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A COMPARISON OF POSTOPERATIVE PAIN MANAGEMENT IN PATIENTS UNDERGOING MODIFIED RADICAL MASTECTOMY UNDER GENERAL ANAESTHESIA WITH OR WITHOUT PECTORAL NERVE BLOCK

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ABSTRACT

Background: This study compared the effect of pectoral nerve block in postoperative pain management in patients undergoing modified radical mastectomy under general anaesthesia.

Materials and Methods: A prospective randomised single blind study was conducted in the Department of Anaesthesiology and Critical Care Medicine, IMS, BHU after approval from the hospital ethical and research committee. This study investigated the analgesic effect of Pectoral block I and II in 39 patients between age group of 16-65 years having ASA PS I or II undergoing breast surgery under general anaesthesia. Patients were divided into Group A: patients who received Pectoral I and II block and Group B: patients who did not receive block. Patients of both the groups were compared for intra operative fentanyl consumption, first opioid demand, pain score at various time intervals, requirement of rescue analgesia, length of hospital stay, sedation score and side effects.

Results: It was found that, amongst the malignant breast cancer surgery patients who received Pectoral block, postoperative opioid consumption was effectively reduced with a mean value of (14.29 ± 24.3) as compared to (75.00 ± 26.72) in patients without pectoral block (p value of 0.003). The satisfaction levels measured in terms of VAS score of 7(5-9) in block patients and 4(3-4) in patients without block ie. a significant p value of 0.002 after surgery for malignant breast surgery but not in case of benign breast disease, p value of (0.266).

Conclusion: Pectoral block as a part of multimodal analgesia regimen is effective in reducing postoperative opioid consumption, NRS pain scores and improving the satisfaction levels expressed by patients after surgery for malignant breast surgery but not in case of benign breast disease.

Keywords: Post Operative Pain, Pectoral Block, Malignant Breast Surgery, Analgesia, Opioids.

INTRODUCTION

Patients need optimal postoperative pain relief for comfort and satisfaction and also to facilitate their early mobilization and rehabilitation. Moreover, optimal postoperative pain relief has been found to be associated with less postoperative cognitive impairment, reduced risk of chronic/persistent post-surgical pain with better overall outcome and reduced clinical expenses. The international Association for the Study of Pain (IASP) defines pain as an unpleasant sensory and emotional experience

associated with actual or potential tissue damage, or described in terms of such damage. Pain carries physiological, emotional and psychological components. A complex neurohormonal mechanism is involved in the expression of pain sensation.[1] Control of the pathophysiologic processes associated with acute postoperative pain may attenuate the stress response, sympathetic outflow, and inhibitory spinal reflexes and contribute to improvements in morbidity, mortality, and patient-reported outcomes.[2]

The surgical stress response consists of complex changes in neuroendocrinological, immunological and hematological systems. As a result, there is increased secretion of ACTH, cotisol, catecholamines, aldosterone etc which leads to hyperglycemia, hypertension, tachycardia and immunosuppression.[3,4,5,6] Regional anaesthesia is found effective in inhibiting the stress response to injury by interfering with afferent neural input to central nervous system, resulting in decreased postoperative susceptibility to infection and metastasis.[3,7]

The most common complications of mastectomy are postoperative acute and chronic pain and slow recovery of shoulder function.[8] So postoperative analgesia remains a challenge for patients with severe acute postoperative pain after breast cancer surgery despite a range of treatment options. Acute pain after breast surgery is traditionally managed with systemic opiates which are associated with excessive vomiting, drowsiness and delay in recovery.

To reduce the use of opioids, multimodal strategy is currently the gold standard practice to manage perioperative pain. Regional anaesthesia techniques have shown to provide better quality of pain control and may reduce the incidence of chronic pain. Measures such as thoracic epidural block, thoracic paravertebral block, inter pleural block, interscalene block have all been used for pain management in breast cancer surgery. However, these blocks are considered as more invasive and require technical expertise and thoracic epidural block and thoracic paravertebral blocks may be associated with serious complications. Pectoral block has emerged as a simple, less invasive and a novel alternative in the management of pain for breast surgery.

In this study, we compared the analgesic effectiveness of Pectoral block in different types of, both malignant and benign breast surgeries performed under GA.

MATERIALS AND METHODS

This prospective randomized single blinded control study was conducted in the Department of Anaesthesiology and Critical Care Medicine of IMS, BHU Varanasi for a duration of 18 months. 47 patients of ASA Physical Status (ASA-PS) I and II of age group 16-65 years were scheduled for breast surgery under general anaesthesia. Eight patients did not meet the inclusion criteria. The remaining 39 patients were included in this study. Informed consent was taken from each patient or their relatives. On the day before surgery, all consecutive patients were assigned to Pectoral I and II block group (Group A) or No block group (group B) by drawing sequentially numbered, coded, sealed opaque envelopes each with a computer-generated allocation numbers. The subjects were unaware, about the block.

Patient refusal or Local site infection, known hypersensitivity or any contraindications to study medication, patients with history of chronic pain or psychiatric illness were excluded from the study.

Group A, patients received Pectoral I block (0.20% Ropivacaine 10 ml) and Pectoral II block (0.20% Ropivacaine 20 ml). No block was administered in Group B patients. All the patients were familiarized about the use of Numerical Rating Scale (NRS) for pain assessment. The patients were premedicated with Tab diazepam 0.2 mg/kg given orally night before surgery.

On the day of surgery, in the patient holding area of the operation theater, peripheral venous assess was secured with 18G iv cannula. The patients were shifted to the operation theatre and multi para monitors were attached. After preoxygenation, induction of anesthesia was done with loading dose of intravenous Fentanyl 1.5 mcg/kg and Propofol 1-2 mg/kg and vecuronium 100mcg/kg. Airway was secured by endotracheal intubation, with appropriate sized endotracheal tube.

After induction of general anaesthesia and before the start of surgery, ultrasound guided Pectoral blocks were performed by using 20-G Tuohy needle under all aseptic precautions in patients who are in Pectoral block group (Group A). Block site was prepared using Povidine Iodine and methylated spirit. Images were obtained using a Sonosite ultrasound machine. The high frequency ultrasound (6—13 MHz) probe was placed at the mid clavicular level and angled inferolaterally, and then the axillary artery and vein was identified. The probe was then moved laterally until pectoralis minor and serratus anterior were identified. The needle (8cm, 22 G insulated needle) was advanced in the tissue plane between Pectoralis major muscle (PMm) and Pectoralis minor muscle (Pmm) at the vicinity of pectoral branch of acromiothoracic artery in the plane with the aid of ultrasound probe. 10 ml of 0.20 % ropivicane, was deposited with the needle. Similarly, 20ml of 0.20% ropivicane, was infiltrated in between Pmm and serratus anterior muscle at the level of third rib. (Blanco et al. 2012) (Blanco 2011). No block was administered in Group B patients.

Anaesthesia was maintained with isoflurane, oxygen, additional vecuronium and fentanyl. We monitored Blood pressure, heart rate, SpO2, EtCO2, and ECG intraoperatively. Supplemental analgesia was provided by 10-20 mcg of Fentanyl IV if heart rate and/or mean arterial blood pressure increased by 20% above the measured baseline. During intraoperative

period, 1gm of intravenous paracetamol was given 15 minutes before the completion of surgery, infused over 15 minutes. Ondensatron (4mg IV) was administered 15 minutes before the end of surgery as a prophylaxis for postoperative nausea and vomiting. Any episode of intraoperative hypotension (MAP lower than 65 mmHg) and bradycardia (heart rate < 50 bpm) was treated with ephedrine 5 mg and atropine 0.4 mg IV respectively. On the completion of surgery, neuromuscular blockade was reversed with 0.05 mg/kg of neostigmine and 10mcg/kg of glycopyrrolate. The patient's trachea was then extubated and patients were then transferred to postoperative recovery room.

In the postoperative recovery unit, blood pressure, pulse rate and oxygen saturation were monitored for two hours. Pain scores at rest, coughing and on shoulder abduction of ipsilateral shoulder along with assessment of nausea and vomiting (PONV) was done in the postoperative recovery unit, immediately after patients were transferred. If the patient had NRS score for pain at rest >4, intravenous tramadol 50 mg was administered. Additional morphine of 2 mg was given after 30 min, if the pain was not controlled. PONV was assessed by a categorical scale from 0 to 2.

This rescue analgesia and antiemetic regimen was followed for next 24 hours of surgery. The patient was then transferred to ward. NRS for pain was the assessed at 2h, 4h, 8h, 12h and 24h of initial assessment. NRS pain score was calculated as 0 being "no pain" and 10 being "worst pain". NRS pain score was also assessed during coughing and abduction of ipsilateral shoulder at 0,2,4,8,12 and 24 hours of surgery. The incidence of post-operative nausea and vomiting was recorded in the first 24 hours.

Postoperative nausea vomiting was assessed on a scoring system, sedation was assessed using 5point scale. Total intraoperative fentanyl consumption was calculated and the total requirement of tramadol was calculated in first 24 hours. The time to first opioid demand was recorded. The frequency of rescue analgesics required in first 24 hours was calculated.

The patients were assessed for the overall satisfaction score, using the VAS score, the length of hospital stay after surgery and the incidence of complications was recorded during the study in both the groups.

RESULTS

Hemodynamic Parameters

Table 1: Comparison of heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure 2 hours after surgery in the two groups

		HR		SBP		DBP		MAP
Malignant breast disease		Median (IQR)	Mean Rank	Median (IQR)	Mean Rank	Median (IQR)	Mean Rank	Mean ± SD
	Pec block	80 (80-100)	8	130 (120-140)	9.14	80 (70-80)	8.64	94 ± 11
	No block	80 (77-95)	8	123 (120-130)	7	76 (70-87)	7.44	93 ± 10
	P value	1.00		0.397		0.613		.063
	Man Whitney U	28.000		20.000		23.500		-
Benign breast disease		HR		SBP		DBP		MAP
		Median (IQR)	Mean Rank	Median (IQR)	Mean Rank	Median (IQR)	Mean Rank	Mean±SD
	Pecs block	76 (66-80)	11.42	110 (92-115)	10.42	70 (60-70)	10.29	81±8
	No block	80 (74-80)	13.58	110 (110-120)	14.58	74 (70-80)	14.71	89±10
	p-value*	0.478		0.160		0.128		0.877
	Man Whitney U	99.000		47.000		45.500		-

The two groups with malignant and benign breast diseases had comparable heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure after 2 hours of surgery ie. (P>0.05)

Table 2: Comparison of heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure after 4 hours of surgery in the two groups

		Heart Rate	SBP		DBP		MAP	
Malignant breast disease		85±10	Median (IQR)	Mean Rank	Median (IQR)	Mean Rank	Median (IQR)	Mean Rank
	Pecs block		120(110-140)	7.57	80 (70-80)	9.21	90(80-100)	8.36
	No block	78±8	120(117-130	8.38	73 (69-80)	6.94	90(86-96)	7.39
	p-value*	0.152	0.779		0.336		0.779	
	Man Whitney U		25.500		19.500		25.500	
Benign breast disease		Heart Rate	SBP		DBP		MAP	
			Median	Mean	Median	Mean	Median	Mean

	Pecs block	77±7	110 (102-120)	11.96	70 (60-78)	11.58	82 (77-90)	11.63
	No block	78±8	120 (100-128)	13.04	74 (60-80)	13.42	90 (74-101)	13.38
	p-value*	0.674	0.713		0.551		0.551	
	Man Whitney U		65.500		61.000		61.500	

The two groups with malignant and benign breast diseases had comparable heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure after 4 hours of surgery (P>0.05)

Table 3: Comparison of intraoperative fentanyl consumption between the two groups among the patients with malignant and benign breast disease

Pts with Malignant Disease	**Intraperative fentanyl consumption (µg)**	**Pecs block (n= 7)**	**No block (n=8)**	**p-value***
		105.00±16.58	**106.25±13.02**	**0.914**
Pts with Benign Disease.	Intraperative fentanyl consumption (µg)	Pecs block (n=12)	No block (n=12)	p-value*
		104.58 ±19.12	89.58 ±12.87	0.175

Among the patients with malignant breast disease, intraoperative fentanyl consumption was comparable in the two groups. (P>0.05), and in the patients with benign breast disease, intraoperative fentanyl consumption was more for patients who received Pecs block than those who did not receive block. However, the data was not statistically significant.

Postoperative opioid consumption

Table 4: Comparison of total tramadol consumption in first 24 hours of surgery between the two groups among the patients with malignant and benign breast disease. Values expressed as Mean ± SD, Median (IQR) and Mean Rank

		Pecs block group (n=7)			**No block group (n=8)**			**P value**	**Mann Whitney U.**
		Mean ± SD (mg)	**Median (mg)**	**Mean rank**	**Mean ± SD (mg)**	**Median (mg)**	**Mean rank**		
Total Tramadol Consumption	Malignant breast disease.	14.29 ±24.3	0 (0.00-50.00)	4.57	75.00 ± 26.72	75.00 (50.-100)	11.00	0.003	4.000
	Benign breast disease.	20.83 ±25.7	0 (0-50)	12.00	25.00 ±26.1	25 (0-50)	13.00	0.688	66.000

Among the patients with malignant disease, the total postoperative tramadol consumption in first 24 hour after surgery was significantly more for patients who did not receive Pecs blocks(B) than who received Pecs block(A). Similarly in the patients with benign breast disease, the total tramadol consumption in 24 hrs after surgery was more in No block group(B) than group(A) but the difference was not statistically significant.

Table 5: Comparison of time to first opioid demand after surgery between the two groups among the patients with malignant breast disease and benign breast disease

Time to First Opioid demand(h)	**Malignant breast disease**	**Pecs block group (n=7)**		**No block group (n=8)**		**P value**	**Mann Whiteny U**
		Median (IQR)	**Mean rank**	**Median (IQR)**	**Mean rank**	**P value**	**Mann Whiteny U**
		2(0-2)	**5.75**	**1(0-2)**	**5.44**	**0.889**	**7.500**
	Benign breast disease.	Pecs block group (n=7)		No block group (n=8)		P value	Mann Whiteny U
		Median (IQR)	Mean rank	Median (IQR)	Mean rank		
		2(0-2)	**7.00**	**1(0-2)**	**5.43**	**0.403**	**10.000**

Among the patients with malignant and benign disease, patients of group A, who received Pecs blocks demanded for first opioid dose later as compared to those who did not receive Pecs block in the postoperative period. Though the difference was not statistically significant.

Table 6: Comparison frequency of rescue analgesics given in first 24 hours between the two groups among the patients with malignant disease and benign breast disease. Values expressed as Median (IQR) and Mean rank

Frequency of rescue analgesics	**malignant breast disease**	**Pecs block group (n=7)**		**No block group (n=8)**		**P value**	**Mann Whiteny U**
		Median (IQR)	**Mean rank**	**Median (IQR)**	**Mean rank**		
		0(0-1)	**4.57**	**1.5(1-2)**	**11.00**	**0.003**	**4.000**
	Benign breast disease	Pecs block group (n=7)		No block group (n=8)		**P value**	**Mann Whiteny U**
		Median (IQR)	Mean rank	Median (IQR)	Mean rank		
		0(0-1)	**11.50**	**0(0-1)**	**13.50**	**0.418**	**60.000**

Among the patients with malignant breast disease, patients who did not receive Pecs block required opioid more number of times as compared to No block group (P<0.05). Among the patients with benign breast disease, patients in "No block" group required opioid more number of times as compared to patients in "Pecs block" group. However the difference was not statistically significant.

Table 7: Comparison of satisfaction VAS between the two groups with malignant breast disease and benign breast disease when assessed at 24 hours of surgery. Values expressed as Median (IQR) and Mean rank

Satisfaction VAS score	**malignant breast disease**	**Pecs block group (n=7)**		**No block group (n=8)**		**P value**	**Mann Whiteny U**
		Median (IQR)	**Mean rank**	**Median (IQR)**	**Mean rank**		
		11.50	**7 (5-9)**	**4.94**	**4 (3-4)**	**0.002**	**3.5000**
	Benign breast disease	Pecs block group (n=7)		No block group (n=8)		**P value**	**Mann Whiteny U**
		Median (IQR)	Mean rank	Median (IQR)	Mean rank		
		14.13	**8(4.5-8)**	**10.88**	**6(4.25-7.7)**	**0.266**	**52.500**

In the patients who underwent surgery for malignant disease, satisfaction score was significantly more in patients who received Pecs block than who did not (P<0.05), similarly in the patients who underwent surgery for benign disease, satisfaction score was more in patients who received Pecs block than who did not, but the data was not statistically significant, p value (0.266).

DISCUSSION

The use of peripheral nerve blocks along with real time ultrasound-guided techniques, have emerged to deliver effective and goal directed analgesia. This has bought a significant shift in the postoperative pain management. In view of the adverse effects of "opioid only" pain regimen, multimodal pain management is increasingly being practiced. With a goal to overcome substantial component of the pain experienced by patients after breast surgery, we designed this study to evaluate the analgesic usefulness of Pectoral I and II block with ultrasound guided technique as a part of safer multimodal analgesic regimen.

We studied the effectiveness of Pectoral blocks I and II in reducing the total opioid consumption in the first 24h after surgery with general anaesthesia for breast diseases. We also observed for intraoperative fentanyl consumption, NRS pain score, the time of first opioid demand, the number of times the rescue analgesia was requested, occurrence of postoperative nausea and vomiting, level of sedation, patient satisfaction and length of hospital stay after surgery.

Among the patients with malignant breast disease, the variables like age, ASA PS, duration of surgery, heart rate, SBP, DBP, MAP at baseline, 2h and 4h after surgery was comparable in the two groups with or without Pectoral block.

Surprisingly, we found that the intraoperative fentanyl consumption was comparable in the two groups with or without Pectoral block among the patients with malignant disease. Our study did not show any difference in intraoperative opioid consumption as previously described studies by Morioka et al. 2014 and Bashandy & Abbas in 2015. In a retrospective study done by Morioka et al. intraoperative fentanyl requirement was found to be less by 4µg/kg/h in Pectoral block group as compared to the control group.[9,10] In our study, the comparable intraoperative fentanyl consumption in the two groups with or without Pectoral block could be because of the variation in the invasiveness of surgery and ethnicity of the patient, which could have played as confounders.

Among our patients with malignant breast disease, NRS pain scores immediately after surgery i.e. at 0h, was less in Pectoral block group patients as compared to those who did not receive Pectoral block. However, this difference was not statistically significant (due to intraoperative fentanyl, paracetamol along with ketorolac administration during skin closure). Expect for the 0h, NRS pain score during abduction of ipsilateral shoulder was significantly lower in patients with Pectoral block than without block at all time points till 24h after surgery and while coughing, NRS pain score was less in Pectoral block group at all time points till 12h after surgery. Similarly, NRS pain score at rest was less in Pectoral block group than no block group at all time points till 8h hours after surgery expect at 0h. The pain scores between the two groups differed by an average of two. Lower pain scores even at 24 hours after surgery during movement of shoulder among patients who received Pectoral block showed the analgesics effectiveness of Pectoral block till 24 hrs. Our findings were comparable with the findings of a retrospective study done by Morioka et al., who found that the cumulative distribution of NRS was shifted to the right i.e. lower in patients receiving Pectoral block.[9] Similarly, Bashandy and Abbas found that the VAS pain score was ≤ 2 who received Pectoral block and VAS pain score ≥3 who did not receive Pectoral block, when assessed at 0h, 3h, 6h, 9h and 24h after surgery.[10] Our findings was also in accordance to the finding of the study done by Araosta et al. and Soto et al who found lower pain scores of 0-2 in the immediate postoperative period.[11] The result of our study was also similar to the result of Wahba and Kamal to compare the effects of paravertebral block (PVB) and Pectoral block for Modified Radical Mastectomy with general anesthesia where the NRS pain score at rest ranged between 2 to 4 at 1h, 6h, 12h, 18h and 24h

postoperatively and during movement ranged between 4 to 6 at the same time points postoperatively.[12] In our study, the NRS pain score ranged between 0 to 3 in group A patients who received Pectoral block.

In our study, among the patients who underwent surgery for malignant breast disease, total tramadol requirement in th e first 24 hours after surgery was about five times less in those who received Pectoral block compared to those who did not receive Pectoral block. The morphine equivalent for tramadol required in the two groups are 1.4 Vs 7.5 mg for Pectoral block group and No block group respectively. The results of our findings were very much similar to the the finding of the study conducted by Aksu et al. who found postoperative Morphine consumption in 24 hours after surgery was two times more in the control group compared to the Pectoral block group (9 Vs 17).[13]

Among our patients with malignant breast disease, only two out of seven patients in the Pectoral block group required tramadol postoperatively instead, all the patients (8/8) in control group required tramadol as rescue analgesia. This finding of ours was very much similar to the results obtained by Basandhy and Abbas. It has been observed by Ueshima & Ketamura in 2015 that Pectoral block cannot block the anterior cutaneous branch of intercostals nerves which innervate the nearby sternum, therefore the internal mammary region of surgical site may not be blocked by Pectoral block.[14] This could have resulted in pain postoperative period among patients who received Pectoral block.

Among our patients with malignant breast disease, the frequency of rescue analgesics required was 1.5 times less in Pectoral block group than No block group. Our finding is similar to study done by Bashandy and Abbas.

None of the patients in our study had vomiting and one patient in each group had nausea. This finding of ours was similar to study done by Morioka et al.. Similarly, we also prescribed ondensatron during and 24h after the surgery, which could have resulted in lower incidence of PONV. Savargaonkar et al., had found ondensatron is effective in reducing PONV in patients receiving tramadol.[15]

Among our patients with malignant breast disease, those who received Pectoral block had higher satisfaction score compared to those without pectoral block by a factor of 3 which was similar to the findings of a study done by Wahba and Kamal. Among the patients who received Pectoral block, 5 out of 7 patients had satisfaction VAS > 5, whereas all 8 patients who did not receive Pectoral block had satisfaction VAS ≤ 5. This is an indirect evidence supporting the effective analgesic effect of Pectoral block in our patients.

In contrast to the findings of malignant breast disease, among the patients who underwent surgery for benign breast disease, the total tramadol consumption in the first 24h after surgery was comparable in the two groups. We also found intraoperative fentanyl requirement, NRS pain score, the time to first opioid demand, the number of times of request of rescue analgesia, PONV scores, level of sedation, patient satisfaction level and length of hospital stay after surgery were all comparable in the two groups. This could be because of the less invasive nature of surgery for benign breast disease for which paracetamol and ketorolac were probably adequate to control pain.

Our results cannot be extrapolated to benign breast disease patients receiving less robust perioperative multimodal analgesia. Our patients received single dose acetaminophen during surgery along with regular ketorolac and tramadol on demand in the postoperative period. Hence, in a nutshell, Pectoral block may have limited additive effects on acute postoperative pain after benign breast surgery, when used as an adjunct to basic analgesia regimen consisting of regular ketorolac and tramadol on demand. Future trials should explore new combinations of drugs with trial designs that will enable assessment of both individual and combined analgesia effects and potential interactions among such combinations.

CONCLUSION

In conclusion, we found that Pectoral block I and II as a part of multimodal analgesia regimen is effective in reducing postoperative opioid consumption, NRS pain scores and improving the satisfaction levels expressed by patients after surgery for malignant breast surgery but not in case of benign breast disease.

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