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Comparison of Local Infiltration with Modified Pectoralis Block for Post-operative Analgesia after Modified Radical Mastectomy: An Open Label Randomized Trial

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Abstract

Objectives: Owing to safety of Modified Pectoralis block and limited studies available our study will compare the analgesic efficacy of Modified Pectoralis block with the combination of local and pocket infiltration after MRM. Design Open label randomized trial. *Setting:* Indira Gandhi Medical College, Shimla, HP, India. Participants 60 ASA physical status I-II patients (aged 25-65 years), scheduled for elective MRM procedures were recruited for the study. Intervention Group I (PEC 30 patients) received ultrasound guided PEC block preoperatively and Group II (local infiltration 30 patients) received local anaesthetic infiltration at surgical incision and pocket infiltration postoperatively. Patients were induced with standard general anaesthesia and then after reversal and shifted to recovery room. Main Outcome and Measure Post-operative pain assessment was done using Visual Analogue Score at O hour (Time taken as patient is shifted to PACU), 30 min, 1, 2, 4, 6, 12 and 24 hours. *Results:* In the PACU, the mean for rescue analgesia required in group 1 was 30.07 (SD = 3.473) and in group 2 was 8.13 (SD = 1.196) and this was statistically significant. The difference in mean of VAS score in group 2 at 6 hrs was (3.00) and in group 1 was (1.73) and this score increased significantly in next hours. The mean of total analgesic required in first 24 hrs in group1 was 0.00 (SD = 0.000) and in group 2 was 2.63 (SD = 556). *Conclusion:* Ultrasound guided PEC block had prolong post-operative analgesia as compare to local anaesthesia infilteration at surgical incision with pocket infilteration post-operatively.

Keywords: Anaesthesia; Analgesia; Pain; Post-operative; Mastectomy; PEC, Local anaesthesia infilteration.

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Introduction

Breast cancer is the most common cancer amongst women worldwide with an incidence rate that vary greatly worldwide from 19.3 per 100,000 women in Eastern Africa to 89.7 per 100,000 women in Western Europe. In India, the age standardized incidence rate of breast cancer varies from 9 to 32 per 100,000 women.[1] Patients after mastectomy and breast reconstruction suffer from acute nociceptive pain (36%) and chronic neuropathic pain syndromes (20–68%).[2] It is very important to manage the post-operative pain in patients undergoing modified radical mastectomy.[3] Appropriate post-operative analgesic technique after breast surgery is always

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dubious. Various practices like combination of both local and pocket infiltration, regional anesthetic and intravenous analgesic techniques have been used for the pain relief. Amongst the regional techniques thoracic epidural is considered as gold standard but is associated with the risk of neuraxial damage and persistent neurological deficits and also result in serious complications like intrathecal spread, epidural hematoma, and inadvertent intravascular injection.[4,5] Owing to the safety and greater pain relief by modified PEC block, it has become more familiar now-a-days among anesthetists compared to paravertebral and thoracic epidural nerve blocks for pain relief following breast surgeries.[6,7] However, so far, no data is available that compares modified PEC block with the combination of local and pocket infiltration. Therefore, we hypothesized that the PEC 2 block may effectively alleviate acute post-operative pain in patients undergoing MRM. The present study evaluated the analgesic efficacy of PEC 2 block in patients undergoing MRM. In addition, this study also compared the analgesic efficacy of Modified Pectoralis block with the combination of local anesthetic and pocket infiltration.

Materials and Methods

This study enrolled patients with breast cancer posted for modified radical mastectomy between *July 2016* and *May 2017*. After obtaining approval from our institutional scientific and research committee with registration number [ECR/533/INST/HP/2014] with ethical number G-5 (Ethic)/2015-10634, written informed consent was taken from 60 ASA physical status I-II patients (aged *25–65 years*), scheduled for elective MRM procedures. Exclusion criteria included history of any allergy to local anesthetic, bleeding disorder or receiving anticoagulant, BMI > *35 kg/m*^{2}, spine or chest wall deformity, pregnancy, prior breast surgery and patient declining to give consent. During preoperative visit, demographic data was recorded and visual analog scale score (VAS score:0–10,(0) No pain, (4–8) mild pain, (8–10) Worst pain) was explained to patients. Before surgery patients were randomly allocated according to the computer-generated sequence into two groups of 30 each. The group allocation numbers were concealed in sealed opaque envelopes that were opened after enrolment of the patients. All baseline and post-operative measurements were evaluated by an independent physician who was blinded to treatment allocation.

Group I (PEC 30 patients) received ultrasound guided PEC block pre-operatively and Group II (local infiltration 30 patients) received local anesthetic infiltration at surgical incision and pocket infiltration post-operatively. PEC block was performed with the patients in supine position, placing the ipsilateral upper limb in abduction position using a linear USG probe of high frequency (*6–13 MHz*, sonosite) with imaging depth of *4–6 cm* after sheathing. The USG probe was first placed at infraclavicular region after skin sterilization using chlorhexidine and moved laterally to locate the axillary artery and vein directly above first rib where pectoralis major and pectoralis minor muscles were identified with the help of USG probe. After infiltration of the skin at the puncture site with *3 ml* of lignocaine 2%, the 23 G needle was inserted in plane with USG probe to the facial plane between pectoralis major and pectoralis minor muscle and *10 ml* of levobupivaciane 0.25% was injected. Then USG probe was moved toward axilla till serratus anterior muscle was identified above 2nd, 3rd and 4th ribs and the needle was reinserted into the facial plane between pectoralis minor muscle and serratus anterior muscle and *20 ml* of 0.25% levobupicaine was injected in increments of *5 ml* after aspiration.

In Group II patients *10 ml* of 0.25% levobupivacaine was given as pocket infiltration and *20 ml* of 0.25% levobupivacaine was infiltrated at the incisional site by the surgeon before closure.

All patients received midazolam *1–2 mg* before induction of anesthesia and monitored with five leads ECG, pulse oximetry, non-invasive blood pressure and capnography. General anesthesia was induced with fentanyl *2 mg/kg*, propofol *1.5–2 mg/kg* and endotracheal intubation was facilitated with atracurium *0.5 mg/kg*. Anesthesia was maintained with isoflurane and O_2/NO_2 mixture with a fraction of 33% inspired oxygen. Fentanyl *1 mg/kg* in bolus doses was given intravenously if mean blood pressure or heart rate exceeded 20% of the pre-operative value. After recovery from anesthesia, patients shifted to post-anesthesia care unit for the first *2 hours*. Post-operative pain assessment was done using Visual Analog Score at rest at *0 hour* (Time taken as patient was shifted to PACU), *30 min*, *1,2,4,6,12* and *24 hours*. Post-operative rescue analgesia was given whenever the VAS score > 4 in the form of I.V. Diclofenac *75 mg* or I.V. Tramadol *100 mg* I.V. stat.

Nausea or vomiting lasting more than *10 minutes* was treated with ondansetron *0.1 mg/kg*. Patient satisfaction for post-operative analgesia was

recorded according to satisfaction score: Poor = 0; Fair = 1; Good = 2; Excellent = 3. Any untoward side effects or complications related to procedure and local anesthetic were recorded.

Statistical Analysis

All analysis was performed using IBM SPSS software version 22.0 (Statistical Packages for the Social Sciences, Chicago). The normally distributed data were compared by using Student's unpaired *t*-test, whereas non-parametric data were compared by chi-square test for intergroup differences. Intra-operative hemodynamic data were compared with baseline by repeated measures ANOVA followed by student's paired *t*–test. The pain scores, time to first rescue analgesia, and total *24 hr* analgesic consumption were compared by using Wilcoson W and Mann-Whitney *U*-test for pairwise comparisons. Confidence intervals were calculated for statistically significant differences. The sample size was calculated on the basis of a pilot study.

Results

This study enrolled patients with breast cancer posted for modified radical mastectomy between *July 2016* and *May 2017*. Before surgery patients were randomly allocated according to the computer-generated sequence into two groups of 30 each. The group allocation numbers were concealed in sealed opaque envelopes that were opened after enrolment of the patients. Group I (PEC 30 patients) received ultrasound guided PEC block pre-operatively and Group II (local infiltration 30 patients) received local anesthetic infiltration at surgical incision and pocket infiltration post-operatively.

The patient characteristic (age, body mass index and ASA) were comparable between the two groups (**Table 1**). The duration of surgery and anesthesia was comparable between the two groups.

Table 1: Patient Characteristics

Parameters	Group 1 (*n* - 30)	Group 2 (*n* - 30)	*p*
Age (*yrs*)	28.42 (mean)	32.58 (mean)	.354
Weigh t(*kgs*)	34.05 (mean)	26.95 (mean)	.114

n - Number of patients;

p - Statistically significance ($p < .05$).

In the PACU, the patients of Group 1 had significantly lower consumption of intravenous fentanyl as compare to Group 2 (**Table 2**). The mean time for first rescue analgesia in Group 1 was higher and statistically significant in Group 2. The mean for rescue analgesia required in Group 1 was *30.07 hrs* (SD = 3.473) and mean of first dose of rescue analgesia in Group 2 was *8.13 hrs* (SD = 1.196) and this was statistically significant (**Table 2**). VAS score was same for first *4 hrs* post-operatively in both the groups. The difference in VAS score became statistically significant between both the groups after *6 hrs* with mean of VAS score in Group 2 at *6 hrs* was (3.00) and mean of VAS score in Group 1 was (1.73) at *6 hrs* and this score increased significantly in next hours. VAS score was found to be statistically significant at 12, 18, 24, 30 and *60 hrs*. The mean of total analgesic required in first *24 hrs* in Group 1 was. 00 (SD = 000) and in Group 2 was 2.63 (SD = 556), (**Table 3**).

There was no significant difference between the groups with respect to HR, SpO_2, and mean arterial pressure during the peri-operative period. However, the intra-operative consumption of fentanyl was less in the PEC block group during MRM but not statistically significant.

No untoward effects like vascular injury, hemodynamic instability, pleural puncture or pneumothorax was seen and no case of allergic to local anesthetic was seen. No patient suffered with PONV in any of the group.

Table 2: Intra-operative and Post-operative data

Parameters	Group 1 (PEC)	Group 2 (LA)	Mann-Whitney U	Z	*p*
Total fentanyl at induction (*mg*)	109 (S.D.-7.348)	112 (S.D.-6.518)	343.5	-1.583	.114
Total fentanyl consumption intra-operatively (*mg*)	160.17 (S.D.-22.042)	168.00 (S.D.-9.777)	337.5	-1.672	.095
Time for 1st rescue analgesia (*hrs*)	30.07 (S.D.-3.473)	8.13 (S.D.-1.196)	.000	-6.696	.000
Total doses of rescue analgesia	.00 (S.D.-.000)	2.63 (S.D.-.556)	.000	-7.282	.000

p- statistically significance ($p < .05$).

Table 3: Comparison of VAS between two groups

	Group	N	Mean	Std. Deviation	Std. Error Mean	Sig. (2-tailed)
VAS 0	LA infiltration	30	.07	.254	.046	.155
	PEC block	30	.00	.000	.000	.161
VAS 30	LA infiltration	30	.60	.498	.091	.003
	PEC block	30	.23	.430	.079	.003
VAS 60	LA infiltration	30	.87	.507	.093	.075
	PEC block	30	.63	.490	.089	.075
VAS 2	LA infiltration	30	1.43	.568	.104	.000
	PEC block	30	.97	.183	.033	.000
VAS 4	LA infiltration	30	2.07	.450	.082	.000
	PEC block	30	1.27	.521	.095	.000
VAS 6	LA infiltration	30	3.00	1.287	.235	.000
	PEC block	30	1.73	.450	.082	.000
VAS 8	LA infiltration	30	5.50	1.676	.306	.000
	PEC block	30	2.23	.971	.177	.000
VAS 12	LA infiltration	30	6.07	1.574	.287	.000
	PEC block	30	2.37	.850	.155	.000
VAS 18	LA infiltration	30	6.43	1.331	.243	.000
	PEC block	30	3.07	.740	.135	.000

Discussion

In this study, we have demonstrated that patients in Group 1 who received PEC block had better post-operative analgesia than patients who had received local anesthesia infiltration. The duration of analgesia was prolonged in Group 1 as assessed by the demand of first rescue analgesia by the patient. Also, the consumption of fentanyl in post-operative period was more in group of local anesthesia infiltration as compare to that of PEC block which was found to be statistically significant. Regional anesthetic techniques appear superior to intravenous analgesics with reduced post-operative pain, decreased post-operative nausea vomiting, respiratory depression and also cost saving.[9]

Various anesthetic techniques such as local wound infiltration, thoracic epidural, thoracic paravertebral and very recent fascial plane blocks have been used to provide analgesia after modified MRM.[10] Amongst the regional techniques thoracic epidural was considered as gold standard but was associated with the risk of neuraxial damage and persistent neurological deficits.[4] Previously many studies have supported the use of paravertebral block in breast surgeries, but it has increased risk of intravascular injection, bleeding, infection, nerve injury, short segment contralateral block and high failure rate as well. So, it might cause less complications than thoracic epidural but still more risky than ultrasound guided PEC 2 block.[11,12]

PEC block 1 was first performed in 2011, on 50 patients who had breast expanders placed as part of breast reconstructive surgery.[12] In 2012, another study compared PEC block 2 with the PEC block I introduced[14] Pectoral nerve block 1 (PEC 1) is given between pectoralis major and minor muscle, and modified pectoralis nerve block 2 (mPEC2) is performed between pectoralis minor and serratus anterior muscle along with PEC 1 block.[17] The advantage of this new modified technique of PEC block 2 was that it covered the axillary clearance in breast surgeries, maintaining good post-operative analgesia.[14] This is because PECs 2 block the pectoral, intercostobrachial, the intercostalis 3 and 6 and the thoracic nerves. The blockage of these all nerves help to provide complete analgesia.[7] Also, the spread of local anesthetic into the axilla has been demonstrated by dissection of cadavers and contrast distribution.[14,15] The pectoral nerve block was also found to be beneficial for axillary surgery.[16]

Furthermore, this technique was compared with paravertebral and thoracic epidural in breast surgeries and concluded that it was quite safe, with less incidence of pneumothorax than paravertebral block and lacking sympathetic nerve block as thoracic epidural.[12]

In 2014, the study was conducted on 60 patients; PEC block was compared with thoracic paravertebral block (second group) for post-operative analgesia. Patients receiving PEC block required decreased intra-operative fentanyl or

morphine consumption as well as had decreased incidence of post-operative nausea and vomiting.[6]

According to previous studies, no complications were associated with PEC 2 block.[3] Owing to safety of PEC 2 block, it has become more familiar among anesthetists now-a-days as compared to paravertebral and thoracic epidural nerve blocks with breast surgeries. A PEC 2 block is given when patient is in supine position and the needle is manipulated easily under ultrasound guidance. Also, the target areas of needle in PEC 2 block is distant from the pleura and epidural space.[3] Direct intravascular injection of local anesthetics is performed very rarely due to the lack of vaculature at the interfascial plane.[18,19] The more invasive techniques such as selective intercostal nerve blocks and thoracic paravertebral blockade may lead to pneumothorax or transient Horner's syndrome because of technique difficulty and dosage of drug used.[13]

In our study, the duration of post-operative analgesia was more in patients with PEC block than the patients who were given local anesthesia infiltration with pocket infiltration of local anesthetic. The total analgesic dose in the form of rescue analgesia required after PEC block was less than the total dose required by the local infiltration of local anesthetic. In general, local infiltration with pocket infiltration of wound is easy and safe but the limitation was the duration of post-operative analgesia and limited by the pharmacodynamics of the local anesthetic.

This study had several limitations. First, the PECS block was performed before the induction of general anesthesia which may have affected post-operative pain. Also, the wound dressing and a surgical crepe bandage dressing may have interfered with the response to sensory level test including post-operative pain. However, we speculated that the PEC 2 block was successfully performed based on the changes in mean blood pressure and heart rate during the incision. Consequently, this study did not present sensory test data. A second limitation was our inability to perform a double blind, placebo controlled study. However, the patients and investigators were blinded to group assignment, suggesting that the lack of ability to perform a placebo controlled study had little influence on study outcomes. One should also be aware that local anesthetic can spread along the fascial plane following PECS block can limit the use of electrocautery by the surgeon.[20]

This new PEC block is another step towards a new generation of ultrasound-guided nerve blocks. It is simple to perform *via* ultrasound guided and should potentially be associated with few side effects. Pending comparative randomized controlled clinical trials, the PEC block might prove to be an important clinical tool for the treatment of pain after thoracic and chest wall surgery.

Conclusion

Ultrasound-guided PEC block reduces post-operative pain scores, prolongs the duration of analgesia and decreases demands for rescue analgesics in the first *24 hours* of post-operative period compared to local anesthetic infiltration after modified radical mastectomy.

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