl was given as a rescue analgesic at a dose of 1µg/kg if MOPS was > 3 at rest.

Data collection

The primary end point was fentanyl consumption during the first 24 h following extubation. The secondary endpoints were MOPS measured at 0, 1, 2, 6, 12, 18, and 24 h after extubation, time needed to perform the block (defined as time between placing the linear transducer on skin till the end of local anesthetic injection and withdrawal of the block needle), intraoperative fentanyl consumption, time to the first analgesic request that measured after extubation, time to extubation and the duration of ICU stay. The incidence of traumatic complications related to the block needle insertion (pneumothorax, vascular injury and neurological injury), local anesthetic toxicity and postoperative complications such as pruritus and vomiting were all reported.

Sample size and statistical analyses

The sample size was calculated using PASS 15 software us-
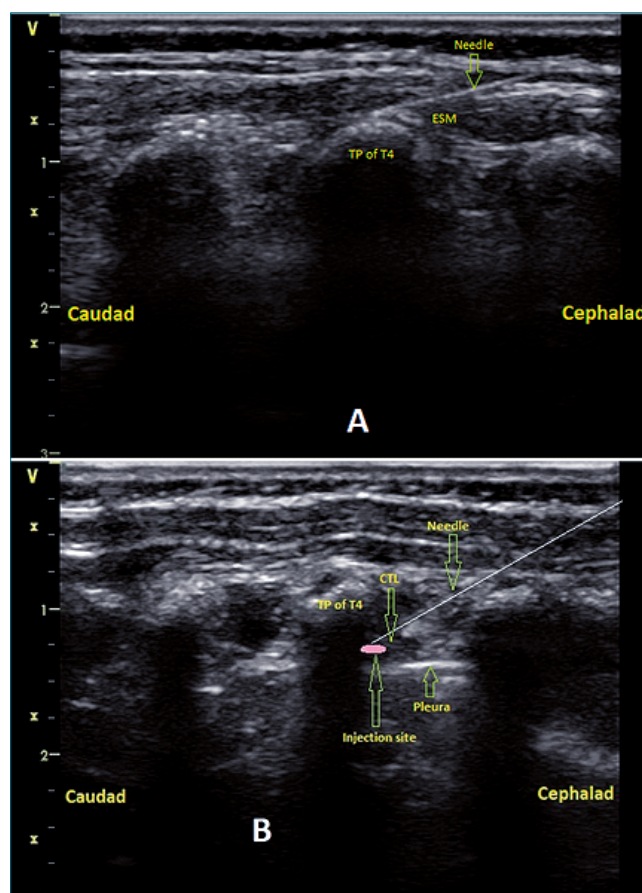
Figure 2. Ultrasound image showing the targeted position of needle tip to inject the local anesthetic in erector spinae plane block (2A) and paravertebral block; (2B). TP: transverse process; CTL: costotransverse ligament.

Figure 1. Ultrasound image showing trapezius muscle (TM), rhomboid muscle (RM), erector spinae muscle (ESM), transverse process (TP) of T4, superior costotransverse ligament, the paravertebral space (PVS) and pleura.

ing the non-inferiority test for the difference between 2 means. The primary outcome was the total fentanyl consumption (µg/kg) during the first postoperative 24 h following extubation. As there were no previous similar studies, we used the results of our preliminary study (unpublished) that included 5 patients in each group to calculate the needed sample size, in which the mean ± SD 24 h fentanyl consumption (µg/kg) was 5.2 ± 1.4 with PVB and 5.9 ± 2.6 with ESPB. The calculated sample size using one-sided, two-sample t-test was 20 patients per group achieved 80% power. The margin of non-inferiority was assumed to be 1, the difference between the 2 means was 0.7 and, standard deviations were 2.6 and 1.4. The significance level (alpha) of the test is 0.05. The number of patients in increased to 25 per group to avoid the probable dropouts.

The statistical data analysis was done using IBM SPSS Version 21.0. Armonk, NY: IBM Corp. Kolmogorov-Smirnov test was used to check the normality of quantitative data distribution. Data analysis was done by the comparison between ESPB and PVB group. Normally distributed quantitative data are expressed as mean ± standard deviation (SD) and were analyzed by unpaired student t-test. Categorical data are presented as number (proportion) and was tested with Chi-square test. Non-parametric data are presented as median (IQR. Q1, Q3) and were analyzed using Mann-Whitney U test. $P < 0.05$ at confidence interval 95% is statistically significant.

The non-inferiority of ESPB to PVB was confirmed because the non-inferiority margin (1) is greater than the upper limit of 95% confidence interval (0.804) of the primary outcome (24 h postoperative fentanyl consumption).

Results

Of 50 patients who were recruited, 6 were excluded, 4 were not meeting the inclusion criteria and the legal guardians of other 2 declined to participate (Figure 3). The remaining 44 patients were randomly allocated to the ESPB group (n=22) and PVB group (n = 22), all of them completed the study and underwent the final analysis (Figure 3).

No significant differences were observed in patient characteristics (age, gender, weight, height and body surface area) and surgical characteristics (CPB time, aortic clamping time, duration of surgery and type of surgery) between the patients in the ESPB group and PVB group (Table 1).

As regard the primary outcome, there was no significant difference (p = 0.612) in the mean ± SD fentanyl consumption (µg/kg) during the first postoperative 24 h after extubation between the ESPB group (4.9 ± 1.7) and PVB group (4.6 ± 1.7) (Table 2).

The median MOPS at rest was similar in both study groups all over the first postoperative 24 h and was kept ≤ 3 except at 18h (Figure 4). The median (IQR) intraoperative fentanyl consumption (µg/kg) was similar (p = 0.083) in both ESPB and PVB group (9[8]-[10], 8[7]-[9] respectively) (Table 2). The median (IQR) time to first analgesic request (h) was similar (p = 0.721) in both ESPB and PVB group (8[6]-[8], 7.5[6]-[10] respectively) (Table 2). There were no significant differences in the median (IQR) time to extubation (h) and the mean ± SD ICU stay (h) on comparing ESPB group with the PVB group (2 [2]-[3] & 21.8 ± 2.6 vs 1[2]-[3] & 21.6 ± 3.6, respectively) (Table 2).
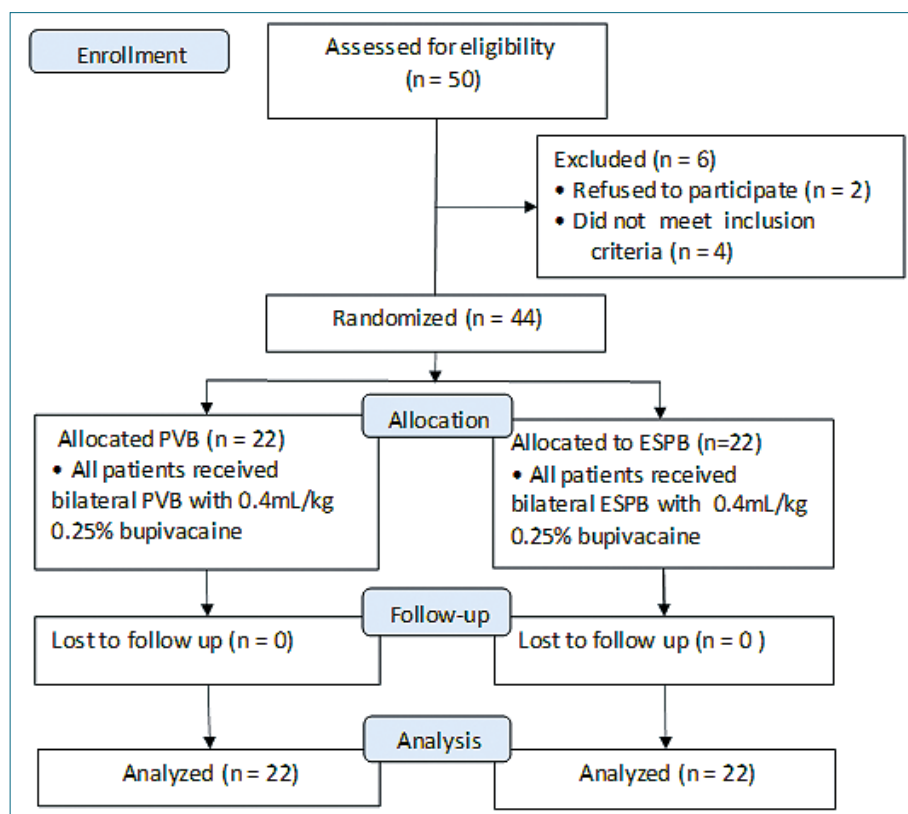
Figure 3. Study flowchart. PVB: paravertebral block; ESPB: erector spinae plane block.

Table 1. Patients and surgical characteristics

Variable	ESPB group (n = 22)	PVB group (n = 22)	P value
Age (year)	5.45 [3.8-7]	4.7 [3.8-6.5]	0.897
Gender (M/F)	9/13	11/11	0763
Height (cm)	108 ± 13.8	106 ± 14.5	0.745
Weight (kg)	13.25 [12-17]	13.5 [12-16]	0.750
BSA (m²)	0.66 ± 0.09	0.61 ± 0.11	0.193
Aortic clamping time (min)	35.5 [25-43]	33 [26-40]	0.565
CPB time (min)	60.2 ± 15.1	59.7 ± 10.7	0.891
Duration of surgery (min)	194 ± 20	197 ±16	0.701
Type of surgical repair: VSD ASD AVSD	 10 10 2	 13 7 2	 0.631

Non-parametric continuous variables are presented as median (IQR. Q1, Q3), parametric continuous variables are presented as mean ±SD and categorial variables are presented as number. ESPB: erector spinae plane block; PVB: paravertebral block; BSA: body surface area; CPB: cardiopulmonary bypass; ASD: atrial septal defect, VSD: ventricular septal defect; AVSD: atrioventricular septal defect.

Table 2. Intraoperative fentanyl consumption, postoperative variables, characteristics of the block and postoperative complications

Variable	ESPB group (n = 22)	PVB group (n = 22)	P value	95% CI
Intraoperative fentanyl (µ/kg) consumption	9 [8-10]	8 [7-9]	0.083	
24h postoperative fentanyl (µ/kg) consumption	4.9 ± 1.7	4.6 ± 1.7	0.612	-1.350, 0.804
Time to first analgesic request (h)	8 [6-8]	7.5 [6-10]	0.721	
Time to extubation (h)	2 [2-3]	1 [2-3]	0.359	
Duration of ICU stay (h)	21.8 ± 2.6	21.6 ± 3.6	0.817	-2.197, 1.742
Time needed to perform the bilateral block (min)	7.5 [7-9]	12 [10-13]	< 0.001*	
Complications of the block	0	0		
Postoperative; Vomiting Pruritus	 5 4	 5 5	 1.000 1.000	

Non-parametric continuous variables are presented as median (IQR. Q1, Q3), parametric continuous variables are presented as mean ±SD and categorical variables are presented as number. ESPB: erector spinae plane block; PVB: paravertebral block; CI: confidence interval; ICU: intensive care unit. P<0.05 is statistically significant.

The median (IQR) time (min) needed to perform bilateral block was significantly shorter (p< 0.001) in the ESPB group (7.5[7]-[9]) than thePVB group (12[10]-[13]) (Table 2). We didn't observe any mechanical complications related to needle advancement (pneumothorax or vascular injury) or local anesthetic toxicity. The number of patients who developed postoperative vomiting and pruritus was similar in both ESPB group and PVB group (5, 4 & 5, 5 respectively) (Table 2).

Discussion

This randomized, controlled, double blind study demonstrated the non-inferiority of bilateral thoracic ESPB compared to PVB in reducing post-extubation 24 h opioid consumption in pediatric patients who underwent open cardiac surgery as the non-inferiority margin was higher than the upper limit of 95% confidence interval of the primary outcome. There were no significant differences between ESPB and PVB regarding intraoperative fentanyl consumption, postoperative MOPS, time to first analgesic request, time to extubation, the incidence of postoperative complications and ICU length of stay. Furthermore, performing ESPB needed shorter time than PVB.

The current study showed the non-inferiority of single shot ESPB to PVB in providing postoperative analgesia after cardiac surgery. Paravertebral block has been shown to provide effective analgesia in terms of opioid consumption and pain scores after cardiac surgery[2],[5]-[7] To the best of our knowledge,
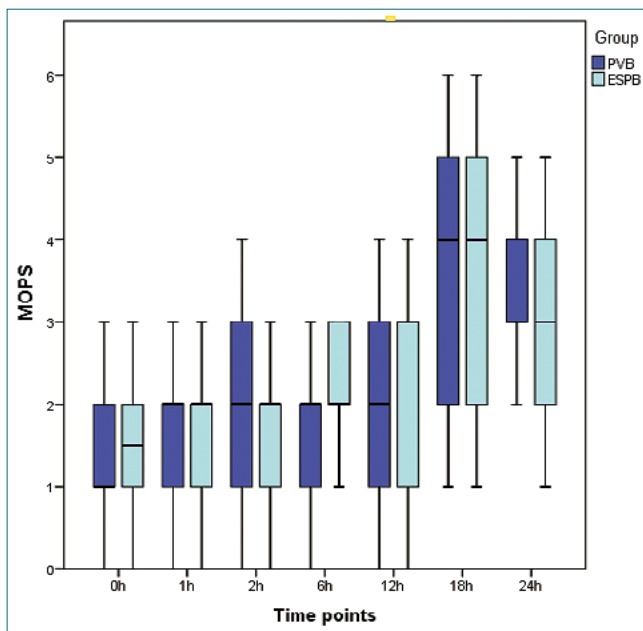
Figure 4. Modified Objective Pain Score (MOPS) measured at 0 h, 1 h, 2 h, 6 h, 12 h, 18 h and 24 h after extubation. PVB: paravertebral block; ESPB: erector spinae plane block.

this is the first randomized clinical trial that compared the effects of ESPB and PVB on postoperative analgesia after cardiac surgery. Kaushal B, et al. performed bilateral thoracic ESPB in 40 pediatric patients who underwent cardiac surgery via median sternotomy and compared its postoperative analgesic effects with those of patients with no block, they found that ESPB was associated with superior and effective postoperative analgesia compared with the control[12]. Macaire P et al., included 50 pediatric patients who were scheduled for cardiac surgery using midline sternotomy in their study that compared the postoperative opioid consumption in patients who received bilateral ESPB with patients who received placebo.[14] Macaire and colleagues found that the use of ESPB in pediatric cardiac surgery provided superior and a more effective postoperative analgesia in terms of morphine consumption and pain scores than the control. In adults open cardiac surgery, several studies have been demonstrated the efficacy of ESPB in reducing postoperative pain severity and opioids requirements[11],[15]-[17].

The results of our study are consistent with the results of previous studies involving non-cardiac surgeries. The non-inferiority of ESPB to PVB in reducing postoperative opioid requirements and pain has been shown after video-assisted thoracic surgery[18],[19] and breast surgery[20]. After thoracotomy, the analgesia provided by single injection ESPB is comparable to PVB[21].

In this study we injected single-dose of 0.25% bupivacaine 0.4 mL/kg bilaterally at the level of transverse process of the fourth thoracic vertebra for ESPB or in the paravertebral space between the third and fourth thoracic vertebra. In our study the median time to first analgesic request was similar in both groups, 8 h in ESPB and 7.5 h in PVB indicating the short duration of postoperative analgesia of single injection of both ESPB and PVB.

Thoracic PVB has been shown to provide equivalent analgesia to thoracic epidural block with lower incidence of adverse effects such as hypotension, bradycardia and urine retention[22]. Therefore, thoracic PVB may be used as an alternative to epidural analgesia, however, the paravertebral space is small with probable risk of pleural puncture even with ultrasound guidance especially with less skilled anesthesiologists. Erector spinae plane block gives analgesia similar to PVB and is a relatively superficial block with transverse process acting as a barrier against pleural puncture by the needle tip. The mechanism of action of ESPB is still not fully understood and several mechanisms have been postulated. Ivanusic et al. in their cadaveric study reported the craniocaudal, posterior and lateral spread of local anesthetic to block the dorsal rami[23]. Adhikary et al., found that the local anesthetic spread between the transverse process and erector spinae muscle with extensive spread to the more anterior structures including the paravertebral and epidural spaces[24]. One possible mechanism is the paravertebral spread of local anesthetics from its site of injection between transverse process and erector spinae muscle 4 segments cranially and 3 segments caudally[25]. Epidural spread of the local anesthetics is also a potential mechanism of action as several studies reported bilateral sensory blockade in some patients after unilateral ESPB that was attributed to the epidural spread[26]-[28].

In this study all patients in both groups were extubated early (less than 6 h) and they were shortly stayed in ICU. We performed ESPB and PVB before surgery and this reduced the total intraoperative opioid consumption. For postoperative analgesia, we used a multimodal analgesic technique consisting of a regional block, intravenous paracetamol and opioid, all of these could act synergistically and reduced postoperative opioid consumption. Multimodal analgesia is widely used to control pain after pediatric cardiac surgery[29]. Reduction of perioperative opioids consumption minimizes their adverse effects and allows early extubation.

We found that the time needed to perform ESPB was shorter than PVB indicating the ease of doing ESPB that can be done by a non-highly skilled anesthesiologist. This is in agreement with previous studies that compared ESPB with PVB[30],[31]. This can be explained by some reasons. First, the anatomical landmarks of ESPB (transverse process and erector spinae muscle) are more superficial and obvious with ultrasonography in comparison with the small deep paravertebral space. Second, needle advancement to the paravertebral space for PVB requires inserting the needle in more acute angle and for longer distance compared to ESPB resulting in better needle visualization in the later.

We didn't report the incidence of any mechanical complications or local anesthetic toxicity in ESPB and PVB indicating their safety. The incidence of postoperative vomiting and pruritus was similar in both groups and was related to opioid analgesics. This study has some limitations. First, we used single-dose injection of 0.25% bupivacaine that produced postoperative analgesia of short duration. Insertion of catheters for local anesthetic infusion to obtain prolonged ESPB and PVB postoperative analgesia is recommended, but the pediatric size of epidural catheter was unavailable in our institutional hospital. Second, the small sample size of this study did not allow us to comment more accurately on the safety of both ESPB and PVB. Third, we

could not test the dermatomal sensory spread of both ESPB and PVB as the block was performed after induction of anesthesia. Fourth, we did not measure the serum local anesthetic levels because the laboratories in our hospital did not have this technology.

Conclusion

In pediatric patients scheduled for open cardiac surgery via median sternotomy, ultrasound-guided bilateral thoracic ESPB is non-inferior to PVB in providing postoperative analgesia in terms of opioid consumption and pain score. Moreover, ESPB is easier and its performance requires shorter period than PVB.

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