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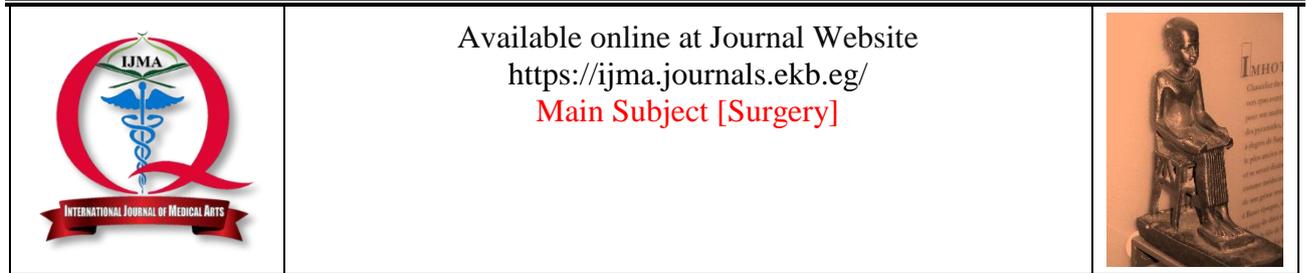
**Original Article**

# Comparison between Flap Fixation and Shoulder Immobilization in Prevention of Seroma Formation Post-surgery for Breast Cancer

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## ABSTRACT

**Background:** Seroma is a strange gathering of serous fluid within the dead space of post-mastectomy skin flaps and axilla, or after breast-conserving surgery [BCS]. Seroma is one of the most commonly reported early post-operative problems following breast cancer [BC] surgery. According to several studies, after a modified radical mastectomy [MRM] or axillary lymph node dissection [ALND], the incidence ranges from 10% to 85%.

**The Aim of The Work:** The current study aimed to investigate the efficiency of two methods in preventing seroma development after BC surgery.

**Patients and Methods:** From December 2018 to January 2022, this prospective comparative study was conducted in the Department of General Surgery, Faculty of Medicine, Al-Azhar University, Assiut, Egypt. Throughout the study period, cases scheduled for MRM had randomly assigned to one of two groups: mastectomy flap fixation [15 cases] or ipsilateral shoulder immobilization [15 cases].

**Results:** Throughout the study period, 30 patients were recruited, 15 patients in group A [flap fixation] and 15 patients in group B [shoulder immobilization]. The proportion of patients who developed seroma requiring aspiration was 40% [n=6] in shoulder immobilization group and no reported cases [n=0] in Flap fixation group [p= 0.006]. In addition, the total amount of drained fluid was 803.3 ml in flap fixation group and 950 mL in shoulder immobilization [p= 0.003]. Regarding Shoulder stiffness, 60% [n=9] in shoulder immobilization group and no reported cases [n=0] in Flap fixation group [p= 0.006]. Flap fixation was determined to be the most effective technique for preventing seroma formation, with a low rate of established seroma and associated problems. Ipsilateral shoulder immobilization, on the other hand, has a limited function in the prevention of established seroma following MRM.

**Conclusion:** The mastectomy flap fixation operation is an effective maneuver to decrease seroma and reducing the volume and duration of drained fluid.

# INTRODUCTION

Following MRM, wound seroma is a frequent complication. This drastic effect is linked to a significant impact on the afflicted person's result and healthcare expenses. Although the best BC surgical approach for reducing seroma formation is uncertain, some researches shows that quilting suture of the dead space may help to limit seroma formation [1]. Seroma is one of the most obnoxious side effects of MRM, causing disruption to afflicted individuals and surgical teams with frequent visits delaying the start of adjuvant therapy and causing significant agony to patients, with the possibility of an increase in surgical site infection [SSI] [2]. Seromas are classified as graded I if they are asymptomatic [only detected by ultrasonography], rated II if they are symptomatic and treated with medical therapy or simple aspiration, and graded III if they are symptomatic and treated with surgery or interventional radiology [1].

Obesity, age, breast size, hypertension, presence of metastatic LN in the axilla, number of excised LNs, early shoulder exercise, and the use of specific drugs, such as tamoxifen and heparin, have all been linked to the development of seroma [3].

Seroma development increases the risk of severe surgical consequences, slows wound healing, increases infection susceptibility, necrosis of the skin flap, persistent discomfort, wound dehiscence, and a longer recovery time [4].

Prolonged suction drainage, flap fixation, shoulder immobilization, pre- and postoperative tranexamic acid, octreotide use, dressing compression, and tissue sealers are some of the measures used to avoid seroma [5].

Post MRM or ALND, more modern procedures recommend to suture the mastectomy or axillary flaps to the underlying muscle with interrupted polyglactin or polyglycolic acid sutures at 2 –3 cm apart, followed by drain insertion [6].

The predicted operative time is increased by 10–20 minutes as a result of these treatments. Suturing axillary and mastectomy flaps to underlying tissue was properly defined and appears to be a successful method of preventing seroma development [7]. The early post-operative immobilization of the afflicted limb is still debatable. Many authors have demonstrated that immobilizing the ipsilateral limb reduces the volume and duration of fluid leakage, however this can be confounded by shoulder dysfunction [8].

Antifibrinolytic drugs, such as tranexamic acid, prevent fibrin complexes from degrading, resulting in less fluid leakage [9]. Many studies have suggested that this technique could provide more experience in dealing with breast wounds wherein the fluid contains high levels of fibrinogen, whilst axillary seromas comprise lymph-like fluid and hence no fibrinogen [3].

In females, BC is the most usually reported malignant tumor. MRM with or without reconstruction, as well as combined with ALND, are frequent procedures. Axillary surgery is associated with a number of serious side effects, including infection, ipsilateral upper extremity lymphedema, and seroma. Seroma is one of the most often reported problems [10]. The specific cause of the genesis of seroma is yet unknown. Many therapies aimed at reducing the development of seroma have been documented, including the use of ultrasound scissors in lymphadenectomy [11], buttress suture [12], fibrin glue [13], fibrin sealant [14], bovine thrombin administration [15], and various surgical technique to fill dead space [16]. However, while the adoption of these therapies may lessen the chance of seroma development, further research is needed to determine the true impact of such approaches on long-term morbidity [17].

# THE AIM OF THE STUDY

The current study aimed to investigate the efficiency of two methods in preventing seroma development after BC surgery.

# PATIENTS AND METHODS

This prospective comparative study was conducted in the Department of General Surgery, Faculty of Medicine, Al-Azhar University, Assiut, between December 2018 and January 2022. According to the Manchester and International Union against Cancer, this study was done on 30 women aged 38 to 65 years old; two cases had stage I cancer of the breast, 22 cases had stage II, and six patients had stage III. The majority of the patients reviewed had a tumor of 2–5 cm in diameter, a mobile axillary lymph node, no cutaneous manifestations, no invasion of the breast skin or chest wall, no patients had received neoadjuvant chemotherapy prior surgery and no distant metastases. After a thorough preoperative assessment, the MRM procedure was carried out. Throughout the study period, all cases scheduled for MRM had been randomly assigned to one of two groups: mastectomy flap fixation [15 cases] or ipsilateral shoulder immobilization [15 cases].

**Inclusion criteria:**

Patients with operable BC who've a normal coagulation profile and are of typical weight.

**Exclusion criteria:**

BC patients who are unable to have surgery, Patients with blood clotting or immune system abnormalities, those on anticoagulant therapy, those with a history of long-term steroid use, patients with uncontrolled diabetes or advanced liver disease, patients with morbid obesity, patients with collagen diseases, administration of neoadjuvant chemotherapy, and those who have had previous surgery on the axilla.

**Data collection:**

Demographic data including name, age, sex, residence, occupation, marital status, body mass index, special habits of medical importance, and menstrual history. Analysis of the main complaint either a breast lump, pain, or bleeding per nipple. History of previous operations especially in the axillary region, chronic diseases. Clinical examination including general examination.

Local examination was done focusing on the site of the breast mass, size of the mass, and presence of palpable axillary lymph nodes. For all cases, routine laboratory tests such as complete blood count [CBC], ALT, AST, Urea, Creatinine, coagulation profile, and serum albumin were performed. Radiological investigations such as superficial probe ultrasonography, soft tissue mammography, and metastatic workup including pelvi-abdominal ultrasonography, CXR, and bone scan to exclude any distant metastasis. Histological type [intraductal carcinoma, intralobular carcinoma, or mixed], stage, grade, hormonal receptor, number of LNs excised, and number of positive LNs were all reported using pathological investigations such as FNAC, Core biopsy, and excisional biopsy.

**METHODS**

The selected cases are divided randomly into 2 groups: **Group A:** There were 15 cases in this group. After completing the MRM [10 procedure in this group, more than one alternating stitch, three cm apart had been achieved in rows between the subcutaneous tissues of the skin flaps and the underlying muscles at numerous parts of the flap [Figures 1 and 2] and additionally at the wound edge with fine absorbable sutures [coated vicryl 3/0]. A two-limb closed suction drain was employed.

**Group B:** There were 15 cases in this category. Following surgery, this group had their shoulder motion restricted to prevent the skin flaps from shearing. The arm was immobilized for the first seven days after surgery by cushioning the axillary fossa with a thick cotton dressing and applying a tight dressing to the chest skin flaps. The arm was then adducted over the axillary fossa and secured with a crepe bandage. When the patient was out of bed, a collar cuff sling was worn, with the arm relaxed and the elbow bent 90 degrees, when the patient was in bed, his arm became propped up on a pillow, and he was allowed to move his hands and wrists. Shoulder exercises began on the ninth postoperative day, with the patient performing active shoulder motions once a day under the supervision of a physiotherapist. All motions were performed until the pain barrier was achieved, including anteflexion, abduction, horizontal abduction, and exo-rotation. All spontaneous movements and arm usage are permitted for the remainder of the day, providing no discomfort occurs. When shoulder function restored to pre-surgery levels, physiotherapeutic monitoring was stopped.



Figure [1]: Fixation of the upper mastectomy flap to the underlying pectoralis major muscle



Figure [2]: Fixation of the lower mastectomy flap to the pectoral muscles

When ante-flexion was restricted by more than 20 degrees or exo-rotation was restricted by more than 10 degrees, home physiotherapy was recommended. Before surgery, on the first day of shoulder movements, and upon discharge, shoulder function, abduction, exo-rotation with the humerus in a neutral position, and exo-rotation with the humerus in abduction, were all measured. The contralateral shoulder was also measured at the beginning and end of the study. As a result, each patient had a "normal" baseline. A two-limb closed suction drain was employed.

Insertion of vacuum drains was done and subcutaneous interrupted sutures were done. Suturing of the skin edges was performed with subcuticular sutures or via clipping of skin [Figure 3]. After complete suturing of the wound, the vacuum drains were activated. The pressure garment application in this study was achieved by large-sized crepe bandages which surround the chest wall and the axilla over the wound dressing as early as possible after surgery. In this study all drains were removed on day seven postoperatively. Weekly follow-up to detect seroma formation was done for all patients up to 2 months. A closed suction drain of 2 limbs was used.

Figure [3]: Mastectomy wound closure after flap fixation

**Adjuvant therapy:** As regard to the final decision to the nature of adjuvant treatment was made following evaluation by a multidisciplinary team. The indication for radiotherapy following MRM was positive excision margins or positive axillary LN. High-risk patients were also, managed with Chemotherapy with respect to the National Institute of Clinical Excellence [NICE] guidelines. Endocrine therapy was offered to hormone receptor-positive patients. The study received ethical approval and signed informed consent from Al-Azhar University's Assiut ethical committee. Every patient completed a written informed consent form to accept the procedure.

**Statistical design:** The data was analyzed using the Statistical Package of Social Services version 24 [SPSS], and the results were presented in tables. Continuous quantitative variables, such as age, were expressed as mean, SD, and median [range], while categorical qualitative variables were expressed as absolute and relative frequencies [percentage]. After checking for normality, appropriate statistical tests of significance were performed. When the significant probability was less than 0.05 [P 0.05], the results were declared statistically significant. P-values less than 0.001 were deemed highly statistically significant [HS], whereas P-values less than 0.05 were deemed statistically insignificant [NS].

## RESULTS

Throughout the study period, between December 2018 and January 2022 that met the inclusion criteria, 30 patients were recruited, 15 patients in group-A [flap fixation] and 15 patients in group B [shoulder immobilization]. The proportion of patients who developed seroma requiring aspiration was 40% [n=6] in shoulder immobilization group and no reported cases [n=0] in Flap fixation group [p= 0.006]. In addition, the total amount of drained fluid was 803.3 ml in flap fixation group and 950 mL in shoulder immobilization [p= 0.003]. Regarding Shoulder stiffness, 60% [n=9] in shoulder immobilization group and no reported cases [n=0] in Flap fixation group [p= 0.006]. Flap fixation was determined to be the most effective technique for preventing seroma formation, with a low rate of established seroma and associated problems. Ipsilateral shoulder immobilization, on the other hand, has a limited function in the prevention of established seroma following MRM.

Table [1] shows description of demographic data and risk factors in all studied cases. The mean age of all studied patients was 48.3 ± 5.4 years [median age 46 years] with minimum age of 38 years and maximum age of 65 years. As regard menopausal state, 18 patients [60%] were premenopausal and 12 patients [40%] were post-menopausal. As regard risk factors for the development of seroma among post modified radical mastectomy, 5 patients [16.7%] were obese, 6 patients [20%] were hypertensive, 2 patients [6.7%] were diabetic and 6 patients [20%] had previous blood transfusion. Table [2] shows the description of staging of cancer according to TNM classification and number of infiltrated lymph node in all studied patients. It was stage I in 2 patients [6.7%], stage II in 22 patients [73.3%] and stage III in 6 patients [20%]. And also shows the description of Number of infiltrated LN in all studied patients. It was more than 4 lymph nodes in 12 patients [40%] and less than 4 lymph nodes in 18 patients [60%].

Table [3] shows statistically significant difference [p-< 0.05] between studied modalities regarding seroma formation and shoulder stiffness. There were no reported cases in Group A, and 6 cases [40%] in Group B. No significant difference among studied modalities regarding wound infection and skin flap necrosis. Table [4] shows statistically significant difference between studied modalities regarding day of drain removal [4.8 days in Group A compared to 6 days in Group B], total drained fluid [803.3 ml in Group A, and 950 ml in Group B], drained fluid in the last 3 days [131 ml in Group A and 154 ml in Group B] and drained fluid in the last day [28.3 ml in Group A and 38 ml in group B].

Table [1]: Description of demographic data and risk factors in all studied patients

| | | Studied patients [n= 30] | |
|---|---|---|---|
| **Age [years]** | Mean ±SD | 48.3 ± 5.4 | |
| | Median [range] | 46 [38 – 65] | |
| **Menopausal state** | Pre-menopausal | 18 | 60% |
| | Post-menopausal | 12 | 40% |
| **Obesity** | | 5 | 16.7% |
| **Hypertension** | | 6 | 20% |
| **Diabetes mellitus** | | 2 | 6.7% |
| **Blood transfusion** | | 6 | 20% |

Table [2]: Description of staging of cancer according to TNM classification and Number of infiltrated lymph node in all studied patients.

| | | Studied patients [n = 30] | |
|---|---|---|---|
| TNM staging | Stage I | 2 | 6.7% |
| | Stage II | 22 | 73.3% |
| | Stage III | 6 | 20% |
| Number of infiltrated LN | More than 4 LN | 12 | 40% |
| | Less than 4 LN | 18 | 60% |

Table [3]: Comparison between studied modalities as regard complications

| | Shoulder immobilization [n = 15] | | Special flap closure [n = 15] | | P-value |
|---|---|---|---|---|---|
| **Seroma formation** | 6 | 40% | 0 | 0% | 0.006 S |
| **Shoulder stiffness** | 9 | 60% | 0 | 0% | <0.001 S |
| **Wound infection** | 2 | 13.3% | 2 | 13.3% | 1.0 NS |
| **Skin flap necrosis** | 0 | 0% | 0 | 0% | - |

S: p-value < 0.05 is considered significant; NS: p-value > 0.05 is considered non-significant.

Table [4]: Comparison between studied modalities regarding post-operative assessment.

| | Shoulder immobilization [N = 15] | Special flap closure [N = 15] | P-value |
|---|---|---|---|
| **Day of drain removal** | 6 ±1.25 | 4.8 ±1.18 | **0.017 S** |
| **Total drained fluid** | 950±125.4 | 803.3±117.2 | **<0.001 S** |
| **Drained fluid in last 3 days** | 154±20.8 | 131 ±13.6 | **<0.001 S** |
| **Drained fluid last day** | 38 ±10.8 | 28.3±9.4 | **0.014 S** |

S: p-value < 0.05 is considered significant.

## DISCUSSION

The current study was performed on thirty patients with demographic as following; the mean age of the studied groups is 48.3 ± 5.4 years old, median age 46 years, with a minimum age of 38 and a maximum age of 65 years [Table no.1]. As regard to menopausal status, 18 patients [60%] were premenopausal, whereas 12 [40%] were postmenopausal. Regarding risk factors for seroma formation after MRM, 5 patients [16.7%] were obese, 6 patients [20%] were hypertensive, 2 patients [6.7%] were diabetic, and 6 patients [20%] previously had blood transfusions.

According to Akinci et al. [8] thesis based on 40 patients; [27.5%] of patients develop seroma after MRM.

Seroma development after mastectomy was more common in hypertensive individuals, that was reported in [50%] of cases. This was compatible with the results of Loo and Chow, in which, hypertension was discovered to be a risk factor for seroma [18].

Also, Kuroi et al. [19] discovered no link between DM and seroma development in diabetic patients, which was agree with the results of the current study.

Seroma production after MRM was shown to differ statistically as regard to stages of BC as Stage I included 2 [6.7%] patients with 1 patient develop seroma [50%]. Stage II includes 22 [73.3%] patients with 3 patients [13.6%] developed seroma. Stage III includes 6 [20%] patients with 2 patients [33.3%] developed seroma. These results were in agreement with the result achieved by many authors, e.g., Mohammed et al. [20]. Hoefer et al. [21] and Kumar et al. [22], found that breast cancer staging had no effect on post-mastectomy seroma, which was not compatible with this study.

This study looked at seroma development after MRM based on whether there were more or less than four lymph nodes invaded. There was no statistical difference among the 2 groups, as the data revealed that 12 patients [40%] had more than 4 LN, and 2 patients [16.7%] had acquired seroma. In 18 patients [60 %], had less than 4 LN been identified, and four patients [22.2%] developed seroma.

Ebrahim [23] showed that the number of LN involved did not have a statistically considerable difference in seroma generation in this investigation. There was no statistically significant difference in the number of positive LN excised in MRM, according to Wolde et al. [24] and Khater et al. [2].

There were no differences in the incidence of seroma development among individuals with no metastasis and those with up to three metastatic LN, according to the study. In this study, two modalities were used to treat seroma development after MRM, three patients had aspiration under complete aseptic conditions, two patients had closed drainage systems, and one patient had an open drainage system. Single or repeated aspirations under complete aseptic circumstances, closed drainage system, and open drainage system are various techniques in the treatment of seroma, according to Kuroi et al. [18].

In this study there was no seroma formation in Special flap closure [0%], and in Shoulder immobilization [40%]. On the other hand, as regard to complications, shoulder stiffness was found to be particular to Group B [60 %] and not in Group A, wound infection, and skin flap necrosis were not found to be specific to any group.

Similar results had been found by Ozaslan et al. [25] in a trial of 100 patients [50 in each group], where seroma rates in the control group were 12 patients out of 50 [24%] and 6 patients out of 50 [12%], respectively [P-value 0.05].

Sakkary [26] reported in comparable research [included 40 patients] that seroma generation was 20% in the intervention group against 50% in the control group [P-value = 0.028]. Khater et al. [2] observed a similar finding, with the incidence of seroma in the suture group being 20% against 78.6% in the control group [P-value 0.001]; and according to Arafa et al. [27] the flap fixation group had a considerably reduced frequency of seroma production than the control group [P-value = 0.028].

In both groups, there was no significant difference in wound infection [P-value = 0.29], and there was no significant difference in skin flap necrosis [P-value = 0.31] [27].

The special flap closure group and the shoulder immobilization group had significantly lower drain removal days [P-value 0.017], totally drained fluids [P-value 0.003], amount of drained fluid in the last 3 days before drain removal [P-value 0.001], and amount drained the last day [P-value 0.001] in this study [P-value 0.014].

According to Akinci et al. [8], seroma occurred more frequently [36.4 %] when a drain was needed for more than 7 days compared to when the drain was needed for less than 7 days [5.6 %] [P-value 0.011].

Early drain removal was also linked to an increased risk of seroma, according to Andeweg et al. [28]. With flap fixation, Sakkary [26] found a reduction in total drainage volume [P-value 0.001].

Wolde et al. [24], in recent research, found that total drainage volume decreased from 2649.79 ml in the control group to 869.29 ml in the intervention group [P value = 0.125].

Khater et al. [2] found similar findings, with the quilting method reducing the mean length of drainage from 11 days in the control group to 9 days in the intervention group [P-value 0.001].

Arafa and his colleagues [27] in comparison to the control group, the drain was cleared in a much shorter period.

The drains were removed between 6 and 15 days in the non-fixation group, whereas they were removed between 3 and 10 days in the fixation group [P-value 0.017]. The total volume of fluid drained was likewise considerably lower in the flap fixation group [P-value 0.003]. The amount of drained fluid was much lower in the flap fixation group during the last three days preceding removal of drain [P-value 0.014]. In the flap fixation group, the amount drained in the last day was much lower [P-value 0.014].

Kelley et al. [29] discovered that there is no difference in drain removal when done early or late.

In the current study, there is a statistically considerable difference [p-value 0.05] between the examined modalities regarding the day drain was removed, total drained fluid, drained fluid in the previous three days, and drained fluid last day, which was similar to results reported with Mannu et al. [30].

**Limitations and future perspectives**

This article adds to our understanding the efficacy of flap fixation in decreasing the rate of seroma formation in breast cancer surgery. However, one of the major limitations of this article is the small size of the sample.

A large-size sample is recommended in the next research to obtain a more representative population. Another obstacle is the relatively short median period of follow-up [2 months].

Also, this work was only directed to one type of management [MRM] only regardless that, we are in the era of conservative and oncoplastic breast surgery. In addition, recall bias may affect the outcomes. In addition, it is necessary to have a control group [different procedure from flap fixation and shoulder immobilization] to compare with the other experimental groups.

**Recommendations:** Based on the mentioned data, we recommend the following:

i. Fix the skin flap to the pectoral muscle as a routine step at the end of any mastectomy.

ii. It should be tried on a much wider scale to prove its

validity.

iii. Evaluation of the efficacy of different methods [conventional scalpel, electrocautery, and harmonic scalpel] of breast dissection during mastectomy on seroma formation.

iv. A prospective [randomized] study with a long median follow-up duration is essential for accurate establishment of the rate of recurrence.

**Conclusion:**

The mastectomy flap fixation strategy is a beneficial technique that minimizes the frequency of seroma development while also reducing the length and amount of drained fluid.

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