

# Efficacy of Ropivacaine in Wound Instillation through Surgical Drains for Post-operative Analgesia in Modified Radical Mastectomy

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## Abstract

**Background:** "Pain" is an unpleasant sensory and emotional experience associated with actual or potential tissue damage after any surgery so as in breast surgery. Successful pain management should be a central component of patient care and it holds true for patients undergoing breast surgery.

**Aim:** The aim of this study is to assess the efficacy of ropivacaine in wound instillation through surgical drains for post-operative analgesia in patients undergoing modified radical mastectomy.

**Study Design:** This was a prospective, randomized, double-blind study

**Materials and Methods:** Our study included 50 patients aged between 15 and 70 years of ASA Grades I and II scheduled for elective breast cancer surgeries. Group R received ropivacaine 0.2% (0.5 mL/kg) through axillary and chest drains, Group C received normal saline 0.9% (0.5 mL/kg) through axillary and chest drains.

**Results:** The result of our study demonstrated that instillation of local anesthetic through axillary and chest drains placed post surgically provided better analgesia and less incidence of post-operative nausea and vomiting.

**Conclusion:** It was concluded that patients receiving local anesthetic (ropivacaine) through surgical drain required less cumulative analgesic dose along with better post-operative analgesia and less incidence of post-operative complications such as nausea and vomiting.

**Key words:** Local anesthetic, Modified radical mastectomy, Post-operative pain, Surgical drains, Visual analog scale

## INTRODUCTION

Modified radical mastectomy remains the mainstay for operable breast malignancies. In contrast to other breast surgeries, modified radical mastectomy involves more extensive tissue dissection.<sup>[1-3]</sup> Pain is a predictable consequence of surgery that can often last for several

days; if left untreated, it is associated with significant adverse consequences for the patient. The relief of pain should be a central component of patient care, as it is the right of the patient. Poorly managed pain can slow recovery, creates burden for patients and their families, and also increases the cost to the health-care system.<sup>[4,5]</sup> Conventionally, various strategies such as nonsteroidal anti-inflammatory drugs, opioids, peripheral nerve blocks, and wound infiltration with local anesthetics were used but reported limited success in providing effective post-operative pain control and moreover were associated with adverse effects such as nausea, vomiting, and dyspepsia.<sup>[3]</sup> Due to the fear of needle track seedings and cutaneous spread of malignancy, infiltration along the line of surgical incision is not recommended in malignant lesions.<sup>[2,3]</sup>

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Recent advancements have led to the development of a local anesthetic with an extended duration of action and a novel delivery platform, thereby broadening its potential role as a component of some post-operative pain management regimens.<sup>[6]</sup> Wound instillation with local anesthetic through surgically placed drains in axilla and chest is nowadays widely used as a part of multimodal approach to provide effective analgesia postoperatively. Until today, many local anesthetics drugs are in use for local wound instillation, for example, lidocaine,<sup>[7]</sup> bupivacaine,<sup>[3,8]</sup> levobupivacaine,<sup>[9]</sup> and ropivacaine.<sup>[8,10-14]</sup> Local anesthetic drugs are becoming increasingly popular because of their analgesic properties and lack of opioid-induced adverse effects for treating post-operative surgical pain. Extensive animal toxicological studies have shown a lower propensity for cardiotoxicity with ropivacaine than with bupivacaine. With its lower toxicity, especially cardiovascular toxicity and less intense motor blockade, ropivacaine has advantage over bupivacaine in pain relief.<sup>[15]</sup> The administration of local anesthetic via instillation through the surgical drain is one component of multimodal approach that allows for minimal invasive exposure and also results in immediate pain relief, which has been proven to increase patient satisfaction and early mobilization.

The aim of the present study was to assess the efficacy of ropivacaine in wound instillation through surgical drains in alleviating early post-operative pain after MRM. The efficacy of ropivacaine in wound instillation through surgical placed drains was assessed by duration of analgesia, number of analgesic demands, and cumulative analgesic requirement for pain relief.

## MATERIALS AND METHODS

In this clinical randomized prospective study, 50 patients, the ASA physical status I and II, 15–70 years scheduled for unilateral modified radical mastectomy were enrolled randomly in two groups after obtaining the institutional ethics committee approval. Patients with a history of allergy to local anesthetic, history of any chronic analgesic drug usage, pre-existing respiratory diseases such as obstructive pulmonary disease, coexisting cardiovascular diseases, pregnant and breastfeeding females, history of any musculoskeletal disorders, and bleeding diathesis were excluded from the study.

Patients undergoing modified radical mastectomy were randomly allocated into two groups, each group containing 25 patients for the assessment of post-operative analgesia following wound instillation through surgical drainage tubes with local anesthetic and normal saline as control.

- Group R: Group R received ropivacaine 0.2% (0.5 mL/kg) through axillary and chest drains.

- Group C: Group C received normal saline 0.9% (0.5 mL/kg) through axillary and chest drains.

During the pre-operative day, patients were thoroughly educated about the procedures to be undertaken and were made well conversant with the visual analog scale (VAS) for post-operative pain assessment and their consent was taken. In the operation theater, I/V access was established and standard monitors were attached. Baseline hemodynamic parameters such as pulse rate, non-invasive blood pressure, respiratory rate, peripheral arterial oxygen saturation (SpO<sub>2</sub>), and electrocardiography were recorded. After premedication, all the patients were induced with injection propofol at the dose of 2 mg/kg and injection succinylcholine at the dose of 1.5 mg/kg to facilitate tracheal intubation, and the patient was maintained with isoflurane and nitrous oxide plus oxygen (60:40). Neuromuscular blockade was achieved using vecuronium 0.04 mg/kg. At the end of the surgical procedure, the surgical drains, one in the axilla near the axillary vessels and the second in the chest wall below the skin flap (over the pectoral muscles), were placed by the surgeon before closing the surgical incision [Figure 1]. After proper oral and tracheal suctioning, the patient was reversed with neostigmine and glycopyrrolate, and extubation was performed on meeting the criteria.

Patients were allocated randomly into two groups of 25 each by computer-generated numbers. The study drug was given through each drain as per randomization after the incision was closed. Group C patients received normal saline 0.9% (0.5 mL/kg). Total volume was divided into equal amount and given through each drain. Group R patients received ropivacaine 0.2% (0.5 mL/kg). The study drug being prepared by a separate anesthesiologist outside operation theater according to randomization number and



**Figure 1: Showing instillation of drug through surgical drain placed in the chest wall**

was labeled as “study drug.” Total volume (0.5ml/kg of 0.2% ropivacaine) was divided in equal amount and given through each drain. After instillation of the study drug, the drains were clamped for 10 min. After a dwell time of 10 min, the clamp was released to allow the test solution into the negative pressure suction drain.

Background analgesia was given to every surgical patient immediately after extubation in the form of intramuscular injection of diclofenac sodium (1.25 mg/kg) every 8 h in buttocks.

Patients were transferred to the post-anesthesia care unit for further monitoring. Pain score at “0” h was noted after extubation and subsequently every 4<sup>th</sup> h for 24 h, by the person who does not have knowledge regarding the solution which the patient had received. Post-operative pain was assessed by VAS using a 10 cm VAS (0 - no pain and 10 - worst imaginable pain). If the VAS exceeded “4” at any point of time, rescue analgesia with injection tramadol 1 mg/kg intramuscular was administered and the study terminated at that time.

The duration of analgesia was defined from the time of instillation of the study drug to the time for the first demand of analgesia. The number of demands and the total cumulative analgesic requirement was noted for 24 h. Surgical site related untoward effects such as hematoma, infection, and wound dehiscence were observed clinically till the patient was discharged. Adverse effects such as nausea and vomiting were noted as all patients received prophylactic antiemetic ondansetron.

### Statistical Analysis

Descriptive statistics was used to describe the baseline characteristics. Numerical data were expressed as mean and standard deviation. Qualitative data were expressed as frequency and percentage. Chi-square test was used to examine the relation between qualitative variables. For quantitative data, comparison between the groups was done using independent sample *t*-test. For descriptive purposes,

*P* value differences <0.05 were noted in the tables. All analysis was conducted using SPSS version.

## OBSERVATION AND RESULTS

Median VAS score value was <4 up to 3<sup>rd</sup> h of the study. Its value was 4 at 12<sup>th</sup> h of the study in Group R and 4<sup>th</sup> h of the study in Group C, which decided the time of rescue analgesia and duration of analgesia [Table 1].

There was statistically significant difference between Group R and Group C, in terms of total tramadol consumption (*P* < 0.0001) [Table 2 and Graph 1].

There was statistically significant difference between the study Groups R and C, in terms of duration of analgesia (*P* < 0.0001) [Table 3 and Graph 2].

Incidence of post-operative nausea and vomiting (PONV) in Group R is 8% and in the Group C is 28% [Table 4 and Graph 3].

## DISCUSSION

Pain is a predictable consequence of surgery, if not treated; it is associated with undesirable clinical consequences. The relief of pain should be a central component of patient care and it holds true for patients undergoing breast surgery. Providing post-operative analgesia to the patient gives subjective comfort and helps in restoring the altered physiology and immunological response. Appropriate acute pain management, however, remains the common goal in all the studies of pain after breast surgery, with the aim of achieving patient satisfaction and accelerated recovery and rehabilitation, and the potential later benefit of a reduction in chronic post-mastectomy pain. Conventionally, various strategies such as nonsteroidal anti-inflammatory drugs, opioids, peripheral nerve blocks, and wound infiltration with local anesthetics were used but reported limited success in providing effective post-operative pain control

**Table 1: Comparison of median VAS score**

VAS (in hours)	Group R			Group C		
	Median	Percentile 25	Percentile 75	Median	Percentile 25	Percentile 75
VAS0	1	0	2	2	2	3
VAS1	0	0	0	2	1	2
VAS2	0	0	0	2	1	2
VAS3	0	0	0	3	2	3
VAS4	0	0	0	4	3	4
VAS8	0	0	0	5	4	5
VAS12	4	4	4			
VAS16	4	4	4			
VAS24						

VAS: Visual analog score

**Table 2: Comparison of total tramadol consumption in 24 h**

Total tramadol (in mg)	N	Mean	P value
Group R	25	55.2	0.0001
Group C	25	112.4	

**Table 3: Comparison of duration of analgesia**

Duration of analgesia (in hours)	Mean	SD	P value
Group R	12.8	1.633	0.0001
Group C	5.92	2.04	

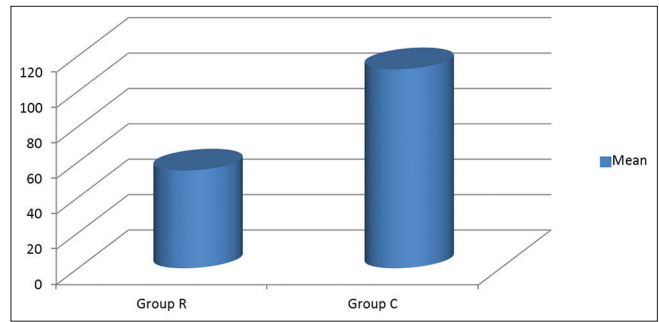
**Table 4: Comparison of PONV**

PONV	Group R	Group C
No	23 (92)	18 (72)
Yes	2 (8)	7 (28)
Total	25	25

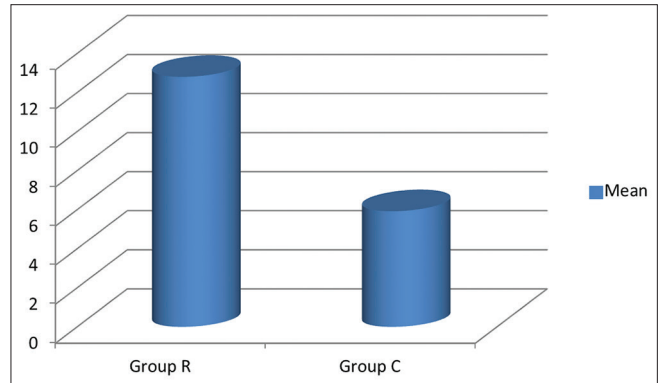
PONV: Post-operative nausea and vomiting

and moreover were associated with adverse effects such as nausea, vomiting, and dyspepsia. Sidiropoulou *et al.* did their study comparing continuous wound infiltration with ropivacaine versus single-injection paravertebral block in patients undergoing modified radical mastectomy. They concluded that both the techniques were similar in respect to morphine consumption and reduction in post-operative pain.<sup>[16]</sup> Paravertebral block needs expertisness,<sup>[17]</sup> sufficient time to perform the block, and necessary guidance, and it has a serious complication like pneumothorax.<sup>[18]</sup> Due to the fear of needle track seedings and cutaneous spread of malignancy, infiltration along the line of surgical incision is not recommended in malignant lesions. All these problems play a key role to search a newer mode of analgesia. Till today, many local anesthetic drugs are in use for local wound instillation, for example, lidocaine,<sup>[7]</sup> bupivacaine,<sup>[3,8]</sup> levobupivacaine,<sup>[9]</sup> and ropivacaine.<sup>[8,10-14]</sup> Local anesthetic drugs are becoming increasingly popular because of their analgesic properties and lack of opioid-induced adverse effects for treating postoperative surgical pain. Extensive animal toxicological studies have shown a lower propensity for cardiotoxicity with ropivacaine than with bupivacaine. With its lower toxicity, especially cardiovascular toxicity and less intense motor blockade, ropivacaine has advantage over bupivacaine in pain relief.<sup>[15]</sup> The administration of local anesthetic via instillation through the surgical drain is one component of multimodal approach that allows for minimal invasive exposure and also results in immediate pain relief, which has been proven to increase patient satisfaction and early mobilization.

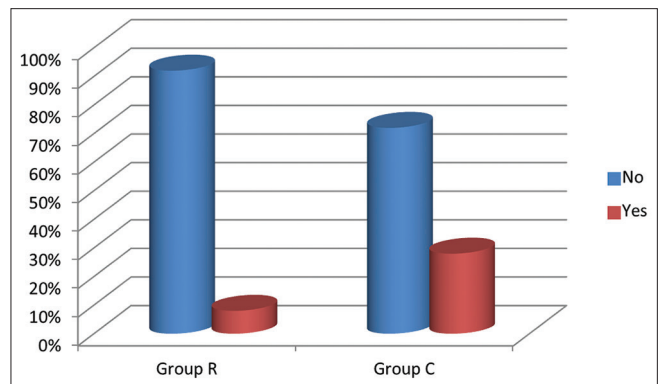
In this prospective, randomized control study, the results showed that patients, who received instillation



**Graph 1: Comparison of total tramadol consumption in 24 h**



**Graph 2: Duration of analgesia (in hours)**



**Graph 3: Comparison of post-operative nausea and vomiting**

with 0.2% ropivacaine through surgical drains following MRM, experienced a better post-operative analgesia as compared with patients of control group who had received saline. Cumulative rescue analgesic consumption and number of demands for analgesia in the first 24 h were significantly lower in ropivacaine group compared with the saline group so as the use of injection tramadol is also less in ropivacaine group and their satisfaction scores were significantly higher as compared to the patients who received saline. Assessment of pain was done using VAS score. Our study showed that VAS score rises significantly early in Group C than Group R. When VAS score reached >4, rescue analgesia in the form of intramuscular tramadol (1 mg/kg) was administered. This finding is in concordance with the study of Jonnavithula

*et al.* who studied the analgesic effect of instillation of 0.25% of bupivacaine versus 0.9% normal saline and control group with no instillation, in cases of modified radical mastectomy through surgical drains.<sup>[3]</sup> Fayman *et al.* conducted a comparative study between analgesic effect of bupivacaine and ropivacaine infiltration in a bilaterally symmetrical breast surgery model. They found that overall analgesia achieved with bupivacaine and ropivacaine infiltrations was not statistically different except for the risk of cardiotoxicity with bupivacaine.<sup>[19]</sup>

Our study was in contrast to the study of Talbot *et al.* who in their study determined the effect of irrigation of axillary drains with local anesthetic on post-operative pain following modified Patey mastectomy. They felt that it did not appear to offer any contribution for post-operative analgesia in some of their patients nor were there any differences in antiemetic or supplemental analgesic consumption. They opined that this could be because of malpositioned drain, blockade of some holes of the drain, or unequal distribution of the local anesthetic due to gravity and concluded that further refinement in the technique was needed.<sup>[17]</sup> Hence, to overcome this limitation, we have instilled through both the chest wall and axillary drains. This could have resulted in more uniform distribution of the drug, thereby improving the efficacy of the technique, and the patients were pain free in the post-operative period.

In our study, there was no case of local anesthetic toxicity observed which was in concordance with the study of Jonnavithula *et al.*<sup>[3]</sup> and Talbot *et al.*<sup>[17]</sup>

## CONCLUSION

Post-operative analgesia is a key component of perioperative nursing care and the pain management paradigm has shifted to an increasing use of multimodal analgesia. Wound instillation with local anesthetics through surgical drains with an extended duration of action and a novel delivery platform has broadened its potential role as a component of post-operative pain management following MRM procedure.

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