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# COMPARISON OF SINGLE VERSUS DOUBLE DRAIN ON POSTOPERATIVE SEROMA FORMATION FOLLOWING MODIFIED RADICAL MASTECTOMY IN A TERTIARY CARE CENTRE IN NORTH INDIA

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**ABSTRACT** **INTRODUCTION:** The usefulness of drains on seroma formation after surgery for breast cancer is the most investigated and most controversial topic of debate for the clinical researchers. Hence this study was conducted to compare single drain and double drain among women with breast cancer who underwent MRM in preventing seroma formation and also to determine the role of other predictors on the same. **MATERIAL AND METHODS:** A hospital based non-randomized controlled trial was conducted among 84 women (42 women each in single drain and double drain group respectively) with breast cancer who underwent modified radical mastectomy in the department of General Surgery, GSVM Medical College, Kanpur from January 2019 to October 2020. All women were followed up after insertion of either single or double drain following MRM for seroma formation.**RESULTS:** The mean age of the study participants was 46.4 (12.1) years. The incidence of seroma formation was found to be 26.2% (95% CI: 17.5%-37.1%). On logistic regression analysis there was a significant association for BMI > 25 kg/m$^2$, hypertension and lymph node status with seroma formation. However, there was no significant association for age, Diabetes Mellitus and number of drains ($p>0.05$) in logistic regression analysis. **CONCLUSION AND RECOMMENDATIONS:** Single or double drain techniques are equally effective in reducing the seroma formation ad associated complications following modified radical mastectomy. Lymph node status, BMI and hypertension were found to influence seroma formation in our study. Further research with a larger sample size at a multicentric level is needed to make our study results robust for better management of these patients.

**KEYWORDS :** Breast Cancer, Modified Radical Mastectomy, Single Drain, Double Drain, Seroma

## INTRODUCTION

Breast cancer is the most common malignancy among women in most developed and developing regions and it is considered as the second commonest cause of cancer-related death in women.[1] Globally, there were 1,960,682 incident breast cancer cases and deaths due to cancer breast was 611,625 in 2017. Not surprisingly, the incidence increased by 123.14% from 1990 to 2017.[2] China accounted for nearly 20% of breast cancer patients among newly diagnosed cases in 2017 followed by the USA and India. In India, one in every 29 females develops breast cancer in their lifetime and it accounts for 25% to 32% of female cancers.[3] Due to improved screening coupled with early diagnosis and treatment in developed countries, there is a substantial reduction in the mortality due to breast cancer in recent years.[4]

The management of patients with breast cancer involves a multi-modal approach which includes local and systemic medical therapy in this modern era and the choice of treatment is based on clinical staging of the disease. The approach of choice for the treatment of breast cancer is based on its clinical staging. For patients without metastasis, surgery is the primary mode of management and the selection of surgical procedure depends upon the patient characteristics, clinical and histopathological characteristics along with patient preference.[5-7] Even though radical mastectomy developed by Halsted WS[8] is the primary modality of treatment, modified radical mastectomy (MRM) is the most commonly practiced approach because it not only has long-term survival probability but also it results in lesser local recurrence of the disease.[9,10]

Hematoma, surgical wound infection and seroma formation are the most common surgical complications following modified radical mastectomy.[11,12] Seroma is the serious of all and it can be attributed to the surgical wound drainage.[13] Seroma is a collection of serous fluid in the dead space of post-mastectomy skin flaps and axilla after MRM. Incidence of seroma formation after breast surgery varies between 2.5% and 51%.[14-16] Seroma accumulation elevate the flaps from the chest wall and axilla, and hampers their adherence to the tissue bed leading to significantt morbidity such as delayed wound healing, wound dehiscence, and wound infection leading to delayed initiation of adjuvant therapy. Seroma formation, in contrast, is found to be higher among the patients who underwent MRM when compared to those patients who underwent breast conservation surgery.[17] Literature shoes that sentinel lymph node biopsy and scalpel dissection results in lesser incidence of seroma formation compared to conventional axillary dissection and use of electrocautery for dissection.[18,19]

Similarly, the use of drains after surgery for breast cancer is the most investigated and most controversial subject of discussion on seroma formation in recent years. The influence of negative pressure causing skin flap opposition to the chest wall facilitates wound healing thereby reducing the incidence of wound infection, wound dehiscence or flap necrosis and eventually less seroma formation.[20] However, various studies have resulted in conflicting results.[21,22] Hence this study was conducted to compare single drain and two drains in the prevention of seroma formation following modified radical mastectomy in a tertiary care centre.

## MATERIAL AND METHODS

A hospital based non-randomized controlled trial was conducted among women with breast cancer who underwent modified radical mastectomy in the department of General Surgery, GSVM Medical College, Kanpur from January 2019 to October 2020. All women who were in early stage of breast cancer and locally advanced breast cancer among whom pre-operative neo-adjuvant chemo therapy was not given and who were operable were included in the study. Women with distant metastasis, synchronous or metachronous contra lateral breast cancers, involvement of chest wall by tumor (T4), previous history of breast cancer, who had undergone radiotherapy/chemotherapy were excluded from the study. Similarly women with any previous breast or axillary surgery, use of anticoagulant drugs and who could not be followed up for one month were also excluded from the study. The study was conducted after approval from the institute ethics committee and informed consent from the patients.

A total of 84 women with breast cancer who underwent MRM were included in the study after examination for inclusion and exclusion criteria. The patients were then randomly allotted equally to either one drain or two drains in the operating room based on the table of random numbers.

After modified radical mastectomy (MRM), patients were divided in to two groups on the basis of number of drain placement as follows: **Group A** (42 patients with single drain placed in axillary area) and **Group B** (42 patients with double drain placed, one in pectoral (under skin flap over pectoral muscle) and one in axillary area).

## SURGERY AND DRAIN PLACEMENT

All surgeries were performed by the same surgeon. Mastectomies were performed with diathermy and all tissues found inferior to the axcillary vein (between the anterior border of latissimus dorsi and the medial border of pectoralis minor up to the apex of the axilla) were removed for axillary lymphadenopathy. Preservation of thoracodosal nerve, long thoracic nerve ad intercostobrachial nerve was done after retracting pectoralis minor.

After completion of surgery, normal sterile dressing was applied after placement of one drain or two drains based on the random allocation to either Group A or Group B. Breast tissue was subsequently sent for histopathological examination.

## FOLLOW-UP

In the early post-op period, patients were trained how to empty the drains, measure and record the volume of the fluid and were advised to removing drains when there discharge was below 30 mL in 24 hours. Patients were discharged after removal of drains, depending on general health condition (fever, nausea, vomiting, wound complications, physical activity). After surgery, patients were followed up for one month. Patients were also followed up on the 2nd and 10th day. After removing the last drain, all patients were seen weekly for one month, and on detection of any seroma formation, it was aspirated and the wound was dressed with the compressive bandages.

## STATISTICAL ANALYSIS

Data was analysed using SPSS v21 for Windows. Categorical variables are presented as frequency and percentages and continuous variables are presented as mean (SD) or median (IQR) depending on the type of distribution. The incidence of seroma formation and flap necrosis are presented as percentages with 95% confidence interval (95% CI). Chi square test and independent samples t test was used to compare the baseline characteristics and volume of drain discharge between the groups. Mann-Whitney U test was used to determine the association between the days for drain removal between the groups. Univariate and multivariable logistic regression analysis was used to determine the association between the factors associated with seroma formation. A p value of less than 0.05 was considered statistically significant.

## RESULTS AND OBSERVATIONS

A total of 84 women who underwent modified radical mastectomy was included in the study with 42 patients in Group A (One drain) and 42 patients in Group B (Two drains). The mean age of the study participants was 46.4 (12.1) years. The median age was 45.0 (38.1-55.0) years with a minimum of 20 years and a maximum of 78 years. **Table 1** shows that the participants were comparable on their baseline characteristics between the intervention groups like age, BMI status, stage of cancer, lymph node status, diabetes mellitus and hypertension. The mean volume of drain discharge and the median days for removal of drain was more and longer for patients with two drains but it was not found to be statistically significant between the groups (p>0.05). **(Table 2)**

The incidence of seroma formation was found to be 26.2% (95% CI: 17.5%-37.1%) with the patients in Group A and Group B reporting an incidence of 28.6% and 23.8% respectively. The incidence of flap necrosis was found to be 10.7% (95% CI: 5.3%-19.8%) with 9.5% and 11.9% in Group A and Group B respectively. **(Table 3)**

**Table 4** shows the univariate and multivariable logistic regression analysis for the factors associated with seroma formation among the women with breast cancer who underwent MRM. It was found that BMI>25 kg/m$^2$, hypertension and lymph node involvement were found to have significantly higher incidence of seroma formation on unadjusted analysis. Even after adjusting for confounders, BMI>25 kg/m$^2$ (Adj. OR: 5.04 (95% CI: 1.15-22.08); p=0.032), hypertension (Adj. OR: 8.72 (95% CI: 2.12-35.82); p=0.003) and lymph node involvement (Adj. OR: 5.22 (95% CI: 1.41-19.33); p=0.013) were significantly independently associated with seroma formation. There was no significant association between the number of drains and seroma formation both in unadjusted ad adjusted analysis. Similarly, there was no significant association for age and diabetes mellitus with seroma formation.

**Tables and Figures:**

**Table 1. Baseline characteristics of the study participants (N=84)**

| Characteristics | Intervention group | | p value |
|---|---|---|---|
| | Group A (N=42) n (%) | Group b (N=42) n (%) | |
| **Age in years** | | | |
| ≤50 | 26 (61.9) | 30 (71.4) | 0.355 |
| >50 | 16 (38.1) | 12 (28.6) | |
| **BMI (kg/m$^2$)** | | | |
| ≤25 | 33 (78.6) | 37 (88.1) | 0.242 |
| >25 | 9 (21.4) | 5 (11.9) | |
| **Stage of cancer** | | | |
| I & II | 31(73.8%) | 34(80.95%) | 0.217 |
| III & IV | 11(26.19%) | 8(19.04%) | |
| **Lymphadenopathy** | | | |
| Present | 20 (47.6) | 23 (54.8) | 0.513 |
| Absent | 22 (52.4) | 19 (45.2) | |
| **Hypertension** | | | |
| Present | 9 (21.4) | 10 (23.8) | 0.794 |
| Absent | 33 (78.6) | 32 (76.2) | |
| **Diabetes Mellitus** | | | |
| Present | 2 (4.8) | 5 (11.9) | 0.236 |
| Absent | 40 (95.2) | 37 (88.1) | |

**Group A: Single drain Group B: Double drains**

**Table 2. Post-operative characteristics between the two groups among the study participants (N=84)**

| Characteristics | Intervention group | | p value |
|---|---|---|---|
| | Group A (N=42) | Group b (N=42) | |
| Volume of drain discharge (ml) **Mean (SD)** | 263.8 (65.8) | 284.9 (76.3) | 0.231 |
| Drain removal (POD in days) **Median (IQR)** | 7 (7-8) | 7 (7-9) | 0.175 |

**Group A: Single drain Group B: Double drains**

**Table 3. Incidence of seroma formation and flap necrosis among the study participants (N=84)**

| Complications | Frequency (n) | Percentage (95% CI) |
|---|---|---|
| Seroma formation | 22 | 26.2 (17.5-37.1) |
| Flap necrosis | 9 | 10.7 (5.3-19.8) |

**Table 4. Univariate and multivariable logistic regression on factors associated with seroma formation among patients undergoing modified radical mastectomy (N=84)**

| | Unadj. OR (95% CI) | p value | Adj. OR (95% CI) | p value* |
|---|---|---|---|---|
| **Number of drains** | | | | |
| One | Reference | | Reference | |
| Two | 0.78 (0.29-2.07) | 0.620 | 0.64 (0.19-2.18) | 0.479 |
| **Age in years** | 0.99 (0.95-1.03) | 0.675 | 0.96 (0.91-1.01) | 0.117 |
| **BMI(kg/m$^2$)** | | | | |
| >25 | 5.33 (1.59-17.88) | **0.007** | 5.04 (1.1522.08) | **0.032** |
| ≤25 | Reference | | Reference | |
| **Diabetes mellitus** | | | | |
| Absent | Reference | | Reference | |
| Present | 2.29 (0.47-11.16) | 0.305 | 1.45 (0.2010.31) | 0.713 |
| **Hypertension** | | | | |
| Absent | Reference | | Reference | |
| Present | 6.75 (2.21-20.64) | **0.001** | 8.72 (2.1235.82) | **0.003** |
| **Lymphadenopathy** | | | | |
| Present | 3.46 (1.19-10.02) | **0.022** | 5.22 (1.4119.33) | **0.013** |
| Absent | Reference | | Reference | |

***Number of drains, age, BMI, Diabetes Mellitus, Hypertension and lymph node status were included in the model**

**Fig. 1: Image showing double drain placement after MRM**

**Fig. 2: Image showing single drain placement after MRM**

## DISCUSSION

In this era of medical advancements, the usefulness of drains on seroma formation after surgery for breast cancer is the most investigated and most controversial topic of debate for the clinical researchers. Hence it becomes imperative to study the importance of drains in preventing seroma formation along with other factors that might contribute to seroma formation which in turn might help in devising strategies for probable interventions thereby reducing the morbidity due to seroma formation as a complication following surgery.

Based on the available literature, it has been found that the incidence of seroma formation after breast surgery varies between 2.5% and 51%.[14-16] The incidence of seroma formation in our study was found to be 26.2% (95% CI: 17.5%-37.1%). A study by Pan XF et al[23] had reported a similar incidence as our study (22.55%) and a study by Gonzalez EA et al[17] had reported the incidence of seroma formation among MRM patients to be 19.9%. Similarly a study by Unalp HR et al[24] had reported an incidence of 14.28%. However, studies by Hashemi E et al[19] had reported a higher incidence of 35%. The range of fluctuation could be explained by the probability that the definition of seroma and diagnostic tools used might be different across different study populations. Moreover, it is also plausible to argue that the variation could be also due to the varying skills of the surgeons in minimizing the dead space and the duration of surgery.

The mean age of the patients in our study was 46.4 (12.1) years which is in line with the study conducted by Douay N et al[25] but differs to those reported by Banerjee et al[26] where the median age of the patients was 62.38 years. This difference might be due to different population types, with developed nations tend to have higher life expectancy when compared to developing countries like India. on regression analysis, there was no significant association for age with seroma formation. Our study observations are supported by studies by Kuroi K et al[27] and Hashemi E et al[19] where they have reported that the evidences are inconclusive for association of increasing age with seroma formation. On the contrary, Menton M. et al[28] have concluded that the seroma formation increases with increasing age. The absence of significance in our study might be explained by the lesser sample size which could have reduced the power of the results.

One of the important predictors of seroma formation in our study was higher the BMI (>25 kg/m$^2$), higher the chances of seroma formation and it was found to be statistically significant. The underlying mechanisms are not yet fully understood, but we suppose that in obese people the area of surgical incision is larger, which implies that a higher number of lymphatic vessels may be damaged. Even though some studies[13,17] failed to show any association between BMI and seroma formation, studies by Zieliński J[29] and Theunissen D et al[30] observed an association between BMI and seroma formation. Hence from the above observation it could be ascertained that preventive measure aimed at reduction of obesity might help a long way in prevention of complications among breast cancer patients.

In accordance with other research, the effect of diabetes mellitus on the development of seroma was not found to be statistically significant in our study also. However there was a significant association between seroma formation and hypertension status of the patient. It is a well know phenomenon that seromas are caused by inflammatory exudation or by lymphogenous exudation and hypertension as such could result in exudation from the raw surface area of the wound, to some degree and hence this could explain the seroma formation.[31,32] The study results by Douay et al[25], Kumar et al[33] and Khan H et al[34] well supports our study findings. However, in the view of smaller sample size, it is always advisable to triangulate with the clinical significance. There was a significant association between the lymph node status and the seroma formation in our study. However, some studies failed to arrive at any association between the two.[13,19,29]

One of the important findings of our study is that our study failed to establish association between number of drains and seroma formation. The earlier study by Taylor et al. [16] on the results of surgery before and after implementing no drain policy found that there was no significant difference in the seroma formation.[35] Similarly, Saratzis et al compared the seroma formation between one, two and three drains and reported that there was no significant difference in seroma formation between any of the groups.[36] Studies by Chintamani et al[37] and Kapur N et al[38] also had supported our study findings as do many other study results. A randomized controlled trial by Guneri et al[39] had reported that seroma formation was significantly higher among the single drain group, which contradicts our study findings. Hence it could be well argued that there is no need for double drain for the patients in terms of seroma formation but under strict clinical significance, owing to the lesser sample size of our study.

One of the important limitations of our study is the smaller sample size, which makes it difficult to be generalizable to the larger setting. In addition to it, the sample was limited to a single study setting which also could affect the patient characteristics. It could be concluded that the single or double drain techniques are equally effective in reducing the seroma formation ad associated complications following modified radical mastectomy. Lymph node status, BMI and hypertension were found to influence seroma formation in our study. Further research with a larger sample size at a multicentric level is needed to make our study results robust which might therefore help in the better management of the patients with breast cancer.

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