Continuous Unilateral Erector Spinae Plane Block versus Intravenous Analgesia in Minimally Invasive Cardiac Surgery: A Randomized Controlled Trial

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Abstract

AIM: The study was conducted to assess the safety and efficacy of anesthesia under the erector spinae plane block (ESPB) in minimally invasive cardiac surgery (MICS).

METHODS: A prospective, randomized controlled trial was carried out in 56 adults’ patients who underwent MICS through a right thoracic incision at Vietnam National Heart Institute, Bach Mai Hospital, Vietnam. Patients were randomly allocated into two groups: ESPB and conventional analgesia (intravenous [IV] morphine patient-controlled analgesia, [PCA]). Patients in the ESPB group received ultrasound-guided unilateral ESPB at the T4/T5 transverse process level, and the tip of the catheter was advanced 5 cm beyond the tip of the needle; injected with 20 ml ropivacaine 0.5%. At the cardiac intensive care unit, patients received paracetamol (1 g every 6 h), continuous infusion ropivacaine 0.1% 0.2 ml/kg/h. Patients in the PCA group received paracetamol (1 g every 6 h) and IV morphine PCA. All patients were followed for 72 h after being extubated.

RESULTS: The resting visual analog scale (VAS) score was significantly lower in the ESPB group at the time H4, H8, H12, H16, H36, H42, H48, H54, H60, and H66 after extubated compared to that of the PCA group (p < 0.05). The dynamic VAS score was also significantly lower in the ESPB group at all measured time points (p < 0.05). Only four patients in the ESPB group required IV morphine PCA with the mean amount morphine were statistically lower in the ESPB group compared to the PCA group at 24 h, 48 h, and 72 h postoperative. No serious adverse events such as neurological complications, bleeding, or infection were observed in both groups.

CONCLUSION: ESPB is an effective analgesic for MICS through thoracic incision in reducing the VAS score and the morphine required. It is also a safe method with no severe ESPB-related complications.

Introduction

In recent years, minimally invasive cardiac surgery (MICS) has become a trend in the surgical treatment of cardiovascular diseases. Acute pain after minimally invasive thoracic surgery originates from incisions in the chest wall, mediastinum, pleura, and pericardium. Management of acute pain after thoracic surgery includes many measures: Systemic analgesics: Paracetamol, non-steroid analgesics, morphine analgesics; or regional anesthesia: Epidural, paravertebral, pleural, intercostal nerve, and local anesthetic at incision site [1]. Chest pain restricts breathing and cough, leading to hypoxemia, sputum stagnation, atelectasis, pneumonia, myocardial ischemia, slow recovery, and prolonged hospital length of stay. Conventionally, thoracic epidural anesthesia was found to be the most effective pain relief approach for thoracic surgery. When applied in cardiac surgery, however, it is associated with several disadvantages due to the use of anticoagulation during cardiopulmonary bypass, such as the high risk of spinal hematoma and epidural abscess. ESPB block under ultrasound guidance is a novel technique to manage acute pain for the chest, abdomen, spine, and lower extremities surgery. This method was first introduced in 2016 by Forero for pain relief in patients with thoracic neuropathic pain [2]. The local anesthetic was injected deep into the erector spinae muscle at the transverse process of the thoracic vertebrae under ultrasound guidance. The anesthetic will then spread into the paravertebral space blocking the dorsal and ventral branches of the spinal nerve in the abdomen and chest. This blockage of the dorsal and ventral rami of the spinal nerves helps to achieve a multi-dermatomal sensory block of anterior, posterior, and lateral thoracic and abdominal walls. Recent studies have shown that ultrasound-guided erector spinae plane block (ESPB) for cardiac surgery is a new pain management modality with good pain control, few complications: Low-risk hematoma associated with intraoperative anticoagulation, infection at the needle insertion site, vascular puncture, and pleura puncture [2], [3], [4]. To date, there have been some studies investigating the efficacy of this method in a multitude of procedures including thoracotomies, cardiac surgery, breast surgery, abdominal surgery, and spine surgery [5], [6], [7], [8].
We hypothesized that bolus and continuous infusion of 0.1% ropivacaine into the fascial plane deep to the erector spinae muscle and superficial to the tips of the transverse process may reduce pain after thoracic surgery. Therefore, this randomized controlled clinical trial aimed to evaluate the analgesic efficacy of ESPB compared to patient-controlled anesthesia (PCA).

Patients and Methods

Patients

This study was approved by the Institution Research Board of Hanoi Medical University (No. TD10NCS/HMUIRB on November 5, 2018). Patients were introduced to the study and written informed consents were obtained if he/she agreed to participate in the study. A total of 58 consecutive patients were enrolled in this study from November 2018 to June 2020.

Patients were selected in this study if he/she: (1) Patients from 18 to 75 years of age, undergoing minimally invasive heart surgery through the right thoracic tract; (2) had any of the following conditions: Mitral valve disease with or without tricuspid valve disease; congenital heart disease such as atrial septal defect, atrioventricular septal defect, and heart tumor such as atrial myxoma. Exclusion criteria were as follows: (1) Patients had chronic conditions such as liver and/or kidney failure; (2) allergic to anesthetic; (3) patients required emergency surgery; (4) ASA: 4; (5) Euro score >6; (6) patient used the pain relievers regularly due to chronic pain; (7) patients in reoperation due to complication of previous surgery and anesthesia that unrelated to ESPB; and (8) patients on mechanical ventilation for >24 h.

Study design

This study was a single-center, single-blinded randomized controlled trial at Vietnam National Heart Institute, Bach Mai Hospital, Vietnam. Patients were allocated randomly into two groups by a sealed envelope technique following computer-generated randomization.

Sample size

We applied a sample size calculation based on the study by Marret et al. [9]. Specifically, a 30% reduction in morphine requirement was expected in the ESPB group compared to that of the PCA group [9]. With $\alpha = 0.05$ and $\beta = 0.20$, the minimum number of participants needed in each group was 20 patients. In reality, we have recruited 28 patients in each group.

Procedure

The minimally invasive heart surgery with thoracic incision was performed through anterior right thoracic opening 4–6 cm long in the fourth intercostal space or thoracotomy 4–6 cm in the third intercostal space right parasternal line.

In the pre-operative phase, patients in both groups were pre-anesthetized with midazolam 0.04 mg/kg. Basic monitoring included ECG DII, V5; temperature, urine, depth of anesthesia by a sensor (Patient State Index [PSI]), cerebral oxygen saturation (rO2) (The SedLine® sensor processes; O3 (Masimo Corporation; Irvine, CA, USA); and radial artery catheter was placed under local anesthesia. Patients were given prophylactic antibiotics cefazolin 30 mg/kg, or vancomycin 15 mg/kg, and pantoprazole 40 mg, tranexamic acid 40 mg/kg intravenously.

The anesthesia was induced with intravenous (IV) fentanyl citrate 2 $\mu$g/kg; etomidate 0.3 mg/kg or propofol 2 mg/kg; and rocuronium bromide 1 mg/kg. Patients were intubated with the left double-lumen endotracheal tube (Silbroncho DLT; Fuji System, Tokyo, Japan). Propofol was infused during surgery (TCI mode; Schnider model, pump Terumo) from 2-4 $\mu$g/mL (with a PSI target value between 25 and 50). The PSI was aimed to maintain at 25–50. Muscle relaxants: Rocuronium 0.2 mg/kg every 60 min. The amount of fentanyl repeated intraoperatively indicated by anesthesiologist based on assessing the mean arterial blood pressure and heart rate. IV heparin 300 IU/kg was indicated before femoral artery catheterization. Cardiopulmonary bypass was performed after ACT >400 s. Before extubating, neostigmine 0.03–0.05 mg/kg and atripine 0.01–0.02 mg/kg were used for reversal of neuromuscular blockade.

Intervention

In the ESPB group, after induction, the patient is placed in the right lateral decubitus position at 90° to perform ESPB. We disinfected the skin area to be punctured with povidone-iodine solution, covered the surgical towel with a sterile hole, and located anesthesia from right T4/5 or T5/6.

If the thoracic incision at the fourth intercostal space is used, the anesthetic location is at the transverse process of the fifth thoracic vertebra. Alternatively, if the thoracic incision at the third intercostal space is applied, the anesthetic position is at the transverse process of the fourth thoracic vertebra. We used an ultrasound machine (Affiniti 50G; Philips, USA) to identify anatomical landmarks. The physician placed the transducer with a frequency of 5–12 MHz of ultrasound in a cephalocaudal orientation over the midline of the back at the desired level.

Next, we identified three muscle layers from outside to inside: the trapezius muscle, rhomboid major...
In the ESPB group, patients received continuous infusion of ropivacaine 0.1%: 0.2 ml/kg/h. When the patient is ineligible for extubation, sedated midazolam 0.5–1 mg/h until criteria for extubation was met. If patients have a visual analog scale (VAS) score >4, she/he would get bolus 10 ml ropivacaine 0.1%. If the patient still has pain after 30 min, VAS >4, IV morphine is titrated and morphine PCA is infused with the following protocol: Concentration: 1 mg/ml; bolus dose of 1 mg/time; lockout time: 7 min; and limit dose: 15 ml/4 h. Complication and analgesic use were recorded by nurses.

Outcome measurements

Before the surgery, all patients were taught how to evaluate their pain intensity using the VAS, scored from 0 to 10 (where 0 = no pain and 10 = worst pain imaginable), and how to use the patient-controlled analgesia (PCA) device (PCA Machine, Company B Braun, Germany).

The main post-operative outcomes were intensity of pain measured by VAS pain scores at rest (resting VAS), VAS score at movement (dynamic VAS: Cough, deep inhalation, and movement), and the cumulative amount of morphine after surgery. The VAS scores were measured in study time: 0, 4, 8, 12, 16, 20, 24, 30, 36, 42, 48, 54, 60, 66, and 72 h after extubating. The secondary outcomes were respiratory muscle strength and adverse events of ESPB and PCA. The respiratory muscle strength was measured by maximum inspiratory pressure (MIP), maximum expiratory pressure (MEP) recorded with a handheld electronic pressure transducer (Care Fusion® MicroRPM Chatham, UK) at the time before surgery, 8 am on the 2nd and 3rd day after surgery.

Statistical analysis

Statistical analysis was carried out using Stata v.15.1 (College Station, TX: StataCorp LLC). We checked the normality of continuous data distribution using the Kolmogorov–Smirnov test. Normally distributed continuous data were described as mean and standard deviation. We applied independent samples Student’s t-test for comparison between two independent groups (ESPB and PCA). Meanwhile, non-parametrically using Mann–Whitney U-test was applied to test differences between the two groups if the independent data were skewed. The multilevel mixed effects linear regression model for longitudinal measurements was used for variables that were measured over time (VAS score). p < 0.05 was considered statistically significant.

Results

The flow of the patients through the study is illustrated in Figure 1. The patients’ demographic characteristics are presented in Table 1. There was no difference between ESPB and PCA groups regarding baseline characteristics (p > 0.05).
Regarding the VAS score at rest, there is a statistically significant in the VAS score between the ESPB and PCA groups at times H4, H8, H48, H54, and H60 (p < 0.05) (Figure 2).

The results from multilevel mixed effects linear regression indicated that there was a statistically significant between the two groups over the time of follow-up (p = 0.001). Furthermore, the VAS score at dynamic was significantly lower in the ESPB group compared to that of the PCA group (Figure 3) (p < 0.0001).

There were no differences in the MIP and MEP between the ESPB and PCA groups at pre-operative (p > 0.05) (Table 2). However, the MIP and MEP were higher significantly in the ESPB group at 2 days post-operative (p < 0.01) and 3 days post-operative (p < 0.001) (Table 2).

There were only 4 (14.3%) patients in the ESPB group who required morphine after the surgery (Table 3). The mean amount of morphine in the ESPB group has significantly lower compared to that of the PCA group during the first 24 h, 2 days, and 3 days after the surgery (p < 0.001). The amount of fentanyl analgesia consumed during surgery was lower in the ESPB group compared to that in the PCA group (p < 0.001). The time of extubation and hospital length of stay in ESPB were lower than that of the PCA group (p < 0.05).

Regarding adverse events, there were 3 patients (10.7%) who experienced nausea and vomiting after surgery in the ESPB group, while this figure for the PCA group was 8 patients (28.5%). There were no neurological complications, bleeding, or infection related to ESPB.

Table 2: Lung muscle strengths between erector spinae plane block and patient-controlled analgesia group

| Variables          | ESPB group (n = 28) | PCA group (n = 28) | p   |
|--------------------|---------------------|--------------------|-----|
| MIP                |                      |                    |     |
| Pre-operative      | 68.28 ± 11.83       | 66.32 ± 8.76       | 0.48|
| 2 days post-operative | 43.18 ± 6.83    | 35.18 ± 10.32      | 0.002|
| 3 days post-operative | 48.92 ± 8.97    | 39.64 ± 9.18       | <0.0003|
| MEP                |                      |                    |     |
| Pre-operative      | 73.21 ± 10.53       | 70.00 ± 9.01       | 0.40|
| 2 days post-operative | 47.96 ± 8.32    | 39.75 ± 9.57       | 0.001|
| 3 days post-operative | 53.75 ± 8.34    | 45.43 ± 9.14       | <0.0009|

Regarding adverse events, there were 3 patients (10.7%) who experienced nausea and vomiting after surgery in the ESPB group, while this figure for the PCA group was 8 patients (28.5%). There were no neurological complications, bleeding, or infection related to ESPB.

Discussion

The study showed that after surgery with the basic analgesic dose: Paracetamol 1 g every 6 h, the resting VAS score, and dynamic VAS score in the ESPB group were lower than that of the IV morphine PCA group at different points. The difference was statistically significant.
significant p < 0.05 at some points in time. In the ESPB group, the number of patients using morphine after surgery was 4/28 (14.3%) with the cumulative dose of morphine up to 24 h, 48 h, and 72 h lower than in the PCA group with statistical significance (p < 0.001).

The mechanism of action of the ESPB method is that the injected local anesthetic spreads to the spinal nerve root and intercostal space through the connective tissue, blocking the dorsal and ventral branch of the spinal nerve, and the sympathetic branch of the spinal nerve. Blockage of this spinal nerve branch facilitates the achievement of polycutaneous sensory block of the thoracoabdominal wall [2], [10]. The target of the injection is the paravertebral space, while the tip of the needle site is a relatively superficial myofascial plane located between the erector spinae muscles and the posterior aspect of the transverse processes, so for the technique to work, a large enough volume of local anesthetic is required. According to Ivanusic's study [11] for achieving a wide enough spread of local anesthetic, a large volume of local anesthetic of 20–30 ml is required for one injection. To prolong the effect, it is necessary to place a catheter for repeated injections or continuous infusion. In this study, the initial dose of ropivacaine 0.5% was 20–30 ml administered preoperatively. This dose was in the range of the mean ESPB dose for adult local anesthetics suggested by the previous studies [2], [3], [4]. For post-operative, the doses of ropivacaine and 0.2% continuous infusion of 0.1 ml/kg/h were also found to be useful to relieve pain in thoracic surgery [4], [12]. With a need for a large enough volume of local anesthetic, the study used ropivacaine 0.1% after surgery with an anesthetic dose of 0.2 ml/kg/h. The study showed that after surgery with the basic anesthetic dose: Paracetamol 1 g every 6 h, the resting VAS score, and dynamic VAS score in the ESPB group were lower than that of the PCA group at different points. The difference was significant p < 0.05 at some points in time. In the ESPB group, the number of patients using morphine after surgery was 4/28 (14.3%) with the cumulative dose of morphine up to 24 h, 48 h, and 72 h lower than in the PCA group with statistical significance (p < 0.001).

Cavaleri et al. [13] administered 25 ml of mixed local anesthetic (15 ml 0.5% ropivacaine and 10 ml 1% mepivacaine) followed by a continuous infusion of 0.2% ropivacaine 5 ml/h through a unilateral ESPB catheter for robotic-assisted thoracic surgery. The infusion of local anesthetic was continued for 2 first post-operative days. This was good analgesic management with numerical rating scale (NRS) score <4; rescue analgesics were used in 3/8 patients, opioids were required in one patient, and rescue analgesics were not required in the other cases. Takekta et al. investigated the efficacy of 8 ml/h continuous infusion of 0.2% levobupivacaine combined with IV fentanyl PCA through a catheter ESP, with the addition of 1 g of acetaminophen if required. The results showed that the mean NRS was <4, but some patients required additional pain medication [14].

Treatment of acute pain in MICS through right thoracic incision Borys et al. [15] used a single shot unilateral ESPB ropivacaine 0.375%; 0.2 ml/kg. The post-operative analgesic effect was good, and the 24 h oxycodone dose in the ESPB group was 18.26 (95% confidence interval: 15.55–20.98) mg. Leyva et al. [16] performed unilateral ESPB before surgery with an initial bolus of 20 ml of 0.5% bupivacaine, post-operative followed by a continuous infusion of 0.125% 7 ml/h bupivacaine through the ESPB catheter. Postoperative analgesic regimen consisted of continuous bupivacaine through the ESP catheter, oral acetaminophen 1g 6-hourly and oral tramadol 40mg 8-hourly. The patient continued to report only mild rest and dynamic pain (numeric rating scale <4) at the surgical site throughout the first 20 postoperative hours. From 20 to 48 h, the VAS score at rest is <4, and the VAS score at deep inhalation increases to >4, but rescue analgesia is not required. Sun et al. [17] compared intermittent bolus of ESPB through the catheter was compared with patients not receiving any regional anesthesia. The results showed that ESPB was associated with a reduction in postoperative in-hospital opioid consumption [17].

For open cardiac surgery using a sternotomy approach, Krishna et al. [18] compared unilateral ESPB ropivacaine 0.375%; 3 mg/kg, with conventional analgesia (paracetamol plus tramadol). The mean duration of analgesia was significantly longer and pain relief was better in the ESPB group. Macaire et al. [19] compared intermittent bilateral ESPB ropivacaine 0.5% (before surgery) and 0.2% ropivacaine (after surgery) with usual care (continuous infusions of paracetamol, morphine, and nefopam). The results showed that the ESPB group had a good analgesic effect without the need for morphine. Post-operative adverse events were significantly reduced in the ESPB group [19].

When comparing the effectiveness of continuous ESPB with continuous thoracic epidural analgesia for perioperative pain management in patients with open-heart surgery, Nagaraja et al. [20] found that the effective analgesia of ESPB and epidural was comparable. In addition, it was easier to perform ESPB than perform epidural, the authors emphasize that ESPB is promising and should be an alternative to epidural anesthesia in pain management for open-heart surgery [20].

Effective pain control helps patients breathe deeply, cough well, and reduce lung congestion. The use of effective regional anesthesia reduces opioid use and the associated effects of respiratory depression, sedation, nausea, and vomiting [21].

Measurements of respiratory muscle strength, such as MIP and MEP, are easy techniques. MIP and MEP can be used to measure the combined effect of all muscles used during maximal effort [22]. They provide a useful indicator of muscle weakness and
are a useful follow-up tool during the post-operative period. Post-operative, the MIP and MEP values are decreased. The reasons may be explained by other general anesthesia-related factors associated with the development of respiratory muscle weakness, such as the use of muscle relaxants, intraoperative opioids, and mechanical ventilation itself. In our study, respiratory muscle strength was better preserved in the ESPB group, probably because regional anesthesia may be effective for analgesia without the respiratory effects of opioids. The value of MIP and MEP decreased on the 1st day after post-operative and then gradually increased. Fiorelli et al. [23] compared the analgesic effects of one dose 20 ml 0.75% ropivacaine between ESPB technique and intercostal nerve block (ICNB). After the operation, both groups were given continuous ketorolac and tramadol for analgesia. The results showed that NRS score of ESPB group was significantly lower than that of intraoperative ICNB group, the respiratory muscle strength of the ESPB group was better preserved than that of the ICNB group.

Regarding the adverse events of the ESPB method, we found that there are no serious adverse events related to this analgesia method. There were only 10.7% of patients in the ESPB group experienced nausea and vomiting, which lower than the PCA group (28.5%). In addition, there were no neurological complications, bleeding, or infection related to ESPB. Our results are in accordance with the finding of Adhikary et al. when evaluating the effectiveness of the ESPB method on patients with thoracic trauma with multiple rib fractures [24]. The authors found that while ESPB had good analgesia and improved ventilation function, it is also safe due to the absence of serious adverse events such as neurological complications, bleeding in the area of anesthesia, anesthetic poisoning, or infection of the anesthetic area [24]. Similarly, ESPB on the left side to relieve pain during and after surgery for the left ventricular assist device surgery using left thoracic incision was also found to be safe in another study by Adhikary [25]. The results showed that ESPB is an effective analgesia method without complication despite patients' conditions were severe heart failure and on treatment with anticoagulation [25]. In open-heart surgery with cardiopulmonary bypass, the ESPB was revealed as the safe and effective method to relieve pain, without any serious complications related to anticoagulation, neurological complications compared to regional anesthesia [18], [19], [20]. ESPB also does not associate with any hematological complications even though the patient is taking systemic anticoagulants [19].

Conclusion

The ESPB method has good post-operative analgesia and reduces the need for post-operative morphine compared with PCA with IV morphine. This method does not cause serious complications related to anesthesia for minimally invasive heart surgery with thoracic incision.

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