Comparison of Dexmedetomidine as an adjuvant to Ropivacaine and Ropivacaine Alone for Post-Operative Analgesia in Ultrasound Guided Pectoral Nerve Block in Modified Radical Mastectomy: An Observational Study

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ABSTRACT

Introudction: To evaluate the efficacy of addition of Dexmedetomidine as an adjuvant to Ropivacaine compared to Ropivacaine alone in Ultrasound guided Pectoral Nerve Block after modified radical mastectomy with respect to –
1. Visual Analogue Scale for pain assessment
2. Time for requirement of first rescue analgesia.
3. Total analgesia requirement in 24 hrs.

Methods and material: The study conducted in Department of Anaesthesiology in Tertiary Care Centre. It is Double Blind Randomized Controlled study in which 72 participants undergoing MRM given Ultrasound guided Pectoral Nerve Block (D) with 30 ml 0.25 % Ropivacaine with Dexmedetomidine 1 µ/kg body weight (n=36) or with 30 ml 0.25 % Ropivacaine alone (n=36) given at the end of surgery before extubation. Statistical data will be coded and analysed in statistical software STATA version 10.1,2011.

Results: VAS scores for Group D was significantly lower (P= <0.05) at 1,2,3,6,12,18,24 hours than Group R postoperatively. Time for first rescue analgesia was significantly prolonged (P= 0.0001) for Group D as compared to Group R.
Group D had significantly less mean total rescue analgesic requirement in 24 hours (P= 0.0001) as compared to Group R.

Conclusion: Addition of Dexmedetomidine as an adjuvant to Ropivacaine provides better postoperative analgesia than Ropivacaine alone in Ultrasound guided Pectoral Nerve Block in Modified Radical mastectomy.

Keywords: Dexmedetomidine, Ropivacaine, Ropivacaine Alone for Post-Operative Analgesia, Ultrasound, Pectoral Nerve Block, Modified Radical Mastectomy

INTRODUCTION

Breast cancer is considered as commonest cancer in women. According to GLOBOCAN statistics, recently 19.3 million cancer cases were estimated worldwide and almost 10.0 million cancer deaths occurred in 2020[1]. The most frequently developed operative treatment considered for clinical stage 1 and 2 breast tumor is modified radical mastectomy. Postoperative pain is universal phenomenon experienced by most of the female. Relief of pain postoperatively is most important goal in these patients. For management of pain, a multimodal analgesic approach is usually used. As a part of this approach, PEC 2 block is used for postoperative analgesia and recovery of these patients. In pec block, entire breast containing skin, areola, nipple and axillary lymph nodes are removed.[2.]

In PEC 1 block, local anaesthetic administered in between pectoralis major (PM) muscle and pectoralis minor (Pm) muscle and in PEC 2 block, local anaesthetic administered in between pectoralis minor and serratus anterior muscle. They together blocks long thoracic and intercostobrachial nerve, pectoral nerves and III, IV, V, VI intercostal nerves. These block technique are more authentic, easy, without any sympathetic blockade and lacking resultant adverse hemodynamic effects.(6) However, it states that on incorporation of adjuvants to local anaesthetics, the block quality was improved and it prolonged the duration of analgesia. These adjuvants includes Epinephrine, Dexamethasone, Narcotics, alpha adrenoreceptor agonist (Clonidine and Dexmedetomidine). Newly, in Pectoral nerve block, supplementation of Dexmedetomidine with local anaesthetic was found to be successful in extending the pain free duration by different mechanisms.[8]

Hence, we conducted a study to evaluate the result of Dexmedetomidine on addition with Ropivacaine for PEC 2 block which helps to provide significant postoperative analgesia and anaesthetic sparing effect in Modified Radical Mastectomy.

MATERIAL AND METHODS

The present comparative observational study was conducted in Department of Anaesthesiology in NKP Salve Medical college and Hospital, Nagpur between March 2020 to February 2021 Sample size is determined considering mean difference in VAS score as the main outcome measure. Following assumptions that were made

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from the study by El Sherif FA et al in 2018 .

Assumptions that we made were: Mean (+/-SD) VAS score in Group R =2.4 +/- 1.0 and Mean (+/-SD) VAS score in Group D = 1.7 +/- 1.1 with mean difference (effect size) = 0.7 taking alpha error = 5% (2 sided) and Power (1- beta) = 80 % Required sample size came out to be 36 per group. Therefore, Total 72 participants were included in this study in two groups. First group included patients which were given Dexmedetomidine as an adjuvant to Ropivacaine and second group included patients who were given ropivacaine alone.

Approval from institutional ethics committee was taken before commencing the study. Written informed consent was taken from all patients before including them in the study. Patients undergoing Modified Radical Mastectomy, having American Society of Anaesthesiology (ASA) physical status 1/2, aged between 18-60 years were included in the study. Patients with H/o allergy to local anaesthetics, and local site infection and who refused to participate in the study were excluded in the study. Post-operative pain assessment was done by Visual Analogue Scale [VAS]. Hemodynamic parameters like pulse rate, systolic blood pressure (SBP),diastolic blood pressure (DBP),mean blood pressure (MBP), oxygen saturation [SPO2] and respiratory rate. Patients included in GROUP R were given 30 ml Ropivacaine 0.25% and GROUP D were given 30 ml Ropivacaine 0.25 % with Dexmedetomidine in 1 µg/kg body weight dose. The ultrasound guided Pectoral Nerve Block was given using 6-12 mhz GE HEALTHCARE USG & COLOUR DOPPLER linear transducer.

Preoperatively all participants were instructed regarding how to report their pain on VAS that was used for assessing the pain in the post-operative period. All the participants were kept nil orally for at least 6-8 hours prior to surgery as per ASA fasting guidelines. Preoperatively monitoring of heart rate (HR), noninvasive blood pressure (NIBP), respiratory rate (RR), oxygen saturation (SpO2), electrocardiogram (ECG) and end tidal carbon dioxide (EtCO2) was done. After achieving an intravenous access, ringer lactate infusion was started at the rate of 10 ml/kg.

Participants in the study were given general anaesthesia with endotracheal intubation with intermittent positive pressure ventilation (IPPV) as per standard protocols. All participants received intravenous Paracetamol 1 g infusion intraoperatively at beginning of surgery. As per group allocation participants were given ultrasound guided Pectoral Nerve Block with Ropivacaine alone or Ropivacaine with Dexmedetomidine as an adjuvant before extubation. After extubation participants were kept in Post Anesthesia Care Unit for further observations for 24 hours. VAS score for pain was observed at 1, 2, 3, 6, 12, 18 and 24 hours after surgery

STATISTICAL ANALYSIS

Data was coded and analyzed in statistical software STATA, version10.1, 2011. Descriptive statistics was calculated to summarize quantitative variables with mean and standard deviation, frequency and percentages to summarize qualitative

Group	Mean	SD	t test p value
Group D	24.26	2.81	t = 1.5013
Group R	23.35	2.31	p = 0.1378

Table-1: BMI distribution of subjects in two groups

ASA status	Group D		Group R	
	No.	%	No.	%
1	21	72.22	18	50.00
2	15	27.78	18	50.00
Total	36	100.00	36	100.00
Pearson $chi^2(1) = 0.5035$ p value = 0.478				

Table-2: Distribution of subjects according to ASA status in two groups

Time (hours.)	Pulse rate			t test P value	Mean SBP		t test P value	Mean DBP		t test P value	Mean MAP		t test P value	Mean SPO2		t test P value
	Group A	Group B			Group A	Group B		Group A	Group B		Group A	Group B		Group A	Group B	
	Mean± SD	Mean± SD			Mean± SD	Mean± SD		Mean± SD	Mean± SD		Mean± SD	Mean± SD		Mean± SD	Mean± SD	
1	71.55± 8.53	72.19±6.89	0.72	0.82	119.55±8.99	118.89±9.08	0.75	73.92±7.94	72.39±7.4	0.40	104.29±7.93	103.29±7.78	0.59	99.64±0.54	99.67±0.53	0.82
2	73.05±9.28	73.72±6.37	0.72	0.87	119.61±9.35	116.19±7.66	0.10	74.19±6.75	71.94±5.66	0.12	104.35±7.67	101.29±6.46	0.07	99.36±0.72	99.39±0.73	0.87
3	72.61±8.66	73.78±7.62	0.54	1.0	121.42±10.29	115.30±7.46	0.00*	75.72±8.21	73.33±5.23	0.14	105.76±9.03	104.64±6.52	0.55	99.30±0.75	99.30±0.62	1.0
6	73.86±10.7	74±8.37	0.95	0.86	121.83±12.09	120.14±9.19	0.50	74.69±7.29	73.28±5.95	0.36	106.09±9.77	104.51±7.51	0.44	99.39±0.69	99.42±0.69	0.86
12	76.08±9.97	76.05±7.44	0.98	0.87	119.55±8.99	118.89±9.09	0.75	73.92±7.94	72.39±7.40	0.40	104.29±7.93	103.29±7.78	0.59	99.30±0.71	99.33±0.76	0.87
18	76.53±10.37	75±6.48	0.45	0.37	121.42±10.29	120.30±8.03	0.61	75.61±8.29	73.33±5.23	0.16	105.76±9.03	104.64±6.52	0.55	99.28±0.74	99.42±0.55	0.37
24	76.55±10.51	75.33±6.66	0.5575	0.67	120.72±10.56	119.55±8.82	0.61	74.08±7.47	72.55±6.02	0.34	105.21±8.83	103.51±7.55	0.3839	99.61±0.55	99.55±0.56	0.67

Table-3: Mean hemodynamic parameters of patients in two groups

variables. Inferential statistics was included test of significance and p- value. Between the group, mean differences was analyzed by two
independent samples t -test. Within the group, mean difference was analyzed with repeated measures ANOVA (analysis of variance). Qualitative variables were analyzed with chi square test. P - value < 0.05 was considered statistically significant.

RESULTS

The present study we compared the efficacy of addition of Dexmedetomidine as an adjuvant to Ropivacaine compared to Ropivacaine alone in Pectoral Nerve Block after modified radical mastectomy with respect to Visual Analogue Scale for pain assessment, time for requirement of first rescue analgesia and total analgesia requirement in 24 hours [Figure 1].

When Pearson chi square test was applied to compare age in both the groups,it was not found to be significant. (P value = 0.224).

The mean body mass index in Group D and Group R was 24.26 ± 2.81 and 23.35 ± 2.31 kg/m2 respectively and this difference was not statistically significant (P>0.05) [Figure 2].

VAS score at baseline was 0.00 in group D and 0.36 ± 0.49 in group R respectively. In group D the VAS score increased to 1.05 ± 0.58 at 24 hours whereas in group R it increased to 1.89 ± 0.85. The VAS score in group D was significantly lower as compared to group R at all-time intervals [Figure 3].

There was no statistical difference in mean of different hemodynamic parameters of patients of both the groups except for SBP at 3 hours with p value of 0.00 [Figure 4].

When mean Rescue analgesia in first hour and total analgesic required(mg) was compared in both the groups, there was statistically significant difference in both the groups (p=0.0001).

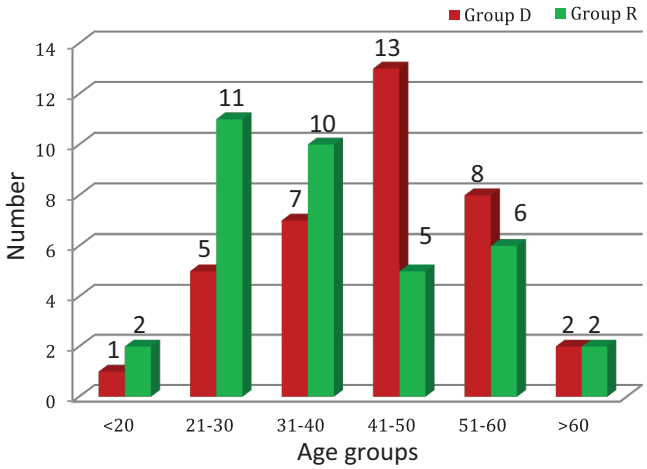

Table-1: BMI distribution of subjects in two groups

DISCUSSION

Breast cancer is observed as the commonest cancer in women of Indian population.(54) Despite of effective operative procedure for breast cancer, pain following it remains a major challenge.(56) Multimodal analgesia techniques such as paracetamol, opioids, NSAIDs , local infiltration, peripheral nerve block, etc., along with general anaesthesia provided better perioperative care in inhibiting the pain and discomfort in patients undergoing breast cancer surgeries.(4)

By 2014, Erector spinae block was first introduced in mastectomy surgery which was modification of paravertebral block. Kulhari et al(41), Islam Gamal Hamed et al(50), in their studies compared pectoral nerve block with TPVB and concluded that Pectoral nerve block provided superior relief from pain in patients after breast surgery. The study conducted by Omer Karaca et al(45), observed that use of ultrasound guided PEC 1 and PEC 2 blocks together provided better postsurgical pain relief and shortened hospital stay in patients undergoing breast surgery.However, S. Goswami et al(44), planned study in which he compared the Pectoral nerve block 2 from Pectoral nerve block 1 with respect to postsurgical analgesia in patients after mastectomy. He found that Pectoral nerve block 2 provided better postoperative analgesia compared to Pectoral nerve block 1.

Also, in recent years Bashandy GM et al(40), Satish Kumar et al(4), Rakhi Khemka et al(48), Alessandro Fancellu et al(51), did the studies to compare Pectoral nerve block with general anaesthesia versus general anaesthesia alone. They reported that combination technique provides excellent pain relief postoperatively than only general anaesthesia.

The present study shows that VAS score in Dexmedetomidine group was significantly reduced than to Ropivacaine group at all time interval. The similar result was seen by Mohamed FI et al(38) where he found that the VAS score was significantly lesser and the time required for first rescue analgesia was significantly prolonged in the Dexmedetomidine group with significant P value.Also, study conducted by Ali Hasan et al(42) were in concordance with our study and states that, VAS score was reduced postoperatively at 0, 2, 6, 12, and 24 hour in the Bupivacaine Dexmedetomidine group.

First rescue analgesia is described as time taken from extubation till demand of first analgesia or when VAS

Time (hour)	Group D		Group R		p value
	Mean	SD	Mean	SD	
Rescue analgesia in First (0) hour	12.58	2.90	8.89	2.08	0.0001*
Total analgesic required(mg)	91.67	69.18	227.78	51.33	0.0001*

Table-4: Comparison of Mean of different parameters in two groups

≥4. In present study, we found that time for first rescue analgesia was prolonged in Dexmedetomidine group and was statistically significant with p value 0.0001. Following studies showed similar results. This indicates that analgesia due to addition of Dexmedetomidine to Ropivacaine was more efficacious than only Ropivacaine. The similar result was shown by El Sherif FA et al(47) in his study. wherein addition of Dexmedetomidine in 0.25% Bupivacaine for ultrasound- guided Pecs block prolonged the time required for first request of analgesia (25.4 ± 16.4 hours) and (17 ± 12 hours) in Dexmedetomidine group and Bupivacaine only group respectively (P = 0.029), Also, study conducted by Kaur H et al(46) were in concordance with our study showing significantly prolonged time interval for first request of analgesia in Dexmedetomidine group (group D). The present study shows that pain score was less throughout the study and was statistically significant. This can be demonstrated with reduced total analgesia requirement of inj. Tramadol which was 91.67 ± 69.18 mg in Dexmedetomidine group (Group D) than 227.78 ± 51.33 mg in Ropivacaine group. Senapathi TG et al(19) demonstrated that intraoperative and postoperative pain and the opioid consumption (fentanyl) was effectively reduced by using Pecs II block along with general anaesthesia in patients of mastectomy, at 3, 6, 12, and 24 hrs after surgery than with only general anaesthesia. Similar results were shown by Shaiqa Manzoor et al(8) which states that total requirement of injection Diclofenac sodium in 24 hours was reduced by 23% in Group B i.e. Bupivacaine with Dexmedetomidine group (77.5 ± 13.6 mg) than in Group A i.e. Bupivacaine alone group (100.0 ± 35.9 mg) with P value 0.003.The incidence rate of nausea and vomiting was not statistically significant which might be due to reduced postoperative opioid consumption.

CONCLUSION

Ultrasound guided Pectoral Nerve Block (PEC – 2) block is efficacious and found to be higher in providing postoperative analgesia after Modified Radical Mastectomy. Addition of Dexmedetomidine as an adjuvant to Ropivacaine reduces pain scores, prolonged duration of first rescue analgesia and required less postoperative analgesia compared to Ropivacaine alone. Hence based on this study, addition of Dexmedetomidine to Ropivacaine is highly recommended for post operative analgesia in ultrasound guided pectoral nerve block after Modified Radical Mastectomy.

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