

Journal of Investigative Surgery

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/iivs20

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To cite this article: Agâh Abdullah Kahramanlar, Mehmet Aksoy, Ilker Ince, Aysenur Dostbıl & Erdem Karadenız (2022) The Comparison of Postoperative Analgesic Efficacy of Ultrasound-Guided Paravertebral Block and Mid-Point Transverse Process Pleura Block in Mastectomy Surgeries: A Randomized Study, Journal of Investigative Surgery, 35:9, 1694-1699, DOI: 10.1080/08941939.2022.2098544

To link to this article: https://doi.org/10.1080/08941939.2022.2098544

Published online: 17 Jul 2022.

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JOURNAL OF INVESTIGATIVE SURGERY
2022, VOL. 35, NO. 9, 1694–1699
https://doi.org/10.1080/08941939.2022.2098544

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The Comparison of Postoperative Analgesic Efficacy of Ultrasound-Guided Paravertebral Block and Mid-Point Transverse Process Pleura Block in Mastectomy Surgeries: A Randomized Study

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ABSTRACT

Purpose/Aim of the study: The purpose of this triple-blind randomized study is to compare the postoperative analgesic efficacy of Mid-Point Transverse Process Pleura Block (MTP) and Paravertebral Block (PVB) in patients undergoing breast surgery.

Materials and Methods: The study was retrospectively registered on ClinicalTrials.gov (NCT 05332028). A total of 64 patients undergoing unilateral simple mastectomy operation due to breast cancer were included in the study. Before the anesthesia procedure, participants were randomly assigned to one of two groups: Group 1: Participants undergoing PVB or Group 2: Participants undergoing MTP block. All block applications were performed using 20 mL of 0.25% bupivacaine. Routine general anesthesia protocol was performed on all patients. In the postanesthetic care unit, fentanyl infusion was given to all patients postoperatively via a patient-controlled analgesia device. Postoperative fentanyl consumption, time to the first request for analgesia, VAS score values at rest and in motion, and blocked dermatome areas were recorded.

Results: Postoperative total opioid consumption, the number of patients given rescue analgesia, the time requiring postoperative supplemental analgesia, postoperative pain scores at rest and in motion, and blocked dermatome areas at both anterior and posterior lower and upper limits were not different between groups ($p > 0.05$, for all).

Conclusions: It was concluded that ultrasound-guided PVB and MTP blocks have similar postoperative analgesic efficacy in patients undergoing breast surgery. The MTP block may be preferred as an alternative to PVB for breast surgeries with less risk of complications.

ARTICLE HISTORY
Received 26 April 2022
Accepted 29 June 2022

KEYWORDS
Paravertebral block; mastectomy; mid-point transverse process pleura block; opioid consumption; visual analog scale; postoperative pain; analgesia

Introduction

Breast cancer is the most commonly diagnosed malignancy in women and its incidence has been increasing worldwide [1, 2]. It may be treated with different surgical techniques including skin-sparing mastectomy, partial mastectomy, simple or total mastectomy, radical mastectomy, modified radical mastectomy, and lymph node surgery. The surgical technique is selected according to the localization of the tumor, its stage, its spread to the surrounding tissues, and lymph node involvement [3, 4].

Researchers reported serious post-operative pain experiences in women who undergo breast cancer surgery [5]. It is known that postoperative pain increases postoperative morbidity and mortality [6]. So, pain control methods following breast cancer surgery *gain importance. In recent years,* multimodal analgesic methods are being used effectively for postoperative pain management [7, 8]. In particular, ultrasound-guided regional anesthesia techniques provide safer and more successful results for postoperative pain management after breast cancer surgery [9, 10]. Thoracic epidural block, serratus anterior plane block, paravertebral block (PVB), erector spinae plane nerve block, and intercostal blocks are frequently used in mastectomy operations [7].

Many clinicians hesitate to apply the PVB technique due to the risk of serious complications such as pneumothorax [11, 12]. Therefore, the safest and most effective methods are being tried by clinicians. In a study conducted on cadavers, Costache et al. [13] claimed that an MTP block (an injection point midway between the pleura and posterior

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This article has been corrected with minor changes. These changes do not impact the academic content of the article.

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border of the transverse process) provides a paravertebral block due to the paravertebral spread of the local anesthetic agent through fenestrations and septations in the superior costotransverse ligament. They thought that Mid-Point Transverse Process Pleura (MTP) block may be as effective as PVB in postoperative pain management with less risk of possible complications.

Swathi et al. [14] reported that the MTP block leads to the local anesthetic extension through the internal intercostal membrane and paraspinal space and it provides surgical anesthesia and postoperative analgesia in video-assisted thoracoscopic surgeries. Based on this study, we hypothesized that the postoperative analgesic efficacy of MTP block was non-inferior to PVB in mastectomy surgeries. For this purpose, this study was planned to compare the postoperative analgesic efficacy of the PVB and MTP block after unilateral mastectomy surgery. The primary outcome was to compare the postoperative fentanyl consumption in the first 24 hours after surgery. The secondary outcomes were to compare time to the first opioid analgesic request, the amount of rescue analgesics, and postoperative visual analog scale (VAS) pain scores, between groups.

Materials and methods

This prospective randomized, non-inferiority, triple-blind trial was done after ethics committee approval (Ethical Committee of Atatürk University, Medical Faculty, Erzurum, Türkiye). The study was conducted at the Anesthesiology and Reanimation Department of Atatürk University, Medical Faculty, Erzurum, Türkiye from 26 March 2020 to 20 April 2021. The study was retrospectively registered on ClinicalTrials.gov (NCT 05332028; IRB approval and initiation of the study: March 26, 2020; registration of the study: April 18, 2022). This study was conducted on 64 women between the ages of 18 and 65 years, ASA I–III, undergoing unilateral simple mastectomy operation due to breast cancer. Patients with ASA > III, BMI ≥ 35, bleeding diathesis, neurological disease, infections at the needle site, and those undergoing axillary lymph dissection were excluded.

The day before surgery, patients were assessed by a researcher. Written informed consent was obtained from participants after informing them about the study. This study was planned as triple-blind; patients, investigators, and the statistician performing statistical analysis of the results were blinded to the groups. The patients fasted for 8 hours before surgery. Before the anesthesia procedure, demographic data of all patients (age, ASA physical status, height, weight) and baseline values of heart rate and blood pressure were recorded. Vascular access was established for all patients via 22-gauge intravenous (IV) cannula, and premedication was provided using 0.03 mg/kg of IV midazolam. Patients were randomly assigned to Group 1 (Patients undergoing PVB) or Group 2 (Patients undergoing MTP block) for a ratio of 1:1, including 32 patients each, using a computer-generated table of random numbers and concealed sealed opaque envelopes. An investigator opened the envelopes before the block application. Another anesthetist who was blinded to the group assignment was responsible for collecting intra-and postoperative data. All surgeries were done by the same surgical and anesthetic teams.

All blocks were fulfilled by the same anesthesiologist, who had at least five years of experience in the profession, with the help of a linear probe (1–8 MHz) and using 22 G, 100 mm insulated facet tip needles before general anesthesia. Patients were placed in a sitting position, spinous processes were marked starting from the C7 spinous process to the T6 level. Then, patients were placed in the prone position. After cleaning the area with an antiseptic solution, the sterilized linear USG probe (Esaote MyLab30®, CA631 high-frequency probe, United Kingdom) was covered. The linear probe was placed between two transverse processes on the paramedian plane; superior costotransverse ligament, transverse processes, and pleura were consecutively visualized. The linear ultrasound probe was fixed to the T3-T4 vertebra level. After the skin was anesthetized with 2% lidocaine, a 22 gauge 100 mm needle (Stimuplex ®; B. Braun, Melsungen, Germany) was led in a cranial-cephalic direction to the paravertebral gap. Trapezius, rhomboid, and erector spinae muscles were crossed by seeing the tip of the needle. Transverse processes were reached and the intercostal muscles were passed. When the needle reached the paravertebral space after passing through the superior costotransverse ligament in Group 1, and between the mid-point of the posterior border of the transverse process and the pleura in Group 2, the needle location was confirmed with 0.5–1 mL of saline, and 20 mL of 0.25% bupivacaine was injected. Local anesthetic dissemination was observed in both cranial and caudal directions. Thirty minutes after block application, the sensorial block level was evaluated by pinprick test using18-gauge needle (normal sensation: 0, decreased sensation: 1, insensitivity: 2) at the midclavicular line. Sensory block was determined by the patient's verbal response to the stimulus followed by pinprick and the blocked dermatome area was recorded as front and back. The duration from placing the patient in the prone position to removing the block needle following the end of the local anesthetic injection is defined as the block performance time and recorded. Complications developed during the process (such as hypotension, pneumothorax, vascular injury, and local anesthetic toxicity) were recorded.

Routine general anesthesia protocol was performed using 2–3 mg/kg IV propofol, 0.6 mg/kg IV rocuronium, and 2 µg/kg IV fentanyl. Anesthesia was maintained with desflurane, a fresh gas flow of 3 L/min, and a nitrous oxide mixed with oxygen in a 2:1 ratio. During surgery, the patient's systolic, diastolic and average artery blood pressures and oxygen saturation values were recorded in the 5th, 10th, 15th, 20th, 35th, and 50th minutes, and postoperative 1st and 2nd hours. At the end of the operation, neuromuscular block antagonization was performed using sugammadex (4 mg/kg). All patients were extubated and taken to the postanesthetic care unit (PACU). Patients with a modified Aldrete score ≥9 were transferred to the clinic. Intravenous 1 g of paracetamol was

administered to all patients postoperatively and the same dose was repeated every 6 hours. Intravenous 8 mg of ondansetron was administered to all patients, for the prevention of nausea and vomiting. Intravenous 6 mg of ephedrine was used to treat hypotension (a 20% decrease in systolic blood pressure compared to baseline values) and IV 1 mg of atropine was given in case of bradycardia (the heart rate < 45 beats/minute) during the operation. Nausea and vomiting were treated with an IV of 10 mg of metoclopramide.

In the PACU, fentanyl infusion was given to all patients for 24 hours postoperatively via patient-controlled analgesia (PCA) device. The PCA was set at a 10 µg/mL concentration, 10 minutes lockout duration, without basal infusion, with a bolus of 25 µg and 50 µg loading dose. Postoperative fentanyl consumption was recorded as 0–4 hours, 4–8 hours, 8–12 hours, 12–16 hours, 16–20 hours, 20–24 hours, and 24 hours total. Postoperative pain was assessed using VAS (0: no pain, 10: worst imaginable pain) in the postoperative 1, 4, 8, 12, 16, 20, and 24th hours. Patients with VAS score ≥ 4 received 25 mg of rescue meperidine. The incidence of nausea and vomiting was recorded postoperatively. An independent observer blinded to the group assignment followed up with the patients postoperatively.

Time to the first request for analgesia, postoperative fentanyl consumption, and VAS score values at rest and on the movement of the upper arm at postoperative 1, 4, 8, 12, 16, 20, and 24 hours, the duration of block implementation and the duration of surgery were recorded.

Power analysis for the study was calculated using the NCSS-PASS (NCSS LLC, Kaysville, Utah) software. The primary endpoint of the study was the total opioid consumption for the first 24 hours postoperatively. The minimum sample size required for this study was calculated based on Gürkan et al.'s study [15]. They reported that the difference between the group's opioid requirements in the first 24 hours after surgery was 1.5; the common standard deviation within a group was assumed to be 3.43 and 4.15. As a result of a power analysis, the sample size for a group was determined to be 30 patients with a power of 80% and an alpha of 5%. It was planned to include 64 patients throughout the study, 32 patients in each group, considering potential dropouts.

The SPSS 20 package software was used for data analysis. Categorical data were presented as numbers (n) and percentages (%) and numerical data were expressed as mean and standard deviation. The normal distribution of data was evaluated with the Kolmogorov-Smirnov Z test. Parametric data were analyzed using the Independent sample t-test and non-parametric data were analyzed with the Mann-Whitney U test. Analysis of repetitive measurements in intra-group comparisons was done with ANOVA, and analysis of categorical data was done using the chi-square test. The p-value < 0.05 was considered statistically significant.

Results

During the study period, 90 patients were eligible, and 80 patients had inclusion criteria. The study was completed with a total of 64 patients (n = 32, each group) (Figure 1).

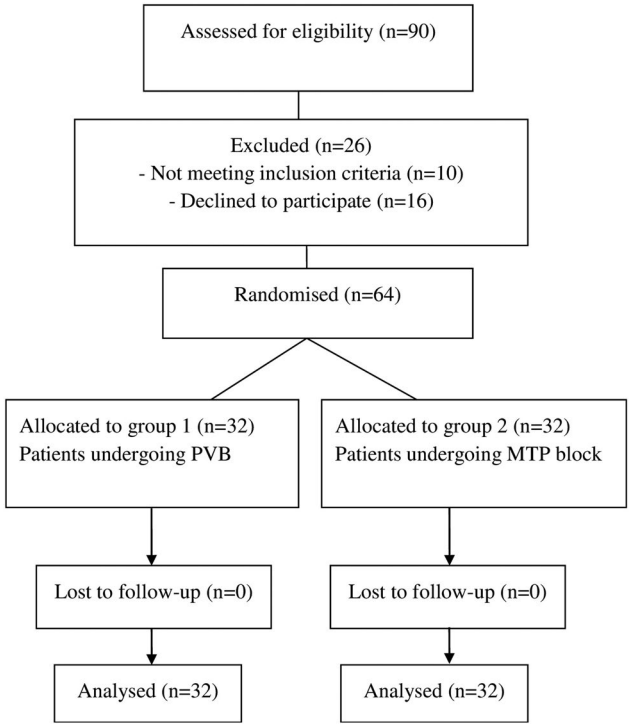


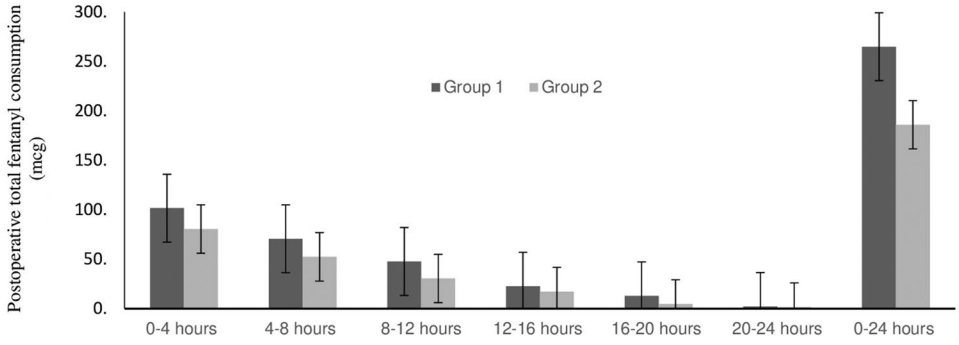
Figure 1. Flowchart of study participants.

Table 1. Demographic and some anesthetic characteristics of the patients.

	Group 1 ($n = 32$)	Group 2 ($n = 32$)	p-value
Age (year)	52.68 ± 6.03	51.09 ± 5.78	0.285
Height (cm)	158.53 ± 6.37	159.34 ± 6.05	0.603
Weight (kg)	74.31 ± 8.49	73.25 ± 8.27	0.614
BMI (kg/m^2)	28.98 ± 3.12	28.77 ± 3.01	0.783
ASA (I/II/III)	2/27/3	5/26/1	0.366
Operation duration (min)	88.31 ± 20.94	91.03 ± 15.45	0.247
Anesthesia duration (min)	129.90 ± 23.14	123.25 ± 21.95	0.242
Block performance time (min)	8.90 ± 1.61	9.43 ± 1.62	0.194

Values are presented as an average ± SD or n. Group 1: Patients undergoing PVB, Group 2: Patients undergoing MTP block.

There were no statistically significant differences between groups in terms of demographic findings, operation time and anesthesia, and block performance time (Table 1). None of the patients had hypotension requiring ephedrine. Also, none of the patients had bradycardia requiring atropine. No statistically significant difference was observed between the groups in terms of postoperative total opioid consumption (Figure 2). No statistically significant differences were detected between groups in terms of the incidence of postoperative nausea and vomiting, the time requiring postoperative supplemental analgesic and the number of patients requiring rescue analgesia (Table 2). Also, both groups had similar postoperative pain scores at rest and in motion (Figure 3). Blocked dermatome areas at both anterior and posterior lower and upper limits were not different in both groups (Table 3).



	0-4 hr	4-8 hr	8-12 hr	12-16 hr	16-20 hr	20-24 hr	0-24 hr
Group 1	101.56±64.73	70.68±63.32	47.65±48.50	22.65±36.12	12.90±27.28	2.15±6.82	264.84±220.23
Group 2	80.46±49.89	52.34±45.06	30.46±34.62	17.18±30.74	4.68±13.37	1.40±5.56	185.93±139.97
P value	0.149	0.051	0.108	0.517	0.132	0.632	0.092

Figure 2. Comparison of postoperative total fentanyl consumption in groups. Group 1: Patients undergoing PVB, Group 2: Patients undergoing MTP block.

Table 2. Comparison of groups in terms of some anesthetic characteristics.

	Group 1($n=32$)	Group 2($n=32$)	p-value
The time requiring postoperative supplemental analgesic (min.)	62.50 ± 40.52	94.06 ± 110.40	0.134
The patients requiring rescue analgesia (n)	16 (%50)	9 (%28.1)	0.073
Nausea n (%)	9 (%28.1)	3 (%9.3)	0.055
Vomiting n (%)	5 (%15.6)	3 (%9.3)	0.708

Values are presented as mean ± SD or n. Group 1: Patients undergoing PVB, Group 2: Patients undergoing MTP block.

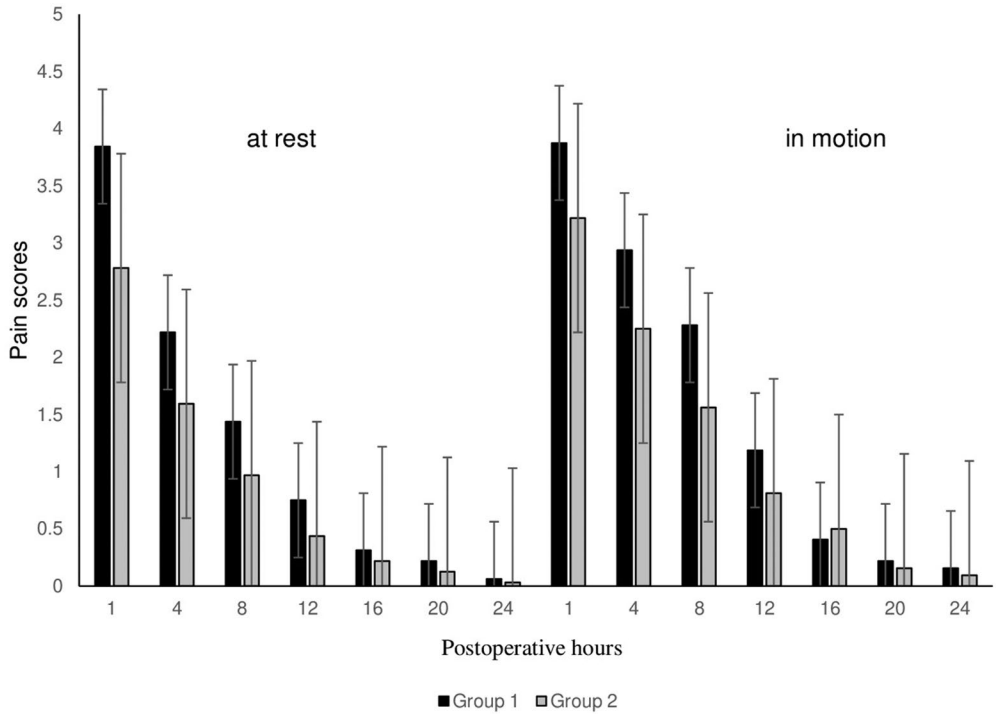


Figure 3. Comparison of postoperative pain scores of groups at rest and in motion. Group 1: Patients undergoing PVB, Group 2: Patients undergoing MTP block.

Table 3. Comparison of groups in terms of blocked dermatome areas.

	Group 1 ($n=32$)	Group 2 ($n=32$)	p-value
Anterior upper limit	T_2 (C_4-T_4)	T_3 (C_4-T_4)	0.088
Anterior lower limit	T_5 (T_2-T_7)	T_5 (T_3-T_7)	0.337
Posterior upper limit	T_4 (C_4-T_4)	T_3 (T_2-T_6)	0.976
Posterior lower limit	T_8 (T_5-T_{10})	T_8 (T_6-T_{10})	0.965

Values are presented as med (min-max). Group 1: Patients undergoing PVB, Group 2: Patients undergoing MTP block..

Discussion

In this study, the effectiveness of PVB and MTP block on postoperative analgesia was compared in patients undergoing breast surgery. The time requiring postoperative supplemental analgesic, the number of patients requiring rescue analgesia, postoperative total fentanyl consumption, and postoperative VAS score values at rest and in motion were found to be similar in both groups. It was concluded that PVB and MTP block applications had similar effects on postoperative analgesia in patients scheduled for breast surgery.

Despite recent advances in breast cancer surgery, this procedure is often associated with postoperative pain [5, 6]. Different analgesia techniques have been identified in the literature so far [14–17]. These methods include epidural anesthesia, pectoral nerve blocks, thoracic paravertebral block (TPVB), serratus anterior plane block (SAP), erector spinae plane block, and MTP block. Effective postoperative pain management is important in patients undergoing breast surgery.

The thoracic paravertebral block is a regional anesthetic technique that provides analgesia to the breast, chest, and abdominal area. In a meta-analysis [18], 24 studies were analyzed. In TPVB, it was observed that single and multiple injections provided similar movement-evoked pain scores after surgery. But pain scores at rest after surgery were observed to be higher in patients who received single injections. This meta-analysis reported that multiple injections increase the risk of vascular damage. This meta-analysis also revealed that an ultrasound-guided block process does not improve block effectiveness, but reduces the risk of complications. In this present study, all blocks were performed using ultrasound, and all blocks were successful and no complications were observed in any patient.

Klein et al. [19] compared the effect of the general anesthesia method and the TPVB added to general anesthesia in patients who underwent unilateral or bilateral breast augmentation or reconstruction surgery. As a result of the study, they reported that pain control was more effective for up to 72 hours, especially in the postoperative first 24 hours in the patients undergoing TPVB. They also reported a lower incidence of nausea and vomiting in the TPVB group in the postoperative first 24 hours and speculated that the reason for this difference was due to the less opioid consumption by patients in the TPVB group. In another retrospective study, Fayh et al. [20] reported reduced postoperative morphine and antiemetic consumption after TPVB in patients undergoing mastectomy. In another study, Kelly et al. [21] retrospectively evaluated 982 unilateral and 340 bilateral PVB patients who underwent breast surgery. They reported that the preoperative PVB block was successful in reducing acute postoperative pain, and rescue analgesics with a low complication rate. Similar to the results of these studies [19–21], we did not observe severe hypotension and bradycardia in patients undergoing PVB. Furthermore, none of our patients developed complications due to PVB block administration. We believe that this is related to the fact that all block applications are accompanied by ultrasound in this current study. Ultrasound guidance for block applications enables viewing of the needle tip and local anesthetic diffusion, as well as monitoring the area to be blocked.

The mid-point transverse process pleura block was designed as an alternative to PVB application considering that the local anesthetic injected from the midpoint of the pleura and the transverse process of the vertebrae spreads in the cephalic and caudal direction, and penetrates to the superior costotransverse ligament, and from there, reaches the paravertebral cavity. It has been reported that compared to the paravertebral block application, MTP block is more easily applicable, with a lower risk of vascular damage, pneumothorax, hypotension, epidural or spinal injection, and nerve damage [22]. Syal et al. [23] published their experiences in the successful perioperative management of two patients who underwent modified radical mastectomies using the ultrasound-guided MTP block. In a prospective, non-inferiority, randomized, double-blinded clinical trial; Swathi et al. (14) compared the postoperative analgesic efficacy of MTP and PVB in patients undergoing thoracic surgeries. In their study, analgesic consumption in the first 24 hours postoperatively was found to be similar in the groups. Also, they observed similar dermatomal distribution, VAS scores at rest and on movement, and complication rates in both groups. Consistent with their results, this present study revealed no differences between groups in terms of blocked dermatome areas, postoperative total opioid consumption, the time-requiring postoperative supplemental analgesic, the number of patients requiring rescue analgesia, and postoperative pain scores at rest and in motion. We speculated that the MTP block is as effective as the PVB for post-operative analgesia in breast surgeries.

This present study is first comparing the effectiveness of the MTP and PVB block on postoperative analgesia in patients undergoing breast surgery. Therefore, the results of our study are novel. The limitation of our study is the absence of a third group that would be undergone only general anesthesia without block. However, the goal of our study was to compare the effectiveness of two different block techniques on postoperative analgesia. Another limitation is that we have got no data about the long-term complications like the chronic postsurgical pain. New studies may be planned to assess the efficacy of the MTP block for preventing chronic postoperative pain after breast surgery.

In a conclusion, ultrasound-guided PVB and MTP block applications have similar efficacy on postoperative analgesia in patients undergoing breast surgery. The MTP block may be used as an alternative to PVB for breast surgeries with less risk of complications. Further studies with a large sample size are needed to detect the

postoperative analgesic effectiveness of PVB and MTP blocks in these patients.

Acknowledgments

We would like to thank Mr. Matt Hadfield and Dr. Mohammad Zafeer Khan for the language editing of the paper.

Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Funding

There is no funding for the research.

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