ORIGINAL ARTICLE



Utility of Pecs Block for Perioperative Opioid-Sparing Analgesia in Cancer-Related Breast Surgery: A Randomized Controlled Trial

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Abstract

Multidisciplinary treatment and multimodal analgesia are the approach to reduce mortality and morbidity of breast cancer. Pectoral nerve block (PECS I and II) is one of the modes of analgesia advocated. The primary aim is to find the risks and benefits of the block in providing analgesia for intraoperative and immediate postoperative cancer-related breast surgery and total morphine consumption. The secondary aim is to evaluate, any additional knowledge acquired, in the reduction of persistent chronic pain state and cancer recurrence, during the time frame studied. The study was conducted after the approval of the ethics committee and National Registry, and included patients of ASA I and II undergoing mastectomy surgery with axillary clearance, under general anesthesia, during the period of 2017 to 2018. A total of 60 patients were recruited, randomizing them into two groups: group 1 (n = 30): ultrasound-guided PECS I (0.2 ml/kg) and PECS II (0.4 ml/ kg) block, post-induction with 0.25% levobupivacaine, maximum dose of 2 mg/kg; group 2 (n = 30): no block, only general anesthesia. Intraoperatively, vitals were monitored at regular intervals and analgesics given as per response. Postoperatively, pain was assessed using the numerical pain score and arm abduction score, until discharge. Data collected was analyzed and interpreted using statistical methods. Patients were followed up telephonically, until six months for any chronic pain and cancer recurrence instances. The PECS block group used less morphine intra and postoperatively, which was statistically significant (p = 0.0001). Group 1- Had a significant decrease in the mean intraoperative systolic blood pressure (p = 0.03). There was significant improvement in the arm abduction in the test group as compared to that in the control group (p = 0.001). The average time for block performance was 7.9 min and no complications were observed. No patients in the study groups reported chronic pain or cancer recurrence issues. The two-level PECS block is safe, effective, reliable, and easy to perform. Clinical Trial Registration Number: CTRI/2017/11/010630

Keywords Pecs block · Breast analgesia · Postoperative pain · Chronic pain management · Opioid-sparing analgesia

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Introduction

Among the overall incidence of cancers, including both sexes, all ages, and specifically in women, breast cancer is the most common. The global cancer burden has escalated to 19.3 million new cases and 10 million cancer deaths in 2020, according to the GLOBOCAN 2020 report. For the first time female breast cancer has surpassed lung cancer as the most often diagnosed cancer, one of every four malignancies, with 2.3 million new cases worldwide and the leading cause of cancer deaths in women, owing to its high incidence in low and middle-income nations (LMICs), with the prediction to further increase by 2040 [1]. India accounts for 25% of the world population and, depending upon the socioeconomic status, is categorized as medium, under the 4-tier Human Development Index (HDI) based on the United Nation's 2019 Human

Development Report [2]. Indian data shows breast cancer as the commonest in women with an incidence of 13.5% of new cases in both sexes and all ages and 26% in females of all ages with the death rate of 10.6% [1]. Among several conventional therapies, a multidisciplinary team approach, early identification and excision of localized lesions, such as, lumpectomy or partial mastectomy, are more favorable for long-term survival. Breast cancer treatment has evolved since the eighteenth century, when William Halsted pioneered radical mastectomy, which came with a slew of sequelae, including paraesthesia, lymphedema, and a loss of upper-limb mobility. The modifications proposed by Madden, in the late nineteenth century, have been implemented. This ranged from radical mastectomy, with or without breast reconstruction to sentinel node biopsy with or without axillary lymph node dissection, keeping both the pectoral muscles which produced the best results. The combinations of advances in adjuvants like chemotherapy, radiotherapy, plastic, and robotic surgery have offered several advantages in the clinical management of breast oncosurgery [3]. More recently, immunotherapy has been added to the armamentarium of breast oncotherapy [4]. Despite the improved efficiency in the surgical treatment, complications still occur, such as peri-mastectomy pain syndrome (PPBCS), which accounts to an incidence of 20-50%. General anesthesia with multimodal analgesia is the standard of perioperative care [5]. There is growing evidence of cancer recurrence with the use of morphine [6]. Previously considered as the "gold standard," thoracic epidural and paravertebral block were commonly used, but associated with several side effects [7]. The pioneering work by Blanco R, in 2011, illustrated the effectiveness of pectoral nerve (PECS) block in reducing pain over the breast and axillary. This was demonstrated by injecting a local anesthetic between the pectoral muscles and serratus anterior, warranting more randomized studies to further authenticate this technique [8]. At the start of this study, only three randomized controlled trials (RCT) were available in the scientific literature.

Inadequately treated acute pain will lead to chronic pain state [9]. Our aim was to investigate the possible benefits and drawbacks of an ultrasound-guided pectoralis nerve block and the amount of morphine consumed, as well as the quality of analgesia, intraoperatively and postoperatively, in order to add to the growing body of research supporting opioid-sparing analgesia and the safety of this block for postoperative analgesia.

Methods

This study was conducted, at the Department of Anaesthesia, in collaboration with Endocrine Surgery, at our quaternary-level hospital and research institution. Following ethics committee approval, and registration in the National Registry, the study design was a randomized control trial (parallel arms). The acute phase studied was within one week postoperatively or up to discharge and the long-term follow-up until six months after the surgery. Independent data and safety monitoring board were in place to review periodically the efficacy and safety of the data collection, which was completed without interim analysis within the stipulated time period.

Inclusion Criteria All ASA I and II consenting patients with breast cancer aged between 18 years and above undergoing radical mastectomy with axillary clearance.

Exclusion Criteria Non-consenting patients, ASA III and IV physical status, bilateral mastectomy, allergy to local and general anesthetic drugs, chest wall anatomical abnormality, presence of infection, patients on anticoagulants or antiplatelet drugs or coagulopathy.

Method of Randomization Block randomization was performed using computer-generated random numbers used to ensure equality of numbers in the two groups studied.

Blinding This was blinded by using concealed opaque envelopes until time of recruitment. However, intervention was not blinded. Evaluation of the outcome was performed by an independent pain nurse in the ward who was unaware of the intervention received by the patient.

Recruitment The study included patients who fulfilled the inclusion criteria. Patients underwent routine preanesthetic evaluation, and written and informed consent was obtained. The same was explained to their closest relative. The confidentiality of the patient was maintained. Following routine fasting protocols, patients were reassessed on the day of surgery. All safety precautions, for standard monitoring and anesthetic care; the patients were induced and maintained with oxygen, and opioids (fentanyl 2–3 μ g·kg⁻¹, morphine 0.1 mg·kg⁻¹), propofol 2–3 mg·kg⁻¹, and vecuronium bromide 0.1 mg·kg⁻¹ were used to facilitate endotracheal, inhalational agent (isoflurane-MAC = 0.8·1), additionally, paracetamol (15 mg·kg⁻¹).

Intervention Group 1 (study arm), Group 2 (control arm). Group 1 (n = 30): Received ultrasound-guided PECS-I (0.2 ml·kg⁻¹) and PECS-II (0.4 ml·kg⁻¹) block with 0.25% levobupivacaine (maximum dose 2 mg·kg⁻¹). Group 2 (n=30): Received only general anesthesia and no block.

The block was performed under strict aseptic precautions with the Sonosite ultrasound machine (US), using high-frequency linear (8–12 MHz) probe, ultrasound gel, and Sono-Plex (Pajunk) locating and stimulating needle. However, we did not use the nerve stimulation option. Slightly rotating the transducer allowing the in-plane needle trajectory from the medical to lateral side was the approach adopted. At all times, the shaft of the needle along with the tip of the needle was visualized. The landmarks identified under USG, for PECSI, at the level of myofascial plane between the pectoralis major and pectoralis minor, within which is also the pectoral branch of the thoracoacromial artery. A further deeper level is between the serratus anterior and pectoralis minor, for PECS-II. Confirming the plane by hydro-dissection with saline to open the space and only then administer the drug.

Outcome Measurements Intraoperative Period: Any increase in heart rate and blood pressure to more than 20% of the baseline was treated as a pain response after the patient was under the adequate plane of anesthesia and supplemented with morphine as required. Intraoperative vitals were monitored on intervals of 5, 10,15 30, 45, 60, 90, 120, 160, and 180. Heart rate (HR), and systolic, diastolic, mean blood pressure (BP) along with EtCO₂ and SpO₂ were recorded. After completion of surgery, neuromuscular blockade was reversed with neostigmine (0.05 mg·kg⁻¹ and glycopyrrolate 0.01 mg·kg⁻¹) and patients were extubated once the criteria for extubation were met. Total morphine and fentanyl consumptions were noted.

Postoperative Period: After surgery, patients were transferred to the postanaesthesia care unit (PACU), monitored for vitals, and discharged to ward when stable. Pain score was documented against Numeric Rating Scale score (NRS, 0 "no pain at all" whereas 10 "the worst pain possible") every 2 h for the initial 24 h and every 6 h for the next 24 h until discharge. Functional activity score (arm abduction score) was used to assess ability for arm abduction postoperative (Table 1) [10].

Statistical Methods

The sample size varied from 28 to 63 for various potential differences in standard deviation to detect differences of 2 mg and 3 mg between two groups intraoperatively. The various sample sizes for potential differences in two groups with possible standard deviations of the dose of morphine.

Postoperative pain was taken as the main outcome. The amount of morphine consumed was noted as one of the primary outcomes. One of the RCT suggests one unit difference in NRS

Table 1 Functional Activity Score (arm abduction score)

No	Comment	Score
1	No limitation of relevant activity	А
2	Mild limitation of relevant activity	В
3	Severe limitation of relevant activity	С

Note: The Score is assessed relative to the patient's baseline functional ability and based on activity that is relevant to the cause of acute pain

scale to be significant, among PECS and control group [11]. So, if we consider one unit difference, we need 20 samples in each arm with a power of 80% and error of 5%. The following formula was used: $\frac{n (per arm)=2\times [Z1-\alpha/2+Z1-\beta/2]^2 \times SD^2}{(mean difference)^2}$

$$n (per arm) = 17 to 20$$

For the present study, it was decided to choose 30 subjects per group. This addition is reserved, in the event of any dropouts.

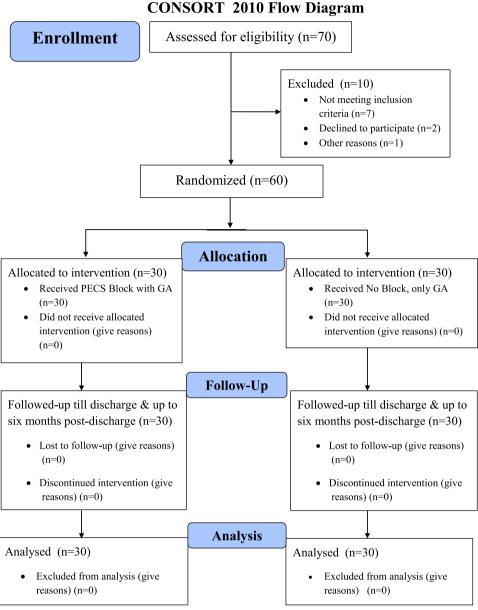
Analytical Methods SPSS software was used for analysis of data. Baseline data was described using frequency, mean, and 95% confidence interval in the two study groups. Continuous variables in the data were compared between two treatment groups for outcome variables measured at different times using "Mixed Model Analysis of Co-Variance" with "Group" as between group variable and "Time" as repeated measures. Baseline data was used as the "Co-variate." Since most of the surgery took less than 180 min, ANOVA measurement included only periods (Time) with outcomes where more than 50% of patients were available. Total dose of morphine and fentanyl were compared using Student's t test. *p*-value of less than 0.05 was considered significant [12].

Results

There were 60 patients recruited as per inclusion and exclusion criteria during the study period. There were 30 patients in each arm, allocated to group-1, the intervention arm (PECS block with GA), and group-2, the control arm (GA alone). There were 1 male and 59 females. The mean age in the study was 49 + 10 years. There was no statistically significant difference noted in the sex, age, weight, and ASA grade in the test and control groups (Fig. 1, Table 2).

Intraoperative Data The duration of surgical time ranged from 60 to 180 min, with a mean of 115 min with standard deviation of 27 min. The time to performing the block varied from 3 to 26 min with mean value of 7.9 min and standard

Fig. 1 CONSORT flow diagram



Category	Parameter	Group 1 (Block+GA) $N=30$	Group 2 (GA alone) $N = 30$	p value
Demographic	Sex (male:female)	0:30	1:29	0.5
	Mean age	51	47	0.14
	Mean weight	59	63	0.1
	ASA grade (1:2)	11:19	17:13	0.12
Type of surgery	Modified radical/simple mastectomy	29/1	27/3	0.28
Intra-op systolic blood pressure	Mean	119.361	130.458	0.03
Total morphine consumption	Mean	3.07	5.63	0.0001
	SD	1.388	1.426	
Arm abduction score	Mean	1.178	1.528	0.001

deviation of 4.4 min. Heart rate (HR): Heart rate in both the test and control groups decreased marginally (mean of 3 beats), which did not reach statistical significance (p = 0.36). Systolic blood pressure (SBP): There was a statistically significant reduction in the SBP in group-1 (p = 0.03) (Fig. 2). Diastolic and mean blood pressure (DBP/MBP): Did not show any clinical or statistical significance in both groups.

Postoperative Data Pain Score: None of the patients required rescue analgesia with morphine in the ward, as the NRS score did not cross 4/10 in both the groups and did not show any statistical difference (p=0.56) between both the groups in the first 18 h. Paracetamol was continued every 6 h as per protocol.

Total Morphine Consumption: The study showed that the mean total morphine dose given to test group was significantly lesser than that of the control group (p=0.0001). However, there was no difference in fentanyl consumption. Figure 3 shows a significant reduction in the consumption of morphine, in the block group, than the control group, during the initial 18 h postoperatively (p=0.001).

The postoperative HR and SBP were not significant.

Arm Abduction Score (Fig. 4): p value for group 1 = 0.001. p value time = 0.0001: Interaction P G \times T = 0.13.

Although the arm abduction score is assessed as A, B, and C, for the purpose of calculating the statistical significance, it was marked as 1, 2, and 3, respectively. Mean and confidence interval were measured for systolic blood pressure and arm abduction score and median and confidence interval for total morphine consumption. None of the patients reported

symptoms of chronic pain or cancer recurrence in the stipulated time of six months follow-up [12].

Discussion

Although, by definition, cancer patients should be categorized as ASA II, as they have a systemic illness, for practical clinical practice and research purposes, this non-specific preoperative risk assessment tool is still utilized. First introduced in 1941, the American Society of Anesthesiologists Physical Status (ASA-PS) cannot serve as a direct indicator of perioperative risk indicator for most cancer patients and should be combined with other preoperative classification systems, depending on the stage of cancer, associated comorbidities, and surgical dissection [13]. With the advent of ultrasound in regional anesthesia and several cadaveric studies, new myofascial plane blocks have emerged, with promising evidence for safer, effective, and satisfying outcomes, one of which is the PECS block [14]. With emphasis on enhanced recovery protocols, the shift in the perioperative care is to provide multi-modal opioid-sparing analgesia. minimally invasive surgical techniques, quicker mobility, and lower levels of intravenous fluid administration. Furthermore, there is growing evidence anesthetic techniques play a role in cancer recurrence through immunological and stress-related mechanisms; nevertheless, more research is warranted in these areas [15].

Paravertebral block is well studied and utilized, however, they may result in serious complications, such as, vascular

Fig. 2 Systolic blood pressure

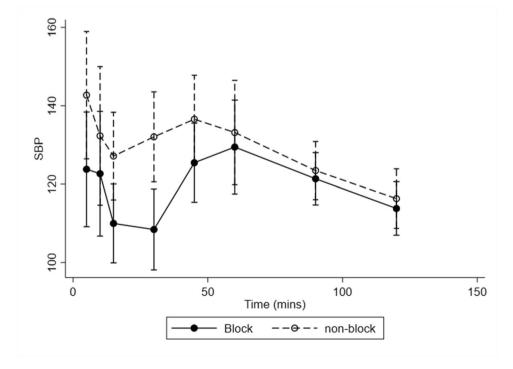
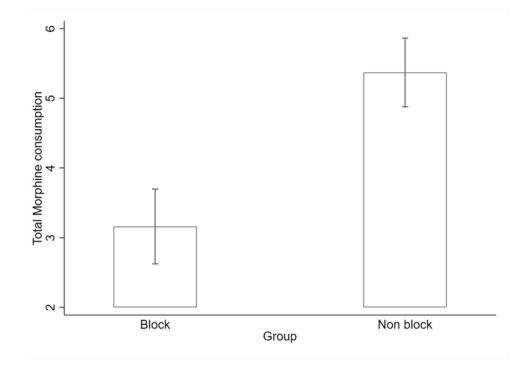
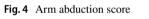


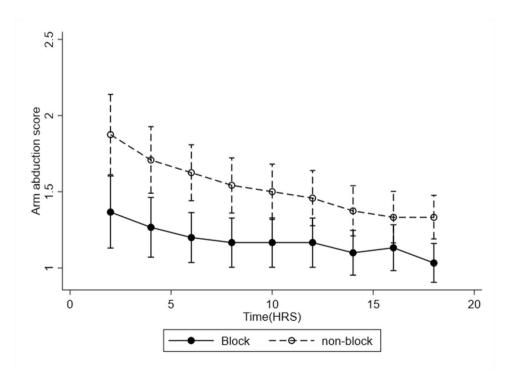
Fig. 3 Total morphine consumption



puncture (3.8%), hypotension (4.6%), pleural puncture (1.1%) and pneumothorax (0.5%), Horner's syndrome, epidural spread and spinal cord trauma [16]. Nevertheless, it is still advocated for its advantages [17]. Cadaveric dissection along with contrast study has demonstrated the spread of the local anesthetic into the axilla [18]. While the first-level PECS-I block targets

the medial and lateral pectoral nerves, the second-level PECS-II block covers one to six thoracic intercostal nerves, mainly the lateral cutaneous branches as the anterior cutaneous branches of the same cannot be approached by the local anesthetic with the barrier of the external and internal intercostal muscles. Additionally, there is sparing of the supraclavicular





nerve, which is a branch of the superficial cervical plexus. These nerves will need a separate approach to the injection. This accounts for the drawbacks of PECS block [19]. Notably, in our study, there were only minor, not significant differences in the heart rate (mean of 3 beats). Heart rate and blood pressure are the most relevant indicators of pain and can reflect intraoperative pain. Warrén et al. had concluded that although these variables may be frequent indicators to pain they are not necessarily precise, due to other changes in sympathetic responses, such as, inadequate depth of anesthesia, intraoperative blood loss, or patients on beta blockers [20]. Yet in outweighing the risk of post-traumatic stress disorder, these indirect variables must be treated accordingly [21]. There was a statistically significant (p=0.03) reduction in systolic blood pressure in group-1. There was no significant change noted in the diastolic blood pressure or mean arterial pressure in the two groups. This is in line with the study reported by Manzoor et al. [22]. Their study patients were under general anesthesia with PEC-I and II, one group got bupivacaine versus bupivacaine with dexmedetomidine for the other group, which recorded no statistical difference in intraoperative blood pressure or heart rate at baseline, at surgical incision, and at 10-min interval until completion of surgery. This may be related to the dexmedetomidine used for block. Postoperatively, the NRS has shown high correlations as compared to other pain assessment tools [23]. Furthermore, our study demonstrated that none of the patients required rescue morphine in the postoperative ward, as the scores were well within 4/10, even up to the first 18 h, in both groups. This could be due to patients in both groups receiving adequate paracetamol, as per protocol. Bashandy et al. [11], who studied the beneficial effects of PECS block versus general anesthesia, documented that VAS scores and morphine-fentanyl consumption in the PECS group stayed significantly lower than that in the control group, at 3 h and 24 h postoperatively. Postoperative arm abduction is considered as reflecting persistent postoperative pain particularly in breast surgery. Our study showed a statistically significant difference in the range of arm abduction in PECS group as compared to control group for 18 h postoperatively. This result was similar to the RCT done by Kim et al., GA and PEC-II [19]. We used the Functional Activity Score, which is categorized as A, B, and C, to measure as the arm abduction score, inferred as 1, 2, and 3, to depict statistical information [10]. Median NRS of the axillary pain during abduction was significantly lower than the control group between groups ($p \le 0.001$), for the first 24 h. In the RCT of Wang et al., the PECS group showed favorable shoulder abduction during the recovery period [24]. Our study demonstrated a mean time taken for the block was only 7.9 min and it was technically simple to perform. The PECS block did not record any complications, and was safe, with a potential to reduce persistent pain after breast surgery, which has an incidence of up to 60% following poorly treated acute pain and 10% for up to one year [25]. A single blocking method

would not provide adequate analgesia in the entire breast area, which would require combination of blocks, due to the multiple innervation of the breast [26].

Recent Advances

The utility of this newly developed block is increasingly supported by the scientific evidence in favor of its use due to its safety and simplicity [27]. It has demonstrated significant opioid-sparing effects when administered for breast surgery, both intraoperatively and up to 24 h postoperatively [28]. Precautions should be taken as for any regional anesthetic procedure, due to the risk of hematoma formation, especially for patients on anticoagulant and antiplatelet drugs [29]. Systematic reviews and meta-analysis guidance with procedure-specific postoperative pain management (PROS-PECT), demonstrating recommendations for optimal pain management after oncological breast surgery, suggest preoperative gabapentin, dexamethasone, intraoperative paravertebral or PECS block, or wound infiltration, along with basic analgesics, such as paracetamol and non-steroidal anti-inflammatory drugs and opioids only as rescue analgesia in the postoperative period [30].

The limitations in this study are as follows: Firstly, the intervention arm is not blinded and hence the outcome measurements have been influenced by the observer (measurement bias), as the same person gave the block and also measured intraoperative outcomes. However, postoperative measurements were taken by a different observer (pain nurses), who was unaware of the allocation into test and control groups. Secondly, PECS was performed under general anesthesia. Hence, dermatome distribution or quality of block could not be assessed before surgery. Thirdly, the shoulder range of motion was not assessed by a standardized method using universal full circle manual goniometer under the guidance of dedicated physiotherapist and hence inter-observer variation could have occurred in the measurement.

Conclusion

Our research backs up current thinking in perioperative medicine, regional anesthesia, and pain management. The findings showed that a two-level PECS block is safe, effective, dependable and simple to perform in breast cancer surgery, reducing morphine consumption, improving postoperative pain and increasing patient satisfaction, thereby, achieving the primary outcome. As with the secondary outcome, there were no reported cases with symptoms of chronic pain or cancer recurrence, therefore, no conclusive inference but certainly contributing to the evidence towards the same. Author Contribution All the authors contributed to the conduct of the study, collection, compiling of data, literature search, and writing of the paper. The manuscript has not been published and is not under consideration for publication in any other journal. All the authors approved the manuscript and its submission to the journal, and the authors have not published or submitted any related papers from the same study.

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Declarations

Consent to Participate taken from all patients.

Consent for Publication agreed by all the authors.

Institutional Review Board Approval Number IRB Min. No:10390[INTERVEN] dated 30.11.2016.

Conflict of Interest The authors declared no competing interests.

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Importance of the Study and Research Question Answered

Advances in Knowledge This original study was conducted in one of the premiere, over a century old, medical educational and research institutions of the country. It adds to the evidence of ongoing quest to determine ideal breast analgesia, with the use of PECS block, by reduction in opioid consumption, lower pain scores, early functionality, and discharge in the time period studied. Our study proved the safety and efficacy of this easily usable block, which advocates many practitioners, in perioperative care, to use it under the set safety guidelines. *Application to Patient Care* There is significant incidence of acute and chronic postoperative pain with oncological breast surgery. Providing clinicians with an evidence-based approach, for better patient care to improve perioperative outcome and patient satisfaction, is certainly beneficial with the use of PECS block, among other modalities for analgesia.