Original Article

Pectoral nerve block and pecto-intercostal fascial block versus thoracic paravertebral block for postoperative analgesia in modified radical mastectomy: A randomised controlled trial

Address for correspondence:
Dr. Ajeet Kumar,
Department of Anaesthesia,
AIIMS, Room 502,
Patna - 801 505, Bihar, India.
E-mail: ajeetanaes@gmail.com

Submitted: 16-Jul-2024
Revised: 29-Dec-2024
Accepted: 29-Dec-2024
Published: 17-Feb-2025

Access this article online

Website: https://journals.lww.com/ijaweb

DOI: 10.4103/ija.ija_734_24

Quick response code

Adarsh M Sheshagiri, Ajeet Kumar[1], Chandni Sinha[1], Abhyuday Kumar[1], Poonam Kumari[1], Amarjeet Kumar[1], Chandan Jha[2]

Department of Anaesthesiology, Critical Care and Pain Medicine, AIIMS, New Delhi, [1]Departments of Anaesthesia and [2]Surgery, AIIMS, Patna, Bihar, India

ABSTRACT

Background and Aims: Modified radical mastectomy (MRM) is associated with persistent postoperative pain. Paravertebral block (PVB) is the gold standard for postoperative analgesia. A pecto-intercostal fascial plane (PIFB) block added to the pectoral nerve block (Pecs) may provide effective analgesia. This trial aimed to compare the analgesic efficacy of Pecs-PIFB with PVB. **Methods:** Fifty American Society of Anesthesiologists (ASA) I/II patients scheduled for MRM were randomly assigned to receive either Pecs-PIFB block with 30 mL for Pecs block and 15 mL for PIFB or PVB block with 20 mL (0.2% ropivacaine). Postoperatively, intravenous (IV) morphine was administered through a patient-controlled analgesia (PCA) pump. The primary outcome was to compare the time to the first demand dose of rescue analgesic. The secondary outcomes were postoperative 24-hour opioid consumption, pain scores (30 mins and 1, 2, 4, 6, 12, and 24 h), patient satisfaction score (24 h), and block-related complications. The unpaired *t*-test compared quantitative normally distributed data, while the Mann-Whitney U test compared quantitative discrete data. A P value < 0.05 was considered to be statistically significant. **Results:** Patients in the Group Pecs-PIFB had an increased median time to first demand dose: 440 [interquartile range (IQR): 360–540] versus 340 (IQR: 180–360) minutes (P = 0.019) and lower median 24-h postoperative morphine consumption: 4 (3–6) versus 6 (4–8) mg (P = 0.020). Patients in the Group Pecs-PIFB had better pain scores at 30 minutes and 1 h. **Conclusion:** Compared to thoracic PVB, the combination of Pecs and PIFB block prolonged the duration of analgesia and decreased postoperative opioid consumption in patients undergoing MRM surgeries. There was no statistical increase in complications in patients receiving this block.

Keywords: Modified radical mastectomy, morphine, postoperative pain, pectoral nerve, paravertebral block, Pecto-intercostal fascial plane, PIFB, pectoral nerve block

INTRODUCTION

Chronic persistent pain is a fairly common consequence of inadequately managed pain in patients undergoing breast surgery.[1] Though paravertebral block (PVB) is considered the gold-standard regional analgesia technique for breast surgery, complications such as pneumothorax and hypotension are known to occur.[2] Hence, there has been an advent of safer interfacial blocks such as pectoral nerve (Pecs) block, which has been used successfully in breast surgeries. However, there is a lack of analgesia in the medial aspect of the breast as the anterior branches of the intercostal nerves are not blocked.[3] Combining it with

How to cite this article: Sheshagiri AM, Kumar A, Sinha C, Kumar A, Kumari P, Kumar A, *et al.* Pectoral nerve block and pecto-intercostal fascial block versus thoracic paravertebral block for postoperative analgesia in modified radical mastectomy: A randomised controlled trial. Indian J Anaesth 2025;69:302-7.

pecto-intercostal fascial block (PIFB), which targets the anterior cutaneous branch of the intercostal nerve, might provide greater coverage and better analgesia.[4]

This study aimed to compare the analgesic efficacy of ultrasound-guided Pecs-PIFB with thoracic PVB in patients undergoing modified radical mastectomy (MRM). The primary objective was to assess the time to first rescue analgesia, while the secondary objective included 24-h morphine consumption, numerical rating score (NRS) at movement, patient satisfaction score (PSS) at 24 h, and adverse effects. We hypothesised that Pecs-PIFB might provide better analgesia than the gold standard, PVB, with no increase in adverse effects.

METHODS

This study was approved by the Institutional Ethics Committee (vide approval number IEC no: AIIMS/Pat/IEC/PGTh/July21/17, dated 05/05/2022) and registered with the Clinical Trials Registry-India (CTRI/2023/02/050011, dated 28/07/2022; accessible at https://ctri.nic.in/). This double-blind, randomised trial was conducted in a tertiary care centre between March 2023 and February 2024 in accordance with the principles of the Declaration of Helsinki (2013) and Good Clinical Practice guidelines.

Fifty patients belonging to American Society of Anesthesiologists (ASA) physical status I/II aged 20–65 years undergoing unilateral MRM were included in the study. Uncooperative patients, patients with body mass index (BMI) <20 kg/m^2 or >35 kg/m^2, infection at the site of injection, and inability to understand pain scores or the functioning of patient-controlled analgesia (PCA) pumps were excluded from the study. Written informed consent was obtained from all the patients for participation in the study and use of the patient data for research and educational purposes.

Online software (Open Epi software version 3.01, Atlanta, GA, USA) was used for block randomisation. Patients were randomly allocated into one of the two groups: Group Pecs-PIFB received combined Pecs and PIFB, while Group PVB received paravertebral block. The allocation sequence was concealed in sequentially numbered opaque, sealed envelopes. The anaesthesia technician opened these envelopes on the day of surgery.

Patients were reviewed, and the procedures were explained to them on the evening before the surgery. They were given the patient information sheet with details of the study methodology. They were explained by a numerical rating scale (NRS): 0: no pain and 10: worst pain. On shifting to the operating room (OR), standard ASA monitors, non-invasive blood pressure (NIBP), electrocardiogram (ECG), and pulse oximeter for oxygen saturation (SpO_2) were connected. Intravenous (IV) fentanyl 2 μg/kg, propofol 2 mg/kg and atracurium 0.5 mg/kg were administered, and tracheal intubation was done using an appropriately sized endotracheal tube. The target was maintaining a minimum alveolar concentration (MAC) of 1–1.2 sevoflurane.

An anaesthesiologist with 25 or more years of experience administered the blocks and was not involved in perioperative management or data collection. The co-investigator who conducted the case was blinded to the group allocated or intervention made. A high-frequency linear ultrasound probe (5–12 Hz) (Sonosite, M-Turbo, Fujifilm) was used to administer the blocks. In Group Pecs-PIFB, the patient was placed in a supine position with the arm abducted. The block was given as described by Blanco *et al*.[5] A linear probe was placed in the parasagittal plane in the infraclavicular region to identify the axillary artery and the vein. The probe was moved laterally to identify pectoralis major (PM), pectoralis minor (Pm), and serratus anterior muscles (SAM) at the third rib level. An echogenic needle (Sonoplex, Pajunk, Germany) of size 8 cm was inserted in an oblique plane to deposit 20 mL of 0.2% ropivacaine between Pm and SAM and 10 mL between PM and Pm. Thereafter, the probe was placed longitudinally 2–3 cm lateral to the sternum, and the needle was inserted in the plane, cephalad to caudad, between PM and external intercostal muscle. Next, 15 mL of the local anaesthetic was deposited in between the muscles. The adequate spread of the LA between the muscles confirmed the successful administration of the block.

For the PVB, the patient was turned lateral, with the surgical side on the upper side. The linear probe (6–13 MHz) was placed longitudinally at T4 and moved laterally to identify the transverse process, costotransverse ligament, paravertebral space, and pleura. The needle was inserted craniocaudally to administer 20 mL of 0.2% ropivacaine between the costotransverse ligament and the parietal pleura. The forward displacement of the parietal pleura while administering the drug confirmed the correct placement of the needle and drug.

The surgery was started 20 minutes after the administration of the drug. The surgeon gave a horizontal incision 2 cm lateral to the sternum to the anterior axillary line. Vitals, including heart rate (HR) and mean arterial pressure (MAP), were documented every 15 minutes till the end of surgery. An increase in HR and MAP by more than 20% was treated with IV fentanyl 0.5 µg/kg, after ruling out other causes. IV dexamethasone 6 mg, ondansetron 4 mg, and paracetamol (PCM) 15 mg/kg (maximum 1 g) were given an hour after the surgery started. After tracheal extubation, the patients were shifted to the post-anaesthesia care unit (PACU), where the PCA pump was attached with the following set-up: 1 mg IV morphine bolus only with a lock-out time of 10 minutes with a maximal dose of 5 mg/h. IV paracetamol 15 mg/kg was administered every 6 hours.

Pain nurses who were unaware of the interventions made the postoperative assessments. The time of first PCA demand dose; morphine requirement in 24 hours; and dynamic pain scores (passive arm abduction till 90 degrees) at 30 minutes and 1, 2, 4, 6, 12, and 24 h after shifting to the PACU were noted. Complications such as pneumothorax, vascular puncture, local anaesthetic toxicity, and postoperative nausea/vomiting were documented. Patient satisfaction score (PSS) was documented at 24 h after surgery on a scale of 0–4, with 4 being maximally satisfied.

The sample size of our study was calculated based on a previous study by Hamed *et al*.[6] The mean time to rescue analgesia in patients undergoing MRM who received PVB was 14 h with a standard deviation (SD) of 4.54 h and 8.3 h with SD: 4.76 h in patients who received Pecs block. Considering an alpha error of 5% and power of 95%, the sample size was 18 in each group. Taking dropouts and the difference in standard deviation into account, we took a sample size of 25 in each group.

Statistical Package for the Social Sciences (SPSS) statistics software version 21.0 (International Business Machines Corporation (IBM Corp), Armonk, NY, USA) was used for data analysis. Kruskal–Wallis test tested the normality of data. Continuous quantitative normally distributed data (demographics) were expressed as mean and SD and compared using an unpaired *t*-test. Quantitative discrete data (NRS and PSS score) and data that were not normally distributed (intraoperative opioid consumption, time to first rescue analgesia and 24-hour morphine consumption) were expressed as the median and interquartile range (IQR) and compared using the Mann-Whitney U test. *P* values < 0.05 were considered to be statistically significant.

RESULTS

Sixty patients were enroled in this study, out of which 10 were excluded. Fifty patients were randomly allocated into two groups, and 49 completed the study protocol [Figure 1]. Both groups were similar in demographic characteristics and duration of surgery [Table 1].

Median time to first demand dose was statistically prolonged in Group Pecs-PIFB in comparison to Group PVB (440 (IQR: 360–540) vs 340 (IQR: 180–360) minutes (P = 0.019)). Intraoperative fentanyl requirement was higher in patients in Group PVB (P = 0.004). Postoperative 24-hour morphine consumption was statistically lower in Group Pecs-PIFB as compared to Group PVB (P = 0.020) [Table 2]. Pain scores were lower in Group Pecs-PIFB at 30 minutes and 1 hour [Table 3]. Two patients of Group Pecs-PIFB and four patients of Group PVB reported nausea. There were no procedure-related complications in either group.

DISCUSSION

Our study shows that PIFB, combined with Pecs block, improves the quality of analgesia compared to PVB in patients undergoing MRM with no increase in adverse effects. These results might be due to the sparing of the PVB's pectoral, long thoracic, and thoracodorsal nerves.

The breast has a complex nerve supply, with the medial breast supplied by anterior cutaneous branches and the lateral breast by lateral cutaneous branches of the T2–T5 intercostal nerve. The nipple-areola complex is innervated by both anterior and lateral branches of the

Table 1: Patient demographics and surgical characteristics

	Group Pecs-PIFB (*n*=25)	Group PVB (*n*=24)
Age (years)	47.5 (10.36)	49.0 (8.87)
Body mass index (kg/m^2)	23.6 (3.63)	23.40 (3.46)
American Society of Anesthesiologists physical status (I/II)	19/6	20/4
Duration of surgery (minutes)	132.8 (25.74)	123.6 (20.59)

Data expressed as mean (standard deviation) or number of patients. Pecs-PIFB=pectoral nerve block and pecto-intercostal plane block, PVB=paravertebral block, n=number of patients

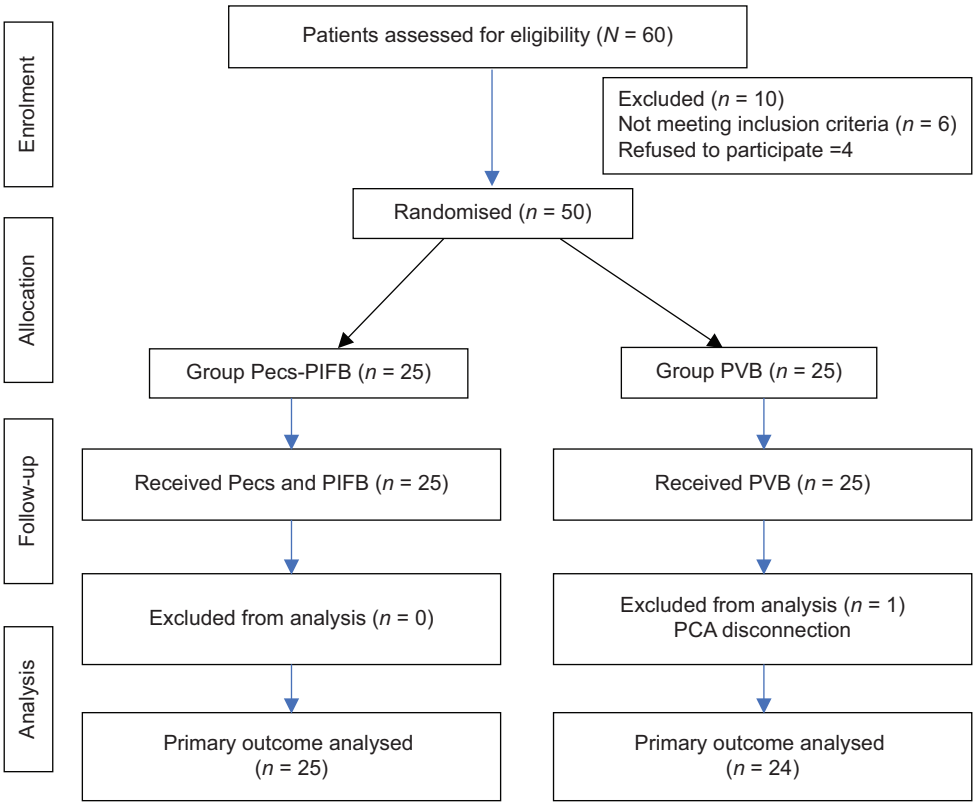

Figure 1: Consolidated standards of reporting trials (CONSORT) flow diagram. n = number of patients. PVB = Paravertebral block, PIFB = pecto-intercostal fascial plane block, Pecs = pectoral nerve block

Table 2: Perioperative opioid requirement

	Group Pecs-PIFB (*n*=25)	Group PVB (*n*=24)	Effect size r (95% CI)	*P*
Additional intraoperative fentanyl consumption (μg)	40 (10–70)	75 (35–115)	0.160 (−0.87, 0.22)	0.004
24-h morphine consumption (mg)	4 (3–6)	6 (4–8)	0.380 (0.134, 1.27)	0.020
Time to demand dose (minutes)	440 (360–540)	340 (180–360)	0.387 (−1.16, −0.026)	0.019

Data expressed as median (interquartile range). CI=confidence interval, Pecs-PIFB=pectoral nerve block and pecto-intercostal plane block, PVB=paravertebral block, *n*=number of patients

Table 3: Postoperative dynamic pain scores

Timepoint (h)	Group Pecs-PIFB (*n*=25)	Group PVB (*n*=24)	Effect size r (95% CI)	*P*
30 min	2 (2–2)	2 (2–3)	0.312 (0.08, 1.22)	0.040
1 h	2 (2–3)	3 (2–3)	0.428 (0.332, 1.500)	0.005
2h	2 (2–3)	3 (2–4)	0.201 (−0.128, 0.993)	0.180
4 h	3 (3–3)	3 (2–4)	0.032 (−0.554, 0.544)	0.841
6 h	3 (3–4)	3 (3–4)	0.07 (−0.734, 0.3769)	0.616
12h	3 (3–3)	3 (3–4)	0.22 (−1.05, 0.074)	0.118
24 h	2 (2–3)	3 (2–3)	0.104 (−0.445, 0.6532)	0.797
PSS	3 (2–3)	3 (2–3)	0.05 (−0.70, 0.40)	0.705

Data expressed as median (interquartile range). CI=confidence interval, IQR=interquartile range, PSS=Patient satisfaction score, Pecs-PIFB=pectoral nerve block and pecto-intercostal fascial plane block, PVB=paravertebral block, *n*=number of patients

T3–T4 intercostal nerve.[3] Anatomical variations are known to exist with overlaps in the sensory supply.

PVB has been considered the gold-standard analgesic technique, which targets the spinal nerve's dorsal and ventral rami, resulting in ipsilateral blockade of somatic and sympathetic nerves. PVB spares the medial and lateral pectoral, long thoracic, and thoracodorsal nerve.[7] There have been unsatisfactory results of its analgesia in patients undergoing axillary dissection.[8]

Procedure-specific postoperative pain management (PROSPECT) guidelines for oncological breast surgery have recommended that Pecs can be substituted

where PVB is not possible.[9] Apart from blocking intercostal nerves (T2–T5), pectoral, long thoracic, and thoracodorsal nerves are also blocked in Pecs II. The anterior cutaneous nerves are targeted in the PIFB block by depositing the drug in the fascial plane between the pectoral and intercostal muscles on either side of the sternum. Hence, combining these two blocks explains better postoperative analgesia in our patients.

When compared to the transverse thoracic plane (TTP) block, PIFB is shallower and hence associated with less chance of injury to underlying structures.[10] Puncture of the internal mammary artery and vein is a potential complication in TTP block, which is avoided in PIFB. PIFB has been shown to attenuate postoperative pain and opioid consumption and also hasten weaning from the ventilator in thoracic and cardiac surgeries.[11-13]

Abu Elyazed *et al*.,[14] in their randomised trial involving 60 women undergoing unilateral MRM, demonstrated that Pecs -PIFB improved perioperative analgesia compared to Pecs II alone. The patients in Group Pecs-PIFB exhibited significantly longer time to the first morphine dose and lower perioperative opioid consumption. Our study shows that the 24-hour opioid requirement was less in Group Pecs-PIFB as compared to PVB. The time to first demand dose was also statistically prolonged in Group Pecs-PIFB. Wahba and Kamal[15] compared Pecs block with PVB in 60 patients undergoing MRM. The 24-hour postoperative morphine consumption and 12-hour pain scores were lower in the group receiving Pecs block after surgery.

Deng *et al*.[16] used 0.2% ropivacaine for Pecs block in breast surgery and reported a prolonged duration of analgesia of up to 20 h. We also chose a similar concentration and found the duration increased up to a median of 7 h.

Various complications are associated with these blocks: hypotension, bleeding, and pneumothorax in PVB and vascular puncture (pectoral branch of the acromiothoracic artery) or pleural puncture in Pecs-PIFB. These blocks are high-volume blocks with chances of local anaesthetic systemic toxicity. We did not encounter these in any of our patients. The use of ultrasound, in-plane needling, and an experienced anaesthesiologist for giving the blocks and keeping the drug dose within the toxic limit would have prevented the complications. In addition, our study was not powered enough to detect these complications.

The strength of this study is that we have conducted a robust study with a sound methodology that compares two blocks recommended by the PROSPECT guideline. Adding another superficial block to Pecs can have immense clinical significance due to its efficacy and safety profile.

The study had a few limitations. Firstly, we administered the blocks after general anaesthesia (GA), which prevented us from assessing the sensory mapping after the block. In our institute, giving this block after GA is a standard practice. Secondly, there is a lack of evidence of an appropriate dosage of the drug for PIFB. We used the dosage of our drugs based on the limited studies available. Hence, future trials might be required for this purpose.

CONCLUSION

Pecs-PIFB is a better analgesic technique than PVB for postoperative analgesia in MRM patients as it prolongs the duration of analgesia and decreases postoperative opioid consumption. Further studies with larger sample sizes might validate our findings.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' Institution policy.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

ORCID

Adarsh M Sheshagiri: https://orcid.org/0009-0002-3597-7252

Ajeet Kumar: https://orcid.org/0000-0002-1464-6684

Chandni Sinha: https://orcid.org/0000-0002-4107-2671

Abhyuday Kumar: https://orcid.org/0000-0002-9247-6713

Poonam Kumari: https://orcid.org/0000-0003-0118-2187

Amarjeet Kumar: https://orcid.org/0000-0002-4272-5750

Chandan Jha: https://orcid.org/0000-0003-0968-3269

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