Submitted: 14 July, 2025 Accepted: 25 September, 2025 Published: 08 February, 2026 DOI:10.22514/sv.2025.179

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ORIGINAL RESEARCH

Thoracic paravertebral versus serratus anterior plane block in thoracic surgery—a randomized trial

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Abstract

Background: Pain after thoracotomy is often severe and may lead to postoperative complications. Although various regional anesthesia techniques are used to manage thoracotomy pain, further evidence is needed regarding the efficacy of the serratus anterior plane block (SAPB). This randomized controlled study aimed to compare the postoperative analgesic efficacy of ultrasound-guided single-injection thoracic paravertebral block (TPVB) with deep SAPB in patients undergoing lung resection via thoracotomy. **Methods**: Sixty American Society of Anesthesiologists (ASA) physical status I–III patients aged 18–75 years scheduled for elective thoracotomy were randomized to receive either TPVB or SAPB using 20 mL of 0.5% bupivacaine. All patients received postoperative patient-controlled intravenous morphine. Morphine consumption, visual analogue score (VAS), postoperative nausea and vomiting (PONV), and analgesia requirements were recorded at predetermined intervals. The primary outcome was 24-hour postoperative opioid consumption. Secondary outcomes included static and dynamic VAS pain scores, rescue analgesia requirements, and complications. **Results**: Data from 58 patients were analyzed. TPVB significantly reduced morphine consumption at all measured time points (3, 6, 9, 12, and 24 hours). Total 24-hour opioid consumption was lower in the TPVB group than in the SAPB group (8 mg *vs.* 14 mg; $p < 0.001$). Rescue analgesia needs were higher in the SAPB group at 9th and 12th postoperative hours. TPVB also resulted in lower VAS scores at multiple time points and lower (PONV). **Conclusions**: Compared to SAPB, TPVB provided superior analgesia following thoracotomy, resulting in lower opioid requirements, improved pain scores, and fewer opioid-related side effects. **Clinical Trial Registration**: The study was retrospectively registered with ClinicalTrials.gov (Registration No: NCT06177652).

Keywords

Thoracotomy; Thoracic paravertebral block; Serratus anterior plane block; Postoperative pain; Regional anesthesia

1. Background

Patients often experience severe pain following thoracotomy, which is considered one of the most intense types of postoperative pain. The main sources include skin incision, retractor placement, rib removal, dislocation of the costovertebral joint, and pleural irritation caused by chest tubes [1]. Effective management of post-thoracotomy pain is crucial, as it improves clinical outcomes by preventing complications, such as atelectasis and hypoxia, reducing the length of hospital stay, and lowering the risk of chronic pain development [2].

Thoracic epidural analgesia is widely recognized as the most effective technique for managing post-thoracotomy pain. However, it may be associated with various complications and undesirable hemodynamic effects [3]. With advancements in regional anesthesia, novel techniques have been introduced to provide effective pain relief with fewer risks [4].

Thoracic paravertebral block (TPVB) offers unilateral somatic and visceral analgesia comparable to epidural analgesia after thoracotomy, and it is clinically significant due to its lower complication rates [3]. Nevertheless, because the injection site in TPVB is close to the pleura and epidural space, complications such as pneumothorax and hemodynamic changes may still occur [5].

To perform the block more distally and minimize these risks, both deep and superficial serratus anterior plane block (SAPB) techniques have been developed. These ultrasound-guided (USG) blocks provide effective analgesia after thoracotomy, with greater ease of application and a lower risk of complications compared to TPVB [6].

This study aimed to compare the postoperative analgesic efficacy of single-injection TPVB and deep SAPB under ultra-

sound guidance in patients undergoing thoracotomy for lung resection. The primary objective was to conduct a comparative analysis of postoperative opioid consumption. Secondary objectives included static and dynamic visual analogue scale (VAS) scores, rescue analgesia requirements, and complications.

2. Methods

2.1 Study design and ethical approval

This randomized prospective study was conducted at the Kocaeli University Medical Faculty Hospital, Türkiye, in accordance with the Declaration of Helsinki and the Good Clinical Practice guidelines. Ethical approval was obtained from the Kocaeli University Ethics Committee (28 April 2021, Approval No: KAEK/10.bI.02). Financial support was provided by the Kocaeli University Scientific Research Projects Coordination Unit (Project No: 2881). The study was retrospectively registered at ClinicalTrials.gov (Registration No: NCT06177652).

2.2 Patient selection and randomization

Informed written and verbal consent was obtained from all participants. Eligible patients were randomly assigned to one of two groups (TPVB or deep SAPB) using research randomizer, a computerized randomization online tool (https://www.randomizer.org). The Consolidated Standards of Reporting Trials (CONSORT) flowchart was used to report patient allocation in the results section. The study was conducted on patients scheduled for elective thoracotomy between June 2021 and April 2024. Patients aged 18–75 years with American Society of Anesthesiologists (ASA) physical status I–III who were scheduled for elective thoracotomy under general anesthesia were included. Exclusion criteria were anticoagulant use, known allergy to local anesthetics, BMI >35 kg/m^2, body weight <50 kg, local infection at the block site, spinal or paravertebral deformities, chronic opioid use, or refusal to participate. All blocks were performed in the block room one hour before surgery by an experienced anesthesiologist (more than 50 prior procedures of each block type) [7]. Standard monitoring included Electrocardiography (ECG), Peripheral oxygen saturation (SpO_2), and non-invasive blood pressure (NIBP). Intravenous midazolam (0.03 mg/kg) was administered for premedication. A 22 G, 50 mm Braun Sonoplex needle (Melsungen, Germany) and an Esaote MyLab™ 6 ultrasound system (Esaote S.p.A., Florence, Italy) with a 2.5–12.5 MHz linear probe were used for both block techniques.

2.3 Block procedures

2.3.1 Thoracic Paravertebral Block (TPVB) technique

The block was performed with the patient in the prone position after appropriate skin cleansing. A linear ultrasound probe (Esaote My Lab 6, Florence, Italy) was placed parallel to the spinal cord at the T5 level and moved 2–3 cm laterally. The paravertebral space, transverse process, and pleura were visualized. Afterwards, 20 mL of 0.5% bupivacaine was injected into the paravertebral space at the T5 level in the caudocranial direction using the in-plane technique (Fig. 1).

2.3.2 Deep serratus anterior plane block (SAPB) technique

This block was also performed after appropriate skin cleansing, with the patient in the lateral position, with the surgical side on top, and the arm on the same side at 90-degree abduction. The fifth rib was marked by counting from the second rib. A linear ultrasound probe (Esaote My Lab 6, Florence, Italy) was moved toward the midaxillary line, and the latissimus dorsi and serratus anterior muscle layers were visualized. Next, the serratus anterior muscle was approached in the craniocaudal direction, and 20 mL of 0.5% bupivacaine was injected using the in-plane technique (Fig. 2).

2.4 Anesthesia and perioperative management

Standard monitoring, including NIBP, SpO_2, and ECG, was applied in all cases. After induction of anesthesia with intravenous (IV) fentanyl (1 μcg/kg) and propofol (2–3 mg/kg), muscle relaxation was achieved with IV rocuronium bromide (0.6 mg/kg). Anesthesia was maintained with sevoflurane inhalation in an O_2/air (1/2 L/min) mixture, with bispectral index (BIS) between 40–60 and remifentanil infusion titrated according to the hemodynamic response.

2.5 Postoperative analgesia protocol

Both groups received 1 gram of paracetamol, 0.05 mg/kg morphine, and 20 mg tenoxicam 30 minutes before the end of surgery. In addition, 8 mg of ondansetron was administered to prevent postoperative nausea and vomiting. At the end of the surgical procedure, patients were extubated and subsequently transferred to the postoperative intensive care unit in accordance with established institutional protocols. All patients were routinely administered 1 g IV paracetamol once every 8 hours during intensive care follow-up. In case of VAS scores >4, IV 0.5 mg/kg meperidine diluted in 10 mL serum saline was administered as rescue analgesia. Nausea, vomiting, hematoma, pneumothorax, and local anesthetic systemic toxicity have been defined and recorded as postoperative complications.

2.6 Statistical analysis

To calculate the sample size, a priori power analysis was performed using G*Power 3.1.9.4 (Heinrich-Heine-University, Düsseldorf, NRW, Germany) software with type 1 error $\alpha = 0.05$, power $(1 - \beta) = 0.80$, and Cohen's $d = 0.80$. This yielded a required minimum sample size of 26 patients per group. We planned to include a total of 60 patients in the study due to possible data loss.

All statistical analyses were performed using IBM SPSS for Windows version 29.0 (IBM Corp., Armonk, NY, USA). Shapiro-Wilk's test was used to assess the normality assumption. Normally distributed continuous variables were presented with mean $\pm$ standard deviation (SD), and non-

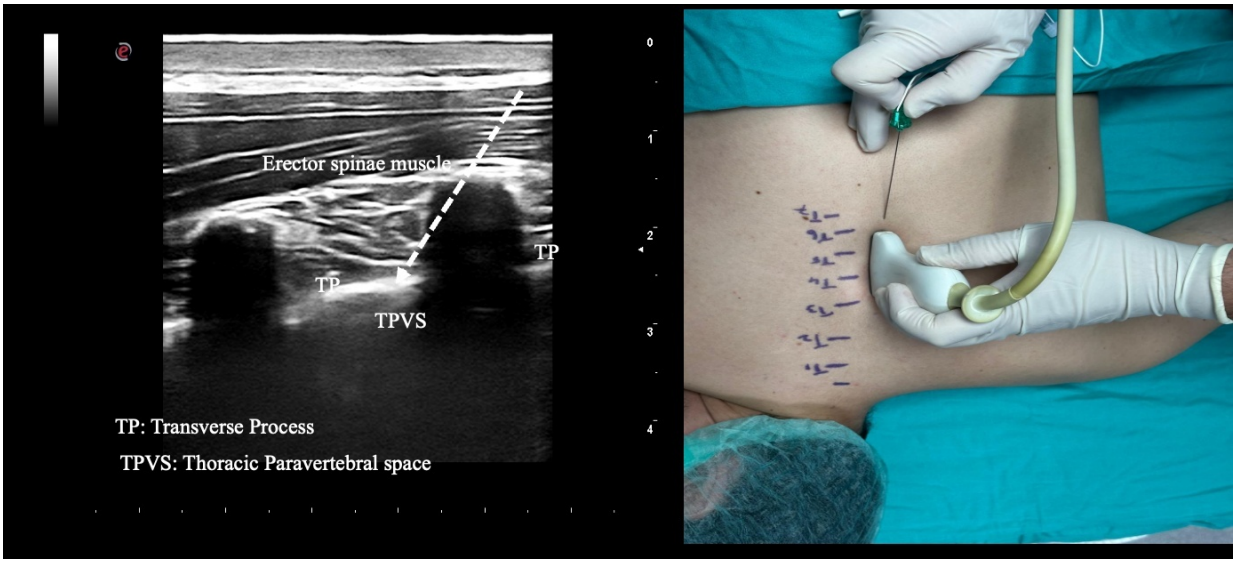

FIGURE 1. Application of the TPVB and an ultrasound image.

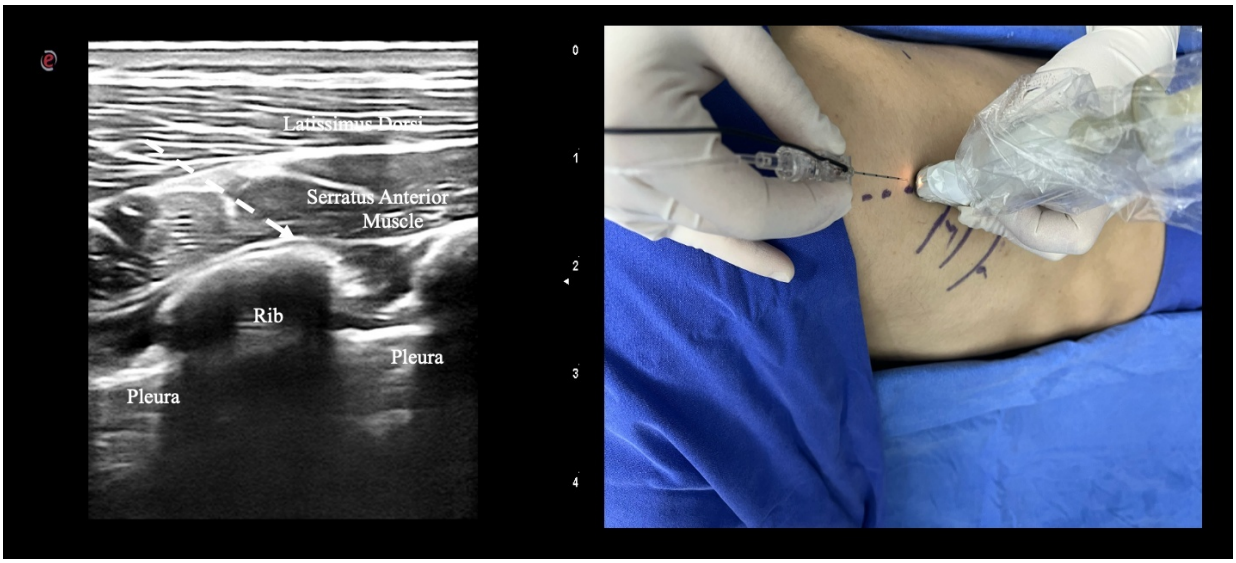

FIGURE 2. Application of the SAPB and an ultrasound image.

normally distributed continuous variables were presented with median and interquartile range (IQR). Categorical variables were summarized as counts and percentages. Comparisons between groups were carried out using an independent samples *t*-test for normally distributed variables and a Mann-Whitney U test for non-normally distributed variables. Associations between two categorical variables were examined by the Chi-square test. A p-value < 0.05 was considered statistically significant.

3. Results

Sixty patients were screened for eligibility in this study. A participation flow chart is shown in Fig. 3. The final analysis included data from 58 patients. The ASA physical status classifications and demographic characteristics of the patients in the two groups were compared (Table 1). The groups were also compared in terms of surgical procedures, anesthesia duration, single-lung ventilation time, and intraoperative remifentanil consumption. No significant differences were observed between the groups (Table 2).

Postoperative morphine consumption was significantly higher at 3, 6, 9, 12, and 24 hours in the SAPB group than in the TPVB group (Table 3). Static visual analog scale (VAS) scores were also higher in the SAPB group at 6, 9, 12, and 24 hours. Dynamic VAS scores were significantly higher in the SAPB group at 9, 12, and 24 hours (Table 4). Effect sizes ranged from medium to large (Cohen's d = 0.65–1.05), suggesting a clinically relevant analgesic advantage for TPVB.

The number of patients requiring rescue analgesia was similar between the groups at 3 and 6 hours, but significantly higher in the SAPB group at 9 and 12 hours ($p < 0.001$ and $p = 0.021$, respectively; Phi coefficients 2.85 and 0.77, both indicating strong associations). No patient in either group required rescue analgesia at 24 hours (Table 5).

A higher incidence of PONV requiring treatment was observed in the SAPB group (12 patients, 40%) compared to the TPVB group (3 patients, 10%; $p = 0.01$, Phi = 0.37, moderate

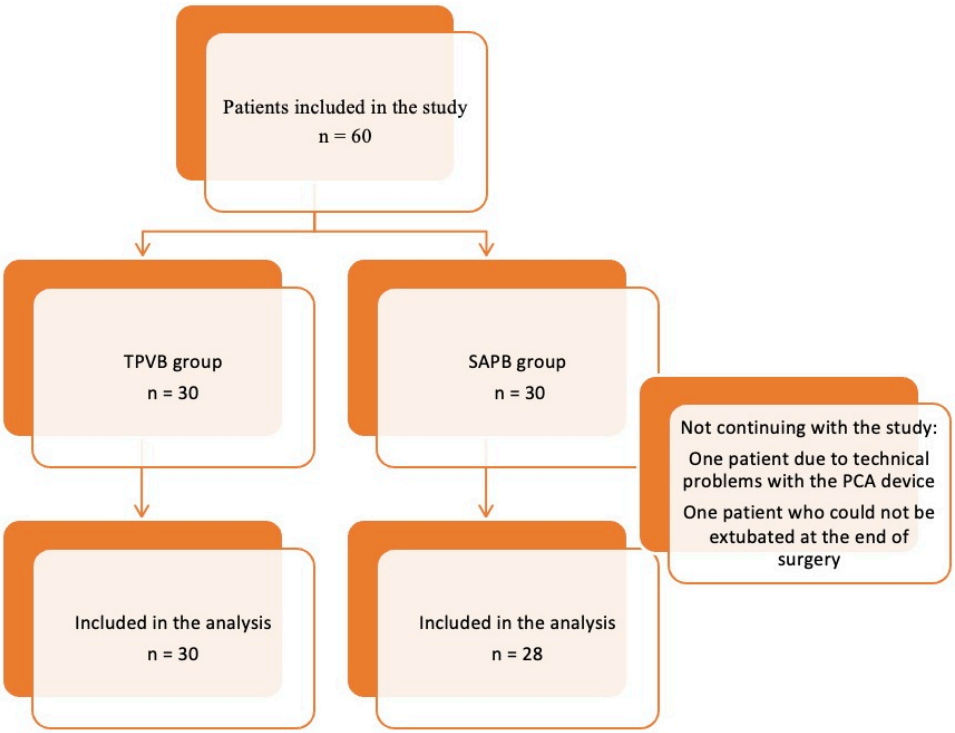

FIGURE 3. Study flow chart: sixty patients were randomized equally into TPVB (n = 30) and SAPB (n = 30) groups. Two patients in the SAPB group were excluded, leaving 28 for analysis, while all 30 in the TPVB group were analyzed. TPVB: thoracic paravertebral block; SAPB: serratus anterior plane block; PCA: Patient-controlled analgesia.

TABLE 1. Demographic data of study participants.

Variable	TPVB (n = 30)	SAPB (n = 28)	*p*
Age (yr), median (IQR) (95% CI)	63.5 (55.25–68.25) (58–66)	56 (23–29.2) (46.4–64)	0.087[a]
BMI (kg/m^2), mean ± SD (95% CI)	26.3 ± 3.73 (24.9–27.7)	26 ± 4.10 (24.4–27.6)	0.721[b]
ASA physical status classification, n (%)			
I	0	0	0.118[c]
II	18 (60)	23 (82)	
III	12 (40)	5 (18)	

TPVB: Thoracic paravertebral block; SAPB: Serratus anterior plane block; BMI: Body mass index; ASA: American Society of Anesthesiologists; IQR: Interquartile range; SD: Standard deviation; n: Count; CI: Confidence interval.
[a]Mann-Whitney U test; [b]Independent samples t-test; [c]Chi-square test.

TABLE 2. Perioperative parameters between the groups.

Variable	TPVB (n = 30)	SAPB (n = 28)	*p*
Surgery, n (%)			
Lobectomy	25 (83)	27 (96)	0.195[a]
Pneumonectomy	5 (17)	1 (4)	
Duration of anesthesia (min), mean ± SD (95% CI)	243.8 ± 64.2 (219.8–267.8)	248.0 ± 52.8 (227.5–268.5)	0.787[b]
Single-lung ventilation duration (min), mean ± SD (95% CI)	141.3 ± 59.4 (119.1–163.5)	149.4 ± 45.1 (131.9–166.9)	0.302[b]
Intraoperative remifentanil consumption (mcg), median (IQR) (95% CI)	1000 (800–1200) (883.5–1200)	1070 (957.50–1400) (1000–1264)	0.082[c]

n: Count; SD: Standard deviation; IQR: Interquartile range; CI: confidence interval; TPVB: Thoracic paravertebral block; SAPB: Serratus anterior plane block.
[a]Chi-square test; [b]Independent samples t-test; [c]Mann-Whitney U test.

TABLE 3. Hourly morphine consumption (mg).

Time point	TPVB (n = 30)	SAPB (n = 28)	*p*	*r*
3rd hour morphine consumption	4 (2–4.25) (2–4)	6 (4–8) (4–7.6)	**0.001**	0.44
6th hour morphine consumption	5.5 (4–6) (4–6)	10 (6.25–10) (8–10)	<**0.001**	0.61
9th hour morphine consumption	6 (4–8) (4–6)	12 (10–13.5) (10–12)	<**0.001**	0.80
12th hour morphine consumption	6 (5–8) (6–8)	13 (12–14) (12–14)	<**0.001**	0.82
24th hour morphine consumption	8 (6–8) (6–8)	14 (12–14) (12–14)	<**0.001**	0.86

Values were presented as median (interquartile range) and 95% confidence interval of the median. The Mann-Whitney U test was used. The bold p-values in the table indicate statistically significant differences ($p < 0.05$).
r: Effect size. TPVB: Thoracic paravertebral block; SAPB: Serratus anterior plane block.

TABLE 4. Postoperative VAS measurements.

Time point	TPVB (n = 30)	SAPB (n = 28)	*p*	*r*
3rd hour static VAS	4 (3–6) (3.2–4)	4 (4–4) (4–4)	0.966	0.01
6th hour static VAS	3 (2.75–4) (3–4)	4 (4–4) (4–4)	**0.004**	0.38
9th hour static VAS	2 (2–3) (2–2)	4 (4–4) (4–4)	<**0.001**	0.71
12th hour static VAS	2 (2–2) (2–2)	3 (2–4) (2–3.6)	<**0.001**	0.52
24th hour static VAS	2 (0–2) (2–2)	2 (2–3) (2–3)	<**0.001**	0.53
3rd hour dynamic VAS	4 (3–6) (4–4)	6 (4–6) (4–6)	0.058	0.25
6th hour dynamic VAS	4 (3–4) (3.2–4)	4 (4–4) (4–4)	**0.020**	0.31
9th hour dynamic VAS	3 (2–4) (3–4)	6 (4–6) (4–6)	<**0.001**	0.63
12th hour dynamic VAS	2 (2–4) (2–3.8)	4 (3–4) (3–4)	**0.001**	0.45
24th hour dynamic VAS	2 (2–2) (2–2)	3 (2–3) (2–3)	**0.001**	0.44

Values were presented as median (interquartile range) and 95% confidence interval of the median. The Mann-Whitney U test was used. The bold p-values in the table indicate statistically significant differences ($p < 0.05$).
r: Effect size. TPVB: Thoracic paravertebral block; SAPB: Serratus anterior plane block; VAS: Visual analogue score.

TABLE 5. Hourly rescue analgesic needs between groups.

Time Point	Response	TPVB (n = 30)	SAPB (n = 28)	*p*	ϕ
3rd hour rescue analgesia required, n (%)					
	Yes	11 (37)	16 (57)	0.194	0.32
	No	19 (63)	12 (43)		
6th hour rescue analgesia required, n (%)					
	Yes	2 (7)	6 (21)	0.138	0.35
	No	28 (93)	22 (79)		
9th hour rescue analgesia required, n (%)					
	Yes	0	15 (54)	<**0.001**	2.85
	No	30 (100)	13 (46)		
12th hour rescue analgesia required, n (%)					
	Yes	0	5 (18)	**0.021**	0.77
	No	30 (100)	23 (82)		
24th hour rescue analgesia required, n (%)					
	Yes	0	0	NA	NA
	No	30 (100)	28 (100)		

n: Count; ϕ: Effect size. The bold p-values in the table indicate statistically significant differences ($p < 0.05$).
Chi-square test was used. NA: Not applicable; TPVB: Thoracic paravertebral block; SAPB: Serratus anterior plane block.

effect size). No other complications, such as hematoma, pneumothorax, or local anesthetic systemic toxicity (LAST), were observed.

4. Discussion

In this study, we found that thoracic paravertebral block (TPVB) was more effective than deep serratus anterior plane block (SAPB) in reducing postoperative opioid consumption and visual analog scale (VAS) pain scores in patients undergoing thoracotomy. Furthermore, the incidence of postoperative nausea and vomiting, as well as the requirement for rescue analgesia, was significantly lower in the TPVB group.

In our study, thoracotomies were primarily performed via a posterolateral approach (through the 5th or 6th intercostal spaces). These incision sites are important when evaluating the anatomical spread of each block [8]. TPVB, by targeting the paravertebral space, anatomically allows both somatic and sympathetic nerve blockade across multiple dermatomes. In contrast, due to the more distal and superficial injection plane of SAPB, coverage at these levels may be less consistent, which could explain the observed differences in analgesic efficacy.

Post-thoracotomy pain is typically severe due to the disruption of intercostal nerves, pleura, and muscles during surgery. Inadequately managed postoperative pain can impair respiratory effort, reduce pulmonary function, and prolong hospitalization. Therefore, optimal pain management is essential. Several regional techniques have been described, including thoracic epidural analgesia (TEA), TPVB, and SAPB. Although TEA has been considered the gold standard, it is associated with potential complications, such as hypotension, urinary retention, and risk of epidural hematoma or abscess. TPVB achieves unilateral somatic and sympathetic nerve blockade by injecting local anesthetic into the paravertebral space, offering effective analgesia with fewer complications. SAPB, a relatively newer fascial plane block, is easier to perform under ultrasound guidance and carries a lower risk of serious complications, although it may be less effective in some cases due to the limited spread of the local anesthetic to the intercostal nerves [9].

In this study, both TPVB and SAPB were performed under ultrasound guidance using the same volume and concentration of local anesthetic (20 mL of 0.5% bupivacaine). We observed significantly lower postoperative morphine consumption and VAS scores in the TPVB group compared with the SAPB group. This is consistent with previous studies in the literature. Amani *et al.* [10] compared TPVB and SAPB using different volumes and concentrations of bupivacaine (TPVB with 20 mL of 0.5%, SAPB with 30 mL of 0.25%) and found lower VAS scores and morphine consumption in the TPVB group. Similarly, Saad *et al.* [11] used 20 mL of 0.5% bupivacaine for TPVB and 30 mL for SAPB and reported lower postoperative opioid use with TPVB. Unlike these studies, we used 20 mL of 0.5% bupivacaine for both blocks, a lower volume than that commonly used for SAPB in the literature (typically 30 mL or more).

Our decision to use a volume of 20 mL for both blocks was based on previously published clinical and cadaver-based anatomical studies. Randomized controlled trials for TPVB have shown that 20 mL provides adequate analgesia, spread, and efficacy after thoracotomy [12]. Although $\geq$30 mL is generally recommended for SAPB in clinical practice, cadaver studies demonstrate that 20 mL can reach the lateral cutaneous branches of intercostal nerves [13]. Therefore, to maintain standardization and minimize local anesthetic use, we selected 20 mL for both groups. Despite this lower SAPB volume, TPVB still provided superior analgesia. In our study, postoperative opioid consumption and VAS pain scores were significantly lower in the TPVB group compared with the SAPB group, and this finding is consistent with previous studies using different volumes.

When evaluating rescue analgesia requirements, both groups had similar needs in the first 6 hours. However, starting from the 9th hour, the SAPB group required significantly more rescue doses. This difference may be attributed to the more distal site of SAPB application and its limited sympathetic blockade, which could result in a shorter duration of analgesia. In contrast, TPVB may provide longer-lasting analgesia by affecting both the intercostal nerves and the sympathetic nerves, and potentially spreading into the epidural space [14].

The statistically significant difference in 24-hour morphine consumption between the TPVB and SAPB groups, as well as the clinical relevance of the 6 mg difference in opioid use between the two groups, should also be taken into consideration. Literature suggests that reductions in opioid consumption may decrease opioid-related side effects in specific surgical populations [15].

SAPB has been shown to be a highly effective technique for postoperative analgesia in patients undergoing video-assisted thoracoscopic surgery (VATS) [16, 17]. This is likely because SAPB covers most VATS incisions and chest tube sites. Authors have described SAPB as simple, safe, and effective, with fewer complications [16]. For thoracotomy, however, SAPB is less effective compared with central blocks [7, 18].

In terms of intraoperative opioid consumption, both blocks showed similar efficacy, which may reflect comparable intraoperative analgesic effects. Saad *et al.* [11] reported a similar finding, suggesting that both techniques can attenuate intraoperative nociceptive responses. Hemodynamic parameters remained stable and exhibited no significant differences between groups in our study, which is consistent with the findings of Mahmoud *et al.* [19] and Saad *et al.* [11], who also observed no significant hemodynamic differences between TPVB and SAPB.

PONV was more frequent in the SAPB group, which may be explained by higher morphine consumption. This finding is in line with known dose-dependent side effects of opioids [20]. One patient in the TPVB group developed Horner syndrome, which we attributed to unintended cephalad spread of the local anesthetic, as supported by previous reports [21, 22].

In our study, no local complications, such as hematoma, pneumothorax, or signs of local anesthetic systemic toxicity (LAST), were observed in either group. The absence of local adverse events, including hematomas, may be attributed to the consistent use of ultrasound guidance. Furthermore, patients

receiving anticoagulant therapy were excluded, as anticoagulation is considered a relative contraindication for central neuraxial and paravertebral techniques due to the potential risk of bleeding and hematoma formation in these anatomical regions [23]. This approach is consistent with current safety recommendations and aims to minimize the risk of serious procedure-related complications.

Both TPVB and SAPB are effective for post-thoracotomy pain management; however, patient selection is crucial. TPVB may be preferred for extensive thoracotomy or patients with severe pain, while SAPB may be better for patients at higher risk of bleeding or those with contraindications to deeper blocks. Contraindications such as coagulopathy, infection, or severe deformity should guide the choice of technique.

This study has several limitations. First, we did not assess the sensory dermatomes to confirm block spread. In our clinical experience, most patients find the repeated pinprick and cold tests uncomfortable after the block during the preoperative period. Therefore, we did not perform these tests to prioritize patient comfort. Second, blinding was not feasible in our study due to the different patient positioning required for TPVB and SAPB procedures. This represents a limitation, as the lack of blinding may introduce potential bias in outcome assessment.

Another limitation is that although the literature, particularly regarding regional anesthesia techniques, demonstrates earlier mobilization and reduced length of hospital stay, these two techniques were not evaluated in our study. However, for a statistically meaningful assessment, the sample size should be calculated with these parameters in mind. Although our study demonstrated that TPVB resulted in lower opioid consumption, reduced VAS scores, and decreased incidence of PONV, we did not collect or analyze data to determine whether it also led to shorter mechanical ventilation and/or hospital stay.

Finally, additional limitations include the inability to estimate the duration of the block effect because the time to first rescue analgesia was not recorded, the absence of long-term follow-up to assess the development of chronic pain, and the lack of cost analyses.

5. Conclusions

In conclusion, both thoracic paravertebral block (TPVB) and serratus anterior plane block (SAPB) can be considered valuable components of multimodal analgesia for thoracotomy. Within the limitations of this study, TPVB provided more favorable analgesic outcomes. These included significantly lower VAS pain scores, reduced opioid consumption, a lower incidence of PONV, and decreased rescue analgesia needs. Together, these findings suggest that TPVB may offer a more reliable and comprehensive analgesic effect in thoracotomy patients. However, our study did not assess long-term outcomes such as hospital stay, pulmonary recovery, or chronic pain. Larger and well-designed trials are required to confirm these findings and better define the roles of TPVB and SAPB in different clinical settings.

6. Key messages

6.1 What is known

1. Thoracic paravertebral block (TPVB) and serratus anterior plane block (SAPB) are both used to manage post-thoracotomy pain.
2. In studies conducted comparing TPVB and SAPB with different local anesthetic volumes and concentrations, it has been found that TPVB provides more effective analgesia.

6.2 What is new

1. This randomized controlled study directly compares TPVB and deep SAPB using the same volume and concentration (20 mL of 0.5% bupivacaine) in thoracotomy patients.
2. TPVB was found to result in significantly lower opioid consumption, better pain scores, and fewer side effects than SAPB.
3. The study suggests that TPVB should be preferred over SAPB as part of multimodal analgesia for thoracotomy, especially when technical expertise is available.

AVAILABILITY OF DATA AND MATERIALS

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

AUTHOR CONTRIBUTIONS

NNY and TÇ—designed the research study; performed the research; wrote the manuscript. SC and HUY—provided help and advice. HFS and AE—contributed primarily to data collection and provided valuable support during the research process. In addition, they contributed to the organization of patient follow-up and assisted in managing study documentation. Their role is expected to expand further in future projects, including potential involvement in broader methodological planning and critical revision of study design. NNY—analyzed the data. NNY, TÇ and SC—edited the manuscript. All the authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Approved by the Kocaeli University Ethics Committee (KAEK/10.bI.02; E-66175679-514.04.01-787040). Written informed consent to participate was obtained from all individual participants included in the study.

ACKNOWLEDGMENT

The authors would like to thank the participants of the study for their valuable contribution.

FUNDING

This study was supported by the Kocaeli University Scientific Research Project Unit (Project Code: TTU-2022-2881).

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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How to cite this article: Nur Nazire Yucal, Tülay Çardaközü, Sevim Cesur, Hadi Ufuk Yörükoğlu, Hüseyin Fatih Sezer, Aykut Eliçora. Thoracic paravertebral versus serratus anterior plane block in thoracic surgery—a randomized trial. Signa Vitae. 2026; 22(2): 47-54. doi: 10.22514/sv.2025.179.