Comparison of Single Versus Two Drains Placement on Occurrence of Seroma Formation and Flap Related Complications after Modified Radical Mastectomy

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ABSTRACT

Objective — *To compare the frequency of seroma formation and flap related complications following placement of single versus two drains after modified radical mastectomy (MRM).*

Study design — *A comparative cross sectional study.*

Place & Duration of study — *Department of General Surgery, Jinnah Postgraduate Medical Centre (JPMC) Karachi, from January-2024 to August-2024.*

Methods — *All patients who underwent MRM were included. Patients were divided into two equal groups. In group A, single drain was placed under the flap after MRM and in group B two drains were kept, one in axilla and the other under the flap. The frequency of seroma formation was assessed. In addition, duration of drain placement, occurrence of hematoma and flap necrosis were also noted. Chi square test and Student t test were applied to categorical and continuous data to find out statistical significance. A p-value <0.05 was considered as significant.*

Results — *A total of 132 patients were divided into two equal groups of 66 each. The age and comorbid condition were comparable between the groups. Seroma formation occurred in 12 (18.2%) patients in group B and 8 (12.1%) patients in group A (p=0.33). The duration of drains was comparable with a mean time of 7.8±2.5 days in group A and 7.3±2.7 days in group B (p=0.27). There was no difference in the occurrence of hematoma, flap necrosis, and blood loss between the groups.*

Conclusion — *There was no difference in frequency of seroma formation between single versus double drains placement. However, the patient comfort and less cost were noted in favor of single drain use after MRM.*

Key words — *Breast cancer, Modified radical mastectomy, Seroma formation, Surgical drains, Flap necrosis.*

INTRODUCTION:

Breast cancer is the fifth leading causes of cancer related deaths worldwide, with approximately 2.3 million cases and 685,000 fatalities reported in 2020.[1] This may rise to 4.4 million by 2070.[2] In 2020, breast cancer accounted for more than 24.5% of all cancer cases and 15.5% of cancer deaths among women globally.[1] The mortality rate of the disease in developed countries has decreased due to the advancements in diagnostic and treatment methods, facilitating early. In contemporary practices, the treatment of breast cancer employs a multimodal strategy that encompasses both local and systemic medical therapies.[3,4]

There is a rising trend towards breast-conserving surgery. Modified radical mastectomy continues to

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be the predominant surgical intervention for breast cancer. Operative morbidity linked to MRM ranges from 30% to 50%. This is related to the extensive raw surface following the procedure.[5] Seroma formation is a prevalent complication following modified radical mastectomy, with a frequency of up to 85%. It primarily impedes wound healing, induces wound dehiscence, facilitates infections, and prolongs the hospital stays.[6]

The use of drains after MRM is a standard approach to remove the seroma. Closed suction drainage in MRM is thought to expedite wound healing and reduce overall consequences.[7] However, there is a concern about the ideal suction pressure, the quantity of fluid in drains, the duration of drainage, and of all the very necessity of drain placement.[8-10] The aim of this study was to compare the frequency of seroma formation and flap related complications in patients after placement of single versus two drains following MRM

METHODS:

Study design, place and duration: This prospective comparative cross sectional study was conducted in General Surgery Unit of Jinnah Postgraduate Medical Center Karachi, from January 2024 to August-2024.

Ethical considerations: The study was approved by the Hospital Institutional Review Board, dated 24-12-2022 by letter no. F.2-81/2022-GENL/320/JPMC. Informed consent was taken from the study participants.

Inclusion criteria and exclusion criteria: Patients with breast cancer who received neoadjuvant chemotherapy as a result of locally advanced disease were included. Pregnant patients, those requiring upfront surgery, having distant metastasis, with history of chronic steroid use, and previous breast or axillary surgery, were excluded.

Sample size estimation: A sample size of 132 was calculated using an online sample size calculator with reference to study by Troost et al.[7]

Study protocol: A non-probability convenience sampling method was used. Patients were divided into two equal groups (66 patients in each arm). In group A single drain was kept under the flap and in group B two drains were used, one in axilla and the other under the flap.

Demographic data collected included age, place of residence, and comorbid conditions. The clinical history of the disease was taken and physical examination performed. The findings of the general investigations and those in relation to tumor work-up, were recorded. All procedures were performed by the same surgical team. The flaps were raised as per standard approach and axillary dissection done with the electric cautery. About 12 to 15 axillary lymph nodes were removed in each patient. Closed suction drains of size 12 Fr were placed based upon patient allocation into group A and B.

Routine postoperative care was provided. On third postoperative day, the wound dressing was removed to check for any flap necrosis, hematoma formation, signs of inflammation and presence of infection. The quantity of seroma was measured for each day and drain was removed when its output reduced to 30 ml per day. Patients were discharged after clinical improvement. The duration of postoperative hospital stay was recorded. All patients were assessed in postoperative period after discharge for any complication in the outpatient department. If there was a clinical suspicion of seroma collection ultrasonography was performed for its confirmation.

Statistical analysis: Data analysis were done using SPSS v23. Categorical variables were compared using Chi-square test between the one drain and two drain groups. Continuous variables like hospital stay and volume of seroms were compared using Student t-test. A p-value <0.05 was considered as significant.

RESULTS:

According to the histopathology classification in group A ductal carcinoma was present in 60 (90.9%) patients while group B 63 (95.5%) patients had same type of tumor. The frequency of lobular carcinoma was 6 (9.1%) in group A and 3 (4.5%) in group B with p=0.30. A Grade II tumor was observed in 34 (51.5%) patients in group A and in 33 (50%) women in group B. Details are given in table I.

Mean age and comorbid were comparable between the groups. Seroma formation occurred in 12 (18.2%) patients in group B and 8 (12.1%) patients in group A (p=0.33). The duration of drains was comparable with a mean time of 7.8±2.5 days in group A and 7.3±2.7 days in group B (p=0.27). There was no difference in the occurrence of hematoma formation, flap necrosis and blood loss between the groups (table II).

DISCUSSION:

This study addressed the issue of seroma formation and its drainage as well as flap related

Table I: Baseline Characteristics

Variables	Group A (n=66)	Group B (n=66)	p-value
Age (days)	48.7±13.2	47.9±12.8	0.72
BMI (Kg/m^2)	23.9±3.7	24.0±3.8	0.87
Diabetes mellitus	14 (21.2%)	12 (18.2%)	0.66
Hypertension	11 (16.7%)	13 (19.7%)	0.65
Smoking status	0 (%)	1 (1.5%)	1.0
Histology Diagnosis			
Ductal carcinoma	60 (90.9%)	63 (95.5%)	0.30
Lobular carcinoma	06 (9.1%)	03 (4.5%)	
Tumor Grade			
I	17 (25.8%)	14 (21.2%)	0.67
II	34 (51.5%)	33 (50%)	
III	15 (22.7%)	19 (28.7%)	

Table II: Study Outcomes

Variables	Group A (n=66)	Group B (n=66)	p-value
Seroma	8 (12.1%)	12 (18.2%)	0.33
Duration of drains in-situ (days SD)	7.3±2.7	7.8±2.5	0.27
Hematoma formation	0 (0.0%)	1 (1.5%)	1.0
Flap necrosis	1 (1.5%)	0 (0.0%)	1.0
Blood loss (ml SD)	93.6±25.9	97.8±23.4	0.33

complications after modified radical mastectomy. Single drain placement efficiently served the purpose. Modified radical mastectomy remains a frequently performed operation for breast cancer.[11] However, the most prevalent complication following mastectomy and axillary procedures is seroma formation, the frequency of which varies between 3% to 85% and is still a challenge.[12] This may impair wound healing and lead to infection and flap necrosis that further complicates postoperative issues including use of adjuvant chemotherapy.[6,13]

The use of drains after MRM has been a point of controversy which is used to prevent seroma collection. The issues regarding the optimal number of drains, the duration for which they should remain in place, and their effect on wound healing and flaps are still debated.[14,15] Previous studies suggested the use of multiple drains that can effectively minimize the occurrence of seroma and related complications.[16] However, this approach has negative consequences as well.[17] Our study also found that use of two drains was not better than a single drain. Other studies also reported the outcomes that are comparable with our study.[18] Hashemi et al reported that the primary factors influencing seroma formation were the type of breast cancer surgery performed and the number of lymph nodes removed during the axillary dissection. In our comparative study both the variables were effectively controlled through appropriate selection criteria.[19]

In present study the seroma formation occurrence was less in single drain group (12.1%) in comparison to two drain group (18.8%). However, this did not achieve statistical significance. Similarly, another study did not report any significant difference in the occurrence of seroma formation in single and two drains groups.[10] Hematoma formation, flap necrosis and blood loss were also comparable between the groups and no significant differences were found in their frequency.

Limitations of the study: This is a single center study though with a good number of patients. However, a randomized controlled trial at multiple locations can provide a more robust data on the subject.

CONCLUSION:

Placement of single drain had similar outcomes in comparison to two drains in terms of seroma formation after MRM in breast cancer patients that included amount of fluid drained, frequency of flap necrosis and hospital stay.

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