Original Article

# Comparative evaluation of continuous infusion versus programmed intermittent bolus techniques in erector spinae plane block in modified radical mastectomy – A preliminary randomised controlled trial

**Address for correspondence:**
Dr. Debesh Bhoi,
Room No. 5013,
5th Floor, Department of Anaesthesiology, Pain Medicine and Critical Care, AIIMS, New Delhi- 110 029, India.
E-mail: debeshbhoi@gmail.com

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*Thamizharasan Datchinamourthy, Debesh Bhoi, Anjolie Chhabra, Virender K. Mohan, Kanil R. Kumar, Poornima Ranganathan*
**Department of Anaesthesiology, Pain Medicine and Critical Care, AIIMS, New Delhi, India**

## ABSTRACT

**Background and Aims:** Single-shot erector spinae plane block (ESPB) provides excellent analgesia in mastectomy in the immediate post-operative period but is not sufficient to maintain for prolonged duration. This study compares the efficacy of programmed intermittent bolus (PIB) versus continuous infusion (CI) techniques after ESPB by placing a catheter for mastectomy. **Methods:** After ethical approval and patient consent, ESPB was performed at the T4 level in 50 patients with an initial bolus of 20 mL 0.375% ropivacaine and a catheter placed 30 min before surgery. In the postoperative period, they were randomised to Group I - intermittent bolus of 20 mL 0.2% ropivacaine every 4 h for 24 h and Group C - continuous infusion of 0.2% ropivacaine at 5 mL/h for 24 h. The primary outcome was the 24-h fentanyl consumption by patient-controlled analgesia device. Data was analysed using Stata 14.0. **Results:** Group I patients had reduced post-operative fentanyl consumption {mean [standard deviation (SD)]: 166 (139.17) μg vs 332 (247.96) μg, $P = 0.002$} and lower median NRS scores (1 h: 3 vs 5), (2 h: 3 vs 5), (4 h: 3 vs 5), (6 h: 4 vs 5) with a higher mean (SD) Quality of Recovery-15 score {134.4 (8.53) vs 127 (12.89), $P = 0.020$} compared to Group C, respectively. The 24-h dermatomal sensory coverage was more comprehensive in Group I compared to Group C. **Conclusion:** The PIB technique after ESPB provides decreased postoperative opioid consumption, better post-operative analgesia and quality of recovery compared to the CI technique in patients undergoing mastectomy.

**Keywords:** Analgesia, catheter, continuous infusion, erector spinae plane block, fentanyl, intermittent bolus, mastectomy, patient-controlled analgesia, ropivacaine

## INTRODUCTION

Breast cancer is the most common malignancy diagnosed among women worldwide; therefore, mastectomy surgeries have become exceedingly common.[1] These surgeries are associated with high incidences of both acute post-surgical pain leading to delayed patient recovery, increased length of hospital stay and post-mastectomy pain syndrome (PMPS) with an incidence of 25%–60%.[2] Erector spinae plane block (ESPB) is an emerging truncal regional anaesthesia technique that has gained popularity due to its simplicity, safety, and efficacy.[3-9] Because the muscle extends throughout the thoracolumbar spine, the drug spreads craniocaudally along the



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tissue plane and covers multiple dermatomes even after a single-point injection.[10] However, single-shot ESPB is not expected to provide adequate analgesia for a longer duration. Hence, catheter placement becomes necessary for providing analgesia in the late postoperative period, through which the drug can be administered either as a continuous infusion (CI) or programmed intermittent boluses (PIB). Though studies have compared the PIB versus CI techniques in epidural anaesthesia and other blocks,[11-13] evidence is scarce in the literature regarding the comparison of these techniques in ESPB, especially in breast surgeries.

Hence, we decided to conduct a study with the aim of comparing the efficacy of PIB versus CI techniques in ESPB in patients undergoing modified radical mastectomy (MRM). The primary objective of the study was to compare the post-operative 24-h intravenous (IV) fentanyl consumption between the two groups. Secondary objectives were to estimate numeric pain rating scale (NRS) score at 0, 1, 2, 4, 6, 12, and 24 h; dermatomal sensory mapping at 30 min and 24 h; post-operative fentanyl consumption at 2, 4, 6, 12, and 24 h; and quality of recovery at 24 h. Because it is a fascial and volume-dependent block, we hypothesise that PIB will have a wider local anaesthetic spread and coverage than the CI technique.

## METHODS

This prospective, preliminary, randomised controlled trial was conducted after approval from the institutional ethics committee (vide approval number IECPG-414/27.06.2019, dated 3 July 2019) and was registered with the Clinical Trials Registry-India (vide registration number CTRI/2019/08/020751, http://ctri.nic.in/). The study was carried out in accordance with the ethical principles of the Declaration of Helsinki, 2013 and good clinical practice principles. All patients were explained the nature of the study, and informed written consent was obtained for participation and use of their data for research and educational purposes. Inclusion criteria were adult patients of American Society of Anesthesiologists Physical Status (ASA PS) I/II posted for unilateral modified radical mastectomy. Patients were excluded if they had a history of coagulopathy, known allergy, local site infection, and a body mass index (BMI) >35 kg/m$^2$.

In the pre-operative area, routine ASA monitors were attached, oxygen by facemask was given and patients were premedicated with IV midazolam (1 mg). In the sitting position, the back was cleaned and draped under aseptic conditions after the initial scout scan to mark the surface anatomy of the thoracic spine. A linear high-frequency (6–13 MHz) ultrasound probe (Sonosite Edge 2, WA, USA) was kept in the para-sagittal plane at the level of the fourth rib. It was moved from the lateral to the medial side until the beak-shaped rib structure was transitioned to take the rectangular shape of the transverse process. After infiltrating the skin with 2% lignocaine, an 18-G Tuohy needle was inserted at the T3 level in-plane in a cranial-to-caudal direction and advanced towards the T3–T4 transverse process. The fascial plane between the erector spinae muscle and the T4 transverse process was hydro-dissected by saline, and then a 20 mL bolus of 0.375% ropivacaine was deposited. Correct block placement was ensured by the linear spread of the injectate solution both cranially and caudally, separating erector spinae muscle from the transverse processes. The extent of the spread was assessed using ultrasound. After injecting the drug, a multi-orifice catheter was inserted 3 cm beyond the needle tip in the fascial plane beneath the erector spinae muscle and secured by tunnelling in the subcutaneous plane [Figure 1]. Sensory dermatomal (T1–T12) levels were assessed in the parasternal, midaxillary, and paravertebral regions 30 min after the block by a 3-point scale (0- no sensation, 1- feels touch/wet, 2- feels pain/cold).

All surgeries were carried out under general anaesthesia. Anaesthesia induction was done with IV fentanyl (2 μg/kg), propofol (2–2.5 mg/kg), and maintenance of anaesthesia with isoflurane in a 1:1 mixture of oxygen and air with minimum alveolar concentration (MAC) of 1. Electrocardiogram, pulse oximetry, blood pressure, and end-tidal carbon dioxide were continuously monitored. In case of tachycardia or an increase in mean arterial pressure (MAP) of >20% of baseline, 0.5 μg/kg IV bolus fentanyl was administered. Any hypotension (MAP <65 mmHg) was treated with IV ephedrine boluses (6 mg). IV paracetamol 1 g, ketorolac 30 mg, and ondansetron 4 mg were administered 30–45 min before the end of surgery in both groups, and paracetamol was repeated six hourly for 24 h. After surgery, all patients were shifted to the post-anaesthesia care unit (PACU).

In the PACU, patients were randomised to either Group I or Group C by block randomisation technique using computer-generated tables, and the allocation was done by opening the sequentially numbered

sealed opaque envelopes by a PACU nurse (who was not part of the study) to ensure allocation concealment. Group I (PIB) – PIB of 20 mL of 0.2% ropivacaine every 4 h for 24 h, Group C (CI) –CI of 0.2% ropivacaine at 5 mL/h for 24 h. Both groups of patients received PIB or CI through a similar-looking automated programmable pump to maintain blinding. After all the settings, the blinded observer entered the PACU area and post-operative pain assessment was done using an 11-point NRS at 0, 1, 2, 4, 6, 12, and 24 h on both rest and movement. Rescue analgesia was given by an IV patient-controlled analgesia (PCA) device (fentanyl: bolus dose- 25 µg, maximum dose- 100 µg/h, lockout time- 10 min). No baseline infusion was given via the PCA pump. At the end of 24 h, thoracic dermatomal sensory mapping was performed again, and the total fentanyl consumption was noted. Quality of recovery (QoR) was assessed by a QoR-15 questionnaire (score out of 150), and the satisfaction score was evaluated by a 5-point Likert scale (5- Excellent, 4- Good, 3- Average, 2- Poor, 1- Extremely bad). Postoperative nausea and vomiting (PONV) score was as follows (0- no nausea/vomiting, 1- nausea but no vomiting, 2- vomiting once in 30 min, 3- two or more episodes of vomiting in 30 min).

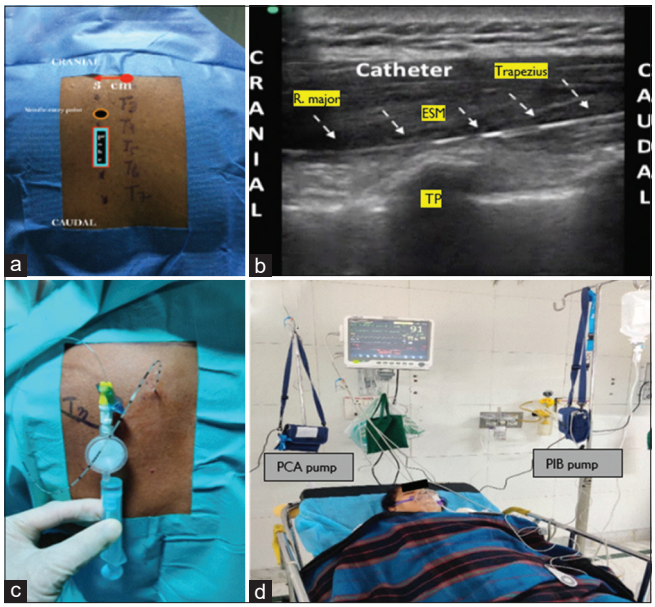


**Figure 1:** Block performance and post-operative care. (a) Picture showing the ultrasound (US) probe position (rectangular mark) and needle entry point (circular mark) with the patient in sitting position after draping. (b) US image showing the sonoanatomy of erector spinae plane (ESP) block and the placement of a catheter (white arrows) in the plane between erector spinae muscles and transverse process (echogenicity made prominent due to column of air-flow movement by continuous negative pressure aspiration). (c) Picture showing the successful placement of the catheter before subcutaneous tunnelling and fixing. (d) Patient kept in post anaesthesia care unit with patient-controlled analgesia (PCA) pump attached intravenously and local anaesthetic administered by programmed intermittent bolus (PIB) automated pump via ESP catheter

Without any existing study, a formal sample size calculation was not feasible for this preliminary study. However, we decided to randomise a convenience sample of 50 patients for this study's two groups. Data were analysed using Stata software (version 14.0; StataCorp LLC, College Station, Texas). Quantitative data (age, weight, height, BMI, anaesthesia duration) are presented in mean (standard deviation [SD]) or median (interquartile range), and categorical data (gender, ASA status, co-morbidities, receptor status) were expressed in frequency (percentage). Chi-square/Fisher's exact test compared categorical variables (NRS score, PONV score, satisfaction score). Continuous variables (fentanyl consumption, QoR-15 score) were compared using an independent t-test/Wilcoxon rank sum test. The change in the continuous variable was assessed by repeated measure analysis of variance (ANOVA)/Friedman's test followed by an appropriate post-hoc test. A *P* value of less than 0.05 was taken as statistically significant.

## RESULTS

A total of 63 patients were assessed for eligibility, of which 50 were included and randomised into two groups, with 25 patients in each group [Figure 2]. Demographic and other baseline surgery and anaesthesia-related parameters were comparable in both groups [Table 1 and Figure 3]. Postoperative 24-h IV fentanyl consumption was significantly lower in the PIB group compared to the CI group [$P = 0.002$] [Table 2]. Similarly, 4, 6, and 12-h fentanyl consumption values were also significantly lower in

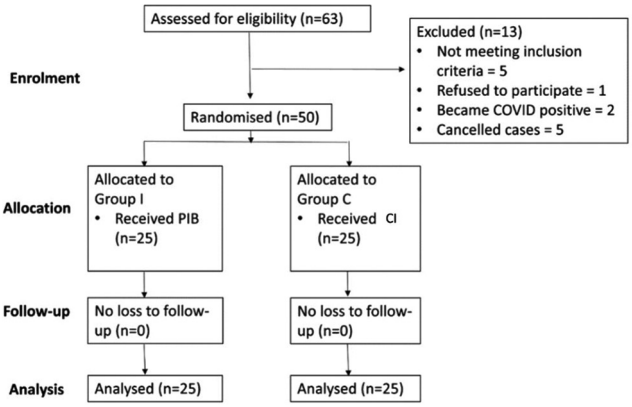


**Figure 2:** Consolidated standards of reporting trials flow diagram. PIB-programmed intermittent bolus, CI-continuous infusion, COVID-coronavirus disease

the PIB group compared to the CI group [Table 2]. Our study showed a statistically significant reduction in the post-operative median NRS score at 1, 2, 4, and 6 h in the PIB group compared to the CI group, both at rest and movement [Table 2]. In addition, PIB group patients had significantly higher mean QoR-15 scores than CI group patients [Table 2].

Dermatomal sensory coverage at 30 min was significantly seen over T1–T8 (paravertebral region), T1–T7 (midaxillary region), and T3–T6 (parasternal region) in all patients [Figure 4]. Dermatomal sensory coverage at 24 h in the PIB group was seen significantly over T2–T7 (paravertebral region), T3–T7 (midaxillary region), and T3–T6 (parasternal region), while the coverage in the CI group was significantly seen over T3–T5 (paravertebral region), T4 and T5 (midaxillary region), and T4 dermatome in parasternal

**Table 1: Patient characteristics**

| Characteristics | Group C (*n*=25) | Group I (*n*=25) |
|---|---|---|
| Age (years) | 46.8 (12.3) | 46.3 (12) |
| Weight [kg] | 64.8 (11.3) | 60.9 (15.4) |
| Height [cm] | 155.9 (6.4) | 157.2 (7.2) |
| BMI [kg/m$^2$] | 26.9 (4.3) | 24.6 (5.5) |
| Gender- Female/Male (*n*) | 25/0 | 25/0 |
| ASA status (*n*)- I/II | 16/9 | 17/8 |
| Number of comorbidities-0/1/2 (*n*) | 16/8/1 | 17/6/2 |
| History of chronic pain:absent/present (*n*) | 24/1 | 24/1 |
| Side of surgery- right/left (*n*) | 14/11 | 12/13 |
| Anaesthesia duration [mins] | 139.2 (28.8) | 143.8 (26.8) |
| Receptor status | | |
| ER+ | 16 | 16 |
| ER− | 9 | 9 |
| PR+ | 15 | 15 |
| PR− | 10 | 10 |
| Her2Neu+ | 13 | 8 |
| Her2Neu− | 12 | 17 |

Data are expressed as mean (standard deviation) or numbers. kg - kilogram, cm - centimetre, SD - standard deviation, BMI - Body Mass Index, ASA - American Society of Anesthesiologists, MRM - Modified Radical Mastectomy, ER - Oestrogen receptor, PR - Progesterone receptor

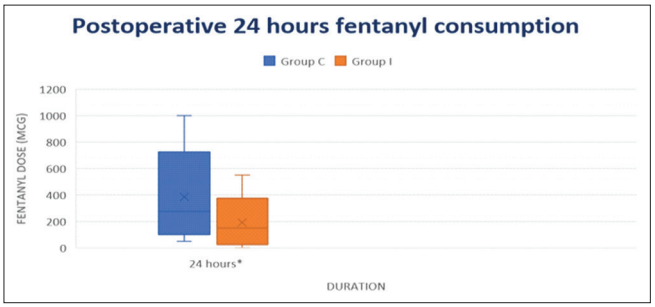


**Figure 3:** Box and Whisker plot of postoperative 24h intravenous fentanyl consumption in both groups. Box- Interquartile range, Whiskers- Extreme values, Horizontal bar inside the box- Median, MCG-micrograms, *represents p-value <0.05 (statistically significant)

**Table 2: Post-operative fentanyl consumption, QoR-15, NRS, PONV, and satisfaction scores**

| Characteristics | Group C (*n*=25) | Group I (*n*=25) | *P* |
|---|---|---|---|
| Post-operative IV fentanyl consumption | | | |
| 2 h | 53 (43.49) (35.04–70.95) | 33 (29.5) (20.81–45.18) | 0.031 |
| 4 h | 117 (83.76) (82.42–151.57) | 69 (67.03) (41.32–96.67) | 0.015 |
| 6 h | 208 (173.01) (136.58–279.41) | 97 (92.51) (58.81–135.18) | 0.003 |
| 12 h | 267 (204.21) (182.70–351.29) | 136 (109.76) (90.71–181.28) | 0.003 |
| 24 h | 332 (247.96) (229.64–434.35) | 166 (139.17) (108.55–223.44) | 0.002 |
| QoR-15 score assessment [out of 150] | 127 (12.81) (121.67–132.32) | 134.4 (8.52) (130.87–137.92) | 0.020 |
| PONV score (*n*)- 0/1/2/3 | 20/2/2/1 | 22/2/2/1 | 0.768 |
| Satisfaction score (*n*)-1/2/3/4/5 | 0/0/4/11/10 | 0/0/1/6/18 | 0.093 |
| NRS score (on rest) | | | |
| 0 h | 4 (2–6) | 2 (0–5) | 0.121 |
| 1 h | 5 (3–6) | 3 (2–5) | 0.031 |
| 2 h | 4 (3–5) | 3 (2–4) | 0.011 |
| 4 h | 5 (3–5) | 3 (2–4) | 0.009 |
| 6 h | 4 (2–6) | 3 (2–4) | 0.039 |
| 12 h | 2 (2–4) | 3 (2–5) | 0.960 |
| 24 h | 3 (2–4) | 2 (2–3) | 0.475 |
| NRS score (on movement) | | | |
| 0 h | 5 (2–6) | 2 (1–5) | 0.119 |
| 1 h | 5 (3–6) | 3 (2–5) | 0.022 |
| 2 h | 5 (4–6) | 3 (2–5) | 0.006 |
| 4 h | 5 (4–6) | 3 (3–4) | 0.001 |
| 6 h | 5 (4–6) | 4 (2–5) | 0.020 |
| 12 h | 3 (2–5) | 3 (2–5) | 0.780 |
| 24 h | 4 (3–5) | 3 (3–4) | 0.221 |

Data expressed as mean (standard deviation) (95% confidence interval), or median (interquartile range) or numbers. QoR-15 score - Quality of recovery assessed using a 15-point questionnaire (out of 150), PONV - postoperative nausea and vomiting, NRS - Numerical Pain Rating Scale, IV-intravenous

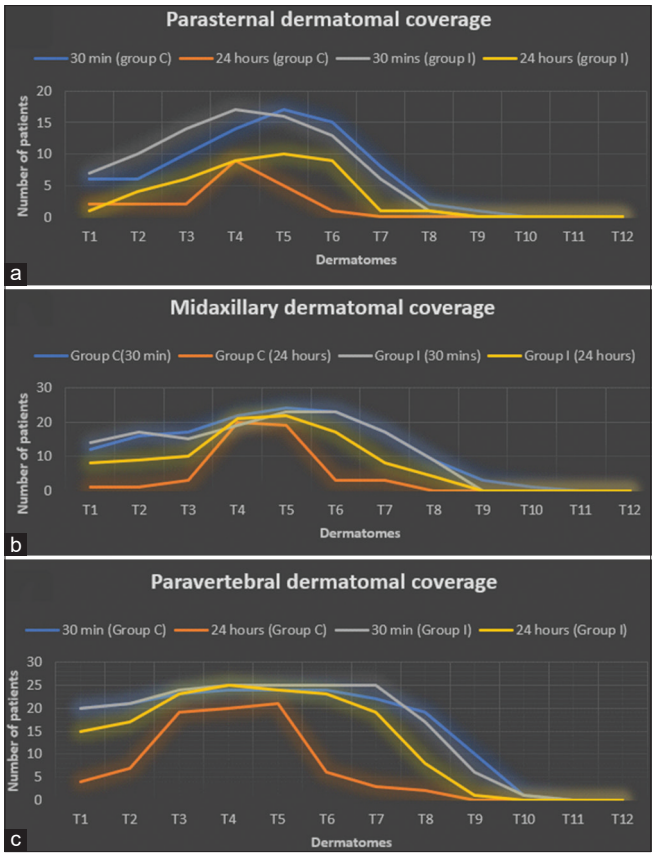


**Figure 4:** Comparison of 30-min and 24-h parasternal (a), midaxillary (b), and paravertebral (c) dermatomal sensory coverage in both groups expressed in line diagram

region [Figure 4]. PONV and satisfaction scores were comparable between both groups [Table 2]. Surgical incision and dissection pain responses were noted among 12%, 8%, and 4% of patients in parasternal, axillary, and infra-clavicular regions, respectively, in the intra-operative period. No significant catheter-related complications were noted throughout the study.

## DISCUSSION

Our study results show that the PIB group has lower postoperative fentanyl requirement, better analgesia, better QoR, and wider 24-h dermatomal sensory coverage than the CI group.

The probable reason for the variation in outcomes in our study is the difference in spread along the tissue plane. The cadaveric study by Hogan in the cryo-microtome section shows that the spread through a potential space is more uniform near the injection segments if administered in large volumes and with high injectate pressure.[14] If the flow rate is very low, especially in continuous infusion, then there is a high probability that the flow through the distal port in a multi-orifice catheter will be almost nil, and the drug will be administered only via the proximal and middle ports, which results in decreased and non-uniform spread, leading to ineffective analgesia.[15] For these reasons, we kept the catheter tip at least 3 cm inside the space so that the distal orifice lies in the fascial plane at the congruent level of the desired dermatome for analgesia (T4, T5). In addition, the fascial plane beneath the erector spinae muscle is not a continuous space (because the attachment of the iliocostalis muscle slips over the ribs)[16]. This implies that the spread through these spaces would be much more compromised if not administered with adequate pressure and flow rate, especially in continuous infusion.

Catheter placement in the fascial plane beneath the erector spinae muscle gives an added advantage for providing long-lasting analgesia in the late postoperative period. Taketa *et al*.[17] compared PIB and CI techniques after paravertebral block in VATS, which showed wider sensory blockade with PIB but similar analgesic consumption in both groups. Taboada *et al*.,[11] Wong *et al*.,[12] and Paul Su *et al*.[13] conducted studies comparing PIB and CI techniques in lower limb, obstetric, and abdominal surgeries. A meta-analysis by Jagannathan *et al*.[18] showed that there is limited data to recommend PIB over CI at present. All such studies comparing these techniques showed mixed results, with the majority proving that PIB is comparatively better than the CI technique. The meta-analysis by Jagannathan *et al*.[18] also mentioned that they could not conclude regarding effective methods, especially automated or manual intermittent bolus for delivery of local anaesthetics. In our study, we used the automated pump for effective and uniform delivery of intermittent bolus and continuous infusion.

Although ESPB has become an established and efficacious block, the mechanism of action still needs to be clarified. A cadaveric study by Ivanusic *et al*.[16] showed craniocaudal and mediolateral spread (confined to erector spinae muscle till attachment to the angle of ribs and enveloping thoracolumbar fascia) of drug anaesthetises, mainly the intercostal nerve, lateral cutaneous branch, and dorsal rami over the supplied territory (somatic analgesia). A review by Chin KJ *et al*.[10] the local anaesthetic also spreads anteriorly into the paravertebral and epidural space by diffusing over small perforations in the intertransverse connective tissue complex, costotransverse foramen,

and later through the intervertebral foramen. These perforations in the inter-transverse ligament complex are the channels for the passage of dorsal rami and its associated vascular structures. They do not allow the rapid bulk flow of local anaesthetic; instead, a gradual seepage explains the slower onset of analgesia at higher levels in some cases. This spread causes blockade of the sympathetic ganglion and ventral rami preferentially (sympathetic blockade and visceral analgesia). Thus, this block provides somatic, visceral analgesia, and sympathetic blockade collectively over the spread territory of local anaesthetics.[10] It is also to be mentioned that some studies still do not provide evidence of drug spread into the paravertebral space and ventral rami blockade by seeping through the costotransverse and intervertebral foramina.[16] Thus, this block's spread and exact mechanism of action need to be determined. Hence, we decided to evaluate the dermatomal coverage after the block [Figure 3] and intra-operative pain response during surgery.

There are additional observations of our study in a relatively small group of patients. We observed that the pain responses occurred when parasternal (12%), axillary (8%), and infra-clavicular (4%) regions were dissected, which were adequately treated with intra-operative fentanyl boluses. These pain responses occurred probably secondary to inadequate spread of local anaesthetics or owing to complex innervation with contribution from supraclavicular nerve and branches of brachial plexus (medial and lateral pectoral nerves), which ESPB does not cover.

Following are some of the strengths and limitations of the study. We studied the dermatomal pattern after ESPB, which provides better knowledge and data to decide ESPB for surgeries involving the chest's anterior, lateral, and posterior parts. However, it was a preliminary study with a small sample size. We did not have a control group with single-shot ESPB alone to assess how efficacious PIB and CI techniques were over the control group. Proper assessment of 24 h sensory dermatomal coverage over the parasternal region was difficult because of the dressing over the incision site.

## CONCLUSION

Our preliminary study results show that the PIB technique can decrease post-operative opioid consumption and provide better post-operative analgesia for up to 6 h with better quality of recovery compared to the CI technique after ESPB in patients undergoing MRM surgeries. However, it was a pilot study, and large RCTs with adequate sample size are needed to validate these results.

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### 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.

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### Conflicts of interest

There are no conflicts of interest.

**ORCID**

Thamizharasan Datchinamourthy: https://orcid.org/0000-0003-1346-3293

Debesh Bhoi: https://orcid.org/0000-0003-2047-3115

Anjolie Chhabra: https://orcid.org/0000-0001-7162-6754

Virender Kumar Mohan: https://orcid.org/0000-0002-9359-0016

Kanil Ranjith Kumar: https://orcid.org/0000-0001-6490-5667

Poornima Ranganathan: https://orcid.org/0009-0000-6358-6676

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