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ORIGINAL ARTICLE

Postoperative Analgesic Efficacy of Intraoperative Pectoral Nerve Block for Modified Radical Mastectomy: a Double-Blind Prospective Randomised Interventional Study

Rohit Jindal[1] · Sushila Meena[2] · Sushil Bhati[2] · Pinakin Patel[1] · Chanchal Gulati[2] · Suresh Singh[1]

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Abstract

Severe acute postoperative pain following breast surgery increases the risk of persistent pain and affects the recovery of patients. Recently, pectoral nerve (PECs) block has gained significance as a regional fascial block that can provide adequate postoperative analgesia. This study aimed to evaluate the safety and efficacy of PECs II block, which was given intraoperative under direct vision after performing modified radical mastectomy for breast cancer patients. This prospective randomised study was comprised of a PECs II group ($n=30$) and a control group ($n=30$). Group A patients received 25 ml of 0.25% bupivacaine for PECs II block intraoperatively after the surgical resection was done. Both groups were compared with respect to the demographic and clinical parameters, total intraoperative fentanyl dose, total duration of surgery, postoperative pain score (Numerical Rating Scale) and the analgesic requirement, postoperative complications, postoperative duration of hospital stay, and the outcome. Intraoperative PECs II block was not associated with any increase in the duration of surgery. The postoperative pain scores were significantly higher in the control group till 24 h after the surgery, and so was the postoperative analgesic requirement. Patients in the PECs group were found to have rapid recovery and decreased postoperative complications. Intraoperative PECs II block is not only safe, time-saving procedure but also significantly reduces the postoperative pain and analgesic requirement in breast cancer surgeries. It is also associated with a faster recovery, decreased postoperative complications, and better patient satisfaction.

Keywords Modified radical mastectomy · Pectoral nerve block · Postoperative analgesia · Bupivacaine

Introduction

Female breast cancer has now surpassed lung cancer as the leading cause of global cancer incidence in 2020, with an estimated 2.3 million new cases, representing 11.7% of all cancer cases [1]. Surgery is one of the mainstay treatment options, which includes breast conserving surgery, simple mastectomy, modified radical mastectomy, skin sparing mastectomy, and nipple sparing mastectomy. Though recent advances in breast surgery have led to the evolution of surgical options with less morbidity, modified radical mastectomy (MRM) is still the most common surgical approach adopted for invasive breast cancer. Despite advances in both surgical and anaesthesia techniques, postoperative pain remains a significant concern for patients undergoing breast cancer surgery. Severe post-operative pain following breast surgery not only increases the risk of persistent pain and affects recovery, it also increases hospitalisation and increases healthcare costs [2]. Non-steroidal anti-inflammatory

✉ Rohit Jindal
doc_rj24@yahoo.com

Sushila Meena
drsushilameena@gmail.com

Sushil Bhati
drsushilbhati@gmail.com

Pinakin Patel
drpinakinp@gmail.com

Chanchal Gulati
chanchal.chanchal1993@gmail.com

Suresh Singh
drsureshsingh@gmail.com

[1] Department of Surgical Oncology, Sawai Man Singh Medical College and Hospital, Jaipur, Rajasthan, India

[2] Department of Anaesthesiology, Sawai Man Singh Medical College and Hospital, Jaipur, Rajasthan, India

drugs (NSAIDs) and opioids are the two most commonly administered analgesic alternatives following any surgery, not excluding MRM. However, this frequently leads to ineffective post-operative pain management, which may even result in chronic pain syndrome, significantly lowering quality of life. Also, opoids are commonly associated with adverse effects such as nausea, vomiting, respiratory complications, hyperalgesia, and immunosuppression [3]. With the advancement in the field of anaesthesia, the latest analgesic adjuncts in the armamentarium include regional anaesthesia such as thoracic intercostal block, paravertebral block, and thoracic epidural injection. Regional anaesthesia attenuates surgical stress-response, provides superior analgesia, promotes early mobilisation, decrease hospital length of stay, and improves patient satisfaction score [4]. Thoracic epidural lock is associated with major complications like intrathecal spread, nerve damage, epidural haematoma, and inadvertent intravascular injection [5].

When compared to central neuraxial blocks like thoracic epidural anaesthesia, regional anaesthesia, particularly peripheral nerve blocks and interfascial plane blocks, is thought to be safer and has fewer complications. Interfascial plane blocks, which include pectoral nerve blocks type I ("PECs I Block") and type II ("PECs II Block"), are novel approaches for blocking the pectoral nerves, long thoracic nerves, and intercostal nerves in the third-to-sixth intercostal, as first described by Blanco and colleagues in 2011 [6]. Unlike paravertebral, epidural, and thoracic paravertebral blocks, PECs blocks do not lead to sympathetic blockade, hypotension, pneumothorax, or spinal cord trauma [7, 8]. PECs block is typically achieved with the patient in the supine position, under ultrasound guidance, with a recommended local anaesthetic dose of 0.4 ml/kg of 0.25% levobupivacaine [9].

While providing complete analgesia for lumpectomy, modified radical mastectomy (MRM), and axillary clearance, the advantages of PECs blocks comprise sympathetic-sparing effect, better T2-dermatomal spread (unlike paravertebral block), allowance for more liberal anticoagulant use, and dense motor and sensory nerve-blockade (unlike wound infiltration) [10]. The PECs block has been reported to significantly reduce the visual analgesic pain (VAS) score and analgesic requirement postoperatively [11, 12]. Despite the multitude of reported superior short- and long-term outcomes, the acceptance of PECs block within the anaesthetic community has been slow. Further adding to the scepticism about the clinical utility of PECs block, two recent studies reported that PECs block does not effectively block the sensory nerves, nor does it exert additional analgesic effects [13, 14]. The limitations of this technique include the requirement for an ultrasound, trained personnel, and additional time-consuming procedures prior to surgery; additionally, the results obtained are subjective. So we decided to perform the PECs block intra-operatively under direct vision after resection of the tumour. Intraoperative placement of blocks has the potential benefits of more precise plane targeting, time-saving, no need for an ultrasound, or a trained practitioner, thus not depleting the vital hospital resources any further. Our study aims not only to ascertain the safety and feasibility but also to assess the analgesic advantages of an intraoperative PECs II block.

Methods

This prospective, randomised, double-blinded, interventional study was conducted from 1 January 2020 to 30 September 2020 after approval of the Institutional Review Board and Ethics Committee (234MC/EC/2022). All the American Society of Anesthesiologists (ASA) physical status I, II, and III female patients, aged between 18 and 60 years, who underwent modified radical mastectomy (MRM) for carcinoma of the breast were included in the study. Patients with local anaesthetic allergy, locally advanced breast malignancies with skin ulceration or infiltration of the chest wall, inflammatory breast cancer, metastatic breast cancer, deranged coagulation profile, obesity with BMI > 35 kg/m^2, a history of opioid use or any substance abuse, and pregnancy were excluded from the study. Patients were randomised into two separate groups (PECs and control group) of 30 each using a computerised random number table.

After obtaining written informed consent, the patient's information was recorded, and a detailed history was taken, including symptoms, co-existing comorbid conditions, personal habits such as smoking or alcohol consumption, and past treatment history. All patients underwent a comprehensive evaluation including all the routine investigations, ASA grading, and evaluation of the breast lesion. All the patients aged 35 years or less underwent ultrasonography of bilateral breasts, and bilateral mammography was done for females older than 35 years. In the case of inconclusive findings from the prior investigations, magnetic resonance imaging of the breast was done. Finally, a core biopsy of the breast lesion was performed, and the patients were only enrolled in the study after histological confirmation "of breast cancer" was established and only those patients where MRM was indicated and chosen by the patient as the preferred surgical modality were included in the study. The patients who had undergone neoadjuvant chemotherapy and were planned for MRM surgery were also included in the study. A note was made of the various socio-demographic characteristics and clinical parameters. Preoperatively, all patients were taught about the 11-point Numerical Rating Scale (NRS) for the measurement of pain after surgery [15].

After a detailed pre-anaesthetic check-up and written informed consent, patients were taken up for MRM surgery.

On the day of the surgery, overnight fasting status was confirmed, intravenous access was secured, monitors were placed, and the patient was premedicated with midazolam (0.03 mg/kg) and ranitidine (50 mg), both given intravenously. Subsequently, general anaesthesia was accomplished by intravenous administration of propofol (2–2.5 mg/kg) and fentanyl (2 mcg/kg) as induction agents. Tracheal intubation was facilitated by 0.5 mg/kg of atracurium given intravenously. Maintenance of general anaesthesia was achieved with sevoflurane, oxygen, and nitrous oxide. 1 mcg/kg of fentanyl was administered intravenously, if the variations in systolic blood pressure and heart rate were $\geq 20\%$ of basal values.

Bupivacaine, a local anaesthetic agent, was used for PECs block. In group A patients, after the completion of the surgery, the surgical field was thoroughly washed with normal saline and adequate haemostasis was achieved. Thereafter, taking all the necessary precautions, 10 ml of 0.25% bupivacaine was injected into the fascial plane between the pectoralis major and pectoralis minor muscles. The needle was reinserted into the fascial plane between the pectoralis minor and serratus anterior muscles at the level of the third rib and another 15 ml of 0.25% bupivacaine was injected. Visual confirmation of the adequate plane is done by taking a note of the formation of a local bleb of the local anaesthetic beneath the fascia, which gradually spreads along the whole fascial plane. This was followed by the placement of two drains, one in the axilla and one over the pectoralis major muscle. Finally, skin closure was done using either sutures or skin staplers, followed by an aseptic dressing. The total dose of the fentanyl administered and the total surgical duration were duly noted. Both the participants (patients) and the investigating personnel (doctor in the ward) did not know whether the patients had received PECs blocks or not.

Following emergence from anaesthesia, the patients were extubated and subsequently shifted to the recovery room. Analgesics were not given prophylactically but only on demand by the patient. The time to rescue analgesia after the surgery was noted. Patients were asked to gauge their pain intensity with the NRS scale at 0, 2, 4, 8, 12, 18, 24, and 48 h during the postoperative period. Two types of analgesics were used for adequate postoperative pain control: nonsteroidal anti-inflammatory drugs (NSAIDS) and opioids. The postoperative analgesic requirement was assessed by calculating the total administered dose and duration of each type of analgesic. We will assume that pain relief will be inadequate and nerve block will be ineffective if the patient complains of pain in the immediate recovery period. Patients will be allowed to receive rescue analgesics on an NRS score of 3 and above. Any complications, namely local anaesthetic toxicity, hemodynamic instability, respiratory depression, paraesthesia, pneumothorax, hematoma, nausea, and vomiting, were recorded. The length of hospital stay during the post-period was also recorded. Patients were followed up weekly after discharge and any complications, if present, were documented. A note of any mortality, if it occurred during the hospital stay or within one month of surgery, was made.

Both groups were compared on the basis of various demographic and clinical parameters, operative time, total intraoperative dose of fentanyl, time to first rescue analgesia, postoperative complications, postoperative pain and analgesic requirement, postoperative hospital stay, and the outcome.

Statistical Analysis

Data analysis was done using the SPSS software. The Student's *t*-test was used to infer differences in means between two groups of numerical data. The categorical variables (NRS) were tested using Fisher's exact test. For significance, $p < 0.05$ was considered significant.

Results

A total of 60 patients were included in the study, which was divided into two groups of 30 patients each:

Group A—patients receiving 25 ml of 0.25% bupivacaine for PECs block; Group B—control group comprising patients who did not receive PECs block.

As shown in Table 1, there was no significant difference between the two groups with respect to age (48.18 ± 10.17 years v/s 48.63 ± 11.31 years), BMI (24.2 ± 1.8 kg/m^2 v/s 23.6 ± 2.2 kg/m^2), and ASA grade. The two groups were also comparable with respect to the duration of surgery and the total administered intraoperative dose of fentanyl. While 5 patients out of a total of 30 patients belonging to group A had received neoadjuvant chemotherapy, in group B, 6 patients had received chemotherapy prior to surgery. Though there was no significant difference in the duration of the postoperative hospital stay between the two groups, there was a trend of reduced hospital stay after the surgery in the patients having received PECs block.

Table 2 compares the analgesic requirements between the two groups. The time to rescue analgesia was significantly delayed in the PECs group as compared to the control group (540 ± 135.03 min v/s 25 ± 20.08 min). The required total dose of NSAIDs in the postoperative period was significantly lower in the PECs group (467.04 ± 71.92 mg) than in the control group (672.92 ± 238.12 mg). Similarly, the required total dose of opioids was also significantly higher in the control group than in the PECs group (204.17 ± 44.69 mg v/s 130.25 ± 30.02 mg). The total number of days for which NSAIDs had to be given in the PECs group (2.07 ± 0.56 days) was less than that

Table 1 Comparison of demographic and clinical parameters between the two groups

Clinical parameter	Mean		
	PECS group ($n=30$)	Control group ($n=30$)	p-value
Age (years)	48.18 ± 10.17	48.63 ± 11.31	0.878
BMI (kg/m^2)	24.2 ± 1.8	23.6 ± 2.2	0.659
Tumour location (left/right)	17 (56.67%)/13 (43.33%)	14(46.67%)/16 (53.33%)	
ASA grade			
I	12	15	0.817
II	14	13	0.934
III	4	2	0.690
Duration of surgery (mins)	80.39 ± 33.26	83.50 ± 35.55	0.727
Intraoperative fentanyl dose (ug)	123 ± 12.04	119 ± 10.07	1.243
Neoadjuvant chemotherapy	5(16.67%)	6(20%)	0.897
Duration of postoperative hospital stay (days)	2.8 ± 0.61	3.1 ± 0.75	0.162

BMI body mass index, *ASA* American Society of Anesthesiologists

Table 2 Comparison of analgesic requirement between the two groups

Clinical parameter	Mean		
	PECS group ($n=30$)	Control group ($n=30$)	p-value
Time to first rescue analgesia (mins)	540 ± 135.03	25 ± 20.08	< 0.001
Post operation Analgesia required			
NSAIDs total dose (mg)	467.04 ± 71.92	672.92 ± 238.12	0.006
NSAIDs total no. of days (n)	2.07 ± 0.56	2.72 ± 1.09	0.003
Opioids total dose (mg)	130.25 ± 30.02	204.17 ± 44.69	< 0.001
Opioids total no. of days (n)	1.63 ± 0.84	2.17 ± 1.32	0.003

NSAIDs non-steroidal anti-inflammatory drugs

required in the control group (2.72 ± 1.09 days). Similarly, the requirement for opioids was even much lesser for the PECs group (1.63 ± 0.84 days) than for the control group (2.17 ± 1.32 days). All the values were statistically significant (p-value < 0.05). Group A patients had a significantly decreased pain score, as assessed by NRS, as compared to Group B till 24 h after the surgery (Table 3). However, at 48 h after the surgery, though the mean pain score was higher in the control group, the difference was statistically insignificant when compared to the PECs group.

No patient was lost to follow-up during the hospital stay. However, three patients out of a total of 60 patients, two belonging to the PECs group, and one belonging to the control group, were lost to follow-up after discharge from the hospital. Postoperatively, during the hospital stay, while only two patients belonging to the PECS group complained of nausea and vomiting, it was noticed in seven patients belonging to the control group ($p < 0.001$). None of the patients developed any other adverse events during hospitalisation, such as local anaesthetic toxicity, hemodynamic instability, respiratory depression, paraesthesia, pneumothorax, hematoma, or re-exploration. Wound infection was noted in three patients at around 15–20 days postoperatively. One patient belonged to Group A and two patients to Group B. None of them required any major interventions and all were managed successfully and conservatively. Seroma formation was seen in 5 patients belonging to the PECS group and 4 patients belonging to the control group. All these patients

Table 3 Comparison of pain score (NRS) between the two groups

Clinical parameter	Mean		
	PECS group ($n=30$)	Control group ($n=30$)	p-value
Pain score by NRS			
0 h	2.8 ± 1.3	4.9 ± 1.5	< 0.001
2 h	3.0 ± 1.4	3.8 ± 1.2	0.002
4 h	2.9 ± 1.1	4.3 ± 1.6	0.005
8 h	3.5 ± 1.7	5.1 ± 1.4	0.035
12 h	2.4 ± 0.9	3.7 ± 1.3	0.015
18 h	2.1 ± 1.0	3.9 ± 1.1	< 0.001
24 h	3.1 ± 1.5	4.4 ± 1.8	0.016
48 h	3.3 ± 0.8	3.7 ± 1.0	0.09

NRS Numerical Rating Scale

were managed conservatively with axillary drainage without the need for any additional intervention. No perioperative mortality was seen in any of the patients.

Discussion

Currently, an increase in the usage of peripheral nerve blocks as a part of comprehensive anaesthesia care regimens is seen [16]. Even single-shot regional techniques seem to give excellent analgesia [17]. Our study demonstrated that compared to systemic analgesia, PECs block is associated with significantly better postoperative pain relief and decreased analgesic requirements. Blocking the sensory supply to the breast, axilla, and over the pectoral muscles provides adequate analgesia within the immediate postoperative period.

The blockade of the lateral and median pectoral nerves in an inter-fascial plane between the musculus pectoralis major and musculus pectoralis minor muscles, the long thoracic nerve, the thoracic intercostal nerves from T2 to T6, and the thoracodorsal nerve are the goals of the PECs II Block [18, 19]. The PECs block is safer, easier, and faster to work with, and has longer analgesia than a paravertebral nerve block or epidural nerve block in MRM for carcinoma. The PECs block applied to MRM can not only reduce postoperative use of analgesics but also provides stable hemodynamics and better patient satisfaction. Thus, for patients with hypertension and coronary heart disease undergoing breast cancer surgery, this strategy greatly reduces the risk of postoperative complications and improves the postoperative quality of life of patients [2]. However, whether this strategy can lower the prevalence of persistent pain after breast cancer treatment is not known. Recent studies have shown that the PECs II block can prevent chronic pain 3 months after breast surgery [20]. Few scholars have focused on the use of the PECs II block and its effect on residual pain following breast cancer therapy.

In our study, both groups were matched with respect to age, BMI, and ASA grade. Also, there was no significant difference in the two groups with respect to the number of patients having received chemotherapy preoperatively and the total dose of fentanyl administered intraoperatively. This is important as variations in these parameters can result in varied susceptibility to pain and responses to analgesics. Our study reported a similar operative duration in both the groups, thus indicating that administering PECs blocks intraoperatively is not time-consuming and thus does not affect the operative time utilisation rates, a parameter that the hospital administrators are more worried about. Though the difference in the mean duration of hospital stay postoperatively was statistically insignificant, there was a trend towards faster discharge in the PECs group. This can be explained by the fact that adequate analgesia results in early mobilisation of the patient, better patient satisfaction, and expeditious recovery.

In our study, there was a significant difference between the two groups in terms of the NRS pain score till 24 h. However, this difference was not seen at 48 h after surgery, probably due to the diminished analgesic effect of the PECs block and also due to time-dependent decreased pain in the control group. As expected with the reduction in the pain, there was a significant decrease in the postoperative analgesic requirement, resulting in a decreased amount and duration of the analgesics administered. Blanco et al. employed the PECs block in 50 patients and found that following a modified radical mastectomy, the patients had acceptable postoperative analgesia for 8 h [6]. Bashandy and Abbas compared patients receiving the PECs with patients receiving only general anaesthesia and reported lower VAS scores and reduced postoperative morphine doses in patients receiving the PECs along with general anaesthesia [21]. Consistent with the findings in our study, Bashandy et al. reported that in the patients receiving pectoral blocks, opiate consumption was reduced both intraoperatively and for 12 h postoperatively, and pain scores were reduced for 24 h postoperatively [21].

One obstacle to the adoption of the PECs block is the need for an ultrasound and an expert operator who is generally an interventional radiologist. Therefore, this becomes time-consuming and also results in an added burden on the hospital resources. However, in our study, there was no need for these resources as the PECs block was administered by the surgeon under direct visualisation of the fascial planes. This can be quite helpful for centres with time constraints due to high turnover. Nevertheless, patient discomfort related to the breach of privacy of receiving a nerve block around the breast when she is awake is also avoided in this method. Fluid-filled tissue planes were encountered during axillary tail dissection in patients who received the preoperative pecs block through ultrasonography. Due to local anaesthetic diffusion along tissue planes, electrocautery could not be used during surgical dissection [22].

An average of 8 h of postoperative analgesic duration before the need for analgesics appeared was noted after ultrasound- guided PECs block in patients who underwent cosmetic breast surgery [6]. Similarly, in our study, the typical postoperative analgesic duration was about 9 h in spite of the fact that all patients underwent modified radical mastectomies, a potentially more destructive surgery. The mean time to first request of analgesia was 310.4 ± 12.7 min in the study by Ahmed [23] in the PECs group in their study as compared to 540 ± 135.03 min in our study. This shorter duration of analgesia is possibly due to the very fact that the block was given preoperatively in their study. Ultrasound-guided PECs block provided perioperative analgesia but reduced the duration of postoperative analgesia. Furthermore, because

our block was placed at the end of the resection and after washing, the local anaesthetic solution was more likely to be contained within the tissue plane in which it was deposited than a preoperatively deposited solution, which could leak intraoperatively during tissue dissection. In our technique, because the infiltration is completed under vision after dissection and identification of the structures, there were no reports of any block-related complications like bleeding or pneumothorax.

However, our study is not without limitations. The NRS scale, used for measuring postoperative pain in our study, is a subjective tool. Also, the sensory level of the block was not assessed in our study. We did attempt to overcome this by using two additional measures: duration of analgesia (time to first request for analgesia) and total cumulative analgesic consumption postoperatively. Another limitation of this study was that the opioid sparing effect of regional anaesthesia could not be utilised intraoperatively as the PECs block was given post breast resection. The PECs II block addresses the lateral branches of the thoracic intercostal nerves; therefore, the anterior branches of the intercostal nerves supplying the anterior mammary region might be spared. We did not perform the transversus thoracic muscle plane block, which could possibly further increase the standard of analgesia. This warrants another study where the effect of adding transverse thoracic muscle plane block can be studied.

Conclusion

PECs II block with bupivacaine administered intraoperatively under direct vision is not only safe and time-saving but it also significantly reduces postoperative pain and analgesic requirement.

Author Contribution RJ: concept, design, literature search, writing; SM: analysis and/or interpretation; SB: supervision; critical review; design; PP: analysis and/or interpretation; literature search; SS: critical review; supervision.

Declarations

Ethical approval and consent to participate The research involved human Participants and a well informed consent was taken from each individual. Also, approval was taken from the institutional ethical committee.

Conflict of Interest The authors declare no competing interests.

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