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Comparative study between intraoperative and postoperative analgesic effect of ultrasound-guided thoracic paravertebral block versus pectoral nerve block in patients undergoing modified radical mastectomy: a randomized controlled trial

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Abstract

Background: The primary goal of modified radical mastectomy is to remove cancerous cells and reduce the risk of breast cancer spreading. This operation is associated with considerable acute postoperative pain and restricted shoulder movement. If this acute pain is neglected most patients will develop chronic post-mastectomy pain, which reduces the quality of life. Regional anesthesia using ultrasound-guided paravertebral nerve block or pectoral nerve block has become an ideal addition to general anesthesia for providing analgesia after breast cancer surgery. This was a randomized clinical trial conducted between February 2018 and February 2019. This study compared between the two nerve blocks regarding the efficacy in terms of analgesic consumption.

Results: The study included 30 female patients who were undergoing modified radical mastectomy under general anesthesia and randomly divided into 2 groups of 15 patients in each. This study showed there was a statistically significant increase in the amount of total fentanyl used intraoperatively in TPVB group than PECs group with p value = 0.008. Less VAS score in PECS group with statistically significant difference between groups at 4 h, 5 h, 6 h, and 8 h. More time needed for 1st requested rescue analgesia in PECS group with P value = 0.013. Patients in PECS group received a less total dose of fentanyl in the first 24 h postoperative with P value = 0.040. There was no statistically significant difference found between groups regarding postoperative complications.

Conclusions: In female patients undergoing breast surgeries, the PECs block can be used efficiently and safely, providing better pain relief than the TPVB and reducing intraoperative and postoperative opioids use.

Keywords: Paravertebral block, Pectoral nerve block, Radical mastectomy

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Background

The primary goal of modified radical mastectomy is to remove cancerous cells and reduce the risk of breast cancer spreading. This operation is associated with considerable acute postoperative pain and restricted shoulder mobility. If this acute pain is neglected most patients will develop chronic post-mastectomy pain, which reduces the quality of life (Wahba & Kamal, 2013).

Regional anesthesia using ultrasound-guided paravertebral nerve block or pectoral nerve block has become an ideal addition to general anesthesia for providing analgesia after breast cancer surgery. Using ultrasound reduces the risk of penetrating the pleura and vascular puncture, reduces failure rates of block and local anesthetic toxicity (Barrington & Uda, 2018). Benefits include a decrease in intra-operative narcotics consumption, reduction in post-operative nausea and vomiting, prolonged post-operative pain relief, better shoulder range of motion and decrease length of hospital stay (Kulhari et al., 2016).

Several interfascial plane blocks have been described. Pectoral nerve block (PECs) was first described by Blanco et al. relies upon the placement of local anesthetic into the plane lying between the pectoralis major and the pectoralis minor muscles (pecs 1 block) which was devised to anesthetize the medial and lateral pectoral nerves. The Pecs II block is an extension that involves a second injection lateral to the Pecs I injection point in the plane between the pectoralis minor and serratus anterior muscles. These novel techniques result in blocking the medial and lateral pectoral nerves in addition to lateral branches of intercostal nerves (Blanco et al., 2012).

Thoracic paravertebral block (TPVB) is the technique of injecting local anesthetic adjacent to the thoracic vertebra into the Paravertebral space, where the spinal nerves emerge from the intervertebral foramina. This results in ipsilateral somatic and sympathetic blockage of the nerve in several adjacent thoracic dermatomes above and below the injection site (Gupta et al., 2017).

A promising recently described technique in the context of surgical pain of radical mastectomy is the erector spinae plane block. A meta-analysis involving 679 patients was done to verify the analgesic efficacy and safety of the block in patients underwent breast cancer surgery and showed a significant reduction in morphine consumption at the first 24 h after surgery, lower pain scores than the GA group, significantly reduce in the intraoperative consumption of fentanyl and the incidence of PONV (Zhang et al., 2021).

Aim of the study

To compare the efficacy and safety of ultrasound-guided PECs II block versus the thoracic paravertebral block

(TPVB) in addition to general anesthesia for intraoperative and postoperative analgesia within 24 h after a modified radical mastectomy.

Methods

This randomized prospective comparative clinical study was carried out after approval of the Research Ethics Committee (REC), number FMASU M D 68/2018 and obtaining written informed consent from the patient. ASA grade II female patients in the age group of 18–65 years, body mass index (BMI) less than 40 who were undergoing modified radical mastectomy under general anesthesia between February 2018 and February 2019, were included. This study was registered as clinical trial in the Pan African Clinical Trials Registry (PACTR) and, identification number for registry is PACTR202112739714566.

Exclusion Criteria were patient refusal, block site infection, coagulopathies (INR > 1.6 and platelets < 100000), any organ dysfunction such as severe cardiac, pulmonary, renal, or liver dysfunction, systemic infection, dementia, or known hypersensitivity to local anesthetic agents

Ethical considerations

Thorough preoperative assessment was done which includes full history taking, number of fasting hours, clinical examination, routine laboratory investigations including complete blood count (CBC), liver function test (LFT), kidney function test (KFT), prothrombin time (PT), and partial thromboplastin time (PTT).

Study tools

The study included 30 female patients who were undergoing modified radical mastectomy under general anesthesia and randomly divided into 2 groups of 15 patients in each. Group A received PECs block and group B received TPVB. During the pre-anesthetic visit, the patients were explained about the study purpose, advantages, and risks of the procedure and instructed to demand analgesia as per requirement. Patients were educated about the 10 cm visual analogue scale (VAS) during the pre-operative assessment. All the patients were kept nil orally for 8 h before surgery, and pre-medication with Midazolam 2 mg and Ondansetron 4 mg was given 30 min before surgery.

All patients received general anesthesia. Pre-oxygenation was done with 100% oxygen for 3 min. the induction was done with propofol 2 mg/kg intravenous (IV), fentanyl 1 µg/kg IV, and atracurium 0.5 mg/kg IV to facilitate endotracheal intubation. Maintenance was done with Mac of isoflurane 1.2% and monitored with end-tidal gas analyzer. Muscle relaxation was maintained with atracurium 0.1 mg/kg IV with monitoring of

neuromuscular blockade using train of four every 20 min over the path of the ulnar nerve and response was seen in thumb twitches.

For group A (Pecs II block), the goal of the Pecs II block was to infiltrate two fascial compartments by dividing the dose of local anesthetic (0.2 mL/kg of bupivacaine 0.25) between the pectoral nerves (the pectoral fascia and clavipectoral fascia) and under the pectoralis minor muscle (between the clavipectoral fascia and the superficial border of the serratus muscle). Block was performed with the patient in a supine position after intubation, placing the ipsilateral upper limb in abduction position with a 22-gauge spinal needle using an ultrasound machine. The main landmarks to identify are the pectoralis major and pectoralis minor muscles and the pectoral branch of the thoraco-acromial artery. In the paramedian sagittal plane, the operator tried to find the coracoid process in the US. The transducer's caudal border was moved laterally, while the proximal border remained unchanged. The proper fascial plane was confirmed by hydro-dissection to open the space between the pectoralis muscles. The second injection was made at the anterior axillary line at the level of the third rib between pectoralis minor and serratus anterior muscles.

For group B (TPVB), ultrasound-guided PVB was carried out with the patients in the lateral position after intubation. It is performed unilaterally with ultrasound guidance on the surgical side with a 22-gauge spinal needle. The linear transducer is placed longitudinally parallel and medially in search of the spinous process of T4. Then, the probe was moved laterally in search of the transverse process. Between the bright hyperechoic cortices of the transverse process and the underlying acoustic shadow, costotransverse ligament was delineated; paravertebral space was confirmed by viewing the CTL and the underlying echogenic line (pleura). The needle was advanced in the plane, and 20 ml of LA (0.2 mL/kg of 0.25% bupivacaine) is injected in the paravertebral space.

After completion of surgery, residual neuromuscular blockade was antagonized with neostigmine 0.05 mg/kg IV. Recovery from the neuromuscular block was assessed using the train of four. Satisfactory recovery had not occurred until the train of four ratio was at least 0.7. All patients were extubated and transferred to the post-operative ward.

Primary outcome measure of the study was to compare between the two nerve blocks regarding the efficacy in terms of analgesic consumption of total fentanyl dose used. Secondary outcome measures were postoperative analgesia duration (time to first rescue analgesia), post-operative pain scores which was assessed using a visual analogue scale (VAS, 0–10 as 0 = no pain and 10 = worst imaginable pain) and whenever the VAS > 4,

fentanyl 0.5 µg/kg IV was given. Intraoperative hemodynamics were recorded before induction, after induction, and then every 15 min until the end of surgery. If mean arterial pressure exceeded 20% of baseline for two consecutive readings, a fentanyl 0.5 µg per kg iv bolus was given. Postoperative hemodynamic and any complications such as nausea, vomiting, LA toxicity, vascular puncture, pleural puncture, and pneumothorax were also recorded.

Statistical analysis

Data were collected, revised, coded, and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The continuous variables were presented as mean, standard deviations and ranges when parametric. Also, categorical variables were presented as number and percentages. The comparison between groups regarding categorical variables was done by using *chi-square test* and/or *Fisher's exact test* when the expected count in any cell was found less than five. The comparison between two groups regarding continuous variables and parametric distribution was done by using the *Independent t test* while with non-parametric distribution was done by using the *Mann-Whitney test*. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, p value < 0.05 indicated statistical significance.

Sample size calculation

Using PASS program, setting alpha error at 5% and power at 9% results from previous study (Kulhari et al. 2016), showed that the mean morphine consumption among group 1 received the Pecs II block was 3.90 ± 0.79 compared to 5.30 ± 0.98 in group 2 who received TPVB group. Based on this study and considering 20% drop out rate, the needed sample is 15 cases for each group.

Results

To minimize selection bias, we used randomized exact matching to form two study groups; Fig. 1 presents details of the patient-selection process. As regards age, BMI, and duration of operation, there were insignificant differences between the PECS group (A) and TPVB group (B), while there was a statistically significant increase in the intraoperative heart rate in group B than group A at 45, 60, 75, 90, and 120 min with p value = 0.045, 0.043, 0.0009, 0.028, and 0.010 respectively as well as higher increase in the intraoperative mean arterial blood pressure at 45, 60, 75, 90, and 120 min in group B than group A with p value = 0.021, 0.035, 0.015, 0.039, and 0.042 respectively (Tables 1 and 2).

As regards the amount of total fentanyl used intraoperative, there was statistically significant increase in the

Table 1 Comparison between group A (Pecs) and group B (TPVB) regarding age, BMI, and duration of operation

		Group A No. = 15	Group B No. = 15	P value
Age (years)	Mean ± SD	47.07 ± 9.55	44.07 ± 7.91	0.357
BMI	Mean ± SD	30.4 ± 4.05	28.93 ± 4.22	0.340
Duration of operation in minute	Mean ± SD	126.67 ± 24.69	123 ± 26.04	0.695

•Independent t test

total dose used during operation in group B (TPVB) than group A (PECS) with *p* value = 0.008 (Table 3).

There was statistically significant increase regarding 24 h postoperative mean arterial blood pressure and HR monitoring in the TPVB group than the PECS group that was found at the first 5 h after the end operation. As regards the postoperative pain scores, the pain was significantly lower in group A in comparison with group B with statistically significant difference between groups at 4 h, 5 h, 6 h, and 8 h (Tables 4 and 5). Furthermore, the study showed that more time needed for 1st requested rescue analgesia in PECS group with *P* value of 0.013 and less total dose of fentanyl was received in the first 24 h postoperative in PECS group with *P* value of 0.040 (Table 3).

Discussion

Our study showed there was statistically significant increase in the amount of total fentanyl used

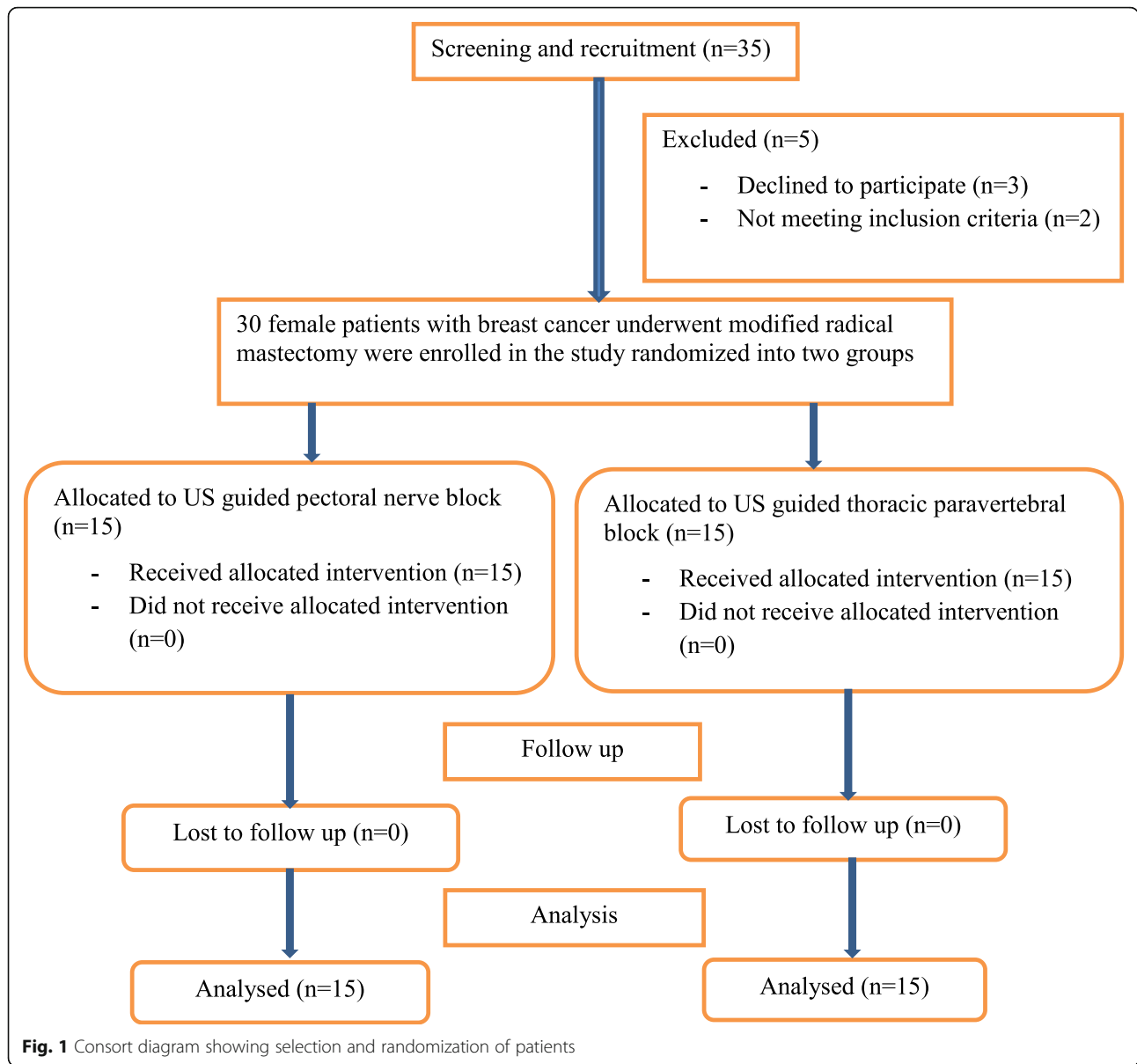
intraoperative in TPVB group than PECS group with *p* value = 0.008. Less VAS score in PECS group with statistically significant difference between groups at 4 h, 5 h, 6 h, and 8 h. More time needed for 1st requested rescue analgesia in PECS group with *P* value = 0.013. Patients in PECS group received less total dose of fentanyl in the first 24 h postoperative with *P* value = 0.040. There was no difference found between groups regarding postoperative complications, which were negligible.

Blanco et al. (2012) used the PECS block in 50 female patients undergoing modified radical mastectomy and this technique provided adequate postoperative analgesia for the first 8 h postoperative (Blanco et al., 2012). In another study, Bashandy and Abbas (2015) discovered that patients receiving the PECS block with general anaesthesia had lower VAS scores and lower postoperative morphine doses than patients receiving only general anaesthesia (Bashandy & Abbas, 2015). Kulhari and his colleagues (2016) reported that duration of analgesia was

Table 2 Comparison between group A and group B regarding heart rate and mean arterial blood pressure at different times of measurement intra-operative

		Heart rate			Mean arterial blood pressure intra op		
		Group A No. = 15	Group B No. = 15	P value	Group A No. = 15	Group B No. = 15	P value
Baseline	Mean ± SD	84.47 ± 8.12	83.2 ± 7.28	0.656	90.44 ± 4.78	91.07 ± 7.88	0.796
After induction	Mean ± SD	77.13 ± 6.2	76.87 ± 7.4	0.916	89.84 ± 8.56	89.93 ± 4.68	0.972
After block	Mean ± SD	80.4 ± 7.64	83.93 ± 7.15	0.202	84.4 ± 7.66	85.89 ± 5.07	0.535
15 min	Mean ± SD	81 ± 7.81	84.27 ± 7.9	0.264	80.02 ± 6.46	84.24 ± 8.61	0.140
30 min	Mean ± SD	79.33 ± 8.34	85.13 ± 11.09	0.117	77.67 ± 10.58	86.02 ± 13.46	0.069
45 min	Mean ± SD	79.47 ± 10.26	88.47 ± 13.1	0.045	75.62 ± 1.67	88.69 ± 17.17	0.021
60 min	Mean ± SD	77.27 ± 10.55	86.87 ± 14.02	0.043	73.64 ± 13.18	87.56 ± 20.38	0.035
75 min	Mean ± SD	74.73 ± 11.3	86.33 ± 11.49	0.009	69 ± 10.83	84.02 ± 19.68	0.015
90 min	Mean ± SD	76.33 ± 10.1	84.07 ± 8.07	0.028	70.6 ± 12.37	79.67 ± 10.43	0.039
105 min	Mean ± SD	74.13 ± 9.41	81.13 ± 10.56	0.065	69.51 ± 11.32	80.36 ± 18.14	0.059
120 min	Mean ± SD	71.13 ± 8.06	80.67 ± 10.65	0.010	69.76 ± 8.45	79.78 ± 16.11	0.042
135 min	Mean ± SD	75.2 ± 7.91	79.87 ± 8.81	0.138	72.11 ± 7.69	78 ± 14.11	0.167
T0 the end of surgery	Mean ± SD	77.53 ± 6.01	79.93 ± 10.19	0.439	76.22 ± 7.15	79.11 ± 8.24	0.314

•Independent t test



significantly prolonged in patients receiving the PecS II block compared with TPVB, the 24 h morphine consumption was also less in the PecS II block group and postoperative pain scores were also lower in the PecS II group (Kulhari et al., 2016).

Several studies have shown that when the TPVB is performed under general anaesthesia, patients often report pain in the axilla and upper limb on the same side of surgery (Blackshaw et al., 2018). While the Pecs block, on the other hand, blocks the medial and lateral

Table 3 Comparison between group A and group B regarding total fentanyl used intra-operatively and in the first 24 h postoperatively and the time needed for the first requested rescue analgesia

		Group A No. = 15	Group B No. = 15	P value
Total Fentanyl used intra-op in µg	Mean ± SD	110 ± 20.7	136.67 ± 29.68	0.008
Time needed for 1st requested rescue analgesia	Mean ± SD	9.13 ± 3.48	5.47 ± 4.07	0.013
Total Fentanyl use in first 24 h in µg	Mean ± SD	93.33 ± 37.16	133.33 ± 61.72	0.040

•Independent t test

Table 4 Comparison between group A (Pecs) and group B (TPVB) regarding mean arterial blood pressure and HR changes during 24 h post-operative

		Post-operative Mean ABP at 24 h			Post-operative HR at 24 h		
		Group A	Group B	P value	Group A	Group B	P value
		No. = 15	No. = 15		No. = 15	No. = 15	
1 h	Mean ± SD	79.38 ± 8.4	86.98 ± 8.13	0.018	78 ± 8.82	89.07 ± 4.17	0.000
2 h	Mean ± SD	82.78 ± 5.51	89.87 ± 7.12	0.005	77.93 ± 7.26	92.4 ± 3.56	0.000
3 h	Mean ± SD	85.24 ± 4.16	90.84 ± 7.77	0.017	80.07 ± 7.04	89.13 ± 8.56	0.004
4 h	Mean ± SD	87.24 ± 4.97	91.47 ± 6.36	0.002	81.93 ± 6.75	90.27 ± 9.57	0.010
5 h	Mean ± SD	87.69 ± 4.15	92.91 ± 5.77	0.008	83.47 ± 7.53	92 ± 9.86	0.013
6 h	Mean ± SD	87.47 ± 4.47	91.51 ± 7.88	0.095	86.87 ± 7.61	90.73 ± 10.12	0.247
8 h	Mean ± SD	84.91 ± 5.85	88.96 ± 6.53	0.085	89.93 ± 5.54	93.73 ± 5.36	0.067
10 h	Mean ± SD	88.71 ± 5.12	91.13 ± 5.40	0.218	92 ± 4.05	91.8 ± 7.36	0.927
12 h	Mean ± SD	88.36 ± 3.8	91.29 ± 7.22	0.175	91.33 ± 6.95	92.8 ± 2.4	0.446
16 h	Mean ± SD	87.58 ± 4.06	91.13 ± 5.81	0.062	89.8 ± 9.99	88.6 ± 10.87	0.755
20 h	Mean ± SD	88.22 ± 4.05	91.13 ± 5.86	0.125	92.87 ± 7.49	89.73 ± 7.82	0.272
24 h	Mean ± SD	88.8 ± 4.63	91.96 ± 7.65	0.183	88.73 ± 8.8	91.6 ± 6.51	0.319

•Independent t test

pectoral nerves, as well as the lateral branches of the intercostal nerves and the long thoracic nerve, by injecting local anaesthetic into the fascial planes where all these nerves are located leading to better pain relief (Bashandy & Abbas, 2015).

Despite using different volumes of local anaesthetic (30 ml in the PECs group and 15–20 ml at the T4 level in the TPVB group), Wahba and Kamal (2013) observed a longer period to first analgesic requirement, less morphine intake and reported lower pain scores at 1, 6, and

12 h after breast surgery in patients receiving a pectoral nerve block compared to a thoracic paravertebral block (Wahba & Kamal, 2013). Siddeshwara et al. (2019) in another study recorded a significant prolongation of analgesic duration in the PECs group than PVB group (474.1 ± 84.93 versus 371.5 ± 51.53 min, respectively; $P < 0.0001$) and postoperative consumed morphine at 24 h was less in the PECs group than PVB group (11.25 ± 4.75 and 15.0 ± 4.86 mg, respectively; $P = 0.018$) (Siddeshwara et al., 2019).

On the other hand, Volodymyr Martsiniv and his colleagues (2020) reported that there were no statistically significant differences between pectoral block group and paravertebral block group in intraoperative fentanyl consumption and in the pain intensity during the first 24 h after operation but time to the first analgesia request was longer in pectoral block group (Martsiniv et al., 2020). Our result was inconsistent with Syal and Chandel (2017) who found that the postoperative VAS scores were lower in the TPVB group than PECS group at 0, 2, 4, 12, and 24 h ($P < 0.05$) with mean analgesic durations significantly longer in the TPVB group ($P < 0.001$) with lower analgesic rescue consumption up to 24 h (Syal & Chandel, 2017). In another study, Sopena-Zubiria et al. (2012) performed combined pectoral nerve block with TPVB and found a more important reduction in pain scores after breast surgery (Sopena-Zubiria et al., 2012).

Inconsistent with Naja and his colleagues who used TPVB as a sole anesthetic technique for morbidly obese patients undergoing mastectomy using nerve stimulator to guide TPVB and found that the use of TPVB could be used as an alternative to general anesthesia and reduce

Table 5 Comparison between group A (Pecs) and group B (TPVB) regarding visual analog score (VAS)

VAS score		Group A	Group B	P value
		No. = 15	No. = 15	#
1 h	Mean ± SD	2.07 ± 0.59	2.27 ± 1.53	0.872
2 h	Mean ± SD	1.67 ± 0.72	2.67 ± 1.8	0.116
3 h	Mean ± SD	2.27 ± 1.22	2.93 ± 1.33	0.138
4 h	Mean ± SD	2.07 ± 1.22	3.40 ± 1.45	0.014
5 h	Mean ± SD	2.40 ± 0.91	3.40 ± 0.99	0.013
6 h	Mean ± SD	2.33 ± 1.29	3.60 ± 1.24	0.012
8 h	Mean ± SD	2.73 ± 0.96	3.73 ± 0.96	0.018
10 h	Mean ± SD	3.4 ± 1.45	3.47 ± 1.19	0.966
12 h	Mean ± SD	4.2 ± 1.15	3.8 ± 1.15	0.273
16 h	Mean ± SD	4 ± 0.76	4 ± 0.93	1.000
20 h	Mean ± SD	4.13 ± 0.74	3.8 ± 0.94	0.369
24 h	Mean ± SD	4.07 ± 0.7	4.33 ± 0.49	0.283

#Mann-Whitney test

the side effects associated with general anesthesia. TPVB was associated with improved postoperative pain relief, reduced incidence of nausea, and vomiting, as well as shorter hospital stay compared to general anesthesia in patients undergoing breast surgery. Therefore, in our study, the high use of fentanyl in TPVB group could indicate inadequate block (Naja et al., 2003; Naja et al., 2011).

The PECs II block is generally safe. Some complications may occur such as accidental intravascular injection, pneumothorax, local anaesthetic toxicity, hematoma at injection site or failure of the block but we used ultrasound guidance and an echogenic needle to perform of the blocks for better viewing of the structures and the spread of local anaesthetic (Blackshaw et al., 2018). In our study, no block-related complication was reported in any group. The incidence of PONV was low in both the groups.

The main limitation of our study is that the patient and the anaesthetist performing the block was not blinded to the group assignment. However, the person involved in data collection was not aware of the group distribution. Furthermore, since our research was designed to compare the two groups after a single injection, we cannot use continuous injection with catheter insertion. Small sample size was another limitation.

Conclusions

In female patients undergoing breast surgeries, the PECs block can be used efficiently and safely, providing better pain relief than the TPVB and reducing intraoperative and postoperative opioids use.

Recommendations

More research is needed to determine the effectiveness of catheter insertion for continuous injection for better and longer post-operative analgesia, as well as its impact on chronic post-mastectomy pain.

Abbreviations

ASA: American Society of Anaesthesiologists; BMI: Body mass index; MRM: Modified radical mastectomy; PECs: Pectoral nerve block; REC: Research Ethics Committee; TPVB: Thoracic paravertebral block; VAS: Visual analogue score; PONV: Postoperative nausea and vomiting; IV: Intravenous; CTL: Costotransverse ligament

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Not applicable.

Authors' contributions

MA designed the study, revised the literature, performed the blocks, followed up the patients, and wrote the manuscript. AM designed the study, performed the analysis, and critically revised the manuscript. HG revised the literature, performed the analysis, and critically reviewed the manuscript. AH revised the literature, collected the data, performed the analysis, and critically reviewed the manuscript. DM revised the literature, performed the analysis, and critically reviewed the manuscript. All authors read and approved the final version of the manuscript.

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Availability of data and materials

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

Declarations

Ethics approval and consent to participate

After approval of the ethical committee in faculty of medicine, Ain Shams University number FMASU M D 68/2018, this prospective randomized controlled clinical study was conducted over 30 patients for 1 year from March 2018 to March 2019. Written informed consent was obtained from patients after explaining of the procedure and its potential complications.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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