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EFFECT OF DEXMEDETOMIDINE AS AN ADJUVANT TO BUPIVACAINE AND ROPIVACAINE IN PECTORAL BLOCK FOR POST OPERATIVE ANALGESIA IN MODIFIED RADICAL MASTECTOMY UNDER GENERAL ANAESTHESIA

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ABSTRACT **BACKGROUND AND AIM** Breast cancer incidence is rising globally these days. One strategy for successful perioperative pain management following mastectomy has been identified as regional blocks. There is sparse literary evidence evaluating the effect of dexmedetomidine as an adjuvant with bupivacaine and ropivacaine in Pectoral block in patients undergoing MRM surgery. **METHOD:** This randomized prospective double-blind study was conducted on 68 participants, aged 30-60 years with ASA Grade I- III, posted for MRM. Patients were randomly assigned into two study groups according to the drug used for pectoral nerve block: Group A (bupivacaine 0.25% 30 ml plus dexmedetomidine 1mcg/kg) and group B (ropivacaine 0.25% 30 ml plus dexmedetomidine 1mcg/kg). **RESULTS** In group A analgesia lasted for 1772.62±152.93 min as compared to group B 1657.94±124.48 min (p= 0.001) which was statistically highly significant. Patient satisfaction score was comparable in both groups (4.74±0.45 in group A and 4.65±0.49 in group B; p = 0.44, clinically not significant). None of the patients had any side effects or complications in either group. **CONCLUSION** PEC block administered with dexmedetomidine as an adjuvant with bupivacaine in MRM patients provide superior analgesia and patient satisfaction with no complications.

KEYWORDS : Dexmedetomidine, Bupivacaine, Ropivacaine, Pectoral block, General Anaesthesia,

INTRODUCTION

Breast cancer accounts for 25–32% of all female cancer cases, making it the most common cancer among women in India. [1] Globally 1.8 million women have been diagnosed with the disease and 53,00,000 have succumbed to it. According to research by the American Cancer Society, one in eight women may acquire breast cancer over their lifetime.

Surgical excision of the primary tumour along with axillary dissection is one of the main treatments for breast cancer. 40% of the females report moderate-to-severe pain in the immediate post-operative period after breast cancer surgery.[2,3] Acute post-surgical pain leads to delayed discharge from post-operative recovery area, impairs pulmonary and immune functions, increases risk of thromboembolism, myocardial infarction and may lead to increased length of hospital stay.[4] Hence, effective perioperative pain management of patients undergoing breast surgery is essential.[5]

Regional blocks have been identified as a strategy for successful perioperative pain management. Regional blocks provide effective acute pain management and protect immunological function by suppressing the surgical stress response and reducing the need for general anaesthetics.

Blanco R first described the analgesic efficacy of Pectoral Nerve (PECS) block after breast reconstruction surgeries.[6] Unlike wound infiltration procedures that exclusively block sensory nerves, PEC type I and II blocks block both motor and sensory nerves.[7,8] The ultrasonography guided pectoral block is a simple and effective superficial myofascial block which involves administering local anaesthetics with the goal of blocking the medial and lateral pectoral nerves (PEC I), the lateral branches of intercostal nerves (innervate the skin from T2 to T6), inter costo-brachial nerve and long thoracic nerve (PEC II), which must be inhibited for complete analgesia.[9]

Limited duration of analgesia provided by local anaesthetics has warranted the use of various adjuvants, such as tramadol, dexamethasone, epinephrine, clonidine, dexmedetomidine, ketamine aiming at synergistically enhancing the quality and duration of analgesia.[10]

Dexmedetomidine, a potent alpha-2 adrenergic receptor agonist, provides analgesia by central action, α-2 receptor-mediated vasoconstriction, attenuation of inflammatory responses, direct action on peripheral nerves, or by enhancing the activity-dependent hyperpolarization through blocking the hyperpolarization-activated cation (Ih) current. Available data suggests that the combination of dexmedetomidine with local anaesthetics is well tolerated with minimal side effects.[11,12] However, to the best of our knowledge, very few studies have been conducted to evaluate the effect of a combination of these drugs for post operative analgesia in pectoral block in patients undergoing MRM.

Thus, the present study was conducted with the aim to assess the effect of dexmedetomidine as an adjuvant to bupivacaine and ropivacaine in pectoral block for post operative analgesia in MRM. The primary outcome was to determine the total duration of postoperative analgesia and secondary outcome to assess the patient satisfaction score and side effects or complications.

METHODOLOGY

This randomized controlled trial was conducted at a tertiary care hospital, from March 2023 to May 2024 after approval from Institutional Scientific and Ethics Committee. A total of 72 adult patients aged 30-60 years undergoing modified radical mastectomy under General anaesthesia (GA) with ASA Grade II and III were randomly recruited in the study. Out of these, two patients in each group had a failure of PEC block and two were accidentally given routine postoperative analgesia, and were hence eliminated from the study. Finally, 68 patients were allocated into two groups A and B, 34 in each group. The selected patients were randomized into two groups A and B by closed envelope technique. Trained personnel prepared the opaque envelopes with code and the drugs as per the allocation group. Double blinding was ensured as both participant and investigator were unaware of drug administered in either group. Exclusion criteria were patient refusal, skin infection at block site, chest deformity, pregnancy, patients with known allergy to study drugs, patients undergoing extensive flap (eg- thoraco epigastric) post mastectomy, patients on antipsychotics and analgesics. Confounding variables in our study included patients' subjective perception to pain and those who were diagnosed cases of neuropathy. The sample size was derived by taking reference from a pilot study done in 10 subjects in each group which was calculated by mean difference of duration of analgesia in the two groups, which was the primary objective of our study.

Sample size calculation for the means (group A and group B). Sample

size was calculated using G Power software v. 3. 1. 9. 7. Statistical test for difference between two independent means (Group A and Group B) was used. Assuming 5% level of significance, 90% power and 0.80% effect size (d) and allocation ratio as 1, the minimum required sample size was calculated to be 34 in each group.

Preanesthetic checkup was done a day before surgery. All patients gave written informed consent prior to being enrolled in the trial. As per institutional protocol, patients were kept nil per oral for 6 hours prior to the surgery. On the day of surgery patient's identification, consent form, diagnosis was reconfirmed.

Inside the operation theater, patients were positioned supine and standard ASA monitors were attached. Baseline vital parameters such as Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Respiratory Rate (RR), Oxygen Saturation (SpO2) and Electrocardiogram (ECG) were recorded. Intravenous line was secured with 18/20 G cannula and warm intravenous(iv) fluid was started.

Preoxygenation was done with 100% oxygen for 3 minutes. Premedication consisted of 1.5 µg/kg iv of fentanyl, 0.01 mg/kg iv of glycopyrrolate, and 0.05 mg/kg iv of midazolam. Induction was carried out with propofol 2 mg/kg iv in titrated dose till loss of verbal response. After eliciting satisfactory ventilation, neuromuscular blocking agent rocuronium 0.6 mg/kg iv was given. LMA was inserted and fixed after confirmation of correct placement. General anaesthesia was maintained with isoflurane 1%, nitrous oxide in oxygen (60:40) and maintenance dose of rocuronium.

Post induction of GA, the Sono-anatomy was delineated using USG (SONOSITE MICRO MAXX), 6-13 MHz linear array probe. PEC block was performed and study drug was administered as per the group assigned. Patients in group A received USG guided PEC I block with Inj. bupivacaine 0.25% 10 ml injected between pectoralis major and pectoralis minor muscle in mid clavicular line at the level of third rib and PEC II block 0.25% bupivacaine 20 ml injected between pectoralis minor and serratus anterior muscle at anterior axillary line of the fourth and fifth ribs, in combination with dexmedetomidine 1mcg/kg body weight as adjuvant. Group B received USG guided PEC I Block with Inj. Ropivacaine 0.25% 10ml and PEC II block 0.25% 20ml, in combination with dexmedetomidine 1mcg/kg.

At the end of surgery, patients were reversed with iv neostigmine 0.05 mg/kg and iv glycopyrrolate 0.01mg/kg LMA was removed when patient's spontaneous respiration and sensorium were acceptable. After removal of LMA 100% oxygen was given via facemask and patient was shifted to recovery room for further assessment.

INTRAOPERATIVE AND POSTOPERATIVE ASSESSMENT

Hemodynamics parameters such as HR, SBP, MAP was recorded before induction of general anesthesia (considered as baseline value), then every 5 min, 10 min, 15 min, 20 min, 25 min, 30 min, 45 min, 60 min, 90 min, and 120 min intraoperatively. Duration of postoperative analgesia was defined as the time (in minutes) from administration of study drug till request of first rescue analgesic by patient (injection Paracetamol 1gm iv). Postoperatively, at the end of 48 hours, Quality of satisfaction was evaluated using patient satisfaction score (1=Poor, 2=Fair, 3=Good, 4= Very good, 5=Excellent).11 Side effects and complications such as bradycardia, hypotension, and pneumothorax, if any, were noted and treated. Hypotension was defined as SBP <90 mmHg or fall of >20% from baseline value and was planned to be treated with inj. mephentermine 6 mg iv. Bradycardia was defined as HR <60/min or fall of >20% from baseline value and was proposed to be treated with atropine 0.6 mg iv. However, no patient suffered from any of the above said complications in our study.

The data was collected in a master chart on Excel and was exported to the Statistical Package for Social Science (SPSS) 20.0 for statistical analysis. The frequency of nominal and ordinal measures of quantitative variables were expressed in terms of percentage. The Pearson's Chi-square test was used to measure statistical difference for qualitative data. Between the two groups, continuous quantitative variables that can take up any value in a range were analysed and described using Mean and Standard Deviation (SD). The independent student's t-test was used to measure statistical difference between both groups and compare the mean values of quantitative data. p value >0.05 was considered not significant, <0.05 was considered significant, <0.01 was considered highly significant.

RESULTS

Total 72 patients were screened for eligibility in the study. In Figure 1, the study's consort diagram is displayed. Elective MRM was performed on sixty-eight female patients who were enrolled for this study. Patient demographic profile and mean duration of surgery (Table 1) show no significant difference between the two groups. The Mean duration of analgesia in group A was 1772.62±152.93 mins and in group B was 1657.94±124.48 mins with p value 0.001 which was statistically highly significant (Table 4). None of the patients in each group required rescue analgesics. Comparison of haemodynamic variables like HR, SBP, DBP and MAP. Changes in HR (Figure 2), in SBP (Figure 3), DBP (Figure 4) and MAP (Figure 5) were statistically insignificant in both groups at all time intervals measured intraoperatively. Quality of satisfaction was evaluated using Patient Satisfaction Score (PSS) (1=Poor, 2=Fair, 3=Good, 4= Very good, 5=Excellent) at the end of 48 hours postoperatively. Mean PSS was 4.74±0.45 in Group A and 4.65±0.49 in Group B with p value of 0.44 which was statistically not significant. In this study, we observed none of the patients in either group had any side effects or complications.

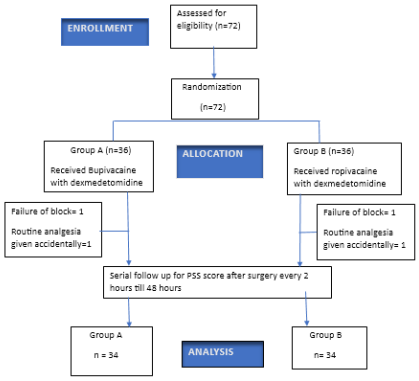

Fig 1. Consort diagram.

Table 1: Patients' demographics and duration of surgery in Both the groups

Variable	Group A (n=34)	Group B (n=34)	p Value
Age(years)	49.41±9.21	49.62±7.87	0.92
BMI (Kg/m^2)	23.62±4.16	23.61±4.66	0.97
ASA(II-III)	20/14	24/10	0.14
Duration of surgery(min)	108.82±14.52	112.94±12.92	0.22

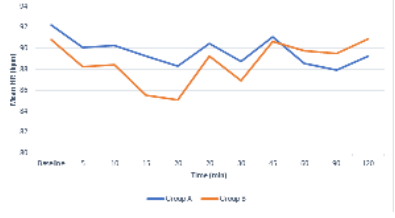

Fig 2: Comparison of mean heart rate in both the groups.

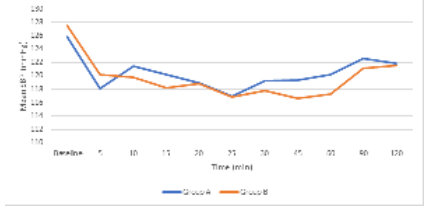

Fig 3: Comparison of mean systolic blood pressure in both the groups.

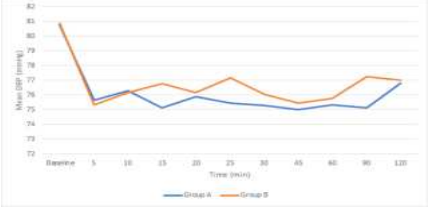

Fig 4: Comparison of mean diastolic blood pressure in both the groups.

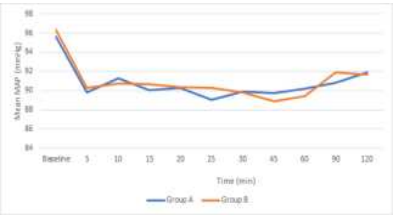

Fig 5: Comparison of mean arterial pressure in both the groups

Table 2: Mean duration of Analgesia and patient satisfaction score in Both the groups

Variable	Group A (n=34)	Group B (n=34)	p Value
Duration of analgesia(min)	1772.62±152.93	1657.94±124.48	0.001
Patient Satisfaction Score (PSS)	4.74±0.45	4.65±0.49	0.44

DISCUSSION:

Optimum peri-operative analgesia following MRM is necessary to prevent complications such as prolonged hospital stay, reduced immunity and development of chronic pain syndromes. Adjuvant enriched PEC block has proven to be a reliable technique in achieving this objective. In this research, we assessed the influence of body weight adjusted dose of dexmedetomidine enriched 0.25% bupivacaine and ropivacaine in PEC I and II block, on total duration of analgesia and patient satisfaction post MRM.

In our study, hemodynamic parameters such as heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure were measured at baseline and then at 5 ,10, 15, 20, 25, 30, 45, 60, 90 and 120 min intraoperatively. It was found that these parameters were lower than the baseline values at all measured time intervals throughout the study period in both groups. On intergroup comparison, HR, SBP, DBP and MAP were statistically comparable. In studies by Bakr MA et al[13] (PEC block with 30 ml 0.25% bupivacaine with 1mcg/kg dexmedetomidine in group II) and Kumar S et al[14] (PEC block with 30 ml 0.25% bupivacaine), it was observed that there was a significant reduction in the intraoperative hemodynamic variables, such as HR, SBP, and DBP starting at 30 minutes until 120 minutes. These findings concur with our research which may be due to similar concentration and volume of bupivacaine and dexmedetomidine used. Thus, it can be said that PEC block has no untoward effect on HR, SBP, DBP and MAP of the patients.

Primary objective of our study was to determine the duration of analgesia in patients receiving PEC block with bupivacaine or ropivacaine, with dexmedetomidine as an adjuvant. In our study, duration of analgesia was defined as the time from administration of study drug till request of first rescue analgesic. Mean duration of analgesia in Group A was 1772.62±152.93 min and in Group B was 1657.94±124.48 min. We found that the patients in Group A had significantly longer duration of analgesia as compared to Group B ((p = 0.001). This finding was similar to the study by Bakr M A et al[13] who observed 30 ml of 0.25% bupivacaine with 1mcg/kg dexmedetomidine had a significantly prolonged duration of postoperative analgesia. Like our research, Kumar S et al[14] also observed that PEC block significantly reduces pain in initial 24 hrs after MRM. The time taken for first rescue analgesia in Group II (GA with PEC Block with 0.25% bupivacaine 30 ml) was prolonged and twenty patients (n=25) did not require any rescue analgesia in 24 h. However, their results showed a gross difference in duration of analgesia to our study (31 hrs vs 19 hrs) they did not use dexmedetomidine as adjuvant to 0.25% bupivacaine. Manzoor S et al[12] observed that 1 mcg/kg of dexmedetomidine was efficacious in prolonging the duration of analgesia when used as an adjunct with 0.25% bupivacaine 30 ml in PEC block in MRM. Mahdy EW et al[15] observed that duration of analgesia in Group II (25 ml of 0.25% bupivacaine plus dexmedetomidine 1 µg/kg in PEC block) was 21±3 hrs. Similar findings present in our study may be due to similar concentration of local anesthetic and same dose of dexmedetomidine used as an adjuvant.

Mohamed SA et al[16], and Kulhari S et al[17] observed that the duration of analgesia was less as compared to our study because in their study plain LA was used and we added dexmedetomidine as an adjuvant.

Analogous to the research by Kaur H et al[11], patient satisfaction score was comparable in both groups in our study.

In our study none of the patients experienced any side effects or complications like bradycardia, hypotension, pneumothorax, and respiratory depression in either group, which was comparable to other studies in literature like Kulhari S et al[17], Bakr MA et al[13] and Kumar S et al[14].

LIMITATIONS

1. Studies with follow-up periods of more than 48 hours to explore its effect on chronic post-mastectomy pain are needed.
2. We could not evaluate effect of PEC Block on metastasis or recurrence of carcinoma breast.

FUTURE SCOPE

Further studies are needed to compare the existing wide plethora of additives in combination with different types, volumes, and concentrations of local anesthetics. Moreover, PEC block needs to be compared to other regional anesthesia techniques to zero in on the optimal technique which is most beneficial to patients undergoing modified radical mastectomy.

CONCLUSION

We conclude that in MRM surgeries, PEC Block supplemented with 1 mcg/kg dexmedetomidine as an adjuvant to 0.25% bupivacaine or ropivacaine provides adequate intraoperative surgical conditions and prolongs the duration of postoperative analgesia as well as improves patient satisfaction, thereby significantly reducing the amount of analgesic requirement in first 48 hours with no side effects. Moreover, in terms of duration of analgesia and patient satisfaction, bupivacaine is superior to ropivacaine.

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