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Research Article

Assessment of Post Operative Analgesia in Modified Radical Mastectomy Patients Using Surgical Wound Irrigation With 0.25% Bupivacaine

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INTRODUCTION

Modified Radical Mastectomy (MRM) is the most common surgical procedure for operable breast malignancies. Various strategies like non-steroidal anti-inflammatory drugs, opioids, peripheral nerve blocks, wound infiltration with local anaesthetics, thoracic epidural anaesthesia were found to have significantly improved the postoperative pain. An alternative technique that has widespread applicability is the insertion of catheters to allow for continuous infusions of local anaesthetics into the surgical wound at the end of the procedure. Continuous wound irrigation catheters with local anaesthetic drugs confer several benefits, including improved analgesia, reduced opioid use and its side effects, increased patient satisfaction and reduced hospital stay. Direct application of local anaesthetic to wounds directly block transmission of pain from nociceptive afferents from the wound surface; reduce release of inflammatory mediators from neutrophils, reduce neutrophil adhesion to the endothelium, reduce formation of free oxygen radicals and decrease oedema formation1,2

Infiltration of local anaesthetic along the line of incision is not recommended in malignant lesions, because of the fear of needle track seedlings and cutaneous spread of malignancy3. The aim of the present study was to assess the role of wound irrigation with bupivacaine through surgical drains in alleviating early postoperative pain after the MRM.

Breast cancer is the most common female cancer worldwide representing nearly a quarter (25%) of all cancers with an estimated 1.67 million new cancer cases diagnosed in 20124. Breast cancer has ranked number one cancer among Indian females with age adjusted rate as high as 25.8 per 100,000 women and mortality

12.7 Per 100,000 women5. Breast surgery can be emotionally distressing and physically painful. Acute pain following surgery is often related mainly to the axillary surgery and is aggravated by arm and shoulder movement.

Effective postoperative analgesia is important from the patient's perspective and can also improve clinical outcomes6. Recent surveys report only modest success providing suitable analgesia, as 30% to 86% of surgical patients report moderate to severe pain after a surgical procedure7,8. Although "advanced" analgesic techniques such as epidural analgesia or perineural catheters, can provide superior analgesia, many of these analgesic modalities are labour-intensive and expensive9,10. A promising modality that might help improve postoperative analgesia is the relatively simple technique in which the surgeon directly places a catheter to infuse local anaesthetic into wounds at the end of the procedure. This modality can be widely used, is technically efficient, offers the potential to provide complete analgesia or to substantially reduce the need for opioids and their related side effects, can be used for several days, and can now, with the introduction of new portable pumps, be used on an ambulatory basis. Surgery and inflammation that follow the intervention, activate peripheral nociceptors in the skin, ligaments and muscles. A noxious stimulus is propagated by thin, unmyelinated C type fibres and thinly myelinated A-delta fibres to the central nervous system11. Postoperative pain after breast surgery is one of the major factors contributing to delay in mobilisation and prolonged hospital stay.

AIMS AND OBJECTIVES

To assess the postoperative analgesic effect of wound irrigation with 0.25% bupivacaine through surgical wound after MRM.

RELEVANCE

The present study was to assess the role of wound irrigation with bupivacaine through wound irrigation catheter in alleviating early postoperative pain after the MRM. This study would provide good understanding of the sufferings of a patient undergoing a major surgery and provide an effective pain alleviation method for it. Hence this study can be used in future application of the said method in post MRM patients.

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MATERIALS AND METHODS

Study Design: A Longitudinal observational study.

Study Setting: MES Medical College, Department of Anaesthesiology

Study Population: Patients undergoing Modified Radical Mastectomy in MES

Medical College, Perinthalmanna.

Sample Size: The data from MRD in MES Medical College showed that there were

cases of MRM in previous year. So we enrolled 30 patients in our study. A purposive sample of 30 patients were studied.

Sampling Procedure: Convenient sampling procedure was utilized.

Study Duration: The data was collected from 1st January 2017 to 31st July 2018, a

total duration of one and a half years.

Inclusion Criteria:

Patients posted for MRM satisfying American society of anaesthesiologists (ASA) physical status I, II and III.

Exclusion Criteria:

Patients with history of adverse drug reaction to local anaesthetics; clinically significant hepatic, neurologic and psychiatric disease and patients with history of chronic analgesic drug usage were excluded.

Study tools:

Informed Consent Form

Proforma

Data Collection: This observational study was carried out in patients after

obtaining written informed consent and applying inclusion and exclusion criteria. All patients underwent a prescribed standard anaesthetic protocol.

Patients underwent general anaesthesia with balanced anaesthesia endotracheal intubation. Before closure of the wound, a 20G scalp vein set was used to prepare for continuous irrigation catheter. Using sterile technique, length of the incision was measured, and multiple puncture was given starting from distal end of scalp vein set; length of which will be equal to the incision length. Distal end was cut and closed. This catheter was placed subcutaneously, and wound was closed.10ml 0.25% bupivacaine was given and patient was reversed. Later patient was shifted to postoperative unit. Continuous wound irrigation was given using 0.25% bupivacaine at 0.04ml/kg/hour for 24 hours. Pain score was noted sixth hourly in a visual analogue scale (VAS). If the VAS exceeded '4' at any point of time, rescue analgesia with IV tramadol 1 mg/kg was administered. The number of demands and the total cumulative analgesic requirement was noted for 24 hour. Surgical site related untoward effects like haematoma, infection and wound dehiscence was observed clinically till the patient is discharged.

Statistical Analysis:

Data was coded and entered in MS excel and analysis was done using Epi-Info (version 7). Descriptive analysis was done. Proportions were expressed in percentage. Mean and standard deviation calculated for continuous variables. Chi- square / Fischer exact test was done to look for associations between categorical variables.

Ethical Consideration:

1. Written informed consent form will be obtained from the care givers before the study.

2. Institutional Scientific & Ethical committee clearance obtained.

RESULTS

This was a longitudinal observational study done in the Department of Anaesthesiology MES Medical College, Perinthalmanna. The study was conducted among patients undergoing Modified Radical Mastectomy, a total of 30 patients were included in the study.

BASELINE CHARACTERISTICS

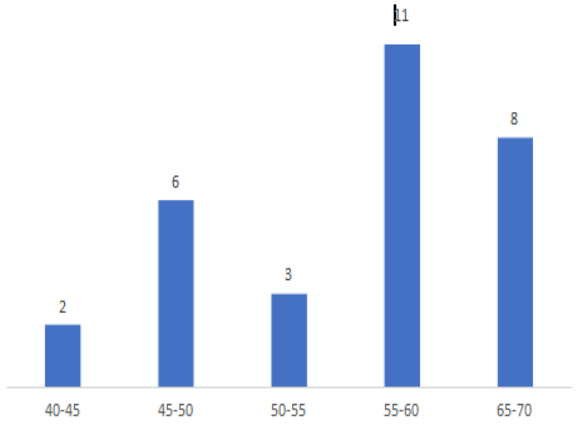
Age distribution

The age of participants ranged 43 to 69 years & mean age 56.3 years (SD=7.68)

Table 1: Age Distribution of participants

Age group in years	Frequency	Percent
40-45	2	6.7
45-50	6	20
50-55	3	10
55-60	11	36.7
65-70	8	26.7
Total	30	100

Figure 7: Age Distribution of participants



The mean weight was 58.13 kg (SD=10.02); & ranged from 45 to 81 kg.

ASA grading

The ASA grading was done on the patient pre-op and 5 patients were in Grade 1 (A normal healthy patient) and 20 patients in Grade 2 (A patient with mild systemic disease) and 5 patients in Grade 3.

Table 2: ASA

Grade	Frequency	Percent
1	5	16.7
2	20	66.7
3	5	16.7
Total	30	100

MALLAMPATI SCORE (MPC)

The MPC score was done on the patient pre-op and 9 patients were in Class I, followed by Class 2 in 13 patients and Class 3 in 8 patients.

Table 3: MPC

Class	Frequency	Percent
1	9	30
2	13	43.3
3	8	26.7
Total	30	100

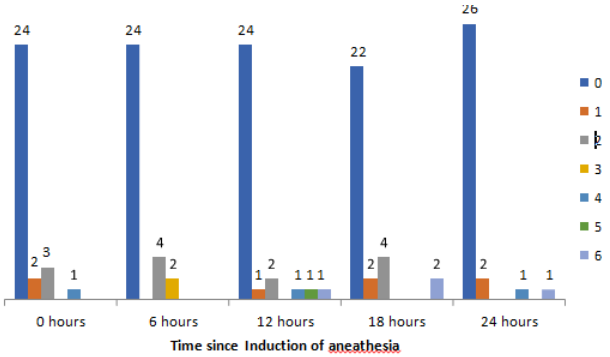
VAS SCORE AT 6-HOUR INTERVALS FOLLOWING SURGERY

The VAS Score at intervals of six hours showed that the score of zero was fluctuating over the hours and number of people with it increased at 24 hours. Rest of the values also improved. At 12 hours there were more people with 4, 5 and 6 VAS scores.

Table 4: VAS Score at 6-hour intervals following surgery

VAS score	0 hours		6 hours		12 hours		18 hours		24 hours	
	n	%	n	%	n	%	n	%	n	%
0	24	80	24	80	24	80	22	73	26	87
1	2	6.7	-	-	1	3.3	2	6.7	2	7
2	3	10	4	13.3	2	6.7	4	13	-	-
3	-	-	2	6.7	-	-	-	-	-	-
4	1	3.3	-	-	1	3.3	-	-	1	3
5	-	-	-	-	1	3.3	-	-	-	-
6	-	-	-	-	1	3.3	2	6.7	1	3
Total	30	100	30	100	30	100	30	100	30	100

Figure 8: VAS Score at 6-hour intervals following surgery



PARTICIPANTS WHO GAVE A VAS SCORE ABOVE 0 AT ANY POINT OF TIME

Around 17 patients (56.7%) scored a VAS score above 0 at one point or the other during the study.

Table 5: Participants who gave a VAS score above 0 at any point of time

VAS score above 0 at any point of time	Frequency	Percent

Yes	17	56.7
No	13	43.3
Total	30	100

Table 6: Mean VAS Score of Participants who gave a VAS score above 0 (n=17)

STD				
Hours interval	**Mean**	**Deviation**	**Minimum**	**Maximum**
0 hour	0.71	1.16	0	4
6 hour	0.82	1.185	0	3
12 hour	1.18	1.976	0	6
18 hour	1.29	1.961	0	6
24 hour	0.71	1.687	0	6

Table 7: Need for rescue analgesia

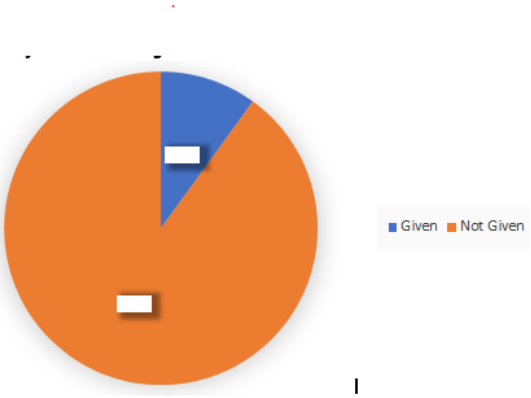
RESCUE ANALGESIA	Frequency	Percent
Not given	27	90
Given	3	10
Total	30	100

Table 8: Mean OP time comparison

Figure 9: Need for rescue analgesia`

		RESCUE ANALGESIA		Total
		Given	**Not Given**	
MPC	1	0 (0.0%)	9 (100.0%)	9
	2	1 (7.7%)	12 (92.3%)	13
	3	2 (25.0%)	6 (75.0%)	8
Total		3	27	30

		(10.0%)	(90.0%)



Comparison of Mean OP time for those who required escue analgesia and for those who did not

The difference between mean operation time for those who requires rescue analgesia and those who did not was not statistically significant.

Table 8: Mean OP time comparison

RESCUE ANALGESIA	N	OP Time		P value (Independent t- test)
		Mean	**Std. Deviation**	
Given	3	173.33	25.658	0.306
Not Given	27	159.07	16.055	

Table 9: Association between need for rescue analgesia and MPC

		RESCUE ANALGESIA		Total
		Given	**Not Given**	
MPC	1	0	9	
		0.00%	-100.00%	9
	2	1	12	
		-7.70%	-92.30%	13
	3	2	6	
		-25.00%	-75.00%	8
Total		3	27	
		-10.00%	-90.00%	30

Table 10: Association between need for rescue analgesia and ASA grade

		RESCUE ANALGESIA		Total
		Given	Not Given	
ASA	1	0	5	
		0.00%	-100.00%	5
	2	2	18	
		-10.00%	-90.00%	20
	3	1	4	
		-20.00%	-80.00%	5
Total		3	27	
		-10.00%	-90.00%	30

Figure 10: Association between need for rescue analgesia and ASA grade

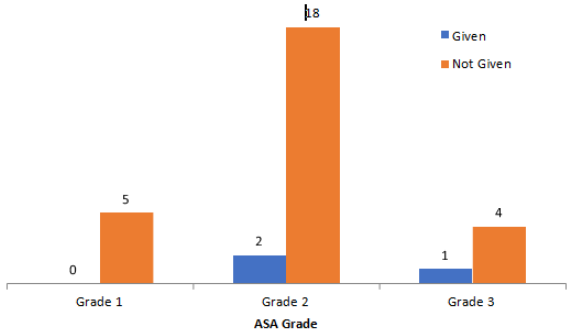


Table 11: Association between Need for Rescue Analgesia and Post-Operative Nausea & Vomiting

		RESCUE ANALGESIA		Total
		Given	**Not Given**	
PONV	Yes	1 (100,0%)	0 (0.0%)	1
	No	2 (6.9%)	27 (93.1%)	29
Total		3 (10.0%)	27 (90.0%)	30

Table 12: Association between need for Rescue Analgesia and Age of patient

		RESCUE ANALGESIA		Total
		Given	**Not Given**	
Age group	40-50	0	8	8
		0.00%	-100.00%	
	50-60	3	11	14
		-21.40%	-78.60%	
	60-70	0	8	8
		0.00%	-100.00%	
Total		3	27	30
		-10.00%	-90.00%	

Table 13: Association between need for Rescue Analgesia and having a VAS score above 0 at any point of time

		PAIN		Total
		Yes	**No**	
RESCUE ANALGESIA	Given	3 (100.0%)	0 (0.0%)	3
	Not Given	14 (51.9%)	13 (48.1%)	27
Total		17 (56.7%)	13 (43.3%)	30

Table 14: Association between having a VAS score above 0 at any point of time and Age of patient

		PAIN		
		Yes	**No**	**Total**
Age	40-50	4	4	
		-50.00%	-50.00%	8
	50-60	6	8	
		-42.90%	-57.10%	14
	60-70	7	1	
		-87.50%	-12.50%	8
Total		17	13	
		-56.70%	-43.30%	30

Table 15: Association between having a VAS score above 0 at any point of time and MPC

		PAIN		
		Yes	No	Total
MPC	1	5	4	
		55.60%	44.40%	9
	2	7	6	
		53.80%	46.20%	13
	3	5	3	
		62.50%	37.50%	8
Total		17	13	
		56.70%	43.30%	30

Table 16: Association between having a VAS score above 0 at any point of time and ASA Grade

		PAIN		Total
		Yes	No	
ASA GRADE	1	2	3	5
		40.00%	60.00%	100.00%
	2	11	9	20
		55.00%	45.00%	100.00%
	3	4	1	5
		80.00%	20.00%	100.00%
Total		17	13	30
		56.70%	43.30%	100.00%

Figure 11: Association between having a VAS score above 0 at any point of time and ASA Grade

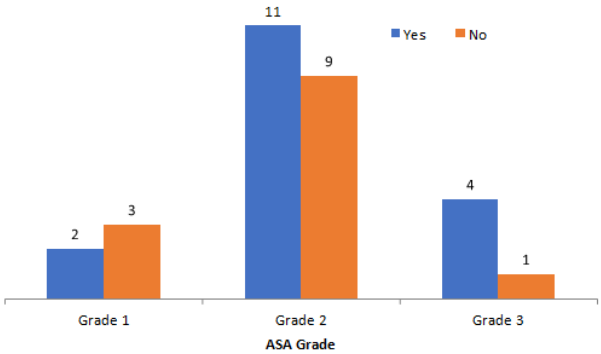


Table 17: Association between having a VAS score above 0 at any point of time and Number of Rescue Analgesia demands

		PAIN		Total
		Yes	No	
No: of Rescue Analgesia Demands	0	14 (51.9%)	13 (48.1%)	27
	1	1 (100.0%)	0 (0.0%)	1
	2	2 (100.0%)	0 (0.0%)	2
Total		17 (56.7%)	13 (43.3%)	30

Table 18: Association between having a VAS score above 0 at any point of time and Post-Operative Nausea Vomiting

		PAIN		Total
		Yes	No	
PONV	Yes	1 (100.0%)	0 (0.0%)	1
	No	16 (55.2%)	13 (44.8%)	29
Total		17 (56.7%)	13 (43.3%)	30

DISCUSSION

Management of acute postoperative pain is required for better outcome and patient's satisfaction. Regional techniques are regarded as the best choice to reduce acute postoperative pain and incidence of chronic pain after breast surgery. Perioperative analgesia has traditionally been provided by opioid analgesics. Large doses of opioids can be associated with an increased incidence of postoperative complications: respiratory depression, sedation, nausea and vomiting, pruritus and ileus. 63,64 Anaesthesiologists and surgeons are increasingly turning to non-opioid analgesic techniques for managing pain during the perioperative period in order to minimize the adverse effects of analgesic medications.64 Local anaesthetics can improve postoperative pain management63.Management of acute postoperative pain is required for better outcome and patients' satisfaction. Regional techniques are regarded as the best choice to reduce acute postoperative pain and incidence of chronic pain after breast surgery. Perioperative analgesia has traditionally been provided by opioid analgesics. Large doses of opioids can be associated with an increased incidence of postoperative complications: respiratory depression, sedation, nausea and

vomiting, pruritus and ileus.63,64 Anaesthesiologists and surgeons are increasingly turning to non-opioid analgesic techniques for managing pain during the perioperative period in order to minimize the adverse effects of analgesic medications. 64

Local anaesthetics can improve postoperative pain management63.They suppress the afferent nociceptive signal and inflammatory reaction65. Local anaesthetics for postoperative analgesia are used in many fields of surgery: orthopaedics, abdominal surgery, gynaecology, urology, cardiothoracic surgery and breast cancer surgery66. The rates of inflammation or hematomas were not higher after the use of local

Anaesthetics compared to the placebo or standard analgesia treatment groups67.Local anaesthetics seem to reduce the occurrence of inflammation.68 Continuous administration of local anaesthetics into the wound via a catheter placed directly at the end of surgery represents a simple and efficacious means to provide postoperative analgesia69,59 Jacobs and Morrison reported the results of a retrospective study, where the wound catheter was connected to an elastomeric pump containing local anaesthetic. They found out that this type of analgesia was safe and reduced postoperative pain.42

In our study the VAS Score at intervals of six hours showed that the score of zero was fluctuating over the hours and number of people with it increased at 24 hours. Rest of the values also improved. At 12 hours there were more people with 4,5 and 6 VAS scores. Duration of surgery ranged from 130 to 195 minutes, with a mean of 160.5 minute. Only one patient complained of PONV. The difference between mean operation time for those who requires Rescue analgesia and those who did not was not statistically significant. There was no significant association between need for rescue analgesia and Mallampati Class, ASA grading, PONV, age of the patients and VAS score. There was no significant association between VAS score and age of the patients, MPC class, ASA grade, number of rescue analgesia demands and Post-operative nausea and vomiting which was seen similar to the reviewed studies by Fredman et al. 70 It was observed that after major abdominal surgery, repeated instillation of the 0.25% bupivacaine solution through a patient-controlled analgesic device and a dual-catheter system did not decrease postoperative pain or opioid requirements. In this case, the authors considered that the lack of uniform distribution, or rather the spread of the drug was unpredictable and that the dose of local anesthetic was insufficient. However, there is little

Literature on its use in MRM procedure. In a study by Legeby et al71 following breast reconstruction, levobupivacaine was injected locally every 3 hour as a supplement to oral paracetamol and PCA-administered morphine produced better pain relief at rest and during mobilization;morphine consumption was reduced, but this was not significant (p=0.28).

Talbot et al. performed a prospective, double-blind, randomized, placebo- controlled trial on 42 patients after a modified radical mastectomy11. They did not find any difference in analgesia between the treatment group, which received levo- bupivacaine irrigation through the axillary wound drain every four hours for the first 24 hours postoperatively, and the control group, which received irrigation with normal saline. Instead of perforated catheters, they used axillary drains, which were clamped for 20 minutes every four hours following the application. Thus, a local anaesthetic was not administered continuously. Patients with a continuous infusion of local anaesthetic had a lower consumption of opioids and a reduced need for antiemetic drugs compared to the standard opioid-based analgesia group of patients. These results are in accordance with the conclusions of the majority of investigators who studied the role of local anaesthetics in postoperative pain management.45,42,65,72,67

CONCLUSION

The irrigation of wound with local anesthetics is a simple, effective and economical way to provide good analgesia to patients who are undergoing MRM procedure without significant side effects. Wound infection and healing do not seem to be a major concern. Local anesthetics are generally well tolerated, provided they are used correctly and in the proper dose. This postoperative analgesic technique can be included in the therapeutic armamentarium of multimodal analgesia. The application of a wound irrigation catheter with a local anaesthetic is safe, easy and effective for reducing acute postoperative pain. Continuous infusion of a local anaesthetic into the wound reduces opioid consumption and results in less postoperative sedation and a reduced need for antiemetic drugs. The patients are more alert, pain free, less respiratory compromise and consequently, do not need

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