

Efficacy of Instillation of Bupivacaine into the Surgical Drain for Post-Operative Pain Relief in Modified Radical Mastectomy

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Abstract

Original Research Article

To study the efficacy of instillation of bupivacaine into the surgical drain for post-operative pain relief in modified radical mastectomy, after obtaining institutional ethical committee clearance and written informed consent from the patient for this randomized prospective controlled double blinded study, 50 female patients with carcinoma breast of ASA I & II between the age group of 35 -65 years posted for modified radical mastectomy were divided into two groups, Group (C) and Group(S). All patients were selected according to the inclusion and exclusion criteria. Post-operative ward nurse monitors and records the data. The investigator collected the data only. GROUP (S)-Receives 0.25% Bupivacaine 30 ml through the surgical drain after skin closure. GROUP (C)-Receives Normal saline 30 ml through the surgical drain. Preoperatively, all patients were educated about the reading of pain score with ten pointed visual analogue scale. General anesthesia was given to all the patients. End of the surgical procedure, two drains were placed by the surgeon. One was placed over the pectoralis muscle beneath the skin flap and one in the axilla. Skin is closed and 15ml of 0.25% Bupivacaine or Saline were instilled in each drain (total of 30ml) by the surgeon or by the assisting nurse. The drain was kept closed for half an hour. Patient was given reversal and extubated after satisfying recovery criteria. Patient was shifted to post anaesthesia care unit and the followings were monitored for 24 hours by the nurse who was blind in this study. (a) vital signs, (b) Time of onset of first analgesic dose requirement, (c) Number of analgesic dose required, (d) Any other additional analgesic required. Intramuscular injection Tramadol was given as rescue analgesia if patient complains of pain or VAS is more than 4. It was concluded that wound instillation with local anesthetics provides good analgesia for patients following the MRM procedure.

Keywords: Bupivacaine, Intradrain Instillation, Modified radical mastectomy (MRM), post-operative pain.

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INTRODUCTION

Modified Radical Mastectomy (MRM) is the commonly performed surgical procedure for operable Breast cancer, which involves extensive tissue dissection. Following surgery, the patients are emotionally disturbed for fear of pain apart from the physical suffering. Various strategies for post operative pain relief are non-steroidal anti-inflammatory drugs, opioids, peripheral nerve blocks, paravertebral block, and wound infiltration with local anaesthetics. Despite these, several studies reported that limited success in providing effective postoperative pain control. 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. In contrast to

other breast surgeries, MRM involves more extensive tissue dissection. Infiltration of local anaesthetic along the line of incision is not recommended in malignant lesions, because of the fear of needle track seedlings and cutaneous spread of malignancy. Moreover, the tissue dissection extends beyond the surgical incision. Infiltration along the line of surgical incision may not provide adequate analgesia. The aim of the present study was to assess the role of wound instillation with bupivacaine 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 the efficacy of the wound instillation with Bupivacaine through surgically placed drains, which was assessed by duration of analgesia, number of analgesic demands.

We hypothesized that in patients following the MRM, instillation of local anaesthetic through axillary and chest drains placed surgically may provide a better analgesia

Aim and Objective

Aim: To Study efficacy of instillation of bupivacaine into the surgical drain for post-operative pain relief in modified radical mastectomy. **Objective:** To assess the efficacy of bupivacaine instilled through surgical drain, the following parameters were observed, (a) Time of onset of first analgesic dose requirement, (b) Duration of analgesia, (c) Number of analgesic dose required.

MATERIALS AND METHODS

This study was conducted in the year of 2017-18 in Shanmuga Hospital and Salem cancer institute. After obtaining institutional ethical committee clearance and written informed consent from the patient for this randomized prospective controlled double blinded study, 50 female patients with carcinoma breast of ASA I & II between the age group of 35 -65 years posted for modified radical mastectomy were divided into two groups, Group (C) and Group(S). All patients were selected according to the inclusion and exclusion criteria.

GROUP (S)-Received 0.25% Bupivacaine 30 ml through the surgical drain after skin closure.

GROUP (C)-Received Normal saline 30 ml through the surgical drain. All patients were selected according to the inclusion and exclusion criteria.

Inclusion criteria

- ASA I & II patients with carcinoma breast patients with age between 35-65yrs. posted for MRM

Exclusion criteria

- ASA category more than II
- Age > 65 years and < 35 Years
- Patients with significant post-operative drain collections
- Patients with prolonged period of analgesic intake

Post-operative ward nurse monitored and recorded the data. The investigator collected data only.

Preoperatively, all patients are educated about the reading of pain score with ten pointed visual analogue scale and premedication was given with Ranitidine 150mg and Alprazolam 0.25 mg orally. Patients were induced with Propofol 2 mg/kg after intravenous glycopyrrolate 0.2 mg and Midazolam 1 mg and intubation facilitated with succinyl choline 2mg/kg. Anaesthesia was maintained with oxygen and nitrous oxide 30:70 with fentanyl 2mg/kg with vecuronium and Halothane 0.5% for initial 30 minutes. End of the surgical procedure, two drains were placed by the surgeon. One was placed over the pectoralis muscle beneath the skin flap and one in the axilla. Skin is closed and a total of 30ml 0.25% Bupivacaine or Saline were instilled with 15 ml in each drain by the surgeon or by the assisting nurse. The drain was kept closed for half an hour. Patient was given reversal and extubated after satisfying recovery criteria. Patient is shifted to post anaesthesia care unit and the followings were monitored for 24 hours by the nurse who was blind in this study,

- Vital signs
- Time of onset of first analgesic dose requirement
- Duration of analgesia
- Number of analgesic dose required
- Any other additional analgesic required.

Intramuscular injection Tramadol is given as rescue analgesia if patient complains of pain or VAS is more than 4. Any post-operative complications till the discharge of the patient like wound infection; excessive collections etc. were also monitored.

All cases completed in stipulated time. Data were collected, compiled, and tabulated. Statistical analysis was done by using social science statistics, online website <https://www.socscistatistics.com>. A $P < 0.05$ was considered statistically significant for all tests.

OBSERVATIONS

This was a randomized prospective controlled double blinded study with 50 female patients suffering from carcinoma breast. The two groups were comparable with respect to demographic data [TABLE-1] and most of patients both in control and study group were in the age between 45 to 55 years.

Table-1: Demographic profile Age in years

	35-45	45-55	55-65
Group C (control) N=25	02	15	08
Group S (study) N=25	03	17	05

Table-2: Time of analgesic requirement

Hour	Group C (control) N=25	Group S (study) N=25	Chi-square statistic	P-value
0-1	13(7)(5.14) (52%)	01(7)(5.14) (4%)	27.6857	0.000014
1-2	08(5)(1.8) (32%)	02(5)(1.8) (8%)		
2-3	02(10)(6.4) (8%)	18(10)(6.4) (72%)		
3-4	01(2)(0.5) (4%)	03(2)(0.5) (12%)		
4-5	01(1)(0.00) (4%)	01(1)(0.00) (4%)		

In the control group, 52% of the patient required analgesic in the first hour itself and in the study group, it was only 4%. 32% of the patients in control group required analgesic in the second hour

whereas 72% of the patients in the study group required analgesic in the third hour. The P-value is 0.000014. The result is statistically significant at $P < 0.05$.

Table-2: Number of analgesic doses requirement

	One dose	Two doses	Three doses	Chi-square statistic	P-value
Group C (control) N=25	03(2.5)(0.1) (12%)	08(14)(2.57) (32%)	14(8.5)(3.56) (56%)	12.4605	0.001969
Group S (study) N=25	03(8.5)(3.56) (12%)	20(14)(2.57) (80%)	02(2.5)(0.1) (8%)		

56% of the patients in the control group required three doses of rescue analgesic on the first post-operative day and most of the patients (80%) in study group required two doses of rescue analgesic. The P-value is 0.001969. The result is statistically significant at $P < 0.05$. Out of 50 patients in this study, three patients had vomiting in the control group and no patient had vomiting in the study group. There were no complications like infection, collections and delayed wound healing in any of the group. The number of rescue analgesic demands was higher in the Group C than Group S. Duration of Analgesia in Study Group was 4-5 hours.

DISCUSSION

In this prospective, randomized double blinded controlled study, we observed that results of this study showed that patients, who received instillation with 0.25% bupivacaine through surgical drains following MRM procedure experienced a better postoperative analgesia as compared with patients who received saline similarly. Number of demands for analgesia in the first 24 h, when the pain score was ≥ 4 was significantly lower in the bupivacaine group compared with the saline group.

Because of their analgesic properties, and lack of opioid-induced adverse effects like nausea, vomiting, drowsiness, pruritus etc. for treating postoperative surgical pain, local anaesthetic drugs have become increasingly popular. In many of the plastic

reconstructive breast procedures, irrigation of the pocket created for the insertion of the prosthesis with local anaesthetics 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.

Nirmala Jonnavithula [3], concluded Wound instillation with local anaesthetics is a simple and effective means of providing good analgesia without any major side-effects. The techniques like para vertebral block, brachial plexus block by infraclavicular approach have been tried for postoperative analgesia following mastectomy. Post-operative pain and analgesic requirements after paravertebral block for mastectomy was adequate [4].

Arunakul P [5] and Ruksa A concluded that PVB (Para vertebral block) can reduce postoperative opioid requirement, pain, and severity of nausea and vomiting in MRM. However, these techniques are laborious and technically challenging. Infiltration of local anaesthetic along the suture line also provides analgesia [6, 7] but, for malignant lesions this method may not be recommended because of fear of needle track seedlings and cutaneous spread of malignancy. Sidiropoulou [8] and his colleagues in their study compared analgesic effect of single injection of PVB with ropivacaine and continuous irrigation of wound with ropivacaine through two dedicated multi-lumen catheters placed subcutaneously at the end of the procedure following mastectomy for 24 h. They found

that early postoperative analgesia (4 h) was good with PVB and late postoperative analgesia was good with continuous irrigation and concluded that continuous wound irrigation is as effective as PVB with low pain scores and good patient satisfaction.

The technique of drug instillation through the drains is technically simple, and operation theatre time is also not a constraint because it takes very little time to instill the drug through the drains. The technique of instillation of the drug through drains is well established in surgical procedures like laparoscopic cholecystectomy, where the results have shown some positive impact on postoperative analgesia. Moreover, this is well accepted by the patient and the surgeons.

Talbot *et al.* [9]. In their study to determine the effect of local anaesthetic irrigation of axillary drains on postoperative pain following a modified Patey's mastectomy felt it did not appear to offer any contribution for postoperative analgesia in some of their patients. They opined that this could be because of malpositioned drain, blockade of some holes of the drain or unequal distribution of the local anaesthetic due to gravity and concluded that further refinement in the technique was needed. We have instilled through both the chest wall and axillary drains placed to overcome this limitation. This could have resulted in more uniform distribution of the drug improving the efficacy of the technique, and the patients were pain free in the postoperative period.

Branka Strazisar, Nikola Besic[10] conducted prospective randomized study comparing continuous local anaesthetic and systemic pain treatment after axillary lymphadenectomy in breast carcinoma patients. They concluded that wound infusion of local anaesthetic reduces acute pain and enables reduced opioid consumption, resulting in less postoperative sedation and a reduced need for anti-emetic drugs.

CONCLUSION

Wound instillation with local anaesthetic is a simple, effective and inexpensive means of providing good analgesia for patients following the MRM procedure without any major side-effects.

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