International Journal Dental and Medical Sciences Research
Volume 4, Issue 5, Sep-Oct 2022 pp 339-348 www.ijdmsrjournal.com ISSN: 2582-6018

Evaluation Of The Post Operative Analgesic Efficacy Of Ultrasound Guided Pectoral Nerve Block After Modified Radical Mastectomy.

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Submitted: 25-09-2022 Accepted: 06-10-2022

ABSTRACT
Breast cancer is the most common malignancy in women in the world. Modified radical mastectomy (MRM) is the common surgical procedure for breast cancer. It is associated with acute postoperative pain, decreasing the quality of life and increased the hospital stay. Regional anesthesia techniques like PEC block have decreased the postoperative pain effectively, thereby improving the patient's quality of life. In this study, 100 patients of age 18-70 years undergoing modified radical mastectomy were randomly allocated into 2 groups of 50 each. Group I received general anesthesia only, while group II received general anesthesia plus PEC block (Pecs I: 10ml 0.25% bupivacaine HCL, Pecs II: 20 ml 0.25% bupivacaine HCL). Postoperative hemodynamic changes, visual analog scale score at 0, 1, 6, 12, and 24 hrs; time of 1st rescue analgesia, the total amount of analgesia consumed and adverse effects were recorded. The time for first rescue analgesia was significantly longer in group II (7.24±0.71hr) compared to group I (5.56±0.83 hr) (P<0.0001). The consumption of tramadol HCL was significantly lower in group II than in group I without any significant side effects. So we concluded that pectoral nerve block is an easy, reliable, superficial block to provide better pain relief after modified radical mastectomy without significant adverse effects.

Key Words: - Analgesia, MRM, PEC Block,

I. INTRODUCTION

Breast cancer is the most commonly occurring cancer in women worldwide and the second most cancer in India[1]. The most common surgical procedure for breast cancer is MRM which removes the entire breast with axillary clearance [2]. In breast cancer surgery general anesthesia is associated with more than 30%-40% incidence of postoperative pain, nausea and vomiting[3]**.** After breast cancer surgery post-operative pain control remains a common problem. Continued research and development of newer analgesics with potent efficacy and minimal adverse effects, and the use of balanced analgesia should improve the potential to treat postoperative pain more successfully [4].

Now a day, a multimodal approach has been used for perioperative pain control in various surgical procedures. Multimodal analgesia is the use of more than one class of medication so minimize the adverse effects of any one class of medication. These medications act via different mechanisms and produce a synergistic effect on acute pain control. A successful multimodal protocol requires coordination between all phases of care: preoperative, intraoperative and postoperative[5]. Uncontrolled, acute postoperative pain can lead to an increased surgical stress response, which has an effect on endocrine, metabolic, inflammatory and immune functions. Thus adequate management of acute postoperative pain can decrease postoperative discomfort and helps in recovery.

The peripheral nerve block technique is associated with superior control of the pain, a reduction in opioid consumption after surgery, a decrease in postoperative nausea and vomiting and over decrease in the length of hospital stay [6].

Thoracic epidural block [7,8], thoracic paravertebral block [9-13], intercostal nerve block [14], erector spinae block[2] and various other techniques are used in anesthesia for breast cancer surgeries. The pectoral nerve block is a technique described by Blanco et al, is a simple new practicable alternative approach to both paravertebral and epidural blockade in the management of pain after breast surgery It is an interfascial plane block where local anesthetic is deposited into the plane between the pectoralis majorand pectoralis minor muscle (PEC I block) and above the serratus anterior muscle (PEC II block). [15,16].

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Volume 4, Issue 5, Sep-Oct 2022 pp 339-348 www.ijdmsrjournal.com ISSN: 2582-6018

The present study was designed to evaluate the analgesic efficacy of ultrasound-guided pectoral nerve blocks I & II in patients undergoing modified radical mastectomy.

II. MATERIAL AND METHODOLOGY

After obtaining institutional ethical committee approval and written informed valid consent, this randomized controlled study was conducted on 100 patients of ASA class I and II, aged 18–70 years of female undergoing elective unilateral modified radical mastectomy. Patients with ASA grade >2, refusal by patients, BMI >35kg/m^2, allergy or sensitivity to local anesthetic agents, having coagulation disorder or on anticoagulant therapy, with a history of treatment for chronic pain condition and were on daily analgesic, with a history of infection at the site of injection, patients who require reconstructive surgery, with a psychiatric disorder, cardiac disorder, renal dysfunction, preexisting neurological deficit, respiratory disease and pregnant female were excluded from the study. A thorough clinical examination of the patient was performed including a complete blood count, serum electrolytes, chest X-ray, renal and liver function test, serology, PT, APTT, INR and 12-lead electrocardiogram (ECG). Airway assessment was done by mallampati grading to anticipate the possibility of the difficult airway. Visual Analog Scale (VAS) was explained to each patient during the preoperative visit. Mark 0 represents no pain and10 represents the worst possible pain.

All Patients were kept nil orally for 8 hrs before the surgery and were premedicated with tab. lorazepam 1mg at night prior to surgery. We randomly assigned 100 patients into two groups equally. Group I received general anesthesia only and group II received general anesthesia + ultrasound guided pectoral nerve block.

In an operating room, a 20 G i.v cannula was inserted on the opposite side and baseline ECG, heart rate, noninvasive blood pressure and SpO_2 were recorded using a multi-parameter monitor. All patients were premedicated with intavenous inj. glycopyrrolate bromide (0.004mg/kg). After 3 minutes of preoxygenation with 100 % oxygen, patients were induced with inj. fentanyl citrate 2 mcg/kg + inj. propofol 2mg/kg i.v and muscle relaxation was achieved with inj. succinylcholine bromide 1.5mg/kg. Endotracheal intubation with a portex cuffed endotracheal tube of size 7.0 mm was done. After checking bilateral air entry, the tube was fixed and connected to the anesthesia machine and mechanically ventilated by standard setting. Anesthesia was maintained with nitrous oxide and oxygen 50% and sevoflurane (1-2%). For muscle relaxation inj. vecuronium bromide 0.1mg/kg given and then followed by top-up dose of 0.02 mg/kg.

Patients in Group II received a USG guided PEC block after GA. The patient was kept in a supine position with the ipsilateral limb in an abducted position. The skin over the ipsilateral breast and adjoining infraclavicular and axillary regions was disinfected and sterile draping of the area was done. A linear ultrasonography probe of high frequency (6-13 Hz) was first placed cephalocaudally in infraclavicular region and moved laterally to locate the axillary vessels above the 1st rib. Then the probe is moved downwards, 3rd and 4th ribs were identified. Structures like pectoralis major, minor and serratus anterior muscles were identified. The puncture site was marked in line with the probe and infiltrated with 2ml of 2% lignocaine HCL. The block was performed at the level of 3rd rib with a 21G insulated needle using a medial to lateral in plane approach into the fascial plane between pectoralis minor and serratus anterior muscle and 20 ml of bupivacaine HCL 0.25% was injected in increments of 5ml after aspiration (PEC II). Then the needle is withdrawn into the fascial plane between the pectoralis major and minor muscles at the vicinity of the pectoral branch of the acromio thoracic artery and 10ml of bupivacaine HCL 0.25% was injected in increments of 5ml after aspiration (PEC I). Care was taken not to cross the toxic dose of bupivacaine HCL. After completion of surgery, residual neuromuscular blockade was reversed by inj. neostigmine sulphate (0.05mg/kg) with inj. glycopyrrolate (0.01mg/kg). Patients were extubated and shifted to postoperative recovery area.

Postoperative pain assessment was done by using visual analog score at rest and at movement at 0, 1, 6, 12 and 24 hrs. Duration of analgesia was defined as the time interval from completion of surgery to administration of 1st rescue analgesia. Time for 1st rescue analgesia was noted when VAS was >4 or if patient demanded. Rescue analgesia in the form of inj. tramadol HCL 2 mg/kg i.v was given. Time of duration of analgesia, total postoperative analgesic requirement in 24 hrs and hemodynamic measurements were recorded.

Any adverse side effects or complications related to procedure and local anesthetic like nausea, vomiting, pruritis, hematoma, bradycardia and hypotension were recorded. Nausea & vomiting was treated with inj. ondansetron 0.1mg/kg. Bradycardia define as HR < 45/min and

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was treated with inj. atropine sulphate. Hypotension defined as BP <20% of baseline and was treated with fluid bolus and inj. mephenteramine.

Statistical analysis:Data in the test and table are statistically described in terms of mean ± standard deviation. Microsoft word, excel has been used to generate graphs and tables. For comparing categorical data, Chi-square test was performed. Unpaired t-test was used to compare two population means. P values less than 0.05 were considered statistically significant. Statistical analysis was done by Graph Pad software. http:\\www.GraphPad.com\quickcalcs\ttest

III. OBSERVATION AND RESULTS

The present study includes 100 patients undergoing modified radical mastectomy and randomly assigned into two groups of 50 each, to study the efficacy of pectoral nerve block along with hemodynamic changes.

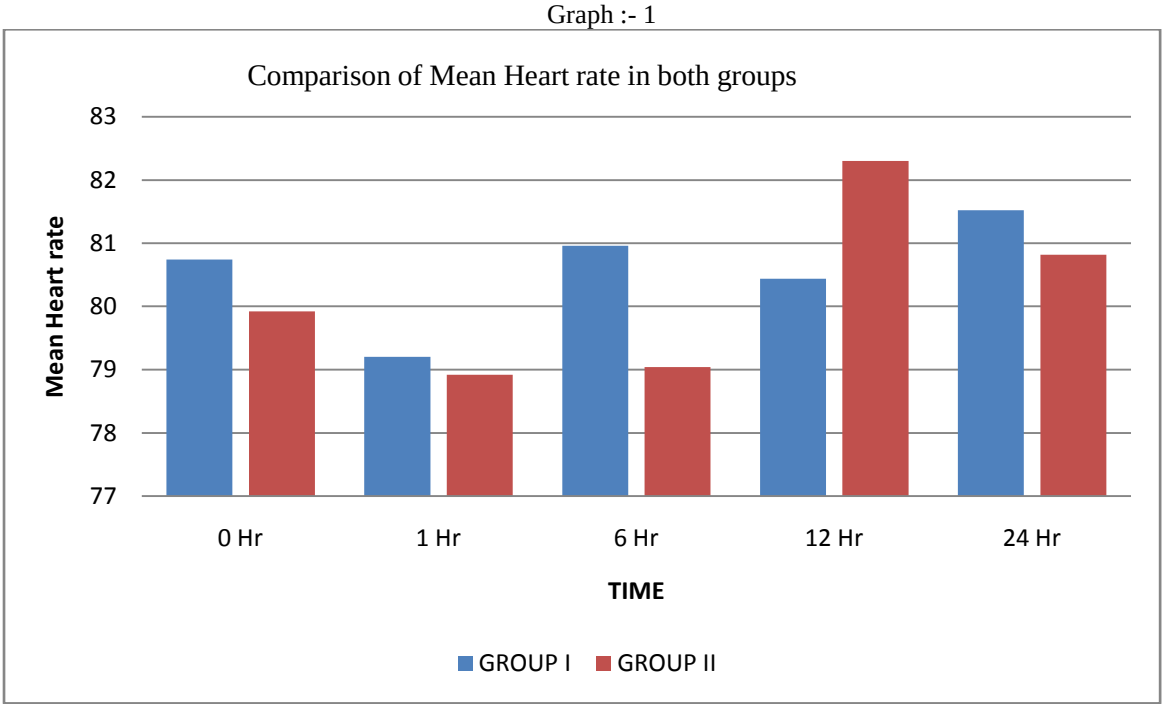
The both groups were comparable with respect to age, height, weight, duration of surgery, baseline HR, baseline MAP with no statistical difference between them as shown in table 1.

Table 1:- Demographic Data

	GROUP I	GROUP II	P VALUE
AGE (YEARS)	48.68±10.29	46.98±10.81	0.4224(NS)
HEIGHT (CMS)	154.3±2.96	154.7±3.244	0.4806(NS)
WEIGHT (KG)	63.9±5.036	61.9±5.16	0.0527(NS)
DURATION OF SURGERY(MINS)	105±13.89	107±15.29	0.3756(NS)
BASELINE HR (MINS)	79.60±5.43	78.16±4.58	0.1555(NS)
BASELINE MAP (MM of Hg)	89.14±4.11	90.12±4.82	0.2771(NS)

Data expressed as Mean± SD. P value <0.05 is Significant

Graph :- 1



Graph 1 shows the mean heart rate changes between both groups. There are no significant changes in both the groups.

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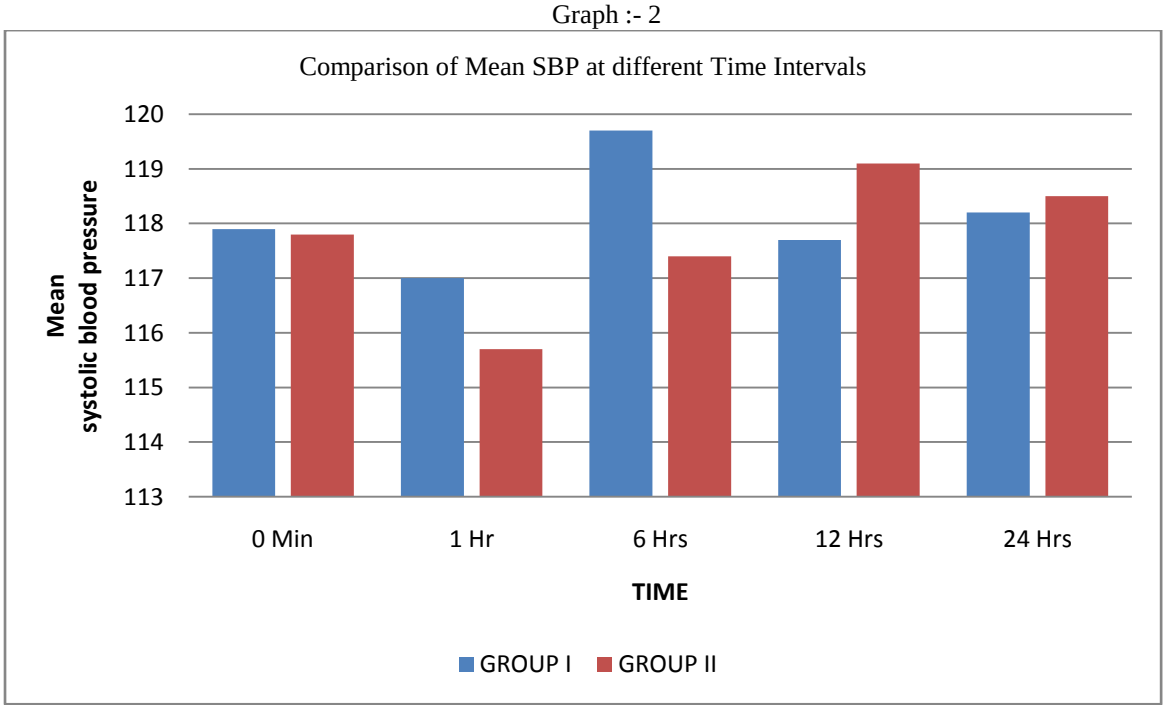
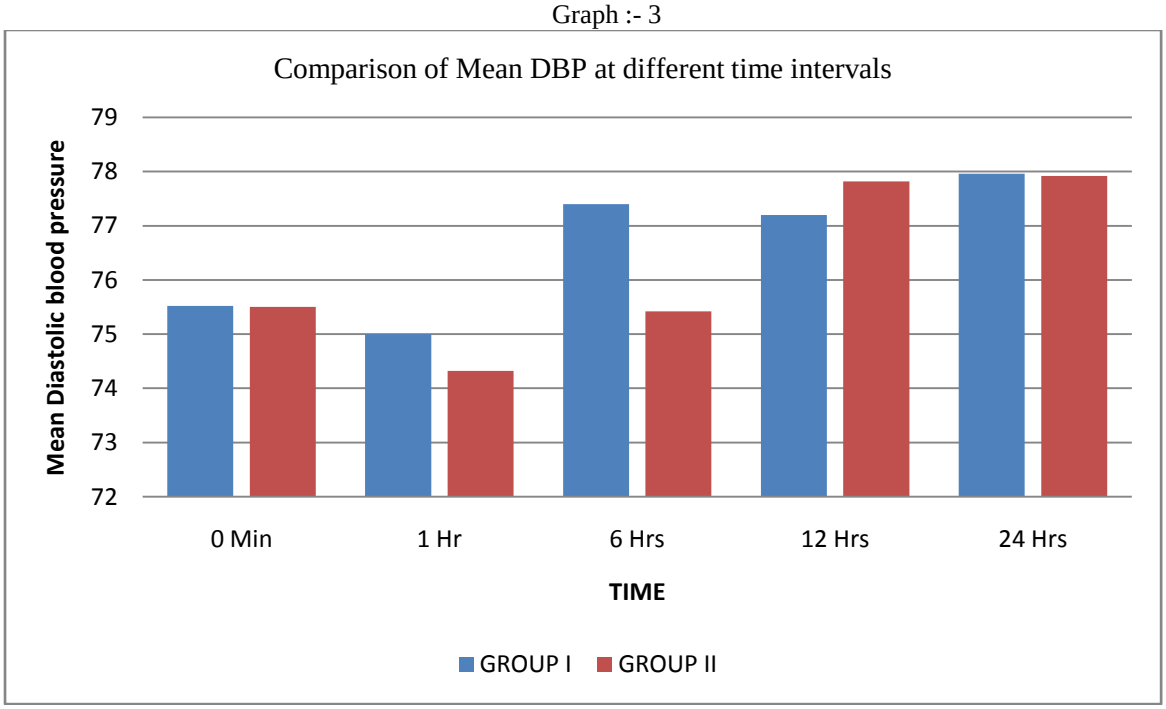
Graph :- 2



Graph :- 3



Graph 2 & 3 shows mean SBP and DBP in both groups at all time interval. The mean SBP and DBP in group II is lower than group I till 6th hr but not statistically significant.

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Table :- 2

Comparison of Mean MAP at different time intervals:

MEAN ARTERIAL PRESSURE (mm of Hg)			
TIME	GROUP I	GROUP II	P VALUE
0 Min	89.62±4.59	89.66±4.07	0.9634(NS)
1 Hr	89.04±4.36	88.14±6.25	0.4063(NS)
6 Hrs	91.56±5.37	89.80±4.64	0.0830(NS)
12 Hrs	90.72±3.22	91.6±4.58	0.2694(NS)
24 Hrs	91.32±4.69	91.42±4.19	0.9108(NS)

Data expressed as Mean±SD. P value <0.05 is significant

Table 2 shows the mean arterial pressure changes between group I and group II. There are no significant changes in MAP in both groups. The MAP in group II is lower when compared to group I till 6th hr. but not statistically significant.

Table :- 3

Comparison of VAS (At Rest) at different time intervals:

VAS AT REST			
TIME	GROUP I	GROUP II	P VALUE
0 Min	0.72±0.53	0.58±0.49	0.1794(NS)
1 Hr	1.54±0.50	1.38±0.53	0.1250(NS)
6 Hrs	5.08±0.72	3.78±0.67	<0.0001(S)
12 Hrs	4.65±0.79	3.16±0.58	<0.0001(S)
24 Hrs	2.22±0.46	2.1±0.54	0.2385(NS)

Table :- 4

Comparison of VAS (At Movement) at different time intervals:

VAS AT MOVEMENT			
TIME	GROUP I	GROUP II	P VALUE
0 Min	1.40±0.49	1.38±0.49	0.8396(NS)
1 Hr	1.90±0.50	1.98±0.55	0.4518(NS)
6 Hrs	5.80±0.67	3.80±0.60	<0.0001(S)

12 Hrs	5.02±0.65	3.9±0.58	<0.0001(S)
24 Hrs	2.82±0.62	2.70±0.61	0.3369(NS)

Data expressed as Mean±SD. P value <0.05 is Significant

Table 3&4 shows the postoperative VAS score at rest and at movement at different time intervals. During 0 & 1 hr there was no significant difference in VAS score between both groups. VAS was higher at 6th and 12th hr in group I which is statistically significant (P<0.05) than group II because of the onset of pain. At all times VAS score is lower in group II compared to group I.

Table :- 5
Comparison of First Rescue Analgesia in both groups:

TIME FOR FIRST RESCUE ANALGESIA IN BOTH GROUPS (Hrs)		
GROUP I	GROUP II	P VALUE
5.56±0.83	7.24±0.71	<0.0001

Data expressed as Mean±SD
P value <0.05 is significant
Table 5 shows the duration of analgesia which was 7.24 hrs in group II, while 5.56 hrs in the group I which was statistically significant (P-value <0.05)

Table :- 6
Total analgesic consumption in both groups (mg):

TOTAL ANALGESIC CONSUMPTION IN BOTH GROUPS(mg)		
GROUP I	GROUP II	P VALUE
180±24.20	114±10.15	<0.0001

Data expressed as Mean±SD. P value <0.05 is significant
Total Analgesic consumption is higher in group I than in group II (118±24.24 vs. 100±0 mg) which is statistically significant (P < 0.0001)

Table :- 7
Incidence of Adverse effects in both groups:

SIDE EFFECTS	GROUP I Out of 50pts/percentage	GROUP II Out of 50 pts/percentage
Nausea/Vomiting	12(24%)	6(12%)
Hypotension	0	0
Pruritis	0	0
Bradycardia	0	0
Hematoma	0	0

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Table 7 shows the incidence of side effects like nausea and vomiting was 24 % in group I and 12 % in group II. There was no report of other adverse effects like hypotension, pruritis, bradycardia, hematoma etc.

A higher incidence of nausea and vomiting in group I is due to the administration of rescue analgesia and treated with inj. Ondansetron 4mg iv.

IV. DISCUSSION

In this era, enhanced recovery after surgery (ERAS) is aimed to improve the patient experience with recovery while reducing the health care costs, and complications with better control of pain. So multimodal analgesia technique with regional blocks improves patient's postoperative pain and has some benefits with decreasing the opiate dosage and side effects of individual drugs after breast surgery [7]. Blanco described an interfascial plane block for breast surgery as a novel peripheral nerve block alternative to neuraxial and paravertebral blocks for ambulatory breast surgeries. In this technique, local anesthetic was deposited between the pectoralis major and minor muscles to anesthetize the lateral and medial pectoral nerves providing analgesia to the chest wall and he reported a variation of his original technique by adding local anesthetic injection between serratus anterior and pectoralis minor muscles (PEC II block) and block the pectoral, intercostobrachial, intercostal III, IV, V, VI and long thoracic nerves and this modification aimed to extend analgesia to the axilla. So this is useful in breast surgeries with axillary clearance [15,16,17].

S. Goswami et al [17] did a study on PEC I & II block and concluded that PEC I was useful in superficial breast surgeries, while PEC II in breast surgeries with axillary clearance. After the breast cancer surgery, contraction of the pectoralis major and minor muscles can lead to continuous postoperative pain leading to difficulty in movement of the upper limb and a decrease in the quality of life. PEC block prevents the contraction of the muscles postoperatively, thereby decreasing the pain. So the combination of PEC I and PEC II block provides better analgesia in patients undergoing MRM with axillary clearance [18]. Doo-Hwan Kim et al[19] concluded that PEC II block reduced pain severity and opioid consumption in patients undergoing BCS and SNB, and had greater effect in reducing axillary pain.

So many authors did a study on the thoracic paravertebral block vs pectoral nerve block and concluded that PEC block is more effective than TPVB, as TPVB does not cover axillary dissection and can also lead to epidural spread[10,11,13,20,21]. Mona Gad et al[2]studied ESP block vs PEC block and concluded that PEC provides better quality of analgesia than ESP block to MRM patients.

As PEC blocks are safe and more superficial with less side effects than other regional techniques, we studied the postoperative analgesic efficacy of PEC I and PEC II block after MRM.

As local anesthetic drugs have increased in popularity for control of surgical pain because of their analgesic properties and absence of opioid-induced adverse effects. In our study we used bupivacaine HCL 0.25 % 20ml for PEC II block and 10 ml for PEC I block.

Satish et al [1] did a study by using bupivacaine HCL 0.25% for pectoral nerve block before induction to evaluate efficacy after a modified radical mastectomy. So many authors also used bupivacaine HCL 0.25% in PEC I&II blocks and evaluated analgesic efficacy postoperatively after breast surgeries [7,8,13,17,20].

Other Local anesthetics like levobupivacaine and ropivacaine are also used in PEC blocks after breast surgery and concluded that postoperative analgesic requirements were less after PEC block [10,11,21,22,23,24].

In this study there were no significant changes in hemodynamic parameters as shown in graph no 2,3,4 and table- 2. Satish et al[1] in his study compared the hemodynamic variables, the change in HR and MAP were statistically insignificant in both the groups at all the time intervals.

Charul Jakhwal et al[8] study showed that statistically significant decrease in SBP and MAP in the TEA group, while there was no significant hemodynamic difference reported in GA and modified PEC. Eldeen et al.[25] compared PEC with thoracic spinal at T5 in breast cancer surgery and observed there is no change in heart rate and mean arterial pressure in PEC block, while thoracic spinal blocks show the incidence of hypotension and bradycardia due to blockage of bilateral sympathetic supply to breast.

Shweta mahajan et al[26] study showed there was no significant difference between the groups with respect to HR and MAP during the peri-operative period. Also other studies done by some authors on efficacy of PEC block after MRM, showed no hemodynamic changes [3,7,8,20].

In a comparison of mean VAS at rest and at movement it was found that VAS was significantly lower ($P<0.0001$) at 6^{th} and 12^{th} hrs after surgery in the PEC group. The mean VAS at rest and on movement was lower in the PEC group at all the time intervals compared to the control

group. This shows that patients in the PEC group had better analgesia.

Satish et al[1] study compared mean VAS at rest and on the abduction of the arm in the postoperative period and found that VAS was significantly lower (P<0.0001) at all times in the first 24hrs after surgery in the PEC group than in the control group. Patients in the PEC group had better analgesia than in the control group. S.Goswami et al[17] study VAS pain score in group mPecs II was significantly less at 6,12,18 and 24 h postoperatively when compared with group PEC (p<0.05).

Islam et al[20], Somia et al[9] , Wahba et al[11] concluded that the VAS scores were significantly lower in patients receiving the PEC at postoperatively compared with the patients receiving TPVB. Magdy et al[7] & Eldeen et al[25] concluded that VAS scores were significantly lower in the PEC group compared to TE and TS group respectively.

In our study, the time for first rescue analgesia was longer in the PEC group compared to the control group (7.24±0.71 hr vs. 5.56±0.83 hr; P<0.0001). The efficacy of the PEC block compared with the control group for analgesic consumption was investigated and the results showed that, the mean consumption of tramadol HCL in the PEC group was highly significant lower (100±0.0) in comparison to the control group (118±24.24) (P-value <0.0001).

A study done by Satish et al[1] concluded that time for rescue analgesia in PEC group was 18.8±0.75 hrs vs 2.42±0.59hrs as compared to the control group. Total tramadol HCL consumption during first 24 hr significantly decreased in PEC group than in the control group (114.4±4.63 mg vs 402.88±74.22 mg, P < 0.0001).

S. Goswami et al[17] studied PEC I vs mPecs II and showed the duration of analgesia was significantly prolonged in mPecs2 (mean 313.45, SD 43.05min) when compared with group Pecs1 (mean 258.87, SD 34.71min), P<0.001. None of the patients in both groups required any rescue analgesia.Islam et al[20] concluded that the time for the first request of analgesia was longer in the PEC group (14.00±4.54hrs) than in PVB (8.30±4.76hrs) which was statistically significant (P < 0.020). Also, total dose of pethidine during 24 hrs was 37.15±4.73 vs 75.66±10.82 mg in PEC and PVB groups respectively.

Madgy Ahmed et al [7] observed that time for rescue analgesia was 473.75±99.61 min in the PEC group while 253.33±93.59 min in TE group. Only 5 patients required pethidine as rescue analgesia in the PEC group compared to 10 patients in the TE group (P <0.034). Eldeen et al[25] conclude that postoperative fentanyl requirement is more in TE group than PEC group. Ganesh annamali et al[13] conclude that time for first rescue analgesia was 180 min in PVB group, while the same was 240 min PEC group and total morphine requirement was less in PEC group. The study shows that the duration of analgesia was 294.5(52.76) vs 197.5(31.35) min and morphine consumption in 24 hr was 3.90(0.79) vs 5.30(0.98) in PEC and PVB respectively. [21]

S Mahajanahajan et al[26] shows that time for 1st rescue analgesia was 30.07 vs 8.13 hr and the total dose of rescue analgesia was 0.00 and 2.63 in mPec and Local infiltration respectively. Somia et al[9] study showed that 1st rescue of morphine in the PEC group was 5.20±4.79 hr compared to TPVB 4.95±3.50 hr, while Wabha et al[11] found 175 min in the PEC group and 137.5 in TPVB group and morphine consumption in PEC was 21 mg while in TPVB group it was 28 mg. Siddeshwara et al[10]also showed that the total dose of morphine consumption in 24 hr was less in the PEC group(11.25±4.75mg) compared to the TPVB group(15.0±4.86 mg). The mean duration of analgesia in the PEC group was 474.1±84.93 min, while in the TPVB group it was 371.5±51.53 min.

Adverse effects like LA toxicity, pruritis, bradycardia and hypotension were not observed in any patient in our study. 6 patients had nausea and vomiting in PEC group, while 12 patients had nausea and vomiting in the control group.

Satish et al[1]study showed no adverse effects like LA toxicity and pruritis. Three patients had nausea and two patients had vomiting in the control group, whereas no patient had any nausea or vomiting in the PEC group. In a similar study by Morioka et al[22] there was no incidence of PONV in either group.

The incidence of nausea and vomiting in PEC was 10%, while 19% in the TPVB group and 2 patients developed pneumothorax in the TPVB group in a study down by Somia et al[9] **.** Wahba et al[11] study, the incidence of nausea and vomiting in PEC was 10 %, while 19 % in TPVB groups and in two patients pneumothorax was found, which was statistically significant (P = 0.002).

The limitations of our study was that we did not insert an epidural catheter to study the prolonged effects of local anesthetics. Block is performed after general anesthesia, so we did not assess the sensory block area to detect potential block failure. Block effect can only be assessed in PACU and we could not measure stress hormone levels.

V. CONCLUSION

PEC block technique is a simple, easy, superficial and effective method for control of postoperative pain without systemic side effects in patients undergoing MRM along with general anesthesia. PEC block also decreased the total tramadol HCL consumption postoperatively. PEC block can be used as a part of multimodal analgesia after breast surgery.

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