

Original Research Article

Post mastectomy pain control using bupivacaine installation via wound drains

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ABSTRACT

Background: This study is a controlled prospective randomized blinded study. Our aim was to evaluate the effect of wound installation with bupivacaine through surgical drains to control postoperative pain and decrease the use of systemic analgesics after mastectomy.

Methods: This study was conducted on 168 female patients candidates for modified radical mastectomy admitted to the Surgical Oncology Unit, Faculty of Medicine, University of Alexandria. Patients were randomly divided into two equal groups. Group A Bupivacaine was installed through axillary and chest wall drains by the end of surgery. While, group B was installed by equal amount of normal saline as placebo. We assessed the visual analogue score (VAS), need and timing for systemic analgesics during the first 24 hours.

Results: The mean values for VAS were always lower in group A. This was reflected on the timing and need for additional analgesia.

Conclusions: We concluded from this study that using bupivacaine instillation through surgical drains is an effective and easy method to control post mastectomy pain and enhance patients' recovery in the first 24 hours postoperative.

Keywords: Breast, Bupivacaine, Mastectomy, Postoperative analgesia, Wound instillation

INTRODUCTION

Surgical management of breast cancer has changed in the past few decades. However, mastectomy is still one of the commonest surgeries performed all over the world.¹ Post-mastectomy pain is a major concern that may add to the patient discomfort, delay mobilization and might prolong hospital stay as well.² Using painkillers as opiates for controlling such pain results in subsequent nausea and vomiting.³

Optimal control for acute postoperative pain is believed to be a crucial step that affects the development of chronic pain.⁴ Pain following mastectomy operations is

nociceptive that results from multiple causes. Neuropathic pain may be neuroma pain, intercosto-brachial neuralgia, phantom breast or from injury to small cutaneous or motor nerves.⁵

A variety of local and regional techniques are used to decrease the need for general anesthesia and post-operative opioids with their subsequent complications. These techniques include local anesthetic infiltration, paravertebral block, epidural anesthesia, intercostal block, and brachial plexus block.⁶⁻¹⁰

Wound instillation rather than infiltration is not a new technique. It was previously described following

surgeries like abdominal hysterectomy and laparoscopic cholecystectomy. The technique is simple and needs no training or special kits without prolongation of the operative time.^{11,12}

In this study, we tried to investigate the role of bupivacaine instillation via the drains in controlling post-mastectomy pain during the first 24 hours to modify our institution practice in multimodal analgesia offered to mastectomy patients.

This study aimed at evaluating the role of post mastectomy bupivacaine instillation via surgical drains in controlling early postoperative pain in comparison to placebo (normal saline).

METHODS

The study was conducted on 168 female patients with operable breast cancer, admitted to the Surgical Oncology Unit, Alexandria Main University Hospital in the age group from 30 to 65 years old. The study extended from January 2016 till November 2018.

The study was conducted in accordance with Helsinki Declaration.¹³ It was approved by the ethical committee in our institution and coded 0104285. All patients signed an informed written consent explaining the nature and aim of the study before being enrolled in the study.

This was a prospective, randomized, double blinded comparative design. One to one using the closed envelope technique. Each group consisted of 84 patients. Group A was the study group and group B was the control (placebo) group.

Both the patients and healthcare givers (surgeons and nurses) were not aware about the patient distribution among which study group. The drug used was prepared by a physician (who did not participate in the study) in pre-coded syringes.

Inclusion criteria

Female patients with operable breast cancer candidates for modified radical mastectomy (MRM) with American Society of Anesthesiologists physical status (ASA) I and II.

Exclusion criteria

- Male patients,
- Bilateral breast cancer,
- Patients with a history of a long duration of NSAID intake, other painkillers, or drug abuse,
- Patients with chest wall pain like Tietz syndrome, history of angina pectoris or recent HZV infection,
- Patients with known psychological or mental problems,

- Patients who were not exposed to axillary dissection,
- Patients with breast cup size less than cup C.

The induction protocol of anesthesia was the same for all patients and by the same anesthesiologist. Patients were submitted to standard modified radical mastectomy (MRM) with level I and level II axillary lymph nodes dissection (ALND). All surgeries were performed by surgical teams from the submitting authors. Two drains were inserted; one beneath the skin flap at anterior chest wall and the other in the axilla. After performing surgery and wound closure, patients were subjected to one of the following procedures according to their enrollment group.

Group A: The wound was installed by 40ml of 0.25% bupivacaine through axillary and chest wall drains (20 ml in each drain). Then, the drains were clamped for 20 minutes.

Group B: The wound was installed by 40ml of 0.9% normal saline through axillary and chest wall drains (20 ml in each drain). Then, the drains were clamped for 20 minutes (Placebo group).

The pain was assessed using visual analogue scale (VAS) score; VAS was recorded two and four hours postoperatively then every four hours thereafter up to 24hours postoperative. VAS represents a 10cm line where score 0 defines no pain and score 10 represents the worst imaginable pain. All patients were taught how to use VAS. Paracetamol 1 gm and ketorolac 30mg were given when VAS \geq 4 or whenever the patient required.

Both groups were compared as regard time for the first demand of analgesia and the number of demands of analgesics during the first 24 hours.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). The Kolmogorov-Smirnov, Shapiro and D'agstino tests were used to verify the normality of distribution of variables, Comparisons between groups for categorical variables were assessed using Chi-square test (Fisher or Monte Carlo). Student t-test was used to compare two groups for normally distributed quantitative variables. Mann Whitney test was used to compare between two groups for abnormally distributed quantitative variables. Significance of the obtained results was judged at the 5% level.

RESULTS

Patients' characteristics

Both groups were checked for any significant statistical difference as regard the age, body mass index (BMI) and

breast cup size. Other parameters as American Society of Anesthesiologists physical status (ASA) and duration of surgery showed no significant difference either (Table 1).

Table 1: Comparison between the two studied groups according to patients' characteristics.

Characteristics	Group A (n=84)	Group B (n=84)	P
Age (years)	54.1±10.6	52.5±9.2	0.293
BMI (kg/m ²)	24.15±12.4	25.22±4.42	0.457
Breast cup size			
C	29 (34.5%)	25 (29.8%)	0.423
D	42 (50%)	50 (59.5%)	
>D	13 (15.5%)	9 (10.7%)	
ASA I	28 (33.3%)	40 (47.6%)	0.059
ASA II	56 (66.7%)	44 (52.4%)	
Duration of surgery (min)	90±17	87±9	0.155

ASA: American Society of Anesthesiologists physical status
 BMI: body mass index. Quantitative data was expressed in mean ±SD, and compared using Student t-test, Qualitative data was expressed in number and percentage and compared using Chi square or (Fisher exact test), *statistically significant at p≤0.05.

Postoperative pain assessment

Assessment 2 hours postoperative: VAS in group A was less than group B with statistical significant difference. This was reflected also on the number of patients who were in need for additional analgesia at or before 2 hours postoperatively (Table 2).

Table 2: Comparison between the two studied groups according to VAS and need for analgesia 2 hours postoperatively.

	Group A (n=84)	Group B (n=84)	P
VAS (pain) [after 2 hours]			
Mean ± SD.	2±0.88	4.1±1.1	<0.001*
Median (min.-max.)	2 (1-5)	4 (3-6)	
Number of patients required analgesia	4 (4.8%)	32 (38.1%)	<0.001*

VAS: Visual analogue score. Quantitative data was expressed in median (min-max) and compared using Mann Whitney test, *statistically significant at p≤0.05.

VAS results assessment thereafter: As shown in both Figure 1 and Table 3, VAS results were always significantly higher in group B than in group A.

Demands for analgesia (yes/no): Forty-four patients in group A didn't require additional analgesia at all during the first 24 hours postoperatively, while the other forty patients who received additional analgesia, their first

demand time ranged between two and twenty hours postoperatively with a mean value of 11.40±6.41 hours.

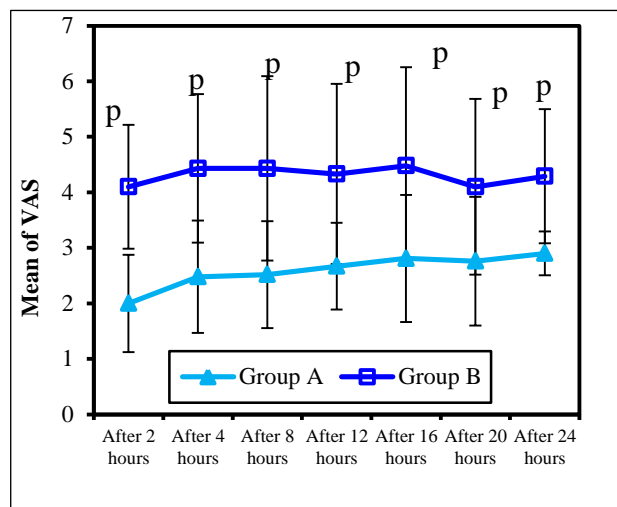


Figure 1: VAS difference among both groups in the first 24 hours postoperatively.

Table 3: Comparison between the two studied groups according to VAS results 4 hours postoperatively and after.

VAS (pain)	Group A (n=84)	Group B (n=84)	P value
After 4 hours			
Mean±SD	2.5±1	4.4±1.3	<0.001*
Median (min.-max.)	2 (1-5)	5 (2-7)	
After 8 hours			
Mean±SD	2.5±1	4.4±1.7	<0.001*
Median (min.-max.)	2 (1-5)	5 (2-7)	
After 12 hours			
Mean±SD	2.7±0.8	4.3±1.6	<0.001*
Median (min.-max.)	3 (1-5)	4 (2-7)	
After 16 hours			
Mean±SD	2.8±1.1	4.5±1.8	<0.001*
Median (min.-max.)	3 (1-5)	5 (2-7)	
After 20 hours			
Mean±SD	2.8±1.2	4.1±1.6	<0.001*
Median (min.-max.)	2 (2-6)	3 (2-7)	
After 24 hours			
Mean±SD	2.2±0.4	4.3±1.2	<0.001*
Median (min.-max.)	2 (2-3)	5 (2-6)	
Average			
Mean±SD	2.5±0.5	4.3±0.3	<0.001*
Median (min.-max.)	2.4 (1.9-4)	4.3 (3.7-4.9)	

All group B patients received additional analgesia, their first demand time ranged between two and eight hours

postoperatively with a mean value of 3.52±1.75 hours (Table 4).

Demands for analgesia (frequency): In group A thirty-two cases received analgesia only once. Only four cases

demanded analgesia twice and another four demanded three times. For group B forty cases received analgesia three times and forty-four cases received analgesia four times during the first 24 hours. These results were significantly different among both studied groups (Table 5).

Table 4: Comparison between the two studied groups according to demand of analgesia.

Demand for analgesia	Group A (n=84)	Group B (n=84)	P value
Yes	44 (52.4%)	0 (0.0%)	<0.001*
No	40 (47.6%)	84 (100%)	
Time to first demand of analgesia, Mean±SD	11.4±6.4	3.5±1.8	
Median (min.-max.)	12 (2-20)	4 (2-8)	<0.001*

Quantitative data was expressed in Median (Min.-Max.) and compared using Mann Whitney test, Qualitative data was expressed in number and percentage and compared using Chi square or (Fisher Exact test), *statistically significant at p≤0.05.

Table 5: Comparison between the two studied groups according to number of demands of analgesia during the first 24 hours.

	Group A (n=84)	Group B (n=84)	P
None	44 (52.4%)	0 (0%)	<0.001*
Once	32 (38.1%)	0 (0%)	
Twice	4 (4.8%)	0 (0%)	
3 times	4 (4.8%)	40 (47.6%)	
4 times	0 (0%)	44 (52.4%)	
Total number of demands	0 (0-3)	4 (3-4)	<0.001*

Quantitative data was expressed in Median (Min.-Max.) and compared using Mann Whitney test, Qualitative data was expressed in number and percentage and compared using Chi square or (Monte carlo), *Statistically significant at p≤0.05.

DISCUSSION

The advances in breast cancer surgery in the last few decades were not associated with similar advancement in the acute or the chronic pain control.²⁻³

In this prospective double blinded randomized controlled study, using Bupivacaine instillation through wound drains showed significant decrease in VAS in the first 24 hours postoperatively. Subsequently, the number and amount of analgesia was significantly reduced.

In this study, the number of included patients was relatively larger than most of the studies in the literature. Up to our knowledge, only the study conducted by Albi-Feldzer recruited a larger number of patients (119 patients).¹⁴ However, the fore-mentioned study included different types of surgeries performed, namely breast conservative surgery (BCS) with ALND and MRM +/- ALND. Many other studies included both MRM and BCS as well.¹⁴⁻¹⁶ We had different inclusion criteria in our study. The reason for not including BCS in our study and exclusion of any patient without ALND is that we believe

that the intensity and demands for analgesics are related to extent of surgery. This extent is related to both extent of flap dissection and the extent of ALND. Thus, all our patients were having breast cup size C or larger, all were subjected to total mastectomy and lastly, all had ALND (at least 10 lymph nodes were dissected in every studied patient). MRM and ALND were selection criteria in some other studies with smaller sample size.¹⁷⁻²⁰

Johansson et al, showed no significant effect of local wound infiltration by local analgesic on postoperative pain control. These results are totally contradicting ours.^{21,22} We attributed this discrepancy to the smaller sample size in the mentioned studies in addition to the different studied population. Both studies included patients with partial mastectomy-not MRM-with/without ALND.

Although Mohamed et al, study had a different aim than ours (to study the effect of adding clonidine to bupivacaine), their results showed a superior effect in all studied groups (including bupivacaine alone) when compared to the control group.²⁰

The role of preemptive analgesia is rising with its major contribution in controlling both acute and chronic postoperative pain.^{16,17} However, in the current study, we did not use bupivacaine in the preemptive settings for 2 reasons. First, preemptive analgesia necessitates a delay of skin incision till bupivacaine causes central sensitization (5 minutes at least).^{23,24}

Second, the amount of drug infiltrated is diluted among larger tissue volume and it is very difficult to estimate the volume of drug in the excised and in the remaining tissues. So, we speculate that we cannot have dose adjustment to control the results if bupivacaine (or whatever drug) is used to achieve preemptive analgesia. This assumption complies with the results of Rica et al who studied the role of ropivacaine both as a preemptive and postoperative analgesic.¹⁸ Though, Zielinski et al

showed superior results to use bupivacaine in the preemptive settings.¹⁹ The authors of the current article believe preemptive nerve blockade is the best way to achieve the goal of preemptive analgesia and not the local wound instillation or infiltration.^{4,25,26} Yet, these techniques are more complicated and require further training with higher costs for implementation as well as a higher rate of significant complications (e.g. pneumothorax).

One more question is to be addressed. Is there a difference between wound instillation and wound infiltration? Another study might be needed to answer this. However, when reviewing the literature together with our findings in this study, we can conclude the following. Wound instillation is an easy technique, adding a very short time to the operative procedure. The distribution of the used drug is more homogenous throughout the dissected surface area and not limited to the incision line. Moreover, there is no skin bruising (might be troublesome to some patients) or localized tenderness reported to associate wound infiltration. This is apart from avoiding the claimed role of needle track seedlings and cutaneous spread of malignancy.²⁷⁻²⁹

In this study, whenever the patients required analgesics or experienced VAS >4, they received traditional analgesics (Paracetamol 1gm and ketorolac 30mg) rather than repeating wound instillation by bupivacaine through the drains as in pain pumps. The data upon the role of post-operative patient controlled analgesia (PCA) via pain pumps needs further verification. Also, the incidence of infection is to be monitored well. Moreover, these pain pumps were not studied well in post-mastectomy conditions.^{30,31}

This study was not without limitations. Effect of this technique on the development of chronic pain was not studied.

CONCLUSION

Wound installation with bupivacaine through surgical drains after modified radical mastectomy offers the following advantages over the ordinary control of postoperative pain. First, it helps in delaying the time for the first demand of analgesia. Also, it decreases the total amount of analgesia required by the patient during the first 24 hours postoperatively. Moreover, it improves the patient performance and enhances rapid recovery postoperatively without the need for sophisticated or costly techniques and/or drugs. Thus, from the previous conclusions, we recommend using the studied technique routinely in mastectomy surgery.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee of Alexandria Faculty of Medicine, Alexandria, Egypt

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