A Comparative Study of Bupivacaine Vs Ropivacaine Wound Instillation through Surgical Drain for Postoperative Analgesia in Modified Radical Mastectomy

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ABSTRACT

Introduction: Modified radical mastectomy (MRM) is associated with extensive tissue dissection and substantial postoperative pain. Various modes of postoperative analgesia have been used to alleviate the suffering of these patients. One of that is wound instillation, in our study we compared the effects of bupivacaine and ropivacaine for post-operative analgesia when instilled through the surgical drains in patients undergoing MRM.

Material and methods: After obtaining the Institutional Ethics Committee approval and written informed consent, 60 female patients aged between 18 and 60 years with American Society of Anaesthesiologist status I/II scheduled to undergo MRM were enrolled for the study. Patients were randomised into two groups (30 each), a total of 40 cc of either bupivacaine (0.125%) or ropivacaine (0.2%) instilled through surgical drains. Visual analogue score and hemodynamics were compared in the postoperative period every 2 hourly till 12 hours. Quantitative data were compared by using unpaired t-test and qualitative data by using Chi-Square test and Fisher's Exact test.

Results: Duration of analgesia was found to be significantly longer in bupivacaine group (512.37±63.06 minutes) as compared to ropivacaine (427.97±43.26 minutes) ($p< 0.0001$). Systolic and diastolic blood pressure were high and statistically significant in bupivacaine group as compared to ropivacaine but clinically not significant.

Conclusion: Both local anaesthetics, bupivacaine and ropivacaine showed near similar pharmacological effects however the duration of analgesia was observed more with bupivacaine when instilled through the surgical drains. Wound instillation, being a non-invasive technique is an effective mode of providing postoperative analgesia in MRM as compare to other invasive modalities.

Keywords: Wound Instillation, Bupivacaine, Ropivacaine, Modified Radical Mastectomy

INTRODUCTION

Carcinoma breast is the commonest female cancer and the leading cause of death in the age group of 40 to 60 years.[1] A modified radical mastectomy (MRM) is a procedure in which the entire breast is removed, including the skin, areola, nipple, and most of the axillary lymph nodes; the pectoralis major muscle is however spared. The extensive tissue dissection and the resulting nociception barrage in modified radical mastectomy initiates a cascade of events that can alter pain perception and cause severe pain and discomfort to patients in the post-operative period.[2] In developed countries, 86% of patients experience postoperative pain and 75% of those who reported pain described its severity as moderate to severe during the immediate postsurgical period.[3] Effective post-operative pain management is an integral part of modern anaesthetic practice. The goal of postoperative pain management is to reduce or eliminate pain and discomfort with least side effects and minimal cost. Effective post-operative pain management not only reduces patient's suffering but also can reduce cardiopulmonary morbidity and facilitate rapid recovery. Various modes are available to counter post-mastectomy pain. Systemic non-steroidal anti-inflammatory drugs (NSAID) and opioids are very commonly used. The use of opioid drugs is often associated with side effects including nausea and vomiting, respiratory depression, drowsiness, pruritus, reduced gut motility and urinary retention and NASIDs are associated with dyspepsia. There is also a common occurrence of delayed administration of analgesics which further adds to patient's suffering. Due to this irregularity in dosage, fluctuating blood levels of the drug occurs because of which patient experiences no analgesia sometimes and more side effects at other times.[4] Therefore, Interventional approaches are increasingly popular such as thoracic epidural block, thoracic paravertebral block and peripheral nerve block but these procedures require skilled expertise and precise administration of local anaesthetic agents for effective pain relief. We are using local wound instillation technique through surgical drain in our study. Bupivacaine is frequently used for local analgesia because of its long duration of action however the major concern is its toxicity, especially when larger doses are used.[5] Ropivacaine is a long-acting amide local anaesthetic agent and produced as a pure enantiomer.

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It produces effects similar to other local anaesthetics via reversible inhibition of sodium ion influx in nerve fibres. Ropivacaine is less lipophilic than Bupivacaine and is less likely to penetrate large myelinated motor fibres, resulting in a relatively reduced motor blockade. Thus, Ropivacaine has a greater degree of motor sensory differentiation, which could be useful when motor blockade is undesirable. The reduced lipophilicity is also associated with decreased potential for central nervous system toxicity and cardio toxicity.[5]

Several authors have investigated the efficacy of instillation of bupivacaine or ropivacaine along the surgical wound of mastectomy[6] but the results were inconclusive. Also, the optimal location for instilling local anaesthetics to reduce pain after MRM is controversial.

Hence we planned to study and compared the effects of bupivacaine and ropivacaine for post- operative analgesia after modified radical mastectomy when instilled through the surgical drains.

MATERIAL AND METHODS

After obtaining written informed consent and the Institutional Ethics Committee approval, this study was conducted in 60 patients scheduled to undergo unilateral MRM under general anaesthesia.

American Society of Anaesthesiologists (ASA) physical status I or II aged between 18-60 years were included. Pregnant women, patients with significant cardiovascular, pulmonary, neurological, hepatic, renal and metabolic disease, patients with chronic analgesic drug usage, patients with a known allergy to local anaesthetic agents and patients weighing less than 30 kgs were excluded.

Patients were educated about visual analogue scale (VAS) for assessing pain preoperatively. VAS is a 10 cm scale (0- No pain, 10 Worst imaginable pain) (Figure 1). All routine investigations relevant to surgery were obtained. After confirming the starvation status and consent, the patients were shifted to operating room. Monitoring consisted of electrocardiography, non-invasive blood pressure, and pulse oximetry. The equipments required for management of difficult airway and emergency drug tray were kept ready. An intravenous line was secured on the hand opposite the proposed side of surgery with an 18-gauge cannula and ringer lactate was started at 2 ml/kg/hour. Baseline pulse, systolic (SBP) and, diastolic blood pressure (DBP) and oxygen saturation (SpO_2) were noted. Preoxygenation was done with 100% oxygen for 3 minutes and premedication was done with inj. glycopyrrolate 0.004mg/kg, fentanyl 2mcg/kg and midazolam 0.02mg/kg, and inj. ondansetron 0.008mg/kg. Standard GA was administered and the hemodynamics were maintained within 20% of the pre-operative values. A repeat dose of fentanyl was given after every hour at the dose of 1mcg/kg for intraoperative analgesia. Intra operatively pulse rate, SBP, DBP, end tidal CO_2 concentration, and oxygen saturation were monitored at regular intervals. At the end of surgery two surgical drains were placed, one beneath chest wall flap and one in the axilla. Using a computer generated randomization table, patients were randomly allocated to one of the two groups depending upon the drug they were to receive after the closure of skin incision.

Group A: inj. 0.125% bupivacaine 40cc, 20 cc through each drain

Group B: inj. 0.2% ropivacaine 40cc, 20 cc through each drain

After instillation of drugs drains were clamped for 10 minutes. After 10 minutes' clamp was released to drain the remaining solution in the negative pressure drain. Reversal and extubation was done with inj. neostigmine 0.05mg/kg and inj. glycopyrrolate 0.008mg/kg. Patients were shifted to post anaesthesia care unit for further monitoring.

VAS was noted immediately after extubation and subsequently 2 hourly for next 12 hours. When VAS exceeded 4, rescue analgesic inj. tramadol 1mg/kg IV was administered. Duration of analgesia was defined as the time interval from the time of instillation of the study drug to the time for the first demand of analgesia.

Pulse rate, SBP, DBP and SpO_2 were also monitored at same time intervals.

Patients were monitored for untoward side effects, such as nausea, giddiness, vomiting, numbness of the tongue, light-headedness, visual disturbances, and muscular twitching for 12 hours post operatively.

STATISTICAL ANALYSIS

Sample size of sixty was calculated with the help of the article 'Role of wound instillation with Bupivacaine through surgical drains for postoperative analgesia in modified radical mastectomy" IJA, JAN 2015[7], taking into consideration mean value and standard deviation of visual analogue score of saline and bupivacaine group. A power analysis was conducted assuming a moderate effect, a power of 80% and type 1 error of 5% and using two sided alternative hypothesis. Data was expressed as percentage and mean ± S.D. Student's t test was used to check the significance of difference between two parameters in parametric data. Fischer's exact test or Chi square test was used to analyse the significance of difference between frequency distribution of the data. P value <0.05 was considered as statistically significant. SPSS© for windows™ Vs. 17, IBM™ Corp NY and Microsoft excel™ 2007, Microsoft® Inc. USA was used to perform the statistical analysis.

RESULTS

The demographic data age, weight and ASA class were comparable. The duration of surgery was found to be significantly longer in ropivacaine group (116.57±3.73874) minutes than in bupivacaine group (113.93±5.98811) (p-0.046). However clinically it was not significant. (Table 1)

The mean duration of analgesia for bupivacaine group was (512.37±63.06) minutes and that of ropivacaine group was (427.97±43.26) minutes. Duration of analgesia was found to be significantly longer in bupivacaine group ($p< 0.0001$). (Table 1)

No significant difference was observed in basal and intraoperative parameter using student's unpaired t test

Group	Mean	SD	SE mean	t	P Value
Age (years) Bupivacaine Ropivacaine	 50.97 51.53	 7.54 6.02	 1.38 1.10	0.32	0.749
Weight (kg) Bupivacaine Ropivacaine	 58.6 58.4	 6.7 9.1	-	-	0.857
Duration of surgery (min) Bupivacaine Ropivacaine	 116.57 113.93	 3.73874 5.98811	 0.68260 1.09327	2.04	0.046
Duration of analgesia (Min) Bupivacaine Ropivacaine	 512.37 427.97	 63.06 43.26	 11.51 7.90	6.05	<0.0001

Table-1: Comparison of demographic data and duration of surgery and duration of analgesia in both the groups

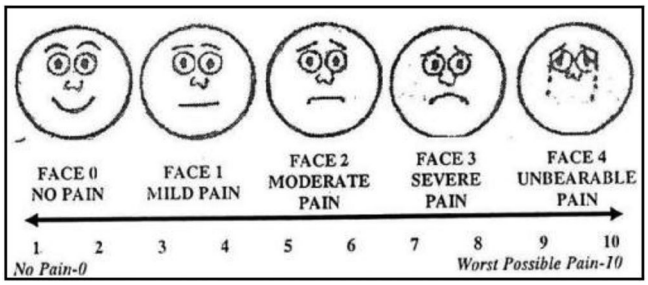

Figure-1: VAS 10 scale point

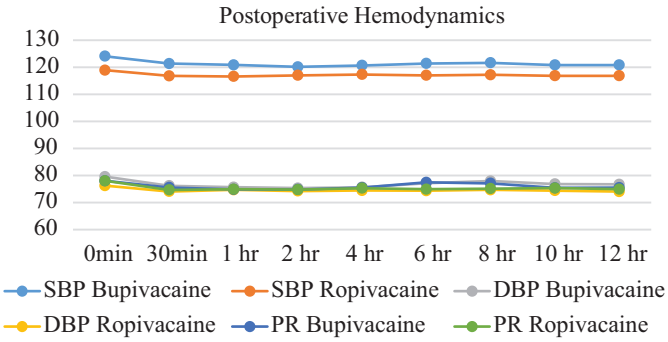

Figure-2: Postoperative comparison of mean pulse rate, mean SBP and mean DBP in both the groups

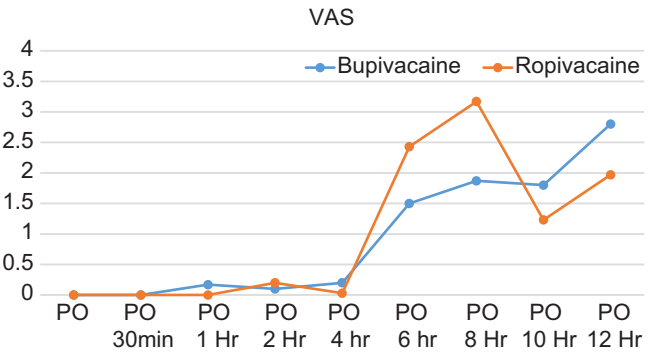

Figure-3: Comparison of mean VAS score in both the groups

(p>0.05) between two groups.

In the post-operative period SBP was significantly higher in bupivacaine group immediate post op, at 30 min, at 1hr, at 4 hr, at 6 hr, at 8 hrs. and at 12 hr. though this difference was statistically significant, it was not significant clinically similarly DBP was significantly higher in bupivacaine group immediately postoperatively and at 8 hrs postoperatively, as compared to ropivacaine group. Though this difference was statistically significant, it was not significant clinically**.** (figure 2) No significant difference was noted in SpO_2 between two groups at any given time interval.

VAS was found to be significantly higher in bupivacaine group postoperatively at 1 hour, at 10 and at 12 hours. In the ropivacaine group, VAS was significantly higher than that of bupivacaine group at 6 hrs. and 8 hrs. postoperatively. At all these time intervals VAS never exceeded 4. (figure 3)

DISCUSSION

Presence of pain indicates presence of some noxious stimuli or damage in the body. Cutting, tearing, stretching and burning of tissues during surgery produces intra-operative and post-operative pain. Various studies have shown that inadequate treatment of pain may lead to decrease in vital capacity and alveolar ventilation, pneumonia, tachycardia, hypertension, myocardial ischemia, myocardial infarction, transition to chronic pain, poor wound healing, and insomnia. Pain is one of the most common medical causes of delayed discharge after ambulatory surgery. So treating pain is necessary to reduce post-operative morbidity and mortality. Pain relief after modified radical mastectomy can be achieved by various methods, which include:

- Parenteral administration of opioid and non-opioid analgesics.
- Regional nerve blocks in the form of paravertebral nerve block, brachial plexus block by infraclavicular approach and intercostal nerve block.
- Wound infiltration and wound instillation by local anaesthetics.[8]
- Thoracic epidural analgesia.

Parenteral injections of opioids require multiple injections. There may be waxing and waning of analgesic effect and are associated with high incidence of nausea, vomiting, respiratory depression, pruritis etc. NSAIDS are associated with high incidence of dyspepsia. Though regional nerve blocks are effective modality of pain relief, they are associated with technical difficulty, require expertise while administration and have chances of complications like pneumothorax. Direct application of local anaesthetic to wounds can provide analgesia through several mechanisms.

Local anaesthetics directly block transmission of pain from nociceptive afferents from the wound surface. Studies have shown that local anaesthetics reduce release of inflammatory mediators from neutrophils, reduce neutrophil adhesion to the endothelium, reduce formation of free oxygen radicals, and decrease oedema formation.[9]

Wound infiltration after surgery is a simple and attractive method for pain relief but risk of needle track seedling of malignant cells questions its use in surgery of malignancy of breast. Also the extensive tissue dissection in modified radical mastectomy leads to severe pain which is far beyond incisional margins, which further makes local anaesthetic infiltration less desirable. Wound instillation with local anaesthetic agents through drains and catheters has been described after cholecystectomy, splenectomy, abdominal hysterectomy and cardiac surgery with good pain relief in postoperative period. The technique of irrigation of local anaesthetic in the breast cavity after checking proper haemostasis in patients undergoing breast surgery, is known and widely practiced. It has been shown to improve patient's satisfaction, to optimize analgesia and, with this, to promote early return to work and daily activities. There were concerns about increased risk of postoperative wound infection with incisional infiltration however various clinical studies have shown that local anaesthetics, particularly Bupivacaine, may have both bacteriostatic and bactericidal actions.

Several published studies have investigated the efficacy of instillation of bupivacaine or ropivacaine for reducing post MRM pain. However, the results were inconclusive. Probable causes of failure cited were inadequate positioning of the drain, inability to confirm the position of drains, blockage of drainage holes and poor local anaesthetic distribution due to influence of gravity. In our study, we had instilled local anaesthetic in the surgical drains, one beneath chest wall flap and one in the axilla, postoperatively. The optimal dose of bupivacaine or ropivacaine for instillation during mastectomy is also inconclusive. Jonavithulla N. et al in their study concluded that a volume of 40 cc of local anaesthetic solution when instilled through two drains was associated with more complete spread of the drug and good pain relief postoperatively[10] On the other hand the studies using 20 cc volume of the drug showed ineffective pain relief after instillation through a single drain.[11] Hence in our study the drug volume of total 40cc was instilled through two surgical drains, one in the axilla and one in the chest wall, 20 cc each.

Polley et al. estimated the relative potencies of epidural ropivacaine and bupivacaine and suggested that ropivacaine appears to be 40% less potent than bupivacaine at ED50 concentration but equipotent at a higher concentration.[12] For this reason we decided to use a concentration of bupivacaine 40% smaller than that of ropivacaine for postoperative analgesia.

Our study was aimed to compare the efficacies of bupivacaine and ropivacaine when instilled through surgical drains of MRM patients for post-operative pain relief. We studied and compared the duration of post-operative analgesia, hemodynamic changes and untoward side effects, if any. The demographic datas were comparable.

Mean duration of analgesia for bupivacaine group was (512.37 ±63.06) minutes and that of ropivacaine group was (427.97±43.26) minutes with $p<0.0001$. This difference was statistically significant. in Jonnavithulla N. et al's study, the mean duration of analgesia in patients receiving 40 cc of 0.25% bupivacaine instillation through axillary and chest wall drains was 14.6 hours, the longer duration of analgesia could be because of higher concentration of bupivacaine used in their study.[10] Michael J. Fredrickson et al concluded that increasing volume and increasing concentration of the local anaesthetic drug independently increased mean duration of sensory and motor block.[13]

Similarly Maaike G. E. Fenten et al's in their study concluded that a higher dose and concentration of local anaesthetic drug (mepivacaine) in a nerve block was associated with a longer duration of sensory and motor blockade.[14] H. Talbot et al[11] in their study to determine the influence of local anaesthetic irrigation of axillary wound drains on postoperative pain during the first 24 h following a modified Patey mastectomy concluded that bupivacaine irrigation does not appear to offer an effective contribution to postoperative analgesia. In their study the reasons for failure to demonstrate benefit were cited to be due to inadequate positioning of the drain, blockage of drainage holes and the influence of gravity that may have resulted in poor local anaesthetic distribution. However, the local anaesthetic dose in their study was 20 ml bupivacaine 0.5%, which was given through only one axillary drain. Whereas we have used 40 ml of local anaesthetic solution through two separate drains probably leading to more uniform distribution of the drug and better analgesia in our study. Fayman et al compared the efficacy of infiltration with bupivacaine or ropivacaine for postoperative analgesia in bilateral breast surgery and it was found that overall analgesia achieved with bupivacaine and ropivacaine infiltrations was not statistically different.[15] With respect to alleviation of postoperative pain, the mean VAS pain scores after infiltration with bupivacaine were predominantly lower than after infiltration with ropivacaine ($p=0.069$). we obtained similar results in our study too. Lu et al in their study on the efficacy of continuous local anaesthetic infiltration in breast surgery concluded that the postoperative VAS and requirement of additional analgesics was much lower in the group that received postoperative bupivacaine instillation as compared to conventional analgesics ($p< 0.01$), and suggested that the continuous infiltration of local anaesthetic (bupivacaine) represents another tool for pain management.[16] In T. Sidiroulo et al's study it was concluded that a continuous wound infiltration with ropivacaine 0.5% infusion (CRI) at a 2 mL/h after modified radical mastectomy was as effective as paravertebral block for analgesia.[17] In Ferreiera Laso et al's study patients receiving continuous infusion of levobupivacaine (0.5%) at 2 ml/hour for 48 hours through a wound catheter after MRM had significantly reduced VAS scores for the first 48 hours postoperatively.[18] Aline Albi et al in their study on wound

and intercostal space infiltration with ropivacaine during breast cancer surgery concluded that the VAS scores were lower in patients who received ropivacaine infiltration for up to 6 hours postoperatively.[19] Ropivacaine wound infiltration thus significantly decreased immediate postoperative pain. In another study done by Primitivo Gómez-Cardero et al concluded that continuous intra-articular infusion with ropivacaine 0.2% at a speed of 5 mL/hour through an elastomeric infusion pump reduced postoperative pain and opioid use.[20] It also improved immediate functionality and patient comfort, without increasing the risk of complications. Patients in both the groups had stable hemodynamics intraoperatively and postoperatively, which indicates that all the patients in study group had adequate analgesia throughout the study period and none of the patients developed toxicity related to local anaesthetic solution.

None of the patients in both groups developed hypotension (fall in SBP>20% baseline) and

no significant difference was noted in oxygen saturation between two groups at any given time interval. VAS was found to be significantly higher in bupivacaine group postoperatively at 1 hour, at 10 and at 12 hours. In the ropivacaine group, VAS was significantly higher than that of bupivacaine group at 6 hrs. and 8 hrs. Postoperatively than bupivacaine group but at all these time intervals VAS never exceeded 4.

None of the patients in either group developed any side effects like nausea, giddiness, vomiting, numbness of the tongue, light-headedness, visual disturbances, and muscular twitching. None of the patients in the study had continued excessive blood collection into the drains so as to have unpredictable action of the drug.

There were certain limitations to our study which need to be further investigated. We did not study the incidence of hematoma formation and wound infection. Continuous infusion of local anaesthetic solution through surgical drains might prolong duration of analgesia. Further studies could be done using infusion catheters along with measurement of serum concentration of local anaesthetics agents. The study is not blinded which might lead to observer's bias.

CONCLUSION

In patients undergoing elective unilateral modified radical mastectomy, wound instillation with bupivacaine or ropivacaine through surgical drains provides good analgesia in the immediate postoperative period without any hemodynamic instability and side effects. Bupivacaine provided longer duration of analgesia than Ropivacaine with similar hemodynamic and side effects profile.

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