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A COMPARATIVE STUDY OF POST OPERATIVE ANALGESIA OF BUPIVACAINE OR ROPIVACAINE INSTILLED THROUGH SURGICAL DRAIN IN MODIFIED RADICAL MASTECTOMY

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ABSTRACT

According to GLOBOCAN fact sheet which was published in 2014 [international agency for research on cancer, WHO] incidence of breast cancer in world was approximately 1.38 million (23% of all neoplasms) on 2012.[1] Modified radical mastectomy is the most popular surgical treatment modality for carcinoma breast. Postoperative pain has been severe in MRM cases and demands for pain relief are high. Various strategies like non-steroidal anti-inflammatory drugs, opioids, peripheral nerve blocks, wound infiltration with local anaesthetics, offered significant improvement in this aspect. We wanted to compare the duration of analgesia of Bupivacaine and Ropivacaine instilled through surgical drain site in patients undergoing modifiedradical mastectomy at government Medical College Thrissur during the period January 2016 – December 2016. **Methods:** In this observational study 130 patients aged 18–65 years were divided into two groups. All patients were administered general anaesthesia. At the end of the surgical procedure, axillary and chest wall drains were placed before closure. Group A received 0.25% of 30 ml Ropivacaine and Group B 0.25 % of 30 ml Bupivacaine and the drain will be clamped for ten min. Post extubationpain was evaluated using VAS and subsequently every eight hourly upto 24 hours. Rescue analgesia with injection tramadol1mg/kg IM will be administered if the patients complain of pain at any point of time. Statistical analysis was using IBM SPSS version 20.0 **Results:** There exists a marginal significance in the duration of analgesia. The meanduration of analgesia in Ropivacaine group was10.323 and Bupivacaine group was 9.600. **Conclusion:** Wound instillation with Ropivacaine is a sensible alternative than Bupivacaine with respect to post operative analgesia and side effects

KEYWORDS: Modified radical mastectomy, Ropivacaine, Bupivacaine, post-operative analgesia

INTRODUCTION

Developed countries (except Japan) have a higher incidence (more than 80 for every 1 lakh persons) as compared to developing nations (less than 40 for every 1lakh persons).[2] In India cancer of breast is second most common cancer in women after the cervical cancer with annual incidence exceeding 80,000[3] It is estimated that in developing nations 70 per cent of new breast cancer cases will be seen by 2024.[4]

Modified radical mastectomy is the most popular surgical treatment modality for carcinoma breast. It usually involves extensive tissue dissection.[5] It has been found that persistent pain after surgical treatment is quite common and is higher among the young patients, those undergoing radiotherapy and in axillary lymph node dissection.[6] About 20-50 per cent women are affected by persistent neuropathic pain after their surgical treatment.[7] It can also be associated with post mastectomy pain syndrome, which is a type of chronic neuropathic pain disorder that can occur following breast cancer procedures, particularly those involving upper outer quadrant of breast/axilla.[5]

Pain can be severe enough to cause long term disabilities, It can interfere with sleep and can impair the performance of daily activities involving the use of affected arm leading to shoulder adhesive capsulitis (frozen shoulder) or complex regional pain syndrome.[5]

Various strategies like non-steroidal anti-inflammatory drugs, opioids, peripheral nerve block, wound infiltration have been tried for pain relief. Despite all these efforts, several studies have reported that there is only limited success in effective post-operative analgesia after the surgery. Infiltration of local anesthetic along the line of incision is not advisable in malignant lesions because of fear of needle track seedling and cutaneous spread of malignancy.[5]

Bupivacaine and ropivacaine are commonly used in the pain management for post operative analgesia. Bupivacaine is a well-established long-acting local anesthetic, which like any other amide local anesthetic has been associated with cardiotoxicity, especially when used in high concentration or when accidentally administered intravascularly. It is a racemic mixture.

Ropivacaine is a long-acting regional anesthetic that is structurally related to Bupivacaine but it is a pure S (-) enantiomer developed for the purpose of reducing potential toxicity and for improving relative sensory and motor block profiles. 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 cardiotoxicity.

Local anaesthetics are used for post operative analgesia as wound infiltration and wound instillation. Wound instillation has been tried for reducing post operative pain in modified radical mastectomy.[5] Ropivacainehas antibacterial activity invitro, inhibiting the growth of Staphylococcus aureus, Escherichia coli, and Pseudomonas aeruginosa.[8] Different studies were carried out for comparing Bupivacaine and Ropivacaine. Several researches had been done to understand the toxicities and pharmacokinetics of bupivacaine and ropivacaine.[9]

Bupivacaine is a long acting local anaesthetic. Due to its long duration of action and combined with its high quality sensory blockade compared to motor blockade it has been themost commonly used local anaesthetic for peripheral nerve blocks. Ropivacaine is a newer, long acting local anaesthetic whose neuronal blocking potential used in peripheral nerve blockade seems to be equal or superior to Bupivacaine. Studies shows that it has significantly greater safety margin over Bupivacaine because of lower CNS and Cardiac toxicity[10] and hence can be used in higher concentrations. One of the drawbacks of ropivacaine mentioned is its less intense motor blockade compared to Bupivacaine.[11] This is being undertaken as an observational study to evaluate the onset time, duration and analgesic efficacy of bupivacaine (0.25%) compared to ropivacaine (0.25%) instilled through surgical drain in modified radical mastectomy.

METHODS

Institutional ethics committee approval was obtained for this observational study and written informed consent was obtained from the patients. This study was conducted on 130 American Society of Anaesthesiologists' physical status of I and II patients, aged 18–65 years, scheduled for the MRM procedure.

Patients with a history of allergy to bupivacaine or ropivacaine, treated with prior Radiotherapy or chemo therapy and Surgeries exceeding more than two hours were excluded from the study. Pre‑anaesthetic medication consisted of injmidazolam 0.02 mg/kg, glycopyrrolate 0.01mg/kg, ondansetron 0.04mg/ kg, fentanyl 2mcg/kg.

Preoperatievely all patients were educated in rating visual analogue score for pain prior to surgery. General anaesthesia was induced with propofol 2 mg/kg and pre oxygenation with 100 percent of oxygen for five min and trachea will be intubated with appropriate sized endotracheal tube, which will be facilitated by vecuronium 0.1mg/kg.Oxygen and nitrous oxide will be kept in a ratio of 30:70, surgery will be maintained with sevoflurane 1-2% throughout the operative period. Infusion paracetamol will be given (1 gm) for maintenance of analgesia

At the end of surgical procedure, two drains, one in axilla near the axillary vessels and the second in chest wall below the skin flap will be placed by surgeon before closing surgical incision.Patients were randomly allocated to two groups of 65 each. The study drug was given through each drain after the incision was closed.Group A received 0.25% of 30 ml Ropivacaine and Group B 0.25 % of 30 ml Bupivacaine and the drain will be clamped for ten min.Clamp will be released to allow the test solution into a negative pressure suction drain. Extubation will be performed upon meeting the criteria and after the reversal of residual neuromuscular blockade with neostigmine (0.05mg/kg) and glycopyrrolate (0.2 mg glycopyrrolate per1mg of neostigmine). Post extubation patients were transferred to the post anaesthesia care unit for further monitoring. Pain score at 0 hour was noted after extubation and subsequently every eight hourly upto 24 hours. Pain scores will be assessed using a Visual Analogue Score (0-no pain, 10- worst imaginable pain).

If the patients complain of pain at any point of time rescue analgesia with injection tramadol1mg/kg IM will bead ministered. Post-operative pain managementafter rescue analgesia will be offered as per institutional protocol (INJ Tramadolplus Promethazine TID).

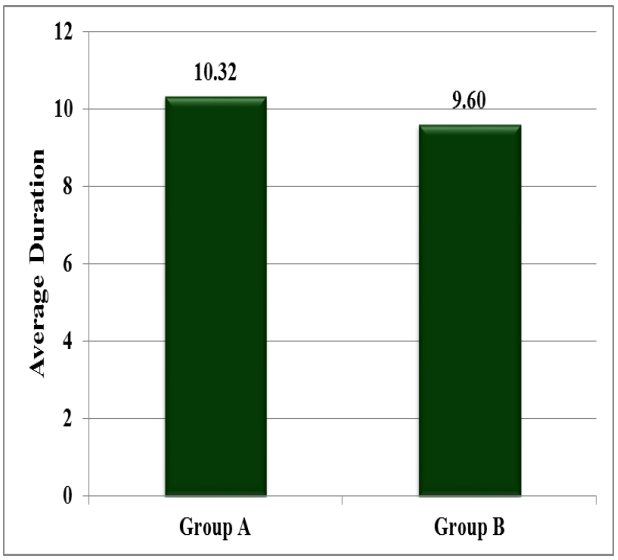
VAS will be monitored eighth hourly and will be correlated with subsequent troutineanal gesicsupto24hrs Statistical analysis was using IBM SPSS version20.0 .Patients in each group calculated using the formula $\frac{(Z\alpha+Z\beta)2\ x\ SD2\ x\ 2}{d2}$ with a power of 80% and significance level of 0.05, coded and entered in Excel

The results obtained from both the groups of patients (A and B) were coded and entered in Excel. Normally distributed data were analyzed using *t* test and categorical data were analyzed using the Chisquare test. Continuous data are presented as mean and standard

deviation, whereas categorical data are presented as number of patients.

RESULTS

The meanduration of analgesia in Ropivacaine group was 10.323 andBupivacaine group was 9.600.There exists a marginal significance in the duration of analgesia.



DISCUSSION

In the present study duration of analgesia was compared and P-value was 0.06 which greater than 0.05 but very near to 0.05. So it can be said that there exists a marginal significance in the duration of analgesia. Group A had higher mean value compared to Group B. In a study, Bupivacaine 0.2% of 40 ml and normal saline of 40 ml were used for instilling through surgical drain concluded that Bupivacaine has got longer duration of post duration of analgesia.[5] Literature suggest, Ropivacaine has less cardiac and central nervous system toxicities compared to Bupivacaine. So we observe that Ropivacaine is a sensible alternative than Bupivacaine with respect to post operative analgesia and side effects.

In a meta analysis randomized control study in which wound infiltration was done by either ropivavaine or Bupivacaine used in different concentrationdone in modifiedradical mastectomy by Kawai Tam Etal,[12] observed that analgesic consumption was not significantly different between patients receiving study drug and normal saline. Bupivacaine or ropivacaine infiltration caused less pain at 2 h postoperatively and no difference in postoperative pain reduction at 1, 12, and 24 h between two groups.

It can be derived that wound infiltration with Ropivacaine or Bupivacaine doesn't offer much post operative analgesia and more over there is a chance for malignant cells to spread by doing wound infiltration. Wound instillation would be a rather good option as it is less invasive, less time consuming, and with less technical difficulty.

In our study we didn't take into account the duration of surgery, level of axillary clearance, Serum study for drug concentration. For assessing the intricate mechanism of study drugs and its analgesic effectst a large, multicentrictrial incorporating all these factors can be studied.

CONCLUSION

In our study, Ropivacaine has got marginally significant duration in post operative analgesia Literature suggest, Ropivacaine has less cardiac and central nervous system toxicities compared to Bupivacaine. So We observe that Ropivacaine is a sensible alternative than Bupivacaine with respect to post operative analgesia and side effects.

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