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Randomized controlled trial to study the efficacy and safety of ultrasound-guided pectoral nerve block for superficial breast surgeries

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Abstract:

BACKGROUND: Our study aimed to compare pectoral nerve (PEC) block with local anesthetic (LA) infiltration for providing analgesia in superficial breast surgeries.

MATERIALS AND METHODS: This prospective comparative randomized study included seventy American Society of Anesthesiologists I and II female patients undergoing excision of fibroadenoma. In Group 1, the LA mixture was infiltrated in the desired planes. In Group 2, PEC I and PEC II blocks were performed under ultrasound guidance. Patients were observed at regular time intervals for pain scores, time to first analgesic request, and the number of patients requiring rescue analgesia with the cumulative analgesic requirement, hemodynamic changes, and any adverse events.

RESULTS: The patients were comparable in demographic profile, duration of anesthesia, and hemodynamic parameters. NRS scores at all times after extubation were significantly lower in Group 2 as compared to Group 1 ($P < 0.0001$). All patients in Group 1 required additional analgesia, while only two in Group 2 received rescue analgesia ($P < 0.0001$). The time to first analgesic request was significantly longer in Group 1 as compared to group 2 ($9.5 + 0.70$ h vs. $1.35 + 0.83$ h) ($P < 0.0001$). The cumulative requirement of tramadol in Group 1 (96.88 ± 16.45 mg) was significantly higher than in Group 2 (6.47 ± 26.38 mg) ($P < 0.0001$). No adverse event was reported in either group.

CONCLUSION: PEC block is a useful method for achieving effective and long-lasting analgesia. It is an efficient and safe alternative to LA infiltration in patients undergoing fibroadenoma excision.

Keywords:

Analgesia, fibroadenoma, pectoral nerve block

Introduction

Benign breast lesions such as fibroadenomas are common among women and when symptomatic, definitive surgical management is preferred both by patients and clinicians.^[1] However, even after minimally invasive breast surgery, one of the common causes for prolonged hospital admission or potential patient dissatisfaction is acute postoperative pain.^[1] Studies have shown that the incidence of postoperative pain may vary between

12% and 57% after breast cancer surgery and 21%–50% after noncancer breast surgery.^[2] Hence, a simple and reliable analgesic technique with the least possible complications is desirable.

To remove postoperative discomfort and limit narcotic analgesic use after breast surgery, thoracic paravertebral block (TPVB), interscalene brachial plexus block, and/or thoracic epidural analgesia are utilized.^[3,4] Many anesthesiologists, however, dislike these procedures because of the potential of significant consequences and their technical difficulty.^[5] In recent

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years, interfascial plane blocks, such as the erector spinae plane block, pectoral nerve (PEC) block, and superficial serratus plane block have gained popularity for postoperative pain management after breast surgeries, as they can be performed more easily and efficiently.^[6]

Superficial breast surgeries at many centers receive general anesthesia or sedation with local anesthetic (LA) infiltration. However, these techniques achieve only a modest analgesic effect for a few hours after surgery.^[7] Pectoral nerve (PEC) block is a safe peripheral nerve block technique that provides analgesia during and after breast surgery.^[5,6]

This study aimed to compare pectoral nerve (PEC) block with LA infiltration for providing analgesia in superficial breast surgeries.

Materials and Methods

Study design and setting: This prospective, randomized, double-blind study was conducted over 5 months (from October 2020 to March 2021).

Ethical consideration: The study commenced after obtaining approval from the Institutional Ethics committee and registration with the clinical trial registry of India (CTRI/2020/10/028413.). The study adheres to the Consolidated Standard of Reporting Trials (CONSORT) statement depicted in the flowchart [Figure 1].^[8]

Study participants and sampling: Seventy female patients aged (18–60 years) belonging to the American Society of Anesthesiologists (ASA) Grade 1 or 2 undergoing excision of fibroadenoma were selected for this study. Only those patients who gave written consent were enrolled in the study. The patients with a history of allergic reactions to LAs, any coagulopathy, infection at the block site, and significant neurological, psychiatric, neuromuscular, cardiovascular, pulmonary, renal, hepatic disease, and chronic pain were excluded from the study.

Sample size calculation

The sample size was calculated using pain scores as the primary variable. An average difference of 10 mm in visual analog scale pain score of 10 cm with a standard variation of 10 mm was observed in a literature search.^[9] With a standard deviation of 10 mm and an alpha error of 0.05 and an 80% power, the minimum sample number required to detect a difference of 10 mm on a pain score of 10 cm was 54. To account for any dropouts, a total of 70 patients were enrolled.

Data collection tool and technique

Patients were randomly divided into two groups of 35 patients each using a computer-generated random

number table. The sealed envelope technique was used for group allocation concealment. Patients in Group 1 ($n = 35$) received LA infiltration with general anesthesia, while patients in Group 2 ($n = 35$) received pectoral nerve block with general anesthesia. All perioperative data (hemodynamic parameters, NRS Score, number of patients requiring rescue analgesia, time to first rescue analgesia, cumulative dose of rescue analgesia, and complications if any) were collected by an anesthesiologist who was masked to the technique of analgesia performed.

In the pre-anesthetic visit, patients were explained about the study, advantages, disadvantages, and risks of both procedures. The patients were educated about the Numeric Rating Scale^[10] (NRS: 0–10, 0 = no pain, 10 = worst pain) and were given rescue analgesia at $NRS \geq 4$. After a fasting period of 8 h before surgery, premedication with intravenous (IV) ondansetron 4 mg and IV glycopyrrolate 0.2 mg was done. On arrival in the operating theatre, the crystalloid fluid infusion (ringer lactate) was initiated. For monitoring, the ASA basic monitoring protocol was used: electrocardiogram, noninvasive blood pressure, heart rate (HR), end-tidal carbon dioxide, and SpO_2 . Following pre-oxygenation with 100% oxygen for 3 min, patients were induced with IV propofol 2.5 mg/kg, IV fentanyl 2 μ g/kg, and IV midazolam 0.04 mg/kg. This was followed by appropriate size laryngeal mask airway (LMA) insertion. Anesthesia was maintained with a mixture of oxygen, nitrous oxide, and isoflurane with spontaneous ventilation. All patients received injection diclofenac sodium 75 mg IV intraoperatively.

In Group 1, after LMA insertion LA mixture (30 ml of 0.25% levobupivacaine) was infiltrated in the desired plane and the skin incision site by the surgeon before the start of surgery.

In Group 2, PEC (I and II) blocks were performed after LMA insertion. With the patient in the supine position, the left infraclavicular and axillary regions were cleaned with betadine. The ultrasound probe (InnoSight PhilipsTM machine, linear high-frequency probe, 6–13 MHz) was placed obliquely between the third and fourth ribs under the lateral one-third of the clavicle. After recognition of the appropriate anatomical structures, the block was performed using a medial in-plane approach. For PEC I block, the needle was advanced to the tissue plane between the pectoralis major muscle and pectoralis minor muscle at the vicinity of the pectoral branch of the acromiothoracic artery and 10 mL of 0.25% levobupivacaine was injected. For the PEC II block, 20 mL of 0.25% levobupivacaine was deposited at the level of the third rib above the serratus anterior muscle (SAM) with the intent to spread the LAs over the axilla.

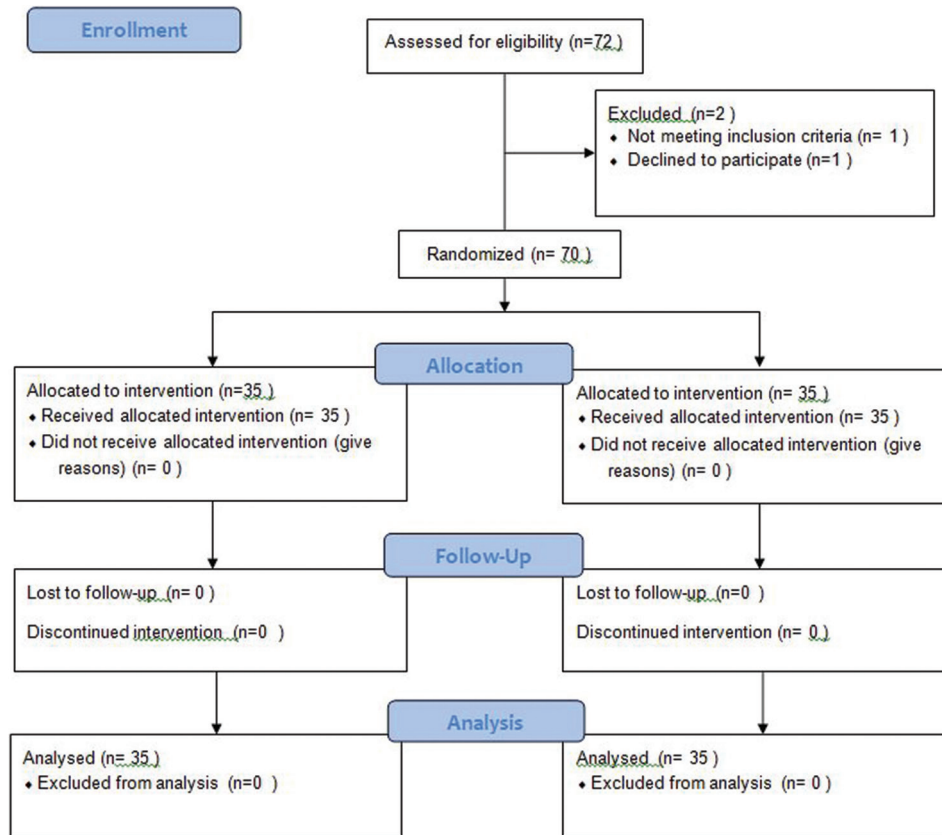


Figure 1: Consort diagram

After surgery, LMA was removed once the patient had gained an adequate level of consciousness with the return of pharyngeal reflexes. All patients were transferred to the postoperative ward. The duration of anesthesia defined as the time between the arrival of the patient in the operating theatre till extubation was noted in both groups.

Measurement of pain and rescue medication

NRS scores were recorded at fixed intervals, i.e., on extubation (0 h), 1 h, 2 h, 4 h, 6 h, 8 h, and 12 h postoperatively and whenever the patient complained of pain. At NRS ≥ 4 , the rescue analgesia was administered (injection tramadol 2 mg/kg IV). Duration of analgesia (DOA) was calculated from the time of LMA removal to the time of the first analgesic request.

Primary and secondary objectives

The primary objective of the study was to compare the NRS between two groups. The secondary objective was to record the time to first analgesic request (DOA), the number of patients requiring rescue analgesia, cumulative dose of tramadol used in each group, and adverse effects like LA toxicity, vascular puncture, pneumothorax, and post block neuropathy. Hemodynamic parameters (mean arterial pressure [MAP] and HR) were recorded intraoperatively and 12 h postoperatively.

Data analysis

Data were collected, entered into Microsoft Excel 2010, and analyzed using SPSS version 22.0 (SPSS Inc., Chicago, IL, USA). The one-sample Kolmogorov–Smirnov test was used to evaluate the normal distribution of data. Normally distributed data were compared between the groups by analysis of variance and Tukey honest significant difference was used for *post hoc* multiple comparisons. Nonnormally distributed data were analyzed using the Kruskal–Wallis test. The value of $P < 0.05$ was considered statistically significant.

Results

The study began in October 2020, and 72 patients underwent surgery during the study period; of which two were excluded as per exclusion criterion, and 70 were randomly divided into two groups of 35 each [Figure 1].

The demographic profile of the patients and duration of anesthesia were comparable in both groups [Table 1]. Intraoperative and postoperative hemodynamic parameters (MAP and HR) were analyzed and no statistical difference was found [Figures 2 and 3].

NRS scores at 0, 1, 2, 4, 6, 8, and 12 h after surgery were significantly lower in the PEC group (Group 2) compared with that in Group 1 ($P < 0.0001$) [Table 2].

All the patients in Group 1 received rescue analgesia (100%), while in Group 2, only two patients required additional analgesia (5.7%) (odds ratio = 0.001, $P < 0.0001$). The time to first analgesic request in Group 1 was significantly shorter as compared to Group 2. (1.35 + 0.83 h vs. 9.5 + 0.70 h) ($P < 0.0001$). Hence, the DOA in Group 2 was significantly longer than in Group 1. The cumulative requirement of tramadol in Group 1 (96.88 ± 16.45 mg) was significantly higher than in Group 2 (6.47 ± 26.38 mg) ($P < 0.0001$) [Table 3]. No block-related complications were observed.

Table 1: Demographic characteristics of the two groups

| Demographic characteristics | Mean±SD | |
|-----------------------------|----------------|----------------|
| | Group 1 (n=35) | Group 2 (n=35) |
| Age (years) | 25.5±10.6 | 28.6±8.5 |
| Weight (kg) | 48.2±8.9 | 50.4±8.7 |
| ASA status (%) | | |
| I | 65 | 69 |
| II | 35 | 31 |
| Duration of surgery (min) | 38.45±4.56 | 40.46±6.32 |

ASA=American Society of Anesthesiologists, SD=Standard deviation

Table 2: Comparison of Numeric Rating Scale scores at various time intervals

| NRS score (h) | Median (IQR) | | P |
|---------------|----------------|----------------|---------|
| | Group 1 (n=35) | Group 2 (n=35) | |
| 0 | 3 (2.75-3) | 0 (0-1) | <0.0001 |
| 1 | 5 (5-5.5) | 1 (0-1) | <0.0001 |
| 2 | 3 (3-3.5) | 1 (0-1) | <0.0001 |
| 4 | 3 (3-3.5) | 1 (0-1) | <0.0001 |
| 6 | 3 (3-3.5) | 0 (0-1) | <0.0001 |
| 8 | 3 (3-3.5) | 0 (0-1) | <0.0001 |
| 12 | 3 (3-3.25) | 1 (0-1) | <0.0001 |

NRS distribution is nonnormal; Hence, median with IQR and Kruskal-Wallis test was applied. $P > 0.05$ - Nonsignificant, < 0.05 - Significant, < 0.001 - Highly significant. NRS=Numeric rating scale, IQR=Interquartile range, SD=Standard deviation

Table 3: Comparison of two groups regarding duration of analgesia and analgesic consumption

| Parameter | Mean±SD | | P | 95% CI of the difference |
|---|----------------|----------------|---------|--------------------------|
| | Group 1 (n=35) | Group 2 (n=35) | | |
| Time to first analgesic request (h) | 1.35±0.83 | 9.5±0.70 | <0.0001 | 7.77-8.50 |
| Number of patients requiring tramadol (%) | 100 | 5.7 | <0.0001 | 0.00-0.02 |
| Cumulative + tramadol (mg) | 96.88±16.45 | 6.47±26.38 | <0.0001 | 100.89-79.92 |

SD=Standard deviation, CI=Confidence interval

Discussion

In this study, we found that the patients who received PEC block had superior analgesia. This is reflected by the lower NRS scores in Group 2 at all time intervals. DOA achieved with PEC block was also significantly longer as compared to LA infiltration. It was also observed that only two patients required rescue analgesia in the PEC group, whereas all the patients in Group 1 were given rescue analgesia. A statistically significant difference in the 12-h postoperative tramadol consumption was present between the two groups.

PEC block is a combination of motor and sensory nerve blockade and aims to block intercostobrachial, intercostal III, IV, V, and VI, and long thoracic nerves. In PEC I block, LAs are injected between the pectoralis major and minor muscles to block the medial and lateral pectoral nerves, which innervate the pectoralis major and minor muscles.^[11]

PEC II block is a compartment block where LAs are injected above the SAM at the level of the third rib.^[12] At the mid-axillary line, the intercostal nerve branches off the lateral cutaneous branch which pierces the external intercostal muscle and the SAM, and divides into posterior and anterior branches. These branches supply the mammary gland and nipple-areolar complex.

Several studies have compared PEC block with the TPVB or intercostal nerve block^[13,14] for postoperative analgesia in patients undergoing breast surgeries. There are only a few studies that have compared the analgesic efficacy of LA infiltration with PEC I and II blocks.^[15,16] However, most of the studies have been done on patients undergoing mastectomy or breast conservation surgeries.^[17-20] To our knowledge, this study is the first to assess the efficacy of PEC blocks in fibroadenoma surgeries.

In this study, the DOA was significantly longer in patients who received PEC block as compared to LA infiltration.

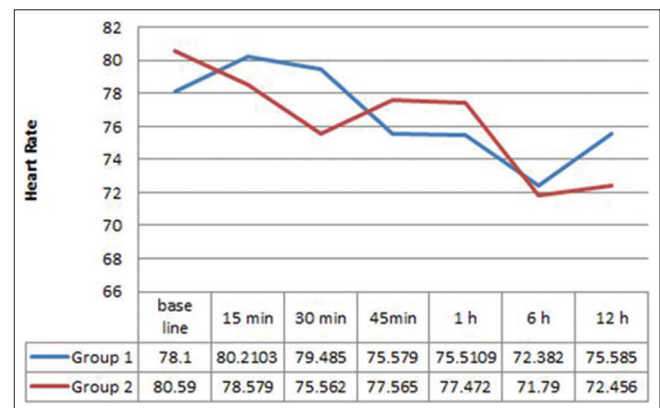


Figure 2: Comparison of heart rates between groups

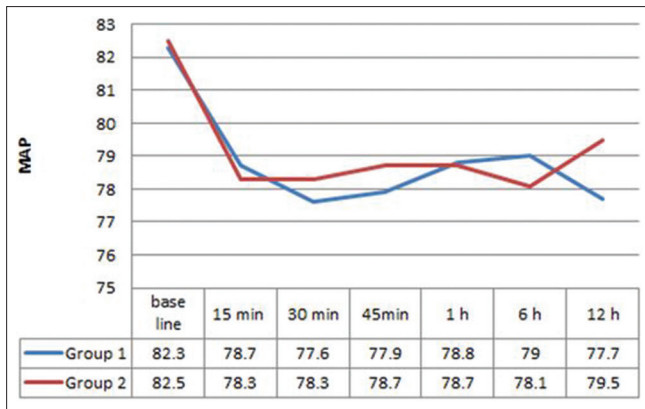


Figure 3: Comparison of mean arterial pressure between groups

This outcome is in agreement with the conclusion drawn in a systemic review by Byager *et al.*^[7] They stated that “although pain after breast surgery is mild to moderate, the analgesic effect of wound infiltration with LAs may only have a modest analgesic effect in the first few hours after surgery.”^[7] Christie *et al.* have also suggested that other noninvasive analgesic methods apart from LA infiltration may be preferable and need to be explored.^[21]

In our study, PEC blocks were done under ultrasound guidance and no procedure-related complications were observed. The target areas of the PEC I and II block are relatively distant from pleura and epidural space as compared to paravertebral blocks.^[22] The pectoral branch of the acromiothoracic artery may be present at the interfascial plane; however, it is easily visualized using ultrasound.^[23] In both groups, the intervention, i.e., LA infiltration or administration of PEC block, was done after administration of general anesthesia. This obviated the patient’s discomfort and anxiety associated with the breach of privacy on receiving a nerve block around the breast in a conscious patient.

Furthermore, fibroadenoma excision can be performed as an ambulatory operation, allowing the patient to be admitted and discharged on the same day.^[24] If breast surgery is performed while utilizing this blocking strategy, it will reduce the use of anesthetics and opioids during and after surgery, allowing the patient to recover sooner and reducing the in-hospital cost.^[25]

One of the limitations of this study was that the extent of sensory blockade in the thoracic wall was not assessed due to wound dressing and anesthetic hangover in the postoperative period. Another limitation of this study was that the length of the hospital stay was not compared between the two groups as fibroadenoma surgeries are performed as a daycare procedure.

Future research with further modifications like using ropivacaine or additives such as ketamine or

dexmedetomidine to increase the DOA could be explored.

Conclusion

PEC block is a useful interfascial block that provides effective and long-lasting analgesia in patients undergoing superficial breast surgeries and is a preferred alternative to LA infiltration.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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