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EFFICACY OF ROPIVACAINE VERSUS BUPIVACAINE FOR POSTOPERATIVE ANALGESIA BY WOUND INSTILLATION THROUGH SURGICAL DRAIN IN MODIFIED RADICAL MASTECTOMY

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ABSTRACT

Introduction: Local anesthetics used in forms of infiltration and instillation in breast surgeries at surgical site to relieve postoperative pain. So, in this study we compared the efficacy of Ropivacaine and Bupivacaine instillation through chest and axillary drains in modified radical mastectomy. **Study design:** A prospective type of study. **Material and Method:** In this prospective randomized controlled study, 90 patients aged 45–60 years, ASA I and II, were divided into three groups. Surgical procedure was done under general anaesthesia. At the end of the surgical procedure, axillary and chest wall drains were placed before closure of surgical incision. Group R received 0.2% (0.5ml/kg) Ropivacaine, Group B received 0.25 %(0.5ml/kg) Bupivacaine and Group S received 0.9% (0.5ml/kg) Normal Saline, through axillary and chest drain. **Results and Conclusion:** There was no significant difference in the cumulative analgesic requirement and the number of analgesic demands between the Group R and Group B. The mean duration of analgesia in the Bupivacine group was 14.8 hr, 12.9 in Ropivacaine group and 5.7 h in saline group. Wound instillations with Ropivacaine and Bupivacaine provide more effective and longer duration of analgesia but Ropivacaine also has less cardiovascular and central nervous system side effects.

KEYWORDS: Ropivacaine, Bupivacaine, Mastectomy, Postoperative pain.

INTRODUCTION

Breast surgery either lumpectomy, or modified radical mastectomy with axillary node dissection, in combination with chemotherapy or radiotherapy remains the treatment of choice for breast cancer. This surgery is usually performed under general anaesthesia, and is associated with post-operative pain, nausea, vomiting and other side effects also.[1] Traditionally, postoperative pain could be reduced by taking narcotics or non steroidal anti-inflammatory drugs; but they also cause nausea, vomiting, and dyspepsia.

Various local and regional anaesthetic techniques (ie, intercostal block, brachial plexus block, thoracic epidural etc.) also evaluated in the past to reduce early post-operative pain after breast surgery, but they were more time consuming, discomforts to patients, fear of needle prick and failure also need more advanced techniques. The technique of infiltration or irrigation of local anaesthetic is widely used as a part of multimodal analgesia in plastic reconstructive breast surgery, with remarkable effectiveness and without adverse effects.[2,3] 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.[4,5] the instillation of local anesthetic through surgical drain is less invasive ,cause prompt pain relief, more patients satisfaction and early mobilization.

Bupivacaine is an ideal choice for local analgesia in breast cancer surgery through instillation in the dissection space because of long-acting efficiency in similar applications. Moreover, Ropivacaine is also structurally related to Bupivacaine and has less central nervous system and cardiovascular side effects.[6 ,7]but effect was not so prolog as by the Bupivacaine.

So in present study we used Bupivacaine and Ropivacaine through surgical drains in alleviating early postoperative pain after the MRM. Normal saline is commonly used as a “control” group for the clinical investigations. The primary objective of the study was to assess and compare the Bupivacaine and Ropivacaine by duration of analgesia, number of analgesic demands and cumulative analgesic requirement for pain relief.

MATERIALS AND METHODS

This was a randomized prospective, controlled, double‑blind study conducted on 90 female patients of age 40-60 yrs and ASA grade I and II, posted for modified radical mastectomy under general anaesthesia. Patients with a history of chronic analgesic drug usage, allergy to local anesthetic drugs, history of clinically significant cardiovascular, pulmonary, hepatic, renal, neurologic, and psychiatric or metabolic disease, breastfeeding and pregnant, expected major blood loss and bleeding diathesis were excluded from the study.

Patients fulfilling the selection criteria were briefly explained about the nature of study and about anaesthetic procedure. A written informed consent was obtained from the patient. Ninety patients were randomly divided into three groups of thirty patients in each group.

1. Group B- received Bupivacaine 0.25% (0.5ml/kg) through axillary and chest drains.
2. Group R- received Ropivacaine 0.2% (0.5 ml/kg) through axillary and chest drains.
3. Group S- received Normal Saline 0.9% (0.5ml/kg) through axillary and chest drains.

All patients were kept nil orally for at least 6 hrs prior to surgery. Baseline monitors of, noninvasive blood pressure, pulse oximeter, $EtCO_2$ and ECG were attached. Preoperatively, all patients were educated about the visual analogue score for pain.

Patients were uniformly premedicated with Inj. Glycopyrolate 0.2mg, Inj. Ondansetron 4mg IV, Inj. Fentanyl 2µg/kg IV. Then after Pre oxygenation, patients were induced with Inj. Propofol 2mg/kg iv, muscle relaxation was facilitated with Inj. Succinylcholine 1.5mg/kg iv. Patient was intubated and maintained on O_2:N_2O (30:70), Sevoflurane and Inj. Atracurium 0.1 mg/kg intermittently. After the completion of surgical procedure, two drains were placed by the surgeon, one in axilla near the axillary vessels and second in the chest wall below the skin flap (over the pectoral muscle) before closing the surgical incision. The study drug was given to patients through each drain in divided doses after the incision was closed. After the instillation of study drug drain was clamped for 10 min and then clamp was released and allow the test solution in to negative pressure suction drain. The study drug was prepared by separate Anesthesiologists outside Operation Theater according to randomization number. All patients were allowed to receive intravenous Paracetamol infusion of 1000 mg in 100 milliliter normal saline as background analgesics immediately after extubation, then 8 hourly. Patients were transferred to the post-anesthesia care unit for further monitoring. Pain score at "0" h was noted after extubation and subsequently every 4th for 24 h by the trained nurse, who was blinded to the study group. Pain was assessed by VAS socre 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 were also noted for 24 h. Surgical site related untoward effects like hematoma, infection and wound dehiscence were observed clinically till the patient was discharged home. As all patients received prophylactic ondansetron so, adverse effect like nausea and vomiting were not noted.

At the end of the study, the observations were decoded, tabulated and statistically analyzed using mean, standard deviation, p value, ANOVA test, chi- square test and student t test. For comparison, p value less than 0.05 was taken to be statistically significant and less than 0.0001 was taken to be highly significant.

RESULTS

The three groups were comparable with respect to demographic data and duration of surgery ($P > 0.05$). (Table 1).

The mean duration of analgesia in Bupivacaine group was 14.8 hr, whereas it was 12.9 hr in Ropivacaine group and 5.7 hr in Saline group. There was a significant difference between Group S and Group B, and between group S and group R ($P < 0.0001$). The analgesia with saline was variable and there was no difference in the duration of analgesia, when compared to Group B and group R. (Table. 2).

The number of rescue analgesic demands was higher in the Group S than Group B and Group R but there was no significant difference between Group B and Group R. (Table 2).

There was statistically significant difference between Group B and Group S and between Group R and Group S, in terms of total tramadol consumption ($P < 0.0001$)).(Table 2). There was no local anesthetic toxicity, wound hematomas, infection or delayed wound healing in any of the patients.

Table. 1. Patients characteristic.

Characteristic	Group B Mean ± SD	Group R Mean ± SD	Group S Mean ± SD	P value
Age in years	46.7±11.05	45.9±8.9	46.58±10.9	>0.05
Weight in kg	59.5±13.2	57.7±18.4	58.9±10.7	>0.05
Height in cm	162.73±8.6	165.32±7.9	164.54±7.5	>0.05
Duration of surgery in hrs	2.8±1.7	3.1±1.2	2.9±1.3	>0.05

Table. 2. Duration and resque Analgesia.

Characteristics	Group B	Group R	Group S	P value Group B vs Group R	P value Group R vs Group S	P value Group B vs Group S
Duration of analgesia in hrs	14.8±8.7	12.9±5.5	5.7±9.4	>0.05	< 0.0001	< 0.0001
Resque analgesic requirement in 24hrs	36.21±43	35.28±11	67.6±64	>0.05	< 0.0001	< 0.0001
VAS	9.2±4.8	11.4±2.5	16.2±7.6	>0.05	< 0.0001	< 0.0001

DISCUSSION

Local anaesthetic drugs (i.e. - Lignocaine, Bupivacaine, Levobupivacaine, Ropivacaine etc.) have become increasingly popular for treating surgical pain because of their long lasting analgesic properties and lack of opioid-induced adverse effects.

Bupivacaine is widely used clinically as a potent, long-acting local anaesthetic. Its known potential for central nervous system, and especially cardiovascular system toxicity stimulated a search for new and safer agents, resulting in the introduction of Ropivacaine.[8] The lesser toxicity of Ropivacaine compared with Bupivacaine on the central nervous system (CNS) and cardiovascular system has been confirmed in numerous animal experiments[9,10] as well as human studies.[11]

There is clinical evidence that infiltration and instillation of local anaesthetic at operative sites can improve postoperative analgesia and reduce opioids requirement after different surgical procedures.[12-13]

Arunakul and ruksa[14] found that single injection Paravertebral block (PVB) cause low pain score by PVB and less opioids consumption. Sidiropoulou *et al*. in their study of single injection Paravertebral block compared with continuous wound infiltration concluded that early postoperative analgesia and patient satisfaction was good with PVB while late postoperative analgesia was good with continuous irrigation. But because PVB technique needs more time to perform the block, necessary and expert guidance,[15] and has a serious complication like pneumothorax[16] and continuous catheter instillation of drug cause mal positioned catheter, drug overdose etc more advanced and better technique are needed.

Local anaesthetic infiltration along the suture line also provides good analgesia but due to fear of needle track seedling and cutaneous spread of malignancy this method may not be recommended in malignant lesion.[4]

In a study by Talbot *et al*.[17] determined the effect of local anaesthetic irrigation of axillary drains following a modified Patey mastectomy offered no contribution for postoperative analgesia in some of their patients, this could be because of mal positioned drain, blockade of some holes of the drain or unequal distribution of the local anaesthetic concluded that further refinement in the technique was needed. Hence, to overcome this limitation, we have instilled drugs through both the chest wall and axillary drains. This could have resulted in more uniform distribution of the drug, thus improving the efficacy of the technique, and post-operative period analgesia also.

In many of the plastic reconstructive breast procedures, irrigation of the pocket created for the insertion of the prosthesis with local Anesthetics is reported with high levels of satisfaction regarding postoperative pain and the authors have recommended this technique of analgesia for all the cosmetic breast surgery.[18, 19] The techniques like para vertebral block, brachial plexus block by infraclavicular approach have been tried for postoperative analgesia following mastectomy.[20-22]

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.

Time for first rescue analgesic request and number of demands for analgesia in the first 24 h were lower in Bupivacaine group then Ropivacaine so as the use of injection tramadol is also less in Bupivacaine group then Ropivacaine group and their satisfaction scores were higher as compared to the patients who received Ropivacaine but it was not very significant.

Our study showed that VAS score rises early in Group R than Group B but not very significant. 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*.[5]

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 cardio toxicity with Bupivacaine.[2]

In our study we observed that 0.25% Bupivacaine cause postoperative analgesia up to 14.8 hrs as shown in a study of jonnavithula and 0.2% Ropivacaine cause

postoperative analgesia up to 12.9 hr as shown by study of patel et al., so difference was not so significant and conclusive.

In our study, there was no case of local anesthetic toxicity, infection, hematoma and wound dehiscence observed which was in concordance with the study of Jonnavithula *et al*.[5] and Talbot *et al*.[17]

CONCLUSION

So In this study, the results showed that patients, who received instillation with Bupivacaine or Ropivacaine, have better postoperative analgesia but due to less cardiovascular toxicity and central nervous system effects Ropivacaine still superior to Bupivacaine.

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