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The effect of ultrasound-guided bilateral single-shot erector spinae plane block on recovery after on-pump coronary bypass graft surgery: a randomized controlled study

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Abstract

Background Fast-track and ultra-fast-track anesthesia techniques can be facilitated with opioid requirements' reduction and multi-modal analgesia techniques that include the regional anesthesia techniques. The study aimed to assess the preoperative effect of single-shot bilateral ultrasound-guided erector spinae plane block (ESPB) on the extubation time and postoperative pain of patients undergoing on-pump CABG surgery.

Results The ESPB group was statistically significant decreased regarding the extubation time, ICU length stay, intraoperative fentanyl, and postoperative morphine consumption than the control group ($p < 0.0001$ for all the previous measurement). The 1st time of rescue analgesia of the ESPB group was longer than the control group ($p < 0.0001$). The numerical rating score (NRS) after extubation of the ESPB group was lower at 2 and 4 h after extubation ($P = < 0.0001$ and 0.0006 respectively) than the control group. The number of patients who required rescue analgesia after extubation was significantly decreased in the ESPB group in comparison to the control group, 2 and 4 h after extubation ($P = < 0.0001$ and 0.004 respectively).

Conclusions The preoperative single-shot ultrasound-guided ESPB in patients scheduled for on-pump CABG surgery shortened the extubation time and the length of ICU, decreased intraoperative fentanyl and postoperative morphine consumption and postoperative pain scores, and prolonged 1st time of rescue analgesia without significant effect on the incidence of complications, re-intubation, or mortality.

Trial registration Approval was obtained from the Research Ethics Committee of the Faculty of Medicine (approval code of 33702/02/20) registered at February 2, 2020, and written informed consent was obtained from the patients. The trial was registered at 17 March 2020 in the Pan African Clinical Trial Registry with a unique identification number for the registry which is PACTR202003822626676.

Keywords ESP block, CABG, Extubation, Postoperative analgesia, ICU stay

Background

Fast-track cardiac anesthesia can be defined as the procedure that allows extubation of the patients in the intensive care unit (ICU) within postoperative 6 h. This procedure had been used safely in cardiac surgery since 1990s (Akhtar et al. 2014). It is safe, feasible, and reduce the incidence of ventilator associated injury, length of hospital and ICU stay, and cost (Wong et al. 2016; Ender

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et al. 2008). Ultra-fast-track anesthesia (UFTA) was then developed for further optimization of the medical resources. It enables the extubation of patient immediately postoperative or within the first hour in the ICU (Zayat et al. 2017).

Fast-track and ultra-fast-track anesthesia techniques can be facilitated with opioid requirements' reduction and multi-modal analgesia techniques that include the regional anesthesia techniques (Chanowski et al. 2019). Regional blocks are considered one of the tools of the enhanced recovery after surgery through reducing the perioperative opioid consumption (Wong et al. 2016).

Erector spinae plane block (ESPB) is performed through deposition of local anesthetic mixtures superficial to the transverse process and deep to the erector spinae block. The local anesthetics spread is dependent on the injected volume. It is performed easily under ultrasonographic guidance in cervical, thoracic, or lumbar regions. It manages acute and chronic pain conditions and can be used in cardiothoracic surgeries (Tsui et al. 2019). ESPB is preferred over the epidural and paravertebral blocks as it is easy procedure as the transverse process is easily visualized by the ultrasound. Moreover, it avoids the risk of epidural hematoma by avoiding the manipulation -around epidural venous plexus. Furthermore, it avoids the risk of pneumothorax (Yang et al. 2018; Krishna et al. 2019).

This randomized controlled clinical trial suggested that the use of preoperative bilateral single-shot ESPB in patients eligible for on-pump coronary artery bypass graft (CABG) may reduce opioid request and, hence, allow the rapid extubation and enhance the recovery. The preoperative effect of single-shot bilateral ultrasound-guided ESPB on the extubation time (primary outcome) and postoperative pain of patients undergoing on-pump CABG surgery was investigated by this clinical study.

Methods

The Ethical Committee of the Faculty of Medicine approved this clinical randomized controlled study. The approval code was 33702/02/20; then, it was resisted before first patient enrollment on Pan African Clinical Trial Registry with its ID (PACTR202003822626676). The study lasted from April 2020 to June 2022. The informed written consent was signed by all patients to participate in the study after the full explanation of the benefits, techniques, and potential hazards of the study was presented. The study guided by the principles outlined in the Declaration of Helsinki (World 2013). The CONSORT 2010 randomized controlled trial (RCT) statement (Schulz et al. 2010) were the guidelines for this randomized controlled study as presented in the CONSORT flow chart (Fig.1).

Patients aged greater than 40 years and scheduled for on-pump CABG surgery were included in the study. While the patients were excluded if they rejected to participate in the study, have moderate to severe pulmonary hypertension or heart failure, have poor ventricular function (ejection fraction less than 45%) or severe arrythmias, have uncontrolled chest conditions, are scheduled for combined cardiac surgery, are on preoperative intra-aortic balloon pump, have anticipated difficult airway, or have major hepatic or renal dysfunction.

Random assignment of the patients to one of the following two groups was performed using computer-generated software of randomization with the results placed in opaque sealed envelopes:

- *Control group (group A)*: bilateral ultrasound-guided single-shot ESPB at the level of 4th thoracic vertebra (T4) with injection of 1 ml normal saline on each side 30 min before induction of general anesthesia were performed
- *ESPB group (group B)*: bilateral ultrasound-guided single-shot ESPB was performed at the level of T4 with injection of 20 ml of plain bupivacaine 0.25% on each side. The induction of general anesthesia was started 30 min after performing the block

Anesthesia technique

Adequate preoperative assessment was performed for all enrolled patients (history, examination, and requesting investigation) and risk stratification with calculation of the preoperative Euro SCORE. The cardiovascular risk factors especially the ventricular rhythm and function were assessed and controlled; also, the non-cardiac risk factors (anemia and coagulation studies) and associated co-morbidities were assessed and controlled. The anesthetic plane was established after the control of the cardiac and non-cardiac risk factors. Vitamin K antagonists (warfarin) stopped 5 days before cardiac surgery. Bridging with low molecular heparin (LMWH) or unfractionated heparin (UFH) was recommended only in patients with mechanical prosthetic heart valves, valvular atrial fibrillation (AF), AF with a CHA2DS2-VASc score >4 (European guidelines) or ≥ 8 (American guidelines) respectively, or an acute thrombotic event within the previous 4 weeks (defined as ischemic stroke, ACS, or pulmonary embolism), the presence of a left ventricular apex thrombus, or antithrombin III, or protein C, and S deficiencies LMWH should be discontinued 24 h before cardiac surgery, and UFH is stopped 6 h before procedures. Oral anti-coagulant was stopped for the duration ranging between 2 and 3 days. Oral antiplatelets were stopped for the duration ranging between 5 and 7 days. The ease of

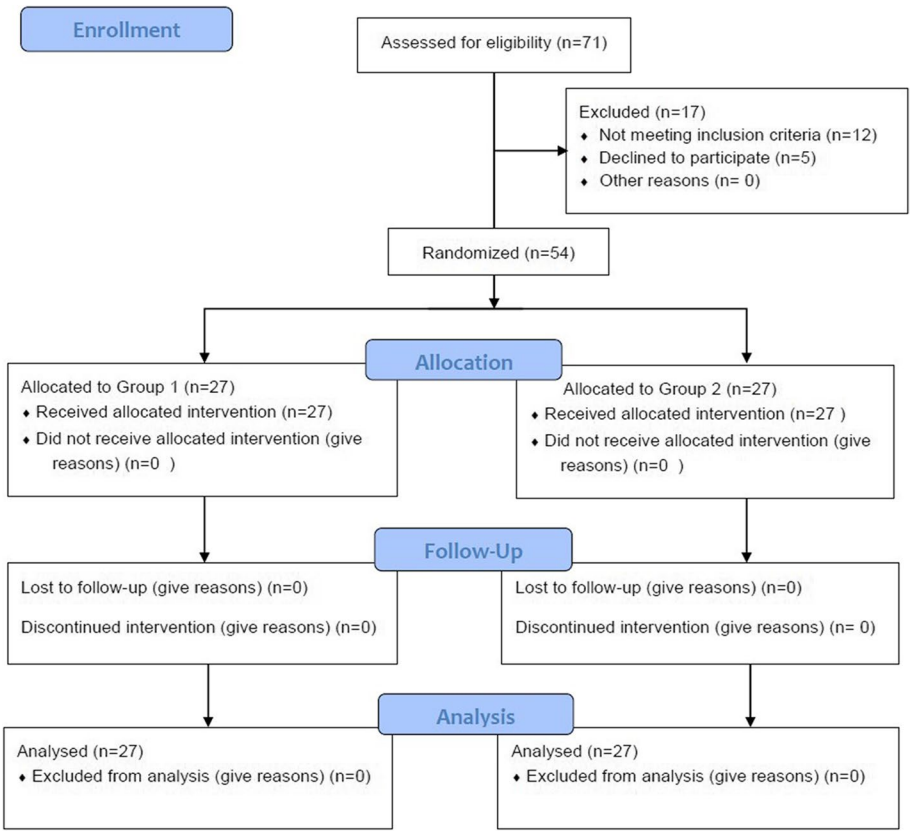

Fig. 1 CONSORT flow chart of the study

venous and arterial lines access was assessed during pre-operative physical examination.

On the day of the surgery, the patient was admitted to the operating room. Monitoring of 5-lead electrocardiogram (ECG), pulse oximetry, and non-invasive blood pressure monitoring were started. Moreover, a 18-gauge venous cannula was inserted. The ESPB was performed in the two sides and in a sitting position with ultrasound guidance for all enrolled patients according to study allocation groups (control and ESPB groups). The ESPB was performed with an anesthesiologist who was expert at ultrasound-guided regional blocks and was not responsible for the progress of cardiac anesthesia of all enrolled patients. Another anesthesiologist was responsible for the completion of the anesthetic plan as described below in details and was blinded to study group allocations.

Technique of US-guided ESPB

In a sitting position and under complete aseptic conditions, the ESPB was performed by the low-frequency probe of the ultrasound machine (Philips CX 50 Extreme edition) on both sides at the level of T4. The proposed level was reached by counting the laminae of the sacrum. The probe was placed in the midline longitudinally over the spine of the vertebra; then, it was slided laterally till the transverse process and paraspinal muscles were identified. The needle was introduced from the cephalic side of the probe till reaching the transverse process. The intravascular needle placement was excluded by negative aspiration; then, local anesthetic mixture (20 ml of plain bupivacaine 0.25%) was injected slowly with visualization of the spread of the injectate by the US (Forero et al. 2016).

After performing the ESPB, the patient was turned to supine position, starting sedation with midazolam (0.02–0.04 mg/kg) and fentanyl (0.5 ug/kg) with oxygen supplementation through the nasal cannula at a flow rate of 2–3 L/min. The modified Allen's test was performed; the arterial line was established under local anesthesia in the radial artery of the non-dominant hand with starting invasive blood pressure monitoring. Furthermore, a central line was introduced under complete aseptic precautions and local anesthesia infiltration in the internal jugular vein using triple-way catheter.

Induction of anesthesia was carried out after at least 30 min from performing ESPB and 5 min of pre-oxygenation through well-fitted face mask using 80% oxygen. The anesthesia induction consisted of intravenous

fentanyl 5 ug/kg, titrating dose of propofol 0.5 mg/kg till loss of verbal contact, and rocuronium 0.6 mg/kg to facilitate tracheal intubation through suitable sized cuffed endotracheal tube with starting end-tidal carbon dioxide monitoring and introducing nasopharyngeal temperature probe. Anesthesia was maintained by sevoflurane (concentration based upon the reading of bispectral index (BIS) and the hemodynamic parameters). The BIS was maintained 40–60. Insufficient analgesia was defined as an increase in HR and MAP greater than 20% above baseline values, and an IV bolus of 2 g/kg fentanyl was administered and repeated as necessary.

After the end of the surgery, the patient was transported under close monitoring from the operating room to the ICU. Mechanical ventilation was continued in the ICU without supplantation of sedation or muscle relaxant. Weaning from mechanical ventilation was started immediately provided that the hemodynamic parameters of the patients were stable and the absence of surgical complications. The patient was extubated once he regained conscious level. The patient was hemodynamically stable without vasoactive agent support and was stable for 30 min during spontaneous breathing trial (SBT). After extubation, oxygen supplementation was carried out by oxygen mask at a flow rate of 4 L/min. All the patients had received a standard protocol of postoperative analgesia composed of paracetamol 1 gm i.v/6 h and ketorolac 30 mg i.v/12 h. Morphine was administrated slow intravenous in a dose of 3 mg with greater than 20% increase of the heart rate and/or mean arterial pressure in non-extubated patient and when pain score reached 4 or more in extubated patient.

Outcome assessment

All the measurements were obtained by the aid of anesthesia resident who was blinded to the group of patients and was not participating in the study. The surgeon was also blinded to study group allocations. The primary outcome of the study was the extubation time which was the interval of time from the end of the surgery till successful extubation of the patient. The secondary outcome was the numeric rating score (NRS) (a metric score for assessment of pain: 0 for no pain and 10 for the worst pain) that was measured immediately after successful extubation of the patient, then, every 2 h till 8 h, and then every 8 h till 24 h. A bolus dose of morphine 3 mg i.v was administrated when NRS reached 4 or more. The total intraoperative fentanyl and postoperative morphine consumptions were measures. The ICU stay, the incidence of re-intubation, and the 30-day mortality were assessed. Furthermore, the incidence of complications including cardiac (postoperative myocardial ischemia, arrhythmia), respiratory (atelectasis, pneumonia, pulmonary oedema, acute lung injury), and renal impairment and the incidence of postoperative hematoma at the site of block were measured.

Statistical analysis

A preliminary study was carried out upon 10 patients (not included in the final study) scheduled for on-pump CABG under either sham or real US-guided ESPB. The use of real ESPB significantly decreased the extubation time from 319 ± 139 min to 109 ± 59.4 min ($P = 0.027$), based on these results. A significant difference in the extubation time of 60 min at alpha value 0.05 and power of the study 90% was detected by at least 22 patients who were required in each group. To overcome the possible dropout cases, 27 patients were included in each group. The statistical analysis was formulated using the SPSS computer program (SPSS Inc., Chicago, IL, USA) with the use of the Kolmogorov–Smirnov test for checking the assumption of normality. Categorical data was expressed as number and percent and analyzed by Fisher's exact test, while parametric data was analyzed by unpaired *T*-test and expressed as mean ± standard deviation. The Mann–Whitney *U* test was performed for pain score assessment which was expressed as median and interquartile range. The values were considered statistically significant when *P* value decreased less than 0.05.

Results

Seventy-one patients were assessed for eligibility to this study; 5 of them declined to participate, and 12 were not meeting our inclusion criteria (5 patients undergone combine cardiac surgery, 2 patients had severe pulmonary hypertension, 3 patients had poor ventricular function, and 2 patients had severe liver impairment). The other 54 patients were distributed into the two groups randomly with successful follow-up and analysis of the data of the patients (Fig. 1). The basic data of the patients that included age ($P = 0.778$), gender ($P = 0.786$), body surface area ($P = 0.712$), duration of the surgery ($P = 0.596$), the number of graft vessels ($P = 0.766$), and co-morbidities incidence ($P = 0.821$) were statistically insignificant between the two groups (Table 1).

The extubation time was significantly decreased from 140.85 ± 43.38 min in the control group to 75.30 ± 15.31 min in the ESPB group ($P < 0.0001$). Furthermore, the length of ICU stay was higher in the control group (68.33 ± 23.36 h) as compared to the ESPB group (29.17 ± 8.65) ($P < 0.0001$). The intraoperative fentanyl consumption showed a statistically significant decrease from 753.33 ± 87.71 μg in the control group to 236.3 ± 42.17 μg in the ESPB group ($P < 0.0001$). In addition, the postoperative morphine doses were significantly higher in the control group (11.44 ± 1.86) than

Table 1 Demographic and surgical data of the studied groups

		Group A ($n=27$)	Group B ($n=27$)	*p*-value
Age (years)		56.85 ± 7.46	56.19 ± 9.54	0.778
Gender	Male	15 (55.56%)	13 (48.15%)	0.786
	Female	12 (44.44%)	14 (51.85%)	
BSA (m^2)		1.72 ± 0.16	1.74 ± 0.23	0.712
Duration of the surgery (min)		172.89 ± 23.08	177.22 ± 35.31	0.596
Number of grafted vessels	2 vesseles	9 (33.3%)	7 (25.9%)	0.766
	3 vessels	18 (66.6%)	20 (74.1%)	
Co-morbidities incidence	Diabetus	11 (40.7%)	13 (48.1%)	0.821
	Hypertension	12 (44.4%)	11 (40.7%)	
	Thyroid diseases	2 (7.4%)	1 (3.7%)	
	Auto-immune diseases	0	1 (3.7%)	

Group A (control group), group B (ESPB group). Data were presented as mean ± SD or *N* and %. *BSA*, body surface area

Table 2 Extubation time, opioid consumption, and the postoperative outcome of the studied groups

		Group A ($n=27$)	Group B ($n=27$)	*p*-value
Extubation time (min)		140.85 ± 43.38	75.30 ± 15.31	< 0.0001*
Intraoperative fentanyl consumption (µg)		753.33 ± 87.71	236.3 ± 42.17	< 0.0001*
Postoperative morphine consumption (mg)		11.44 ± 1.86	3.89 ± 1.39	< 0.0001*
1st time of rescue analgesia (min)		129.4 ± 31.53	397.85 ± 35.4	< 0.0001*
ICU stay duration (hours)		68.33 ± 23.36	29.17 ± 8.65	< 0.0001*
The incidence of postoperative mortality		1 (3.7%)	0 (0%)	0.313
The incidence of postoperative reintubation		2 (7.4%)	1 (3.7%)	0.55
The incidence of postoperative complications	Cardiac	1 (3.7%)	1 (3.7%)	0.82
	Respiratory	1 (3.7%)	2 (7.4%)	
	Renal	0	2 (7.4%)	
	Hematoma formation	3 (11.1%)	1 (3.7%)	

Group A (control group), group B (ESPB group). Data were presented as mean ± SD or *N* and %

* Denoted significant difference between groups ($p<0.05$)

the ESPB group (3.89 ± 1.39) ($P<0.0001$). The 1st time of recue morphine analgesia was significantly longer in the ESPB group (397.85 ± 35.4) than the control group (129.4 ± 31.53) ($P<0.0001$). On the other hand, the incidence of postoperative reintubation, the 30-day mortality, and the incidence of complications were insignificant between the two group ($P=0.55$, 0.313, and 0.820 respectively) (Table 2).

The numeric rate score after extubation showed statistically significant decrease in the ESPB group as compared to the control group, 2 and 4 h after extubation ($P=$ < 0.0001 and 0.0006 respectively). However, there was insignificant difference in the NRS between the two groups immediately after extubation, 6 h, 8 h, 12 h, 16 h, 20 h, and 24 h after extubation ($P=0.788$, 0.306, 0.423, 0.097, 0.119, and 0.081 respectively) (Table 3). Moreover, the number of patients who required rescue analgesia after extubation was significantly decreased in the ESPB group in comparison to the control group, 2 and 4 h after

Table 3 The numerical rating score (NRS) after extubation in the two groups

NRS after extubation	Group A ($n=27$)	Group B ($n=27$)	*p*-value
Immediately after extubation	1 (1–2)	1 (1–2)	0.788
2 h	4 (1–5)	1 (1–2)	< 0.0001*
4 h	2 (1–4)	1 (1–3)	0.0006*
6 h	2 (1–3)	2 (1–4)	0.306
8 h	2 (1–4)	2 (1–4)	0.423
12 h	2 (1–3)	2 (1–3)	0.097
16 h	2 (1–4)	2 (1–4)	0.148
20 h	2 (1–4)	2 (1–3)	0.119
24 h	1 (0–3)	1 (0–2)	0.081

Group A (control group), group B (ESPB group). Data were presented as median and interquartile range

* Denoted significant difference between groups ($p\leq0.05$)

extubation ($P = < 0.0001$ and 0.004 respectively) with insignificant difference between the two groups at all other time intervals ($P > 0.05$) (Table 4).

Discussion

Prolonged mechanical ventilation after cardiac surgeries is associated with increased morbidity, mortality, length of hospital stays, and cost. Endotracheal intubation for longer periods is associated with increased the risk of ventilator associated pneumonia (Rajakaruna et al. 2005; Flynn et al. 2019). The modern practice of cardiac anesthesia involved adjustment of the doses of opioids and hypnotics in order to facilitate FTA and UFTA and shorten the duration of mechanical ventilation and ICU length of stay while maintaining patient safety (Wong et al. 2016; Flynn et al. 2019). The cornerstone in allowing postoperative early extubation of the patient is the reduction of opioids consumption together with adjuvant analgesics (Bainbridge et al. 2017; Zhang et al 2018).

The preoperative neuraxial and regional anesthesia techniques in cardiac surgeries may provide adequate analgesia and allow reducing the dose of opioids (Chanowski et al. 2019). The use of neuraxial anesthesia techniques had been increased and became a part of multi-modal analgesia techniques and opioid-sparing techniques that conserve the use of opioids in cardiac surgeries (Noss et al. 2018; Chaney 2006). However, the use of neuraxial anesthesia techniques may be limited in certain centers by the risk of hematoma formation owing to the systemic heparinization for CPB (Djaiani et al. 2005). The use of fascial plane blocks (PECS I, PECS II, and serratus anterior plane block) had emerged as a recent alternative to epidural and paravertebral blocks in cardiac surgeries. However, none of them can provide complete coverage of the median sternotomy as the innervation of the sternum is T2 to T6 intercostal nerves (Noss et al. 2019).

ESPB is fascial plane paraspinal block that is performed through deposition of local anesthetic mixture deep to the erector spinae and superficial to the transverse process. It is considered as a safe technique with minimal side effects as compared to epidural anesthesia and paravertebral block. It can be used as a single shot or continuous infusion in thoracic, breast, lumbar, and spine surgeries (Onishi et al. 2019). It has an analgesic effect through diffusion of local anesthetic mixtures to the paravertebral space where it blocks the spinal nerves (Fusco et al. 2017). Recent evidences demonstrated the safety and efficacy of thoracic ESPB as an analgesic tool in cardiac surgeries (Munoz-Leyva et al. 2019).

The results of this clinical trial demonstrated that the use of preoperative bilateral single-shot ultrasound-guided ESPB in patients presented for on-pump CABG significantly decreased the extubation time, postoperative pain score, perioperative opioid consumption, and the length of ICU stay without effect on the incidence of perioperative complications, the need for re-intubation, or the mortality rate.

The clinical study of Pirsaharkhiz et al. revealed that ultrasound-guided ESPB is an effective analgesic tool in thoracic surgeries and chest trauma and represent a vital tool of the protocol of enhanced recovery after thoracic surgery (Pirsaharkhiz et al. 2020). Moreover, the case report of Leyva et al. illustrated the successful use of ESPB as a part of multimodal analgesia in patient undergoing minimally invasive mitral valve surgery. It facilitated opioid sparing, early extubation, early mobilization, effective physiotherapy, and enhanced recovery (Leyva et al. 2018).

The randomized controlled study of Krishna et al. included 106 patients and evaluated the analgesic effect of bilateral ESPB in adult patients presented for cardiac surgeries. It revealed that ESPB significantly decreased the postoperative pain score, the intraoperative fentanyl and the postoperative opioid consumptions, and the extubation time (Krishna et al. 2019). Also, the randomized clinical trial of Gawęda et al. examined 30 patients scheduled for mini-thoracotomy for mitral or tricuspid valve repair where patients received either single-shot ESPB alone or PECS block combined with ESPB. The patients were extubated within 2 h after surgery. They concluded that addition of PECS block to ESPB significantly decreased the postoperative pain score, decreased postoperative oxycodone consumption, and improved postoperative patient satisfaction (Gaweda et al. 2020).

A structured protocol of Misra provided best evidence topic and concluded that the use of ESPB in adult cardiac surgeries improves the postoperative analgesia and

Table 4 Number of patients required rescue analgesia

	Group A ($n = 27$)	Group B ($n = 27$)	*p*-value
Immediately	0 (0%)	0 (0%)	-
2 h	18 (66.67%)	0 (0%)	< 0.0001*
4 h	8 (29.63%)	0 (0%)	0.004*
6 h	7 (25.92%)	3 (11.11%)	0.050
8 h	5 (18.52%)	3 (11.11%)	0.704
12 h	3 (11.11%)	5 (18.52%)	0.704
16 h	6 (22.22%)	4 (14.81%)	0.727
20 h	4 (14.81%)	2 (7.41%)	0.668
24 h	0 (0%)	0 (0%)	-

Group A (control group), group B (ESPB group). Data were presented as *N* and %

* Denoted significant difference between groups ($p < 0.05$)

enhances the recovery. They recommend the need for more randomized controlled trial for the assessment of ESPB in cardiac surgeries (Misra & Awal 2021). Furthermore, the clinical trial of Wasfy et al. compared the use of continuous ESPB or multimodal intravenous analgesia in 40 patients undergoing CABG surgery. They suggested that bilateral ultrasound-guided ESPB significantly provided safe and effective analgesia for CABG surgery, decreased postoperative opioid consumption, and allowed early tracheal extubation (Wasfy 2021).

The retrospective study of Vaughan et al. tested the preoperative continuous bilateral ultrasound-guided ESPB in comparison to the routine protocol of standard practice in patients scheduled for cardiac surgery. They suggested that ESPB significantly decreased opioid consumption, shortened the extubation time, and shortened the length of ICU and hospital stay (Vaughan et al. 2021). In addition, the clinical trial of Nagaraja et al. compared thoracic epidural analgesia with bilateral ESPB in 50 patients undergoing cardiac surgery. They concluded that ESPB is comparable to thoracic epidural analgesia as regards postoperative pain and opioid consumption (Nagaraja et al. 2018).

The study is limited by the use of single shot ESPB without introducing a catheter, lack of comparison to the thoracic epidural analgesia, and lack of comparison to other regional anesthesia techniques. Furthermore, the low sample size and the use of single concentration of local anesthetics were added to the study limitations.

Conclusions

It can be concluded that preoperative single-shot ultrasound-guided ESPB in patients scheduled for on-pump CABG surgery shortened the extubation time and the length of ICU, decreased intraoperative fentanyl and postoperative morphine consumptions, prolonged 1st time of rescue analgesia, and decreased postoperative pain score without significant effect on the incidence of complications, re-intubation, or mortality.

Abbreviations

ICU	Intensive care unit
UFTA	Ultra-fast-track anesthesia
ESPB	Erector spinae plane block
CABG	Coronary artery bypass graft
PACTR	Pan African Clinical Trial Registry
ECG	Electrocardiogram
BIS	Bispectral index
SBT	Spontaneous breathing trial
NRS	Numeric rating score
FTA	Fast-track anesthesia
CPB	Cardio-pulmonary bypass
PECS	Pectoralis nerve block

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None

Authors' contributions

SA: performed study concepts, clinical studies, data acquisition, statistical analysis, manuscript editing and review. MA: performed definition of intellectual content, literature research, data analysis, manuscript preparation and review. TM: performed study concepts, design, definition of intellectual content, clinical studies, experimental studies, data acquisition, data analysis, manuscript review, and acted as guarantor. The manuscript has been read and approved by all the authors.

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Availability of the data and materials

The data and the material sets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Approval was obtained from the Research Ethics Committee of the Faculty of Medicine, Tanta University (approval code of 33702/02/20), and written informed consent was obtained from the patients. The trial was registered in the Pan African Clinical Trial Registry with a unique identification number for the registry which is PACTR202003822626676. Every patient signed a written informed consent before inclusion after complete presentation of the goal of the research with full details of the study.

Consent for the publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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