

Effect of balanced anaesthesia with and without modified pectoralis nerve block on postoperative analgesia after breast surgeries: A randomised controlled trial

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ABSTRACT

Background and Aims: Modified pectoral nerve block (PEC) has been reported to have variable effects on perioperative pain in patients undergoing surgery for carcinoma breast. This randomised controlled trial was conducted to study the effect of modified PEC on postoperative pain relief in patients undergoing breast surgery. **Methods:** Fifty patients with carcinoma breast undergoing breast surgery were randomised to receive a modified PEC block consisting of 30 ml of ropivacaine 0.2% after induction of anaesthesia (PEC group) or no block (GA group) in this prospective randomised trial. Time to first rescue analgesia was recorded as primary outcome. Other secondary outcomes recorded were postoperative visual analogue scale (VAS) scores, number of rescue boluses and 24-h fentanyl consumption. **Results:** There was no significant difference in time to first rescue analgesia between the two groups, with mean difference (95% confidence interval) of 22.91 (-6.8 to 52.69) min. Amount of fentanyl required to keep pain VAS less than 3 was also comparable between the two groups, mean (standard deviation) of 42.0 µg (17.42) in GA group versus 43.24 µg (17.22) in PEC group; $P = 0.830$. 20/25 patients required rescue analgesia in GA group as compared to 17/25 in PEC group ($P = 0.334$). The postoperative VAS scores were also comparable between the groups at all time intervals. **Conclusion:** Balanced anaesthesia supplemented with modified PEC block performed after general anaesthesia did not improve the postoperative pain in patients undergoing modified radical mastectomy.

Key words: Breast surgery, modified radical mastectomy, pectoral nerves (PECs) block, postoperative analgesia

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INTRODUCTION

Breast cancer is one of the commonest malignancies affecting one out of eight women during their lifetime.^[1] Surgical treatment ranges from breast-conserving technique to radical mastectomy with or without axillary lymph node dissection which is associated with significant postoperative pain.^[2]

Regional anaesthesia is one of the well-documented modalities in reducing acute postoperative pain. Various regional anaesthesia techniques like thoracic epidural, paravertebral blocks and interfascial plane

blocks have been used to allay perioperative pain in breast cancer surgeries. Although epidural and paravertebral blocks at thoracic level have been successfully used to suppress stress response to

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breast surgery, their use has been implicated with life-threatening complications like pneumothorax, total spinal anaesthesia and intravascular injection.^[3] Furthermore, sparing of medial and lateral pectoral nerves with thoracic paravertebral block can lead to inadequate analgesia.

Blanco proposed interfascial plane blocks for breast surgery like the serratus anterior plane block (SAM block) and pectoral nerve blocks (PECs) I and II (modified PEC block).^[4,5] Bashandy *et al.*^[6] documented the effectiveness of modified PEC block compared to intravenous analgesia in improving the postoperative pain scores in breast cancer surgeries. On the other hand, contrasting results were documented by Kamiya *et al.*^[7] who failed to demonstrate improvement in the postoperative quality of recovery scores (QoR 40) or decrease in the requirement of rescue analgesic with use of PEC block, despite improvement in postoperative pain scores.

We hypothesised that modified PEC block compared to intravenous analgesia would reduce the time to first rescue analgesia in carcinoma breast patients who underwent modified radical mastectomy under general anaesthesia.

METHODS

After obtaining institutional ethics committee approval (REF num.: NK/2121/study/1073), this prospective randomised double-blinded study was conducted from July 2018 to January 2019 in the general surgery operation theatre complex of a tertiary care hospital. The study was registered in the Clinical Trial Registry-India (CTRI/2018/07/014728). Fifty adult female patients of the American Society of Anesthesiologists (ASA) status I and II, between 30 and 65 years, scheduled to undergo elective unilateral modified radical mastectomy for carcinoma breast were assessed for eligibility and enrolled into the study after written informed consent. We excluded patients with history of allergy to local anaesthetics, coagulopathy, psychiatric disorder, neurological disorder, major cardiac disorder, local infection or those who refused to consent for enrolment. All enrolled patients were taught and explained to report their postoperative pain intensity on a visual analogue scale (VAS) of 0–10 cm where 0 meant no pain and 10 stood for worst possible pain.

Patients were randomly allocated into two groups, Group 1 = PEC block group and Group 2 = General

Anaesthesia (GA group) following computer-generated randomisation programme (<http://www.randomiser.org>). Allocation was done by sequentially numbered sealed opaque envelopes. Inside the operating room, anaesthetist (JK) who was not involved in the follow-up of the patient picked up a sealed envelope according to serial number labelled on the envelope and prepared the block set accordingly. Anaesthetist (AK) (outcome assessor) who followed up the patients postoperatively was blinded to the group allocation. In this study, the patients and outcome assessor were blinded to group allocation.

In the operating room, 18 G intravenous access was secured in the arm opposite to surgical site. Standard ASA monitoring including electrocardiography, non-invasive blood pressure and peripheral oxygen saturation (SpO₂) was done in all the patients. Anaesthesia was induced with fentanyl 1–2 µg/kg, propofol 1.5–2 mg/kg titrated to loss of verbal response. Vecuronium 0.12 mg/kg was used to facilitate tracheal intubation. Anaesthesia was maintained with isoflurane in O₂/N₂O 30:70 targeting a minimum alveolar concentration of 1–1.3. End-tidal carbon dioxide and nasopharyngeal temperature monitoring were established after intubation. Additional boluses of 0.5 µg/kg fentanyl were administered if heart rate or blood pressure increased by more than 20% of baseline. Ringer lactate was administered as intra-operative fluid to all patients continuously at the rate of 5–8 ml/kg/h.

After the patient was positioned for surgery, study investigator (JK) performed block in PEC group patients. A 38-mm linear array ultrasound (US) probe (SonoSite™ micromax transportable ultrasound device Bothell, WA, USA) of frequency (13.6 MHz) was used, with an imaging depth of 4–6 cm. Using all aseptic precautions, the probe was placed horizontally below the lateral third of the clavicle and then moved laterally to locate the axillary artery and vein directly above first rib. Pectoralis major (PMm) and pectoralis minor (Pmm) muscles were identified in this US window. US probe was then moved towards axilla till serratus anterior muscle (SAM) was identified above second, third and fourth ribs. Needle was advanced in tissue plane between Pmm and SAM and 20 ml of 0.2% ropivacaine was deposited. Needle was then withdrawn and another 10 ml of 0.2% ropivacaine was deposited in plane between PMm and Pmm. The patient was handed over to the surgeon, 10 min after the placement of block.

Towards the completion of the surgery, paracetamol 1 g/100 ml IV infusion and 4 mg of ondansetron was given to all participants. Neostigmine 0.05 mg/kg with atropine 0.02 mg/kg was administered to antagonise residual neuromuscular blockade. Thereafter, patients were extubated and shifted to post-anaesthesia care unit (PACU). Duration of surgery and duration of anaesthesia was noted.

Standard ASA postoperative monitoring protocol was followed. Intensity of dynamic pain was monitored using VAS score at 0 min, 30 min, 1 h, 2 h, 4 h, 6 h, 12 h and 24 h postoperatively by asking the patient to move the shoulders. In case of VAS score more than 3 or if the patient demanded analgesia, fentanyl 0.5 µg/kg was administered as rescue analgesia. Time to first rescue analgesia was noted. Total dose of fentanyl used in 24 h was recorded. Postoperative nausea vomiting (PONV) was recorded using a 5-point scale (0–4) (0 = no nausea or vomiting, 1 = mild nausea, 2 = severe nausea, 3 = vomiting once and 4 = vomiting more than once). Oral diclofenac 75 mg was administered thrice a day to all patients once patient started accepting orally. Ondansetron 4 mg IV was used to treat nausea and vomiting. Patients were shifted from PACU to a monitored ward, once Aldrete score >9.

The primary outcome of the study was time to first rescue analgesia. Secondary outcomes recorded were VAS scores at different time intervals, total fentanyl consumption and incidence of PONV.

Sample size was calculated based on the time to rescue analgesia as the primary outcome. Assuming 50% increase in time to first rescue analgesia in the modified PEC group, 48 patients were required with 80% power and 5% probability of type I error. Fifty patients were thus enrolled in this randomised double-blind trial.

Normality of data was tested using Kolmogorov–Smirnov test. The normally distributed data were compared using Student's unpaired *t*-test. Non-parametric data were compared by χ^2 test for intergroup differences. Pain scores, time to first rescue analgesia and total 24 h fentanyl consumption were compared using the Mann–Whitney *U* test for pairwise comparisons. Data were analysed using Statistical Package for the Social Sciences version 18 (Inc., Chicago, IL). *P* value less than 0.05 was considered statistically significant.

RESULTS

The flow of patients is shown in the CONSORT diagram [Figure 1]. The demographic characteristics of patients like age, sex, weight, duration of surgery and duration of anaesthesia were comparable in both the groups [Table 1].

Time to first rescue analgesia was mean [standard deviation (SD)], 56.06 (36.164) min in PEC group and 79.00 (50.357) in GA group with the mean difference (95% confidence interval) of 22.91 (–6.8 to 52.69) min (*P* = 0.11). The mean intra-operative total fentanyl consumption was comparable in both the groups (GA group = 108.54 (16.516) vs. PEC group = 98.75 (24.727)) (unpaired *t*-test, *P* = 0.11). In addition, the amount of fentanyl required as rescue analgesia to keep VAS scores less than 3 in the postoperative period was also comparable between both the groups, mean (SD) of 42.0 (17.42) in GA group versus 43.24 (17.22) in PEC group. Twenty out of 25 patients required rescue fentanyl in GA group as compared to 17/24 in PEC group (*P* = 0.334). The postoperative VAS scores were also comparable between the groups at all time intervals [Figure 2]. Grade 2 PONV occurred in two patients in GA group and was treated with ondansetron.

DISCUSSION

The results of our study did not show any difference in time to first rescue analgesia between the patients receiving only balanced anaesthesia and those supplemented with modified PEC block. Moreover, the VAS scores were also comparable between both the groups.

Efficacy of PEC block has been attributed to blockade of nerves supplying lateral mammary region, the intercostobrachial and lateral cutaneous branches of the intercostal nerves (T2–T6), the medial cutaneous

Table 1: Patient demographics and other baseline characteristics in both the groups

Parameters	GA group <i>n</i> =25	PEC group <i>n</i> =24
Age (years)	51.4 (10.2)	47.8 (10.3)
Weight	65.9 (11.1)	60.2 (16.6)
Height	158.7 (6.7)	156.7 (5.2)
Sex (proportion) (females)	100%	100%
Duration of surgery (min)	99 (22.6)	103.3 (17)
Duration of anaesthesia (min)	106.8 (22.1)	118.3 (17.8)

Values expressed as mean (SD) for the number of patients in each group.

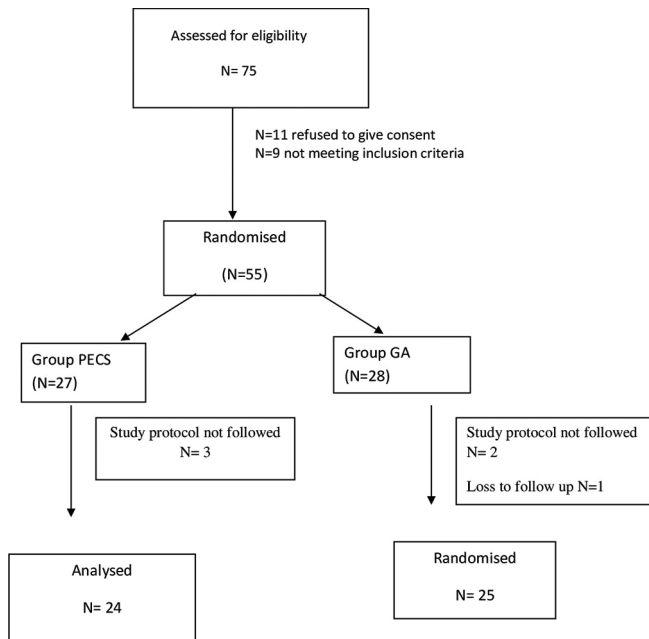


Figure 1: CONSORT diagram showing flow of patients

nerve of the arm and forearm, and the long thoracic and thoracodorsal nerves.^[5] Previous studies have reported excellent analgesia with PECs combined with general anaesthesia for breast cancer surgery with axillary clearance.^[6,8-10] However, we did not observe any difference in time to first rescue analgesia between the patients receiving only balanced anaesthesia and those supplemented with modified PEC block. The difference in results can be attributed to the inadequate time for local anaesthetic to act as the block was performed after general anaesthesia in all our cases, in contrast to the former study where the block was administered 15 min prior to anaesthesia induction. Although the patient was handed over to the surgeon 10 min after administering block, the surgeon reported presence of local anaesthetic in axilla at the time of dissection. As subcutaneous fat in axilla has low blood supply, it is possible that local anaesthetic present in axilla at time of dissection was washed away during surgery, thus providing partial analgesia of long thoracic nerve of Bell.^[11]

Most of the studies administering the PEC block preoperatively had established superiority of the block compared to the balanced anaesthesia alone.^[8-10,12,13] However, a conflicting response has been found with the efficacy of PEC block when given after induction of anaesthesia.^[7,14] Preoperative administration of the block often results in increased preoperative anxiety, especially in patients prone to it. A recent study on breast cancer patients demonstrated

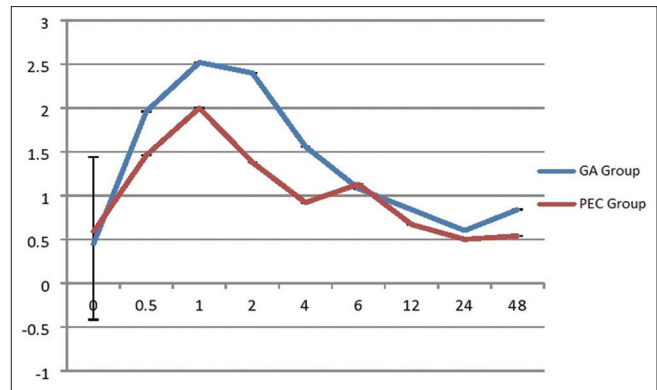


Figure 2: Visual analogue score in both the groups at different time intervals

moderate-to-severe anxiety in almost 50% of the patients.^[15] Additionally, as modified PEC block is not associated with any nerve injury, we decided to perform it after general anaesthesia as it is more comfortable for patients.

In certain studies assessing the postoperative pain, nerve blocks are performed at the end of the surgery. However, owing to various technical and feasibility issues like presence of tissue oedema, we did not prefer the same.

PEC block does not block the multiple anterior branches of intercostal nerve T2–T6 that supply the internal mammary region.^[7] As incision usually extends into this region, limited distribution of local anaesthetic in the region of internal mammary artery might have resulted in ineffectiveness of modified PEC block in enhancing postoperative analgesia after breast surgery.

Kamiya *et al.*^[7] could not demonstrate improvement in the postoperative QoR 40 scores or decrease in the requirement of rescue analgesic with use of PEC block, despite improvement in postoperative pain scores. It is possible that patients in PEC group had breakthrough pain during the first postoperative hour and received a rescue bolus, and thereafter, consecutive pain scores were lower in PEC group.

Our study has a few limitations. First, the efficacy of PEC block was not confirmed as the block was administered after the patient was induced for surgery. The use of multimodal perioperative analgesic regimen consisting of acetaminophen and diclofenac along with a relatively smaller sample size could have contributed to no significant difference in pain scores between the two groups. We believe that in this era of opioid free

analgesia, use of multimodal analgesia would decrease postoperative opioid requirement and hence potential of dose-related side effects and addiction.^[16,17] Lastly, we did not measure the incidence of chronic pain which could have further added on to the results.

CONCLUSION

To conclude, modified PEC block administered after induction of anaesthesia did not prolong the analgesia when compared to balanced anaesthesia alone.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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