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ORIGINAL RESEARCH

A STUDY TO ASSESS THE EFFICACY OF BUPIVACAINE INSTILLATION THROUGH SURGICAL DRAINS FOR CONTROL OF POST-OPERATIVE PAIN IN MODIFIED RADICAL MASTECTOMY

[1]Dr. Mandeep Singh Sandhu, [2]Dr. Kartik Aggarwal, [3]Dr. Manjit Singh, [4]Dr Sumitoj Singh, [5]Dr. Amarbir Singh, [6]Dr. Onkar Vats

[1]Assistant Professor, [2]Junior Resident, [3]Assistant Professor, [4]Professor, [5]Associate Professor, [6]Junior Resident, Department of General Surgery

Correspondence:Dr. Manjit Singh
Assistant Professor, Department of General Surgery, Govt. Medical College, Amritsar, Punjab, India
Email ID: manjits197@gmail.com

ABSTRACT

Background : Breast cancer is a significant global public health concern for women and a Modified Radical Mastectomy(MRM) is one of the most popular procedures for treatable breast cancer and involves extensive dissection.

Aim: To assess the efficacy of Bupivacaine instillation through surgical drains in control of post- operative pain in modified radical mastectomy (MRM).

Methods: 100 female patients with breast cancer planned for an MRM were enrolled in this randomised clinical study. They were randomly divided into 2 groups A & B. At completion of surgery, axillary and chest wall drains were placed. In Group A, instillation with 20ml of 0.25% bupivacaine was done through each drain which were then clamped for 10 mins before extubating. Group B was control group. Pain was assessed using visual analogue scale (VAS) score 2 and 4 hours post op and then every 4^{th} hourly till 24hrs. If the VAS was ≥, Inj. Diclofenac IM was given as rescue analgesia. Data was analysed using IBM SPSS software package version 20.0.

Results: The duration of analgesia was extended in bupivacaine group with the mean duration being 16.88h while in control group it was 4.16h. Moreover the mean VAS score remained <4 at every point in Bupivacaine group. The number of analgesic demands was significantly lower in bupivacaine group as compared to control group ($P<0.001$).

Conclusion: Wound instillation with local anaesthetics via drains is easy and effective in providing extended analgesia without any major side-effects.

Keywords: Modified Radical Mastectomy, Bupivacaine, breast cancer, local anesthetic

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INTRODUCTION

Globally, breast cancer is a significant public health concern for women. Breast cancer remains the most frequent cancer in women and the second most frequent cause of cancer death. Based on current incidence rates, 25.8 per 100,000 women born in the India at present will develop breast cancer at some time during their lifetime. Despite advancements in medical care, surgery remains a key component of its management. When it comes to treatable breast cancers, the most popular surgical procedure is called a modified radical mastectomy (MRM). Thirteen percent of all breast operations involve MRM(1). MRM with axillary lymph node clearance requires extensive tissue dissection. Patients' main complaints following the procedure include pain and the development of postoperative seroma. Up to 50% of women who undergo mastectomy report pain as one of their most frequent symptoms(2). Patients may require potent analgesics exposing them to the side effects of those drugs. Discomfort management techniques are employed to reduce discomfort following surgery. Non-steroidal anti-inflammatory medicines (NSAIDs) are linked to indigestion and heartburn, whereas opioid adverse effects include nausea, vomiting, shallow breathing, drowsiness, and dizziness. Intercostal blocks, paravertebral blocks, thoracic epidural anaesthesia, intrapleural blocks, and ultrasound-guided interfascial plane blocks are examples of regional anaesthesia but require greater skill and expertise and are also cumbersome to perform (3). Because of the risks associated with needle track seedlings and cutaneous cancer spreading, it is not advised to infiltrate local anaesthetic along the incision line in malignant lesions (4). Additionally, since the tissue dissection extends beyond the area of the incision line, It is possible that infiltration along the surgical incision's line won't offer enough pain relief. The aim of the present study was to assess the efficacy of bupivacaine instillation through surgical drains in adequately controlling post operative pain after MRM. It was assessed by average duration of analgesia, total number of analgesic demands and mean pain score.

MATERIALS AND METHODS:

This prospective randomised clinical study was started after approval from Institutional Ethical Committee. After obtaining written informed consent, 100 patients posted for modified radical mastectomy were enrolled in this study after fulfilling inclusion and exclusion criteria. Patients belonging to ASA physical status Grade 1 and 2 were included. Patients with ASA 3 & 4, or

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with Tietze syndrome, or with history of angina pectoris, known psychological and mental illness or with chronic history of NSAID intake were excluded from the study. After going through a pre-anaesthetic check-up before surgery, patients were randomly allocated to one of the 2 groups (A & B) with 50 patients in each group. The investigator was blinded to the patient's allocation. All patients were made familiar with the VAS. The induction protocol of anesthesia was the same for all patients. Patients were subjected to standard modified radical mastectomy (MRM) with level I and level II axillary lymph nodes dissection (ALND). Two drains were inserted; one beneath the skin flap at anterior chest wall and the other in the axilla. As per the randomisation, patients were divided into 2 groups and subjected to one of the following procedures-according to their enrolment group. Patient in Group A were instilled with 40 ml of 0.25% bupivacaine through axillary and chest wall drains (20 ml in each drain). Then, the drains were clamped for 10 minutes and released afterwards to allow the test solution in the negative pressure suction drain. In Group B patients, the wound was closed after putting in the axillary and chest wall drains without instillation of any agent. Anaesthesia was reversed according to standard protocol and extubation done after complete neuromuscular recovery. The pain was assessed using visual analogue scale (VAS) score; VAS was recorded 2 and 4 hours postoperatively and then every 4 hours thereafter up to 24 hours postoperative. Injection Diclofenac Sodium 75 mg IM was given as rescue analgesia when VAS was ≥4. Both groups were compared with regard to time for first demand of rescue analgesia and the number of demands of analgesics during the first 24 hours as well as the total analgesic requirement.

RESULTS AND OBSERVATIONS

The two groups were comparable with respect to demographic data (age, sex, weight), ASA grade and type of surgery. The mean duration of post operative analgesia in bupivacaine instillation group A was 16.88hrs while in the control group B, it was 4.16hrs. This difference was highly significant ($p<0.0001$) depicting that bupivacaine instillation has a longer analgesic effect in the post-operative period. Patients who received bupivacaine experienced significantly reduced requirements for additional analgesia compared to those who did not receive bupivacaine.[Table 1]

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Table 1: Patient Characteristics			
S. No	Group A (Bupivacaine)	Group B (Control)	P Value
Age (years)	50.26±1.68	51.32±1.52	0.441
Duration of Analgesia (hours)	16.88	4.16	0.000
No. of Demands	0.94±0.06	2.16±0.05	0.000
Rescue Analgesic requirement 24 hour (mg)	70.50±4.5	162.00±3.92	0.000

The average number of demands of RA in group A was 0.94±0.06 while in group B it was 2.16±0.05. Specifically, 12% of patients in group A did not require any RA at all, while 82% needed only one dose of RA. This contrasts sharply with group B, where 84% required two doses of RA, and 16% needed three doses. Notably, none of the patients in group A required three doses, underscoring the effectiveness of bupivacaine in minimizing the need for multiple doses of rescue analgesia post-operatively ($p<0.0001$)[Fig.1]. Similarly, the total amount of analgesic requirement (in mg) was significantly lower in group A than in group B. The mean analgesic requirement in group A was 70.50±4.5mg while in group B it was 162.00±3.92mg ($p<0.0001$).

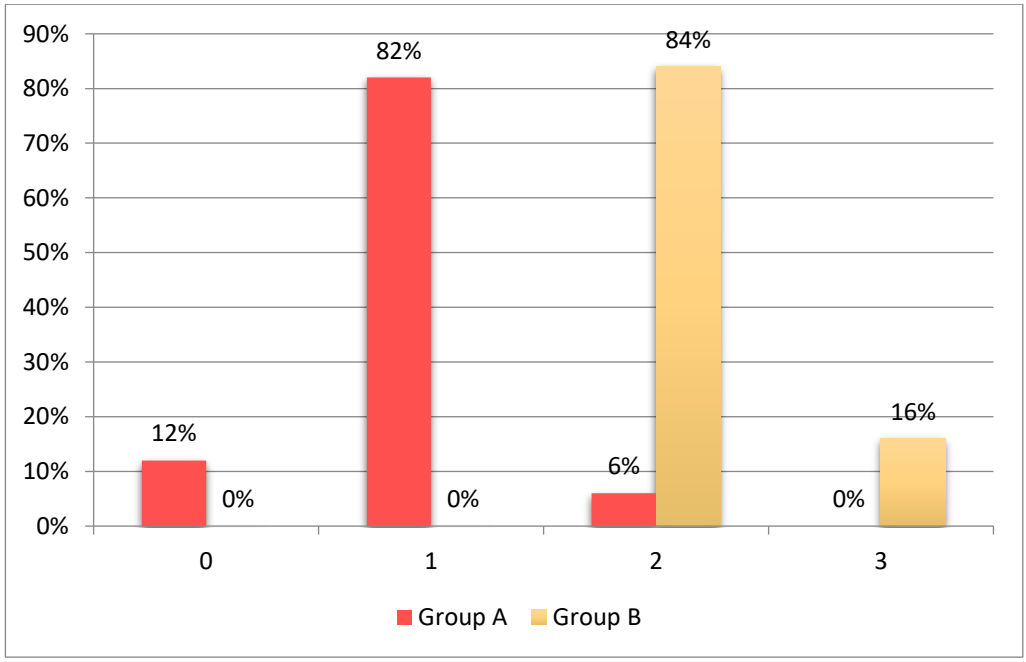

Figure 1: No. of Demands of RA

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For the Visual Analog Scale (VAS) scores at different time intervals, significant differences were observed between the two groups. It was observed that mean VAS was persistently higher in group B than group A[Fig. 2]. The mean VAS score in group A was 0.88, 1.26 and 1.82 during 2nd, 4th and 8th hour versus 2.38, 4.32 and 3.48 in group B respectively. However, a reversal was seen at 16hrs and 20hrs. Since most patients in group B required more than 1 rescue analgesic doses before 16hrs, this led to a decrease in mean VAS score in group B at 16hrs and 20hrs. Conversely, most patients in group A required the 1st dose of RA at 16hrs and this led to an increase in mean VAS at 16hrs. It clearly indicates that frequent requirement for analgesic occurred in group B before 16hrs for pain management, thus decrease in VAS was seen in group B at 16hrs onwards. Patients who received bupivacaine reported consistently lower VAS scores, indicating less pain intensity compared to those who did not receive bupivacaine.

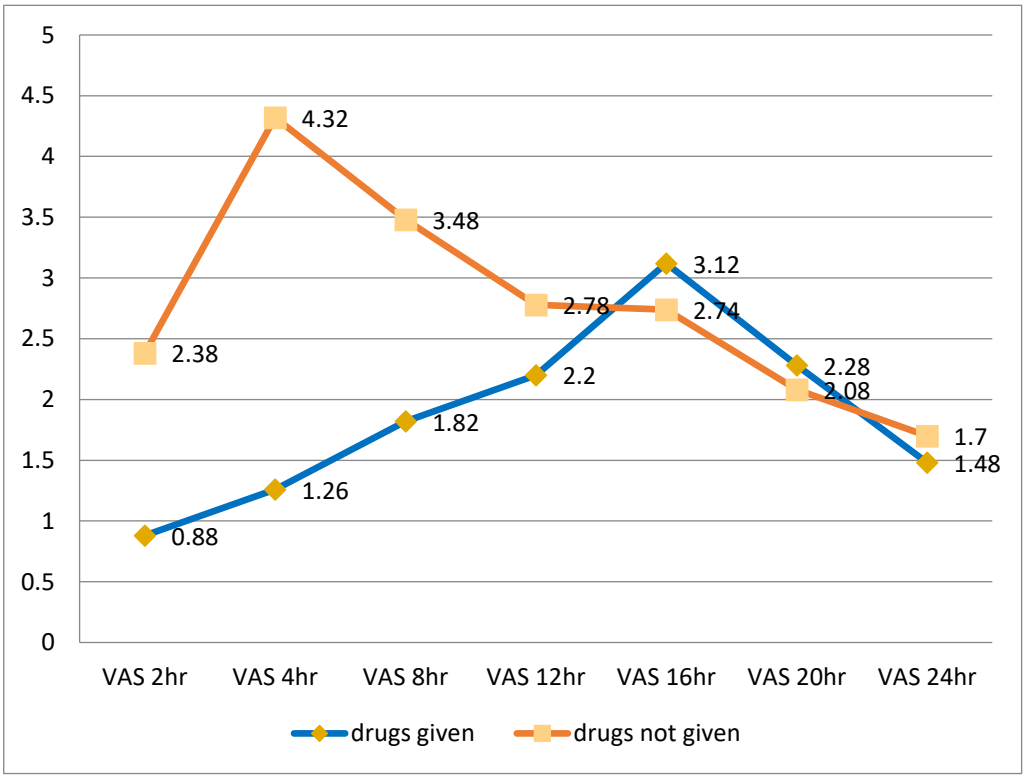

Figure 2: Visual Analog Scale (VAS) scores at different time intervals (2hr, 4hr, 8hr, 12hr, 16hr, 20hr, 24hr)

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DISCUSSION

This prospective randomized clinical study was conducted for a better understanding of post operative pain relief in patients undergoing a modified radical mastectomy in our institute. Popularity and use of local anesthetic agents has increased over the use of systemic analgesics and other invasive methods of pain relief. This is greatly attributed to their better analgesic properties as well as absence of any systemic side effects caused by opioids and other systemic analgesics. In breast reconstructive procedures, a pocket is created for the insertion of prosthesis. This pocket, when irrigated with local anesthetics, reported better results in terms of post operative pain relief and so it was recommended for cosmetic breast surgeries (5).

In our study, a total of 100 patients with MRM were included which were divided into two groups, Group A who were given bupivacaine through surgical drains and Group B who did not receive any drug. The mean duration of pain free period was much higher in the bupivacaine group (16.88hrs) when compared with control group(4.16hrs). In a study, Shamim et al., 2022(6) discovered that the group that received bupivacaine when compared to control group had a significantly longer mean time period of pain relief (10.93±1.84 hours vs. 5.03±1.35), which is consistent with the hypothesis that there is a statistical variation in the mean time period of analgesia in patients undergoing MRM with wounds instilled with bupivacaine.

In our study, at 2 hours post-surgery, the bupivacaine group showed favorable pain management outcomes with 86% patients reporting either minimal or no pain. In contrast, the control group had no pain free patients while 72% had mild to moderate pain. These differences were highly statistically significant ($p < 0.001$). Similar significant outcomes were noted at 4hr, 8hr and 12hr mark post-surgery with consistently lower VAS scores and lower Rescue analgesic demands in Group A when compared to Group B. For the mean Visual Analog Scale (VAS) scores at different time intervals (2hr, 4hr, 8hr, 12hr, 16hr, 20hr, 24hr), significant differences were observed between the two groups. It was observed that mean VAS scores were consistently more in group B than group A at 2hrs, 4hrs, 8hrs and 12hrs which were 2.38,4.32,3.48 and 2.72 as compared to 0.88,1.26,1.82 and 2.20 in Group A respectively. However, a reversal was seen at 16hrs and 20hrs when the mean VAS in group A were slightly higher than group B. This was due to increased and frequent rescue analgesic demands as well

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as no of demands in the control group B at much earlier times. Nevertheless, patients who received bupivacaine reported consistently lower VAS scores, indicating less pain intensity compared to those who did not receive bupivacaine. Since both the pain scores as well as demand for rescue analgesia was significantly decreased in study group, this reflected the efficacy of pain control in post-operative period due to bupivacaine given through surgical drains. Alhussini et al. 2019(7) reported that VAS in group A was less than group B with statistically significant difference. This was reflected also on the number of patients who were in need for additional analgesia at or before 2 hours postoperatively. He also found that there was a marked decrease in VAS in the first 24 hours postoperatively in the bupivacaine group. Subsequently, the use of the analgesic drug was also reduced. Likewise, Chhatrapati et al. 2019(3), studied VAS in the postoperative period at one hour, 10 hours, and 12 hours and was found to show good pain relief in the bupivacaine group. In another study conducted by Culleford *et al*, 2007(8) on 37 patients, 20 patients were treated with intraoperative topical bupivacaine while 17 patients were given a placebo. It was observed that in patients undergoing ambulatory reductive mastectomy, a single dose of tropical intraoperative bupivacaine was able to significantly decrease opioid analgesic requirement when compared to control group patients with placebo (p=0.001). These studies were consistent with the results of our study which depicts efficacy of bupivacaine in both short term as well as long term pain control in post-operative period.

Total analgesic requirement as well as the average number of demands of RA were significantly lower in Group A than Group B in the first 24h postoperative period(p=0.000). In group A, mean of demand of RA was 0.94±0.06 and in group B it was 2.16±0.05. In the study by Jonnavithula et al. 2019(9), the average number of analgesic demands was found to be 0.6±0.7 in group B(Bupivacaine) as compared to 1.2±1 in group S(Saline) and 2.3±1.27 in group C(Control). Therefore, better and extended postoperative analgesia was experienced by patients in group A as compared to the control group B indicating the efficacy of bupivacaine in post operative pain relief.

Opioids are a great painkiller, but they have a wide range of negative effects when used excessively or erratically, from nausea to respiratory depression (10). Its potential for abuse and significant potential for dependence further reduce its advantages. Regional nerve and field blocks are also an effective way to achieve good analgesia after MRM, but they require greater

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skill to perform and are invasive techniques. Nevertheless, the outcomes are not always successful and may result in iatrogenic pneumothorax during infiltration (11). Multiple approaches can be used for good analgesic control, including patient-controlled analgesia, oral plus parenteral NSAIDs, opioids, co-analgesics (anti-depressants), and local anesthetic, according to the WHO analgesic ladder guidelines for pain treatment. Infiltration, infusion, intercostal blocks, paravertebral block, thoracic epidural anesthetic, inter-pleural block, and ultrasound-guided interfascial block are additional methods already employed for post-MRM pain treatment. There are various methods for applying local anesthetic at the site of a surgical wound. In addition to being less complicated to administer and less risky in terms of infiltration—such as tension pneumothorax—local anesthetic wound instillation also does not carry additional risks (12).

CONCLUSION

There are certain benefits of using surgical drains to instil bupivacaine after a modified radical mastectomy above standard pain management protocols. Firstly, it assists in postponing the initial urge for analgesia. Additionally, it lessens the overall quantity of analgesics that the patient needs to take in the first 24 hours following surgery thereby reducing the discomfort associated with intramuscular diclofenac injection. Moreover, it also decreases the limb immobility faced by the patient due to excessive pain and motivates the patient towards early mobilisation. This may help in reducing the lymphoedema of upper limb post-surgery. Overall it helps in early recovery and return to normal activity. If the analgesic medication was continuously given through surgical drains, the duration of analgesia could be further extended. Further research utilizing infusion catheters and various local anesthetics should be done in this direction. On follow-up following discharge, there was no documentation of persistent discomfort and more research can be conducted to investigate potential long-term consequences of local anesthetic wound instillation.

References:

1. Beguinot M, Monrigal E, Kwiatkowski F, et al. Continuous wound infiltration with ropivacaine after mastectomy: a randomized controlled trial. *J Surg Res.* 2020;254:318–326.
2. Gupta K, Srikanth K, Girdhar KK, Chan V. Analgesic efficacy of ultrasound-guided paravertebral block versus serratus plane block for modified radical mastectomy: a randomised, controlled trial. *Indian J Anaesth.* 2017;61:381–386.

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3. Chhatrapati S, Sahu A, Bais S. A comparative study of bupivacaine vs ropivacaine wound instillation through surgical drain for postoperative analgesia in modified radical mastectomy. *Int J Contemp Med Res.* 2019;6
4. Uematsu T, Kasami M. Risk of needle tract seeding of breast cancer: Cytological results derived from core wash material. *Breast Cancer Res Treat.* 2008;110:51–5.
5. Kazmier FR, Henry SL, Christiansen D, Puckett CL. A prospective, randomized, double-blind, controlled trial of continuous local anesthetic infusion in cosmetic breast augmentation. Plast Reconstr Surg. 2008;121:711–5.
6. Shamim Seth U, Perveen S, Ahmed T, Kamal MT, Soomro JA, Murtaza Khomusi M, Kamal M. Postoperative Analgesia in Modified Radical Mastectomy Patients After Instillation of Bupivacaine Through Surgical Drains. Cureus. 2022 Apr 13;14(4):e24125
7. Alhussini MA, Awad AT, Girgis AM, et al. Post mastectomy pain control using bupivacaine instillation via wound drains. *Int Surg J.* 2019;6:1851.
8. Culliford AT, Spector JA, Flores RL, Louie O, Choi M, Karp NS. Intraoperative Sensorcaine significantly improves postoperative pain management in outpatient reduction mammoplasty. PlastReconstrSurg2007; 120: 840-4.
9. Jonnavithula N, Khandelia H, Ramachandran G, Durga P. Role of wound instillation with bupivacaine through surgical drains for postoperative analgesia in modified radical mastectomy. *Indian J Anaesth*. 2015;59(1):15–20.
10. Bateman BT, Choudhry NK. Limiting the duration of opioid prescriptions: balancing excessive prescribing and the effective treatment of pain. JAMA Intern Med. 2016;176:583–584.
11. Cheng GS, Ilfeld BM. An evidence-based review of the efficacy of perioperative analgesic techniques for breast cancer-related surgery. Pain Med. 2017;18:1344–1365.
12. Mesa J, Lalonde D, Vasconez LO. Complications of Regional Anesthesia. Cham: Springer; 2017. Local and regional anesthesia in plastic surgery: safety considerations and management of adverse events; pp. 399–409.