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CLINICAL TRIAL REPORT

Median Effective Volume of 0.25% Ropivacaine for Bilateral Transversus Thoracis Muscle Plane Block in Patients Undergoing Open Cardiac Surgery

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Background: The median effective dose of ropivacaine required to achieve an effective transversus thoracis muscle plane block (TTP) has not been established. This study aimed to determine the EV50 of 0.25% ropivacaine for TTP using Dixon's up-and-down method.

Methods: This prospective study involved 21 patients with American Society of Anesthesiologists physical status II to III, aged 20 to 60 years, with a BMI of 18 to 30 kg/m², who were scheduled for open cardiac surgery. Bilateral TTP was performed preoperatively, and 30 minutes post-block, the cold sensory decrease area (CSDA) was marked and recorded. The initial volume of 0.25% ropivacaine administered was 20mL. The effective block was defined as the CSDA encompassing thoracic nerves 2 to 6, which dictated a 2 mL increment or decrement in the subsequent patient's dosage. The study concluded when volumes reached 5 mL or 40 mL for 7 patients, or after 7 turning points.

Results: A total of 21 cases were evaluated. Twelve (57.1%) of 40 received an effective block, while nine (42.9%) patients received a non-effective block. Analysis using SPSS 26.0 revealed the median effective volume (EV50) of 16.36mL for 0.25% ropivacaine and the 95% effective volume (EV95) of 19.81mL.

Conclusion: In open cardiac surgery, the median effective volume of 0.25% ropivacaine for TTP is 16.36 mL (95% CI 14.35 to 18.43), while the 95% effective volume is 19.81 mL (95% CI 18.60 to 22.75).

Trial Registration Number: ChiCTR2300073449.

Keywords: regional anesthesia, cardiac surgical procedures, sternotomy, pain management

Introduction

At present, median sternotomy is the most common approach in open cardiac surgery. Patients undergoing median sternotomy for open-chest cardiac surgery experience a higher incidence of moderate to severe pain in the early postoperative period, which typically subsides over time.[1] Over 47% of patients suffer from moderate to severe pain.[2] If pain is not adequately controlled, it can develop into persistent postoperative pain (PPP). In most cases, the proportion of patients with PPP does not decrease over time.[3] Approximately 85% of PPP is localized to the mid-sternum, an area innervated by thoracic nerves 2 to 6. Additionally, few patients report pain in the arm, neck, or throat. A meta-analysis summarizing 23 studies (comprising a total of 11,057 cases) reported that 37% of patients experienced persistent postoperative pain (PPP) within six months following cardiac surgery.[3] Adequate perioperative analgesia may prevent the development of PPP.[4–6]

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Currently, opioids, including high dose sufentanil and remifentanil, are frequently utilized for analgesia. Regrettably, opioids can induce numerous adverse effects, including addiction, respiratory depression, and cardiac suppression, among others. Moreover, these opioids may impair postoperative recovery, prolong ICU stays, and elevate patient hospitalization costs.[5] Opioid-free anesthesia is increasingly recommended internationally, often employing a combination of regional blocks and nonsteroidal anti-inflammatory drugs (NSAIDs) for analgesia.[7] The first instance of utilizing thoracic epidural analgesia in cardiac surgery dates to 1954.[8] Additionally, thoracic paraspinal plane block, vertical spinal muscle plane block, and thoracic nerve block have been employed for postoperative analgesia in patients who have undergone median sternotomy for cardiac surgery. Due to the administration of heparin during surgery and the postoperative prescription of anticoagulants, intraspinal anesthesia is contraindicated for these patients. Consequently, regional anesthesia has emerged as the preferred alternative.

The transversus thoracic muscle plane block (TTP) was initially described and applied in breast surgery in 2015.[9] Researchers have found that the combination of the transversus thoracic muscle plane block (TTP) and Pecs II block can anesthetize the medial region of the breast, including the anterior branches of intercostal nerves T2-T6, potentially eliminating the need for additional anesthetic techniques in breast surgery. The Pecs II block is a regional anesthesia technique targeting the pectoral nerves, specifically the medial and lateral pectoral nerves, to provide analgesia to the medial region of the breast and chest wall. This block is commonly used in breast surgery and, when combined with the transversus thoracic muscle plane (TTP) block, can provide extended anesthesia for procedures involving the anterior chest. Studies have demonstrated that a single bilateral transversus thoracic muscle plane blocks with 20 mL of 0.33% ropivacaine can provide up to 17 hours of analgesia in patients undergoing cardiac valve replacement surgery.[10] Furthermore, preoperative TTP has been shown to decrease sufentanil requirements during surgery, alleviate post-operative pain, and expedite patient recovery.[11] Compared to other regional block techniques, the TTP targets the sternal area, encompassing the anterior chest between the bilateral breasts, making it theoretically more appropriate for cardiac surgery.

Ropivacaine, a local anesthetic, is extensively utilized in regional blockade due to its low cardiotoxicity profile. Despite having reduced toxic effects compared to opioids, ropivacaine retains some neurotoxic potential and is susceptible to systemic toxic reactions if administered improperly.[12] Particularly in patients with cardiac disease, the pre-existing cardiovascular conditions, render them more susceptible to local anesthetic toxicity. When administering regional blocks using local anesthetics like ropivacaine, anesthesiologists should be vigilant for signs of local anesthetic systemic toxicity (LAST). Symptoms of LAST can include central nervous system toxicity, such as tinnitus, light-headedness, seizures, or cardiovascular toxicity, such as hypotension, arrhythmias, or cardiac arrest. Given ropivacaine's lower cardiotoxicity compared to other anesthetics like bupivacaine, it remains a safer choice for cardiac surgery patients, though monitoring for these symptoms is still crucial. In the event of toxicity, subsequent rescue efforts become more challenging. Consequently, this study aimed to determine the optimal dose of ropivacaine for TTP to minimize local anesthetic-related complications while maintaining effective blockade.

In summary, the median sternotomy in cardiac surgery can result in significant postoperative pain and diverse adverse reactions. Currently, TTP can effectively mitigate pain associated with median sternotomy. Nonetheless, the administration of high doses of local anesthetics poses a risk to patients. Therefore, this study aims to determine the optimal effective volume of 0.25% ropivacaine for bilateral transversus thoracic muscle plane block.

Materials and Methods

Study Design and Population

This single-arm prospective study was conducted in the operating room with approval from the Ethics Committee of the First Affiliated Hospital of Wenzhou Medical University (Chairperson Zimiao Chen, reference dated July 2, 2023). The trial was registered with the Chinese Clinical Trial Registry (ChiCTR2300073449) on July 11, 2023, and conducted from September 2023 (first patient enrolled: September 20, 2023) to August 2024 (last patient completed: August 7, 2024). This study complies with the Declaration of Helsinki. All participants gave their informed consent to participate in this research. In addition, written informed consent was obtained from all

participants for the publication of any potentially identifiable data or images included in this article. Eligibility criteria included American Society of Anesthesiologists physical status II to III patients, aged 20 to 60 years, with a BMI of 18 to 30 kg/m², and intact front chest skin, scheduled for open cardiac surgery. Patients with allergies to local anesthetics, communication or comprehension difficulties, or prior thoracic or abdominal surgery were excluded.

Blinding Methods

Investigator 1 recorded the procedural data. All blocks were performed by an experienced investigator 2, proficient in ultrasound-guided transversus thoracic muscle plane block (TTP), utilizing a low-frequency (3 to 6 MHz) ultrasound probe (SonoSite X-Porte, SonoSite Inc., Bothell, WA, USA). Investigator 2, who performed the block, was blinded to the volume of ropivacaine. To achieve this, syringes were pre-filled and labeled with unique codes by Investigator 4, who was not involved in either the block or assessments. All volume markings on the syringes were obscured using masking tape. The syringes were only handed to Investigator 2 immediately before use and collected afterward to prevent volume inference by residual fluid. Investigator 2 had no access to patient allocation records or volume data during the study period. Investigator 3 collected the general information from patients one day before surgery, assessed the cold sensory decrease area (CSDA), and documented the occurrence of relevant adverse reactions. Investigators 2 and 3 were blinded to the volume of local anesthetic administered.

Technique of Block Administration

All patients were monitored for noninvasive blood pressure, electrocardiogram, and oxygen saturation in the operating room. Veins in the forearm, internal jugular, and left radial artery were cannulated. The anesthetist administered 1 to 2mL sedative and analgesic mixture (midazolam 1mL/mL and fentanyl 20ug/mL) intravenously to alleviate puncture discomfort. With patients in the supine position, the anesthesiologist marked and disinfected the anterior chest, then placed the ultrasound transducer between ribs 4 and 5. After identifying the pectoralis major, intercostal muscle, transverse thoracic muscle, pleura, and internal thoracic artery and vein, 1 to 2 mL of physiological saline was injected into the plane between the intercostal muscle and the transverse pectoralis muscle to confirm needle position. The observation of the separation of the fascia between the intercostal muscle and the transverse thoracic muscle indicated that the needle tip had reached the corresponding position. This procedure was repeated on the contralateral side (Figure 1). The volume of 0.25% ropivacaine administered was determined using Dixon's up-and-down method.[13] The first patient received a volume of 20 mL of 0.25% ropivacaine. A block was considered effective if the cold sensory decrease area (CSDA) encompassed thoracic nerves T2–T6, which was the primary outcome. If the block was effective, the volume was decreased by 2mL for the next patient; if non-effective, it was increased by 2mL. Starting from the case of the cold sensory decrease area change, the selection was taken as a turning point from the non-effective block to the effective block. When the volume is less than 5mL or more than 40mL and the last 7 patients appear at 7 turning points, the experiment is concluded.

Block Evaluation

The primary outcome of this study was the cold sensory decrease area (CSDA), assessed 30 minutes after block administration. The CSDA was evaluated by an observer using ice cubes. The degree of block was categorized into three grades based on skin temperature perception of ice: grade 0 (sensation disappears), grade 1 (sensation decreases), and grade 2 (normal sensation). Grade 1 cold sensory loss was defined as a clearly perceptible decrease in cold sensation (eg, reported as "cool" instead of "cold" or with delayed response) compared to non-blocked areas like the forearm. This reflects a clinically relevant change often sufficient to reduce nociceptive input from the anterior thoracic wall. The sensory reduction of the skin from the midpoint of the sternum to the anterior axillary line was measured at 2cm/s along T1 to T7. While moving the ice cubes, the observer marked the points where the skin sensation from grade 1 to grade 2. A block was considered successful if the CSDA included T2 to T6 (Figure 2).

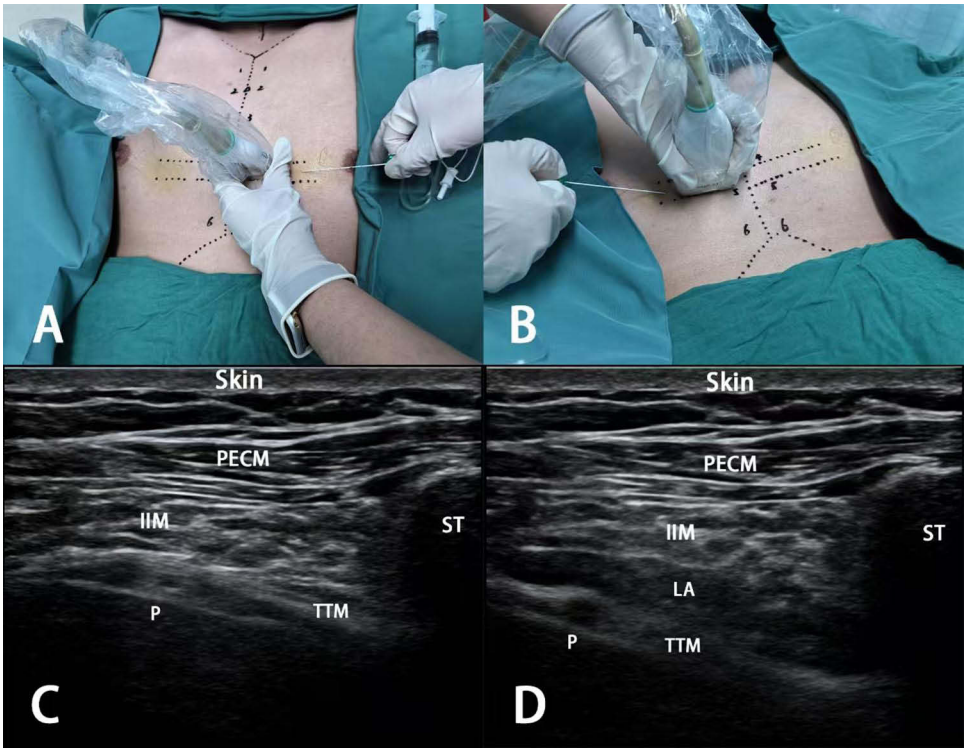

Figure 1 Photograph and ultrasonographic images of the TTP. (**A**) Left TTP. The ultrasound probe is placed between the 4th and 5th ribs. The needle insertion direction from outside to inside. (**B**) Right TTP. (**C**) Ultrasound image before puncture; (**D**) Ultrasound image after puncture. Arrows indicate the trajectory direction of the needle tip. **Abbreviatons**: PECM, Pectoralis major; IIM, Internal intercostal muscle; TTM, Transverse thoracic muscle; ST, Sternum; P, Pleura; LA, Local anesthetic.

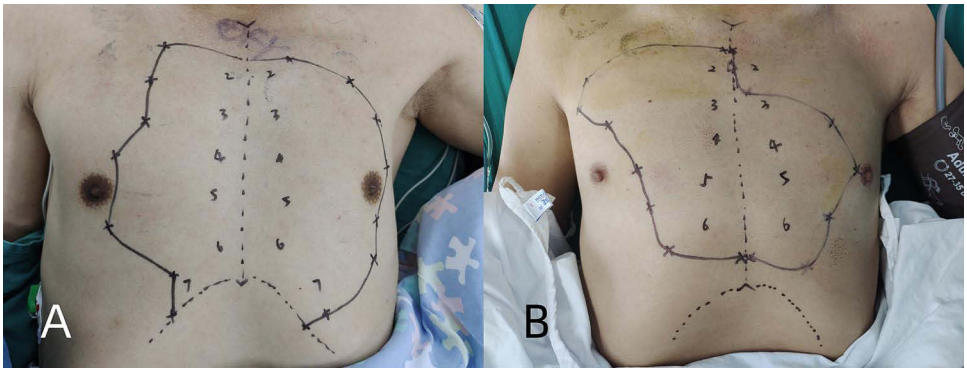

Figure 2 The cold sensory decreased area (CSDA) after 30 minutes of blockade. (**A**) Effective CSDA.The CSDA included T2 to T6. (**B**) Non-effective CSDA.

Statistical Analysis

The sample size was calculated using the formula by Dixon and Massey,[14] n = 2(SD/SEM).[2] With an 8mL SD and 2.5mL SEM, 20 patients were required for the study. The Dixon and Massey up-and-down method was used to calculate EV50. Data were analyzed using SPSS26.0 with statistical software. Measurement data of normal distribution was expressed as mean ± standard deviation (x ± s), and non-normal distribution data was represented by median and quartile[M(P25,75)]. P, with normal distribution data expressed as mean ± standard deviation (x ± s) and non-normal distribution data as median and quartile [M(P25,75)]. Probit probability regression and logistic regression were used to calculate the median effective volume (EV50) and the 95% effective volume (EV95) of 0.25% ropivacaine, with results graphed in R version 4.4.1 (R package Helpers MG6.2). The cold sensory decrease area (CSDA), the primary outcome, was analyzed to assess the EV50 and the EV95 of 0.25% ropivacaine.

Table 1 General Information of 21 Patients

Characteristic	Value
Age (years)	54.4±8.1
BMI (kg/m^2)	23.7±2.4
Sex	
Male	12
Female	9
ASA	
II	10
III	11

Notes: Values are Mean±SD or number. BMI=Weight / Height^2.
Abbreviations: BMI, Body mass index; ASA, American Association of Anesthesiologists grading.

Results

General Information

All 21 patients completed the experiment and the cardiac operation. The baseline demographics are shown in Table 1.

EV50 of the 0.25% Ropivacaine for Transverse Thoracic Muscle Block

In this experiment, the first patient was injected with 20mL of 0.25% ropivacaine which resulted in a effective block. The trial concluded upon the inclusion of the 21st patient, marking the seventh inflection point. The capacity-effect curve is presented in Figure 3, and the range of TTP is shown in Table 2. As shown in Table 2, among the 21 patients, 12 received an effective block and 9 received a non-effective block. The sensory block distribution was assessed at various thoracic dermatomes (T1 to T7). Analyses were performed with SPSS 26.0 for Windows (SPSS, Chicago, IL, USA). By calculation, EV50 of 0.25% ropivacaine for transversus thoracis muscle plane block is 16.36mL (95% CI 14.35 to 18.43) and EV95 is 19.81mL (95% CI 18.60 to 22.75).

A total of 21 patients were enrolled in this study. Only one patient experienced bleeding at the puncture site, which resolved after pressure application, with no other adverse reactions observed during follow-up. The remaining patients did not report additional adverse reactions.

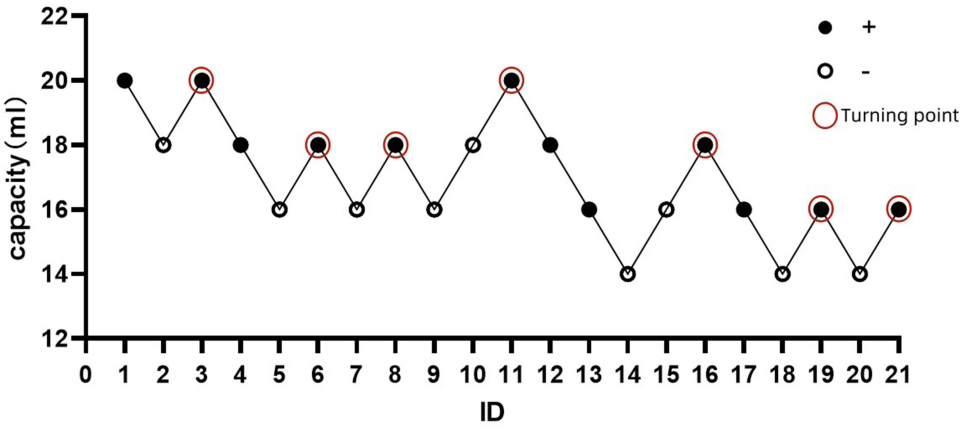

Figure 3 Sequential block results of 0.25% ropivacaine using a TTP technique for median open-chest cardiac surgery according to the Dixon and Massey up-and-down method.
Abbreviatons: TTP, Transversus thoracis muscle plane block; ID, Patient sequential coding.

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Table 2 The Range of TTP

	Effective Block	Non-Effective Block
T1	1(8.3%)	0(0%)
T2	12(100%)	1(11.1%)
T3	12(100%)	7(77.8%)
T4	12(100%)	8(88.9%)
T5	12(100%)	9(100%)
T6	12(100%)	8(88.9%)
T7	10(83.3%)	5(55.6%)

Notes: The number and percentage of patients with effective or non-effective blocks at each intercostal nerve level. Data are presented as the number of patients and percentages (%). The study included 21 patients in total, with 12 having an effective block and 9 having a non-effective block. Sensory block distribution across different dermatomes (T1 to T7) is shown for both the effective and non-effective block groups.

Discussion

In this study, we determined that the EV50 of 0.25% ropivacaine for the transversus thoracis muscle plane block is 16.36mL (95% CI 14.35 to 18.43). The CSDA encompassed T5, with the majority extending from T3 to T6 and, in one instance, reaching T1. The volume-effect curve of 0.25% ropivacaine for TTP is presented in Figure 4.

This study utilized the Dixon up-and-down method to determine the half effective volume (EV50) of 0.25% ropivacaine for TTP. The Dixon and Massey up-and-down method is an adaptive dose-finding strategy where the dose of the local anesthetic is increased or decreased in steps based on whether the previous dose was ineffective or effective.[13] This approach reduces the sample size required to determine the median effective volume (EV50).[15] Although EV50 provides a foundational estimate for future studies, it does not ensure clinical reliability, particularly for high-risk procedures like cardiac surgery. In clinical practice, anesthesiologists typically rely on EV90 or EV95 to minimize block failure. Our findings should therefore be interpreted as preliminary, guiding further dose-finding studies with robust methodologies targeting these higher thresholds. In this experiment, the concentration of ropivacaine is 0.25%, which is meant to ensure the concentration is effective and reduce the adverse effects of ropivacaine meanwhile.

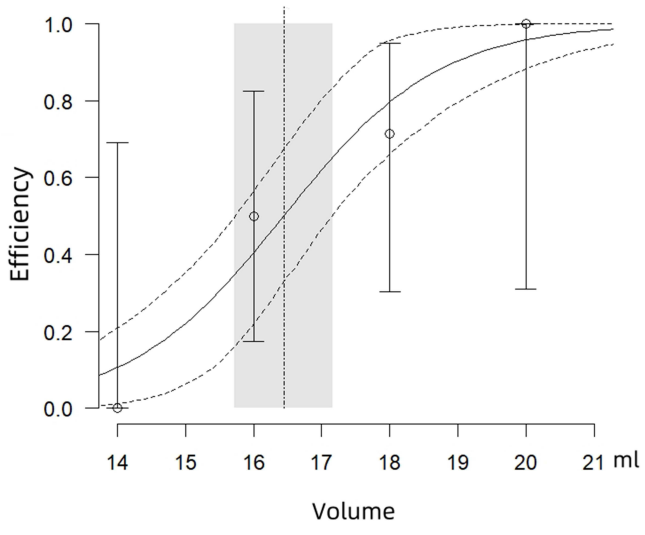

Figure 4 The volume-effect curve of 0.25% ropivacaine for TTP. EV50 estimation by using Probit probability regression and logistic regression. The vertical dash line refers to the EV50 of 0.25% Ropivacaine for TTP.
Abbreviation: EV50, Effective volume in 50% of patients.

According to clinical experience, clinicians usually use 20mL as the volume of TTP, which with little adverse effect.[16] Thus, the initial volume in this study was set at 20 mL per side, with a dosage gradient of 2 mL.

Ropivacaine, an amide local anesthetic,[17] is structurally similar to bupivacaine. This study observed no adverse reactions related to local anesthetic overdose or poisoning, likely due to ropivacaine's low toxicity in the central nervous and cardiovascular systems. Ropivacaine is widely used for local blocks because, at low doses, it can produce a distinct separation of sensory and motor nerve blocks.

Among the 21 patients, one patient experienced bleeding at the puncture site. This may have been due to the needle penetrating the posterior intercostal vessels, which run along the costal grooves.[18] In this study, the needle entry point was chosen between ribs 4 and 5. To avoid puncturing these vessels, the needle should be positioned away from rib 4 and close to the upper edge of rib 5. In the case of this patient, no blood was observed before injection, but bleeding occurred at the puncture site after injection. The blocking effect was unaffected by this incident, and the case was included in the study.

There are several techniques for TTP, each with distinct advantages and disadvantages. There is no standardized method for performing TTP. Two needle insertion sites are commonly used: T3-4 and T4-5. A study by Zhang et al[19] demonstrated that needle insertion at the T4-5 interspace results in a broader block distribution. However, a study by Chen et al[20] indicated that both insertion sites have equivalent efficacy in terms of postoperative analgesia for patients. The dual-injection technique is another approach in TTP. A cadaveric study by Samerchua et al[21] showed that injecting the solution at two points, T2-3 and T5-6, resulted in a wider CSDA compared to single-point injection. Therefore, we propose that the single-point injection method at the T4-5 interspace can effectively alleviate pain while minimizing damage to the chest wall. In this study, the ultrasound probe was positioned parallel to the ribs, which facilitated the visualization of the internal mammary artery within the transversus thoracic muscle and allowed for its avoidance during puncture.

The maximum dose of ropivacaine for acute pain control is 200 mg. In this experiment, the maximum dose used was 100 mg, well below the maximum dose. This aligns with the observation that none of the 21 patients experienced adverse reactions related to the transverse thoracic nerve block. Even patients whose blockade did not meet the target range still had coverage from T4 to T6, with most having incomplete blockade at the T2 level, far from the puncture point. This blockade range can effectively alleviate pain in the lower sternal area.

Although this study defined block effectiveness based on sensory changes (CSDA), we acknowledge that a purely sensory definition may not fully represent clinical effectiveness. Future studies should incorporate postoperative opioid consumption, pain scores, and patient satisfaction to better validate the clinical utility of the block.

Limitations

Firstly, despite limiting patient BMI during screening, variations in body shape and transverse thoracic muscle morphology remained, which may introduce inaccuracies. This could lead to inaccurate results. Secondly, establishing an accurate EV50 with a 2 mL increment may be too broad an approach. Thirdly, the Dixon and Massey up-and-down method is efficient for estimating the EV50 with fewer subjects. However, it is less robust for estimating EV90 or EV95 due to limited data at higher efficacy levels. Therefore, while EV95 was calculated using probit regression, it should be interpreted with caution. Future studies might consider alternative designs, such as the k-in-a-row method or isotonic regression, to improve estimation accuracy for EV90 or higher percentiles. Meanwhile, larger studies with more participants are needed to confirm the results and improve the generalizability of the findings. Finally, this study was conducted solely at the First Affiliated Hospital of Wenzhou Medical University, limiting its scope as a single-center trial, and not as a multicenter trial across various hospitals.

Conclusion

In median sternotomy, the EV50 of 0.25% ropivacaine for ultrasound-guided transversus thoracic muscle plane block was 16.36mL (95% CI 14.35 to 18.43) and EV95 was 19.81mL (95% CI 18.60 to 22.75) without any significant adverse reactions.

Future research incorporating both sensory and clinical outcomes is warranted to validate the practical efficacy of TTPB in open cardiac surgery.

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Disclosure

The authors declare no conflicts of interest in this work.

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