



DOI: 10.32768/abc.202291104-108



Single Versus Double Drainage Insertion After Total Mastectomy and Axillary Dissection

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ARTICLE INFO

ABSTRACT

Received:

20 October 2021

Revised:

07 November 2021

Accepted:

10 November 2021

Keywords:Breast cancer,
mastectomy,
axillary dissection,
seroma

Background: Breast cancer is the commonest malignancy in women of Myanmar. Mastectomy is one of the main surgical treatments of breast cancer. Postoperative seroma is a common complication after mastectomy, which increases chances of infection, delays wound healing, causes flap necrosis, persistent pain, and dehiscence of the wound and thus increases the convalescence period. This study aimed to compare the seroma formation between single drainage and double drainage after total mastectomy and axillary dissection for breast cancer patients.

Methods: One-year hospital based comparative study was conducted at general surgical wards of Yangon General Hospital where 150 patients were included. Patients were randomized into two groups: 75 patients were with single drain into axilla and another 75 patients were with double drains (one into axilla and one into mastectomy bed). Drainage volume was recorded daily and summed up into total amount. The drain was removed when output was <30ml in 24 hours for two consecutive days. Follow-up visits were made at second, third and fourth weeks to check for seroma.

Results: Mean age was 48.66 years in the single drain group and 51.22 years in the double drain group. Mean Body Mass Index (BMI) were 28.20kg/m² in the first group and 28.79kg/m² in the second. Statistically significant differences were not seen between the groups regarding total drain amount (315.13ml and 325.47ml, P=0.38). Duration of drains in the single group remained significantly shorter than in the double group (5.78 days and 6.38 days, P=0.002). Seroma during immediate postoperative period was seen in 29.3% and 36%, respectively (P=0.38). For one month follow-up, seroma was developed in 3 patients (4%) from each group. Statistically significant differences were not observed regarding the number of aspiration and the amount of aspiration between the two groups (P>0.05).

Conclusion: Both single and double drain methods had almost similar rates of seroma formation after total mastectomy and axillary dissection. But single drain is recommended to reduce patients' discomfort with less morbidity and cost.

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Breast cancer is the most common cause of death in middle-aged women in western countries.¹ It is also the commonest malignancy in women of Myanmar and one of the leading causes of death among cancer patients in this country. According to the cancer registry (Yangon General Hospital), breast cancer



accounts for 17 to 19% of all types of cancers.² Once breast cancer is diagnosed, the type of therapy offered to patient is determined based on the stage of the disease. In the absence of metastasis, surgery is the main type of loco-regional control for breast cancer.³

In the majority of women with early breast cancer, excision of the primary tumor (by mastectomy or wide local excision with axillary lymphadenectomy) is a common surgical treatment. This facilitates tumor clearance and staging of the disease.¹⁸ Postoperative seroma is a common complication after mastectomy. Seroma formation has been troubling patients and surgeons for over a century since the first mastectomy was performed by Halsted in 1882.⁴

Seroma is defined as a subcutaneous collection of serous fluid post-mastectomy under the skin flap, in the dead space of the axilla or the breast following breast-conserving surgery and several surgeons consider it an 'unavoidable nuisance'.⁵ Seroma is an uncomfortable inconvenience, but for a few, it can result in pain, skin necrosis, wound dehiscence, or infection, all of which can impair long-term cosmesis. Seroma also has the potential to delay wound healing with a knock-on delay to the commencement of crucial adjuvant therapies with the potential to impact upon future disease course. Due to these risks, it has become routine practice to send patients home with surgical drains in place to manage this problem while appropriate preoperative counselling and postoperative education are provided.^{16,17}

Various techniques have been used to reduce seroma formation, including external compression, arm immobilization, flap-taking sutures, fibrin sealant and the avoidance of electrocautery. These methods can reduce the incidence of seroma, but none has abolished the problem completely. Not surprisingly, the routine use of drains has remained standard practice - despite well-known disadvantages such as prolonged hospital stay and more pain after surgery.¹⁹

There are multiple options for drainage placement following MRM due to the great volume of surgically created free space. Placement in the vector of the gravitational gradient gives a greater performance when compared to the placement of either two or three separate drains. Therefore, a pectoro-axillary drainage system is superior to placement in other vectors.¹⁴ Almond *et al.* demonstrated that drain use is associated with higher cost and so by reducing its use, there would be an anticipated financial benefit.¹⁵ Since mastectomy is still a common procedure, and the drain usage is debatable mainly due to various recommendations, this study was carried out to compare single drain method with double drain in preventing seroma and wound complications.

METHODS

This is a randomized comparative study carried out in Yangon General Hospital from 1 January 2019 to 31 December 2019. One hundred and fifty patients with breast cancer undergoing total mastectomy and level 2 axillary dissections were included. Seventy-five patients were assigned to the single drain group and 75 patients had double drains.

All the breast cancer cases (TNM Stage I and Stage II) undergoing total mastectomy and level 2 axillary dissections were included. Breast conserving surgery and sentinel lymph node biopsy can be rarely performed in Myanmar because of limited resources. Also, patients with recurrent breast cancer, bilateral breast cancer, neo-adjuvant chemotherapy or radiotherapy, and body mass index (BMI)>40 were excluded.

All of the patients were informed of the procedure and consents were taken. Randomization in 1:1 ratio was according to a computer-based system. Patients received single drain or double drain according to the randomization table. Total mastectomy and level 2 axillary dissections were carried out in all cases. There were five consultants performing the mastectomy and axillary dissection and the technique was standardized. All the five surgeons were trained in Yangon General Hospital. The upper and lower skin flaps were raised with approximately 1cm flap thickness, keeping the plane of dissection between subcutaneous fat and breast tissue. Electro-cautery was used for dissection.

In the single drainage group, a low vacuum drain was inserted into axilla. The wound was closed back in two layers with 3/0 vicryl and skin staplers. In the double drainage group, one low vacuum drain was inserted into axilla and the other was inserted into mastectomy bed. The wound was closed back in two layers with 3/0 vicryl and skin staplers.

Early shoulder mobilization was started in post-operative day 1. Axillary padding was applied for 48h in both groups during postoperative period. Drainage volume was recorded daily. The drain was removed when the output was less than 30mL in 24h for two consecutive days. Skin staplers were removed on post-operative day 7. The patients were discharged in post-operative day 3 after dressing change. Post-operative complications were recorded and treated. The patients were seen in the follow-up in the second week, third week, fourth week and sixth week, by the authors, with the help of junior surgeons. In the follow-up visits, seroma was detected clinically by history and examination. The patients were asked whether they had pain or swelling at chest wall and axilla. In clinical examination, chest wall and axilla were examined for swelling and fluctuation test. Seroma was graded



according to the Common Terminology Criteria for Adverse Events v3.0 as:

Grade 1: Asymptomatic.

Grade 2: Symptomatic (medical intervention or simple aspiration indicated).

Grade 3: Symptomatic (interventional radiology or operative intervention indicated).²⁰

The primary outcome in this study was the incidence of grade 2 and grade 3 seroma.²¹

In doubtful cases, ultrasound examination and diagnostic needle aspiration were carried out to detect seroma. In patients with seroma, needle aspiration was carried out with the patient in sitting or supine position and was repeated if required. The total amount of aspirated fluid was recorded. Needle aspiration was done with 18G needle and 20mL syringe. In case of small amount of seroma, 21G needle and 10mL syringe was used. Needle aspiration was carried out till the swelling disappeared and no fluid came out. Needle aspiration was carried out three times in three most

probable sites. In doubtful cases, ultrasound examination was carried out to confirm the complete evacuation of fluid.

Data were collected and analyzed with SPSS version 21. The quantitative data were reported as mean and standard deviation. Differences between means were tested with Student's t-test. The qualitative data were reported as number and percentages and Fisher's exact test was employed. This study was approved by the academic and ethical board held in August 2018, and was done according to the guidelines issued by the Ethical and Research Committee of University of Medicine (1), Yangon.

RESULTS

Biopsy results showed invasive ductal type in 96% and 93.3%, respectively, followed by lobular type (4% and 5.3%) and mucinous type (0% and 1.3%). Age and BMI were not significantly different between the two groups (Table 1).

Table 1. Comparison of patients' characteristics and outcomes in the single and double drainage groups

	Single drain	Double drain	
Age (years), mean ± SD	48.66 ± 10.44	51.22 ± 11.04	P=0.15
BMI (kg/m ²), mean ± SD	28.20 ± 3.48	28.79 ± 3.11	P=0.27
Total amount of drain output (mL), mean ± SD	315.13 ± 51.81	325.47 ± 87.98	P=0.38
Duration of drain (days), mean ± SD	5.78 ± 0.89	6.38 ± 1.33	P=0.002
Flap necrosis, n (%)	2 (2.7%)	5 (6.7%)	P=0.442
Seroma, n (%)	22 (29.3%)	27 (36.0%)	P=0.38
Number of aspirations, mean ± SD	2.42 ± 0.51	2.05 ± 0.60	P=0.09
Total amount of aspirate (mL), mean ± SD	114.17 ± 14.43	113.25 ± 24.83	P=0.91

The mean amount of drain was 315.13 ± 51.81 milliliters in the single drain group and 325.47 ± 87.98ml in the double drain group (P=0.38). Mean duration of drainage was significantly shorter in the single drainage group than in the double drainage group (5.78 ± 0.89 days and 6.38±1.33 days, p=0.002). During postoperative period, patients were checked for occurrence of flap necrosis, showing that two (2.7%) patients with a single drain and five (6.7%) patients with double drain developed flap necrosis.

With regards to development of seroma in postoperative period, 29.3% of the single drainage group and 36% of the double drain group developed seroma but the difference was not significant (P=0.38). One month after operation, seroma formation was present in 3 patients (4%) from each group. The mean number of aspirations was 2.42 times in the single drainage group and the mean number of aspirations was 2.05 times in the double drainage group. The differences were not statistically

significant (P=0.09). The amount of aspiration was 114.17ml in the single drainage group and 113.25ml in the double drainage group. The differences were not statistically significant (P=0.91). Biopsy results showed invasive ductal type in 96% and 93.3%, respectively, followed by lobular type (4% and 5.3%) and mucinous type (0% and 1.3%).

DISCUSSION

Seroma accumulation elevates the flaps from the chest wall and axilla, thereby hampering their adherence to the tissue bed. Thus, it can lead to significant morbidity such as wound hematoma, delayed wound healing, wound infection, flap necrosis, wound dehiscence, prolonged hospitalization, delayed recovery, and initiation of adjuvant therapy.⁶ Drainage is used in most centers to reduce the incidence of seroma, though its application is controversial. There is a lack of consensus on uniform practice regarding the number of drains, as studies have suggested that the number of



drains used does not influence the rate of seroma formation.^{7,8}

The present study was carried out to compare the outcomes between single drainage and double drainage after total mastectomy and axillary dissection for breast cancer patients in Yangon General Hospital. A total number of 150 patients were included and a single drain was used in 75 patients and double drain was used in 75 patients.

In the present study, the mean age of single drainage group was found to be comparable to that of the double drainage group. Zielinski *et al.* found that age ≥ 60 years was associated with an increase in cumulative total seroma volume and total time of seroma treatment.⁹ Also, mean body mass index between the two groups was not significantly different. Burak *et al.* demonstrated that significant risk factors for seroma formation included increased age and patient weight.¹⁰

The present study did not show statistically significant differences between single drain group and double drain group regarding total drainage amount. However, it showed that the use of a single drain led to significantly shorter drain duration than with double drain (5.78 days and 6.38 days, $P=0.002$). In a randomized study including 65 patients undergoing axillary dissection or modified radical mastectomy for breast carcinoma, Petrek *et al.* proved that the use of multiple drains in the axilla conferred no advantage in the amount and duration of drainage.¹¹ As far as the optimum time of drain removal is concerned, the evidence in most published work seems to favor early removal of drains because this does not significantly affect the formation of a seroma.¹²

Flap necrosis was seen in 2.7% and 6.7% of patients with single drain and double drain, respectively. Flap necrosis in this study is comparable with the study by Sérensen *et al.*, who reported skin flap necrosis 6.1% ($4.0 \pm 8.8\%$) and epidermolysis 8.9% ($6.4 \pm 12.1\%$).¹³

This study showed that the rate of seroma formation was slightly higher in the double drain group than in the single drain group, but it was not statistically significant. For one month follow-up visit, 3 patients (4%) from the single drain group and 3 patients (4%) from the double drain group presented with seroma formation. In a study by Ebrahimifard, seroma formed in 14 patients from the first group (30.4%), and 16 from the second group (36.4%) ($P=0.551$).³ According to

Athanasios Saratzis *et al.*, the use of a single drain is as effective as the use of 2 or 3 drains in the context of seroma formation.¹⁴

The mean number of aspirations done and the amount of aspiration were comparable between the two groups. In the study by Ebrahimifard, aspirated seroma was 26.78 ± 55.99 ml in the one-drain group and 43.72 ± 121.32 ml in the two-drain group. Although aspirated seroma was more in the two-drain group, there was no significant difference ($P=0.484$).³ The retrospective study by Athanasios Saratzis *et al.* has demonstrated that drains can be a source of significant discomfort and cause sleep disturbances for the patient postoperatively and prolong hospital stay.¹⁴

According to the findings from the present study, the outcomes of single drainage and double drainage after total mastectomy and axillary dissection for breast cancer patients were not significantly different and both methods were equally effective in reducing seroma formation. Taking into consideration the discomfort caused to the patient, we need to reassess whether drains are in fact necessary for every individual case or should only be placed in specific high-risk groups.¹⁴ Thus, single drain insertion after total mastectomy and axillary dissection for breast cancer is recommended to reduce patients' discomfort with less morbidity and cost.

CONCLUSION

This study showed that the outcomes of single drainage and double drainage after total mastectomy and axillary dissection for breast cancer patients were not significantly different. Although this study suffered from a relatively small sample size, relatively short follow-up, and single center study, it showed that both methods were similar in reducing seroma formation, but single drain is recommended to reduce patients' discomfort with less morbidity and cost.

ACKNOWLEDGEMENTS

The authors would like to thank Professor Aye Mon, Professor Myo Myat Thu, Professor Myo Myint and Professor Soe Myat Mon for their approval and guidance to conduct this study.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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How to Cite This Article

Win TM, Myrint ST, Myat A, Thuya H, Lwin T. Single Versus Double Drainage Insertion After Total Mastectomy and Axillary Dissection. *Arch Breast Cancer*. 2022; 9(1):104-108.

Available from: <https://www.archbreastcancer.com/index.php/abc/article/view/479>