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Comparison of continuous thoracic epidural block and continuous thoracic paravertebral block for management of post thoracotomy pain: a randomised trial

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ABSTRACT

Aim: Pain after thoracotomy is one of the most severe in clinical practice and more effective analgesia can be achieved by combining systemic and regional techniques. Though thoracic epidural analgesia (TEA) is the gold standard in the treatment, its application can be restricted due to side effects and contraindications. We investigated the hypothesis that thoracic paravertebral block (TPVB) reduced morphine consumption, pain scores, and side effects as much as TEA after thoracotomy.

Material and Method: Fifty patients who underwent elective posterolateral thoracotomy were included in this study. Patients were randomly allocated into two groups as TEA (group I, n = 25) and TPVB (group II, n = 25). Postoperative consumption of patient-controlled morphine, visual analog scores (VAS), hemodynamic parameters, and side effects were collected in 72 hours. Additionally, pulmonary function tests (PFT) values were recorded.

Results: Postoperative VAS values during rest were comparable between the groups ($p > 0.005$) and they did not have significantly difference postoperative VAS values during coughing ($p > 0.005$). The cumulative morphine consumption was higher in Group 2 ($p < 0.05$). Side effects were comparable between the groups II ($p > 0.05$).

Conclusion: We conclude that TEA provided more effective analgesia than TPVB in thoracotomy patients in the early postoperative period with comparable side effects.

Keywords: Paravertebral block; post-thoracotomy pain; thoracic epidural block; visual analog scale

INTRODUCTION

Pain after thoracotomy is one of the most severe in clinical practice, and inadequate pain management may be related to outcome (1). Many methods such as systemic analgesia, thoracic epidural analgesia (TEA), cryoanalgesia, thoracic paravertebral blockade (TPVB), intercostal nerve block, and intrapleural analgesia have been used to prevent thoracotomy pain (2-4). Furthermore, more efficient analgesia can be achieved by combining systemic and regional techniques (4,5). Although many new methods such as serratus plane block are used for pain after thoracotomy, TEA and TPVB are still acknowledged (5). Although the epidural block technique is considered to be a gold standard for the treatment of pain after thoracotomy, paravertebral blockade technique has fewer side-effects (2). So, the paravertebral blockade is considered to be a good alternative to epidural analgesia (3,4,6).

Morphine is widely used in the treatment of postoperative pain. Thus, it is an important component of multimodal analgesia to prevent severe pain after thoracotomy (4). However; the potential side effects of this agent are a major concern while using it. The regional techniques used for postoperative pain management can reduce the morphine consumption and the possible side effects associated with these drugs (4,7-10).

Primary and secondary outcomes were determined as morphine consumption for postoperative 24 hours, visual analog scale (VAS) scores, and side effects. In this study, we tested the hypothesis that TPVB reduces morphine consumption, pain scores, and side effects as much as TEA after thoracotomy.

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MATERIAL AND METHOD

The study was conducted with a randomized, prospective design after obtaining approval from the Keçiören Training and Research Hospital Ethics Committee (Date: 04.02.2013, Decision No: B.10.4.ISM.4.06.68.49/). All patients were informed about the procedure and informed consent was also obtained from all patients. All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

Fifty patients aged 18-65 years who were in the American Society of Anesthesiologists (ASA) I-III physical status. Patients were randomly assigned to two groups as TEA (Group I, n = 25) and TPVB (Group II, n = 25). Randomization was performed using computer-generated random numbers. Blinding was performed by concealing information in closed opaque envelopes.

Patients who have chronic pain, mental illnesses, anticoagulation therapy, bleeding disorder; alcohol-illicit drug abuse, allergy to local anesthetics, patients with infection in the intervention area, and patients who did not permit regional anesthesia were excluded from the study.

Midazolam 0.03 mg kg-1 was administered to all patients intravenously (iv) in the premedication room 30 minutes before the operation to prevent anxiety. Preoperative systolic arterial pressure (SAP), diastolic arterial pressure (DAP), mean arterial pressure (MAP), peripheral oxygen saturation (SpO_2), and heart rate (HR) were monitored. 25 mcg IV fentanyl citrate was given to prevent anxiety and pain during the regional intervention.

The catheter insertion site was covered with a sterile technique after the skin was cleaned with povidone-iodine. Group I received 3 mL of 1% prilocaine for skin anesthesia, then an epidural catheter (Perifix®, Braun, Melsungen, Germany) was inserted through the thoracic (Th) Th5-6 or Th6-7 intervertebral space with median approach using the hanging drop technique, and the catheter was advanced 3 cm to cephalad. Later on, the patients were positioned in the supine position, and 5 ug/ mL-1 (1: 200.000) adrenaline and 3 mL 2% lidocaine were administered through the epidural catheter to exclude vascular or intrathecal injection. Group I was given 5 mL-1 of 0.5% bupivacaine for thoracic epidural anesthesia. The bilateral blockade was assessed by the pin-prick test. Infusion of bupivacaine at a concentration of 0.166% with a 270 mL elastomeric infusion pump was initiated for epidural analgesia at a rate of 7 mL/h during and for three days after the operation.

The insertion site was identified as 2.5 cm laterally of the spinous process at the level of Th5- Th7 and 3 mL of 1 % prilocaine was applied for skin anesthesia in group II. The nerve stimulator (Plexygon, Vycon®, Padova, Italy) was set up at 0.1 ms, a frequency of 2 Hertz, and a current of 2.5 mA. The 100 mm and 18 gauge (G) peripheral nerve stimulator needle (Techniplex, Vygon, Ecouen, France) was advanced. After the transverse process was felt with the needle, the needle was pulled back and directed 1 cm towards the upper side of the transverse process. The current was gradually reduced to 0.5 mA, and the paravertebral space was expanded with 10 ml of normal saline after determining that contractions were present in the intercostal muscles. The catheter was advanced 3 cm from the needle tip. Then, the catheter was fixed on the skin. The patients were supine and 5 ug/ mL-1 (1: 200,000) adrenaline and 3 mL 2% lidocaine were administered through the paravertebral catheter to avoid vascular or intrathecal injection. Using a pinprick test, to determine of block level after TPVB. Infusion of bupivacaine at a concentration of 0.25% with a 270 mL elastomeric infusion pump was initiated for paravertebral analgesia at a rate of 7 mL / h during and for three days after the operation.

Anesthesia induction was performed using 2 mg kg-1 propofol, 0.1 mg kg-1 vecuronium bromide and 1.5 μg / kg-1 fentanyl citrate. Anesthesia management was maintained with 2-3% sevoflurane in oxygen/ air mixture and fentanyl boluses in both groups. A 0.03 mg kg-1 vecuronium was administered for the management of neuromuscular blockade. The HR < 50 beats/min which lasted longer than 1 min was defined as bradycardia and hypotension as 20% decrease compared to the preoperative value of MAP. The fluid infusion was increased in case of hypotension. Ephedrine 5-10 mg IV was administered if there was no response. Atropine sulfate 0.015 mg kg-1 IV was planned to be administered in case of bradycardia.

The SAP, DAP, MAP, HR, SpO_2, visual analog scale (VAS) measurements; VAS rest (VASR), and VAS coughing (VASC) scores were recorded on the postoperative 30th minutes and 1st, 2nd, 6th; 12th, 20th, 24th; 36th, 48th, and 72nd hours. Pulmonary function test (PFT) (One Flow Soft V 1.2, Clement Clarke Int, Harlow Essex, England) was performed on the first, second, and third postoperative days, and the results were recorded.

In the early postoperative period, patients received 1 mg morphine IV bolus as an additional analgesic until the first VAS score was less than four, and these were recorded as additional analgesic requirements. A patient-controlled analgesia pump, which was programmed to deliver morphine 1 mg boluses with a lockout interval of 15 min, was attached to the patient for rescue analgesia. A total of 24 hours of morphine consumption was recorded for every patient. Each group received dexketoprofen 50

mg IV every twelve hours and paracetamol 1 gr IV every six hours on the postoperative first day. Paracetamol tablets (500 mg) were administered four times a day, and dexketoprofen tablets (25 mg) twice daily in addition to paravertebral and epidural infusion on the second and third postoperative days. Possible side effects such as hypotension, bradycardia, nausea-vomiting; itching, urinary retention, sedation, and motor block were also recorded. The suprascapular block was performed in case of ipsilateral shoulder pain. The block was applied to all patients by the same anesthesiologist. VAS follow-ups of patients were performed by a pain management nurse; who was blinded to the type of block applied to the patient.

Statistical Analysis

The distribution of continuous variables was investigated with the Shapiro-Wilk test. Descriptive statistics were expressed as mean±standard deviation or median (minimum-maximum) for continuous variables, and the number of cases (%) for nominal variables. The significance of the difference between the groups in terms of means was investigated with the student's t-test and the significance of the difference in terms of median values was investigated with the Mann-Whitney U test. Nominal variables were assessed by Pearson's Chi-Square, Fisher's Exact Result Chi-Square, or Likelihood Ratio test. Analysis of variance was used in repeated measures in evaluating hemodynamic measurements. The Greenhouse-Geisser test was used to examine the importance of group-time interaction. The percentages of change between the observation times which were considered clinically important were calculated and compared among the groups when the group-time interaction was found to be significant. The results with a p-value of < 0.05 were considered significant. However, Bonferroni correction was performed to examine type I error in all possible sub-analyses.

A sample size of 25 patients by the group was calculated to detect a significant difference of 20% or more in morphine consumption with a power of 80% and a significance level of 5% error to test the statistical importance by using G-Power for Mac OS X (Universitat Düsseldorf version 3.1). Data were analyzed using SPSS (Statistical Package for Social Science) software package program for Windows 11.5.

RESULTS

In the present study, 76 patients undergoing thoracotomy were allocated randomly into two groups. 26 patients were excluded from the study. Fifty patients were eligible for the study (**Figure**).

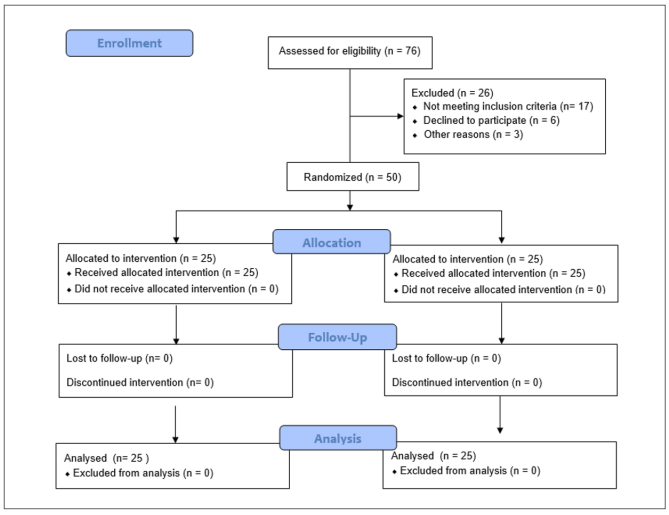

Figure. Flow diagram of the participants.

No significant difference was found between the groups in demographic data, type of surgery, and duration of surgery (p > 0.05) (**Table 1**).

Table 1. Demographic and clinical characteristics of the patients

	TEA group	TPVB Group	p
Age(year)	52.2±11.9	47.7±15.0	0.240
Male	16 (64.0%)	18 (72.0%)	0.544
Female	9 (36.0%)	7 (28.0%)	
Weight (kg)	71.9±11.8	72.3±12.1	0.906
Height (meter)	1.68±0.08	1.69±0.07	0.669
BMI (kg/m^2)	25.3±3.4	25.2±3.4	0.847
Duration of Surgery (min)	180 (75-240)	150 (90-210)	0.555
Intraoperative fentanyl consumption (µg)	119.1±25.3	115.3±22.5	0.560

Data were presented as mean±standard deviation, median range, or percent. BMI: Body mass index; TEA: Thoracic epidural analgesia; TPVB: Thoracic paravertebral block.

The morphine consumption was higher in Group II at the 2nd, 6th, 12th, 20th, and 24th hours (p < 0.05) (**Table 2**). Preoperative and postoperative PFT values were comparable between groups (p>0.05). There was no significant difference in the postoperative MAP measurements between Group I and Group II at each follow-up time (p > 0.005). There was no significant difference at VASR scores between Group I and Group II at each follow-up time (p > 0.005) (**Table 3**). There was no significant difference between the groups in terms of VASC scores (p > 0.005) (**Table 4**).

Table 2. Groups' cumulative morphine consumption in the first postoperative 24 hours.

Follow up times	TEA group		
Mean±SD	TPVB group		
Mean±SD	p		
30th min	1.0±0.9	1.5±1.0	0.090
1st hour	2.5±1.7	3.4±1.8	0.081
2nd hour	4.4±3.8	6.6±3.6	0.042*
6th hour	7.4±5.8	12.1±6.4	0.009*
12th hour	10.6±8.3	16.3±9.0	0.023*

Table 3. Visual Analog Scale scores during rest

VASR	Group I		Group II		P
Follow up times	Mean±SD	Median (Min-Max)	Mean±SD	Median (Min-Max)	
30th min	2.8±2.1	2 (0-7)	4.0±2.2	4 (0-7)	0.049
1st hour	1.8±1.4	2 (0-5)	2.6±1.0	3 (1-4)	0.020
2nd hour	1.6±1.1	2 (0-3)	2.0±0.9	2 (0-3)	0.160
6th hour	1.4±1.0	2 (0-3)	1.9±1.0	2 (0-3)	0.112
12th hour	1.1 1.0	1 (0-3)	1.6±0.9	2 (0-3)	0.055
20th hour	0.9±1.0	1 (0-3)	1.4±1.3	1 (0-5)	0.204
24th hour	1.2 1.0	1 (0-3)	0.7±0.9	0 (0-3)	0.064
36th hour	0.8±0.9	1 (0-3)	0.6±0.8	0 (0-2)	0.331
48th hour	1.1 1.1	1 (0-3)	0.5±0.7	0 (0-2)	0.039
72th hour	0.8±0.8	1 (0-2)	0.2±0.4	0 (0-1)	0.005

Data presented as mean±Standard deviation and minimum-maximum. TEA: Thoracic epidural analgesia; TPVB: Thoracic paravertebral block; VASR: Visual Analog Scale during rest.

Table 4. Visual analogue pain scale at coughing.

(VASC)	Group I		Group II		P
Follow up times	Mean±sd	Median (Min-Max)	Mean±sd	Median (Min-Max)	
30th min	2.8±2.1	2 (0-7)	4.2±2.0	4 (1-7)	0.019
1st hour	2.1±1.5	2 (0-5)	2.0 ±0.9	3 (1-4)	0.034
2nd hour	1.9±1.1	2 (0-4)	2.5 ±0.7	3 (1-3)	0.030
6th hour	1.7±1.1	2 (0-3)	2.4±1.0	3 (1-4)	0.033
12th hour	1.7±1.0	2 (0-3)	2.2±0.9	2 (1-3)	0.075
20th hour	1.7±1.1	2 (0-4)	2.1±1.4	2 (0-6)	0.512
24th hour	1.7±1.2	1 (0-4)	1.5±0.9	1 (0-4)	0.705
36th hour	1.5±1.1	1 (0-4)	1.2±1.0	1 (0-4)	0.403
48th hour	1.6±1.0	1 (0-3)	1.0±0.9	1 (0-3)	0.028
72th hour	1.4±0.9	1 (0-3)	0.7±0.7	1 (0-2)	0.006

Data presented as mean±Standard deviation and minimum-maximum.
TEA: Thoracic epidural analgesia; TPVB: Thoracic paravertebral block; VASC:Visual analogue pain scale at coughing.

20th hour	14.2 ±11.1	22.9±13.8	0.018*
24th hour	16.3±11.0	24.5±14.2	0.027*

*($p < 0.05$): The results were statistically significant between the groups. Data presented as mean + standart deviation. TEA: Thoracic epidural analgesia; TPVB: Thoracic paravertebral block; SD: Standard deviation

Hypotension and bradycardia, which were not significant, were more frequently observed in Group I ($p > 0.05$). One patient in Group I had nausea and vomiting while two had motor blockade. No itching and urinary retention were observed in both groups. When patients were evaluated in terms of ipsilateral shoulder pain 6 patients Group 1, and 2 patients in Group 2 had shoulder pain ($p > 0.05$).

DISCUSSION

The present study showed that bupivacaine infusion through the elastomeric infusion pump had better analgesic effects in TEA patients who underwent thoracotomy. However, the complication rate was lower in the TPVB group than the TEA group.

Effective treatment of acute post-thoracotomy pain is very important in terms of patient comfort and pulmonary functions (10,11). Atelectasis and pneumonia may develop due to difficulty in breathing and effective coughing, and the respiratory functions of the patient may deteriorate postoperatively. The protection of postoperative respiratory functions after thoracotomy is crucial to prevent potential complications (10-15). In a study comparing the effect of TEA and TPVB on pulmonary functions in patients with post-thoracotomy pain, spirometry values were better on the postoperative 72nd hour in the epidural group (16).

However, Richardson et al. (10) found that postoperative pain scores were significantly lower in patients with preoperative TPVB in thoracotomies and postoperative pulmonary functions were better preserved in these patients. Davies et al. (13) reported that respiratory functions in patients receiving paravertebral analgesia were statistically better at only 24 hours. Gülbahar et al. (17) reported no difference in postoperative respiratory function between the epidural and paravertebral groups in the study conducted in 44 patients who underwent thoracotomy. Respiratory functions were comparable in both groups preserved similarly in the postoperative period in the present study. This was also supported by the low requirement and usage of 24-hour morphine. Thus, impairment of pulmonary function due to the use of morphine in high doses was also avoided.

The efficacy of TPVB and TEA methods on hemodynamic parameters was investigated by many authors. Richardson et al. (14) found that hypotension was observed more frequently in the TEA group when compared to the TPVB method. Karmakar (18) stated that TPVB is a functional method because of the inhibition of neuroendocrine response to surgery by unilateral somatic and sympathetic block. Continuous TPVB administration is a part of balanced analgesia after thoracotomy and due to the lack of side effects; it may be a safe alternative to the TEA method which is considered the gold standard. Lönnqvist et al. (19) observed a 4.6% risk of hypotension due to TPVB catheterization in their trial investigating TPVB complications on 367 patients. In the present study even if hypotension was observed frequently in the TEA group, it was not significant. The high incidence of hypotension in the TEA group can be attributed to the TEA-dependent hemodynamic suppression due to the bilateral blockade of cardiac sympathetic fibers. Morphine and its derivatives are very effective in the treatment of severe pain due to thoracotomy. However, parenteral administration of opioids is known to cause undesirable effects such as respiratory depression, nausea, vomiting, decreased intestinal motility, and increased sphincter tone (20). Postoperative pulmonary

complications were reported to be 64% after parenteral opioid administration and 24% in the cases of epidural analgesia (21). Wu et al. compared the systemic and epidural administration of opioids. The epidural group had lower nausea, vomiting, and sedation scores than the IV opioid group. Nevertheless, complications such as itching, urinary retention, and motor block were more common in the epidural group. Although the mechanism of action was different, the incidence of nausea and vomiting in epidural and intrathecal opioid use was claimed to be similar to that of parenteral usage (22). Complications due to IV morphine administrated in the postoperative 24 hours were very limited in our study. Although morphine consumption was higher in the TPVB group in 24 hours, the average amount of morphine consumption in both groups was quite low. We think that low morphine consumption resulted from multimodal analgesia methods. We also did not encounter paracetamol and dexketoprofen-related adverse reactions in both groups.

Messina et al. (16) compared the efficacy of epidural and paravertebral block in patients undergoing thoracic surgery. They reported that postoperative IV rescue morphine use was underestimated and less morphine consumption was achieved in epidural block cases. Contrarily, Richardson et al. (14) assessed the efficacy of epidural block and TPVB in patients undergoing thoracotomy. Patients in the epidural group needed additional analgesics. Richardson et al. (10) showed that postoperative pain scores were significantly lower in the paravertebral group in another study comparing postoperative continuous epidural and TPVB methods after thoracotomy. In our study, morphine consumption was lower in the TEA group. Considering morphine requirement, effective analgesia was thought to be achieved TEA group.

Ipsilateral shoulder pain common complication in post-thoracotomy patients (23,24). While shoulder pain is often caused by diaphragm irritation due to surgical manipulation, inappropriate positioning of the patients during surgery can also cause shoulder pain. The non-steroid anti-inflammatory drugs administration, suprascapular block, intraoperative phrenic nerve block, or interscalene block might be used for the management of shoulder pain (23-25). In our study, shoulder pain was observed in eight out of 50 patients. Six of these patients were in the TEA group. We performed suprascapular block in patients with shoulder pain, and pain relief was provided to all patients.

Compared with the TEA and TPVB studies (2, 3, 10), the rate of side effects such as hypotension, nausea, vomiting, bradycardia, and motor block was within clinically acceptable limits in this study, and there was no statistically significant difference between the TEA and TPVB groups. Based on this result, we think that TEA is still a preferred method in terms of side effects, especially in patients with thoracotomy.

We have some limitations in this study. First of all the sample size of this study is small and results may need to be confirmed with a larger number of subjects. Even though we evaluate acute postoperative pain, the follow-up of chronic post-thoracotomy pain that may develop can give significant results in comparing TEA and TPVB. In our study, thoracic paravertebral catheter insertion was not performed under US guidance. However, the localization was confirmed using a nerve stimulator. In addition, since the procedure was performed while the patient was awake, the success of the block was evaluated with the pinprick test. The location of the catheter in the intraoperative period was also evaluated by direct observation.

CONCLUSION

Even if morphine consumption was within the clinically limits in both groups, patients who received TPVB needed more morphine doses to achieve sufficient analgesia. We think that TEA is a good alternative in thoracotomy with less morphine consumption and clinically acceptable incidence of side effects.

ETHICAL DECLARATION

Ethics Committee Approval: The study was initiated with the approval of the Keçiören Training and Research Hospital Ethics Committee (Date: 04.02.2013, Decision No: B.10.4.ISM.4.06.68.49/).

Informed Consent: All patients were informed about the application and their informed consent was obtained.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper and that they have approved the final version.

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