



ORIGINAL ARTICLE

Comparison of seroma formation between flap and non-flap fixation technique of mastectomy for different stages of breast cancer.

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ABSTRACT... Objective: To compare the effect of flap fixation and non-flap fixation for preventing seroma formation depending upon stage of surgery in patients undergoing mastectomy at RMU Allied Hospitals following mastectomy in our local population. **Study Design:** Randomized Controlled Trial. **Setting:** Surgical Units of Holy Family Hospital, Benazir Bhutto Hospital, DHQ Hospital (RMU & Allied Hospital). **Period:** October 2020 to April 2021. **Methods:** Sample size of 114 cases was included in the study. It was Non probability, consecutive sampling technique. Patients were equally randomized to flap-fixation (Group A) and non-flap fixation (Group B). Patients of both groups were followed up to 48 hours postoperatively for seroma formation. Results were analysed using SPSS software and compared by applying chi-square test and p-value ≤ 0.05 considered significant. **Results:** Statistically significant difference (p-value ≤ 0.05) for seroma formation was noted only in disease stage IIIA. In group A (Flap Fixation), seroma formation was noted in 22.8% (n=13) patients, while in group B (Non-Flap Fixation) it was noted in 45.6% (n=26) patients only. **Conclusion:** The patients with stage IIIA undergoing mastectomy are significantly (p-value ≤ 0.05) associated with seroma formation. Whereas, flap fixation is more useful technique for minimizing seroma formation.

Key words: Flap Fixation, Mastectomy, Seroma Formation.

INTRODUCTION

Breast cancer is the one of the common malignancy in women all over the world including Pakistan.¹ Surgical procedures are the mainstay treatment for operable breast tumors. According to the stage of disease and patients preferences breast conservation and modified radical mastectomy with or without reconstruction are most commonly performed procedures.² In Pakistan, various factors leads to late presentation of breast malignancy.^{3,4} Resultantly, modified radical mastectomy is being performed on most of the patients. Modified radical mastectomy involves resection of whole malignant breast tissue with level 2 axillary clearance as its part.⁵ This aggressive resection of breast tissue makes a dead space under the mastectomy flaps and axilla, resultantly it leads to seroma formation.

Surgical site infections (SSIs) after breast

surgery has been reported with range from 1% to 26%.⁶ Formation of seroma, flap necrosis and wound infection are known postoperative complications of breast tumor surgery. It is observed that seroma formation is the most common complication after mastectomy and axillary clearance with an incidence range of 3% to 85%.⁷ Prolonged drainage is associated with greater risk of infection and can considerably postponed oncological interventions. Seroma is been defined as accumulation of serous fluid in dead space underneath the skin flaps or in the axilla after mastectomy and/or axillary clearance. Multiple factors such as advanced age, obesity, type of primary breast surgery, diabetes mellitus, number of lymph nodes involved, extent of axillary clearance and neoadjuvant treatment attributes to seroma formation.⁸ Seroma formation results in poor healing of wound due to lack of flap adherence to the chest wall. It increases the

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stay of hospital, morbidity and frequency of hospital visits. Many studies has declared that without closed suction drainage, the incidence of seroma formation has not been affected in patients undergoing mastectomy.⁹ Ideal closure of wound results in minimum spillage of lymph and oozing of serum, so that flaps of skin are securely adhered to the underlying chest wall structures, dead space is properly obliterate and rapid drainage of fluid formed.¹⁰

The objective of this study was to compare the effect of flap fixation and non-flap fixation for preventing seroma formation depending upon stage of surgery in patients undergoing mastectomy at RMU Allied Hospitals following mastectomy in our local population.

METHODS

It was a Randomized controlled trial conducted in surgical units of Holy Family Hospital, Benazir Bhutto Hospital, DHQ Hospital (RMU & Allied Hospital). The study was conducted from October 2020 to April 2021. Sample size of 114 cases was included in the study. Sampling Technique was non probability, consecutive sampling.

Approval was obtained from the hospital research and ethical board (183/IREF/RMU/2020) before starting the study. 114 patients meeting the inclusion criteria with the diagnosis of breast cancer were selected from the surgery outpatient department of RMU and Allied Hospital. These patients underwent mastectomy, mastectomy & sentinel node procedure or MRM having age between 18 to 60 years were selected in this study after the informed consent from every patient. Patients with history of diabetes mellitus, regular steroid intake and immunocompromised status were excluded. The diagnosis was established with detailed history, thorough clinical examination and necessary investigations. Informed consent were taken from all patients. Pre-anaesthesia workup was completed. Appropriate same intravenous antibiotic prophylaxis (inj. Amoxicillin/Clavulanic Acid 1.2 gram) was given to all patients before surgery. Patients were randomly divided into two groups Group A and Group B by lottery method. All surgical procedures were done

under standard general anaesthesia. In group A surgeries were performed by Flap Fixation while in group B with Non Flap Fixation. After the operation all of the patients will be kept NPO for 06 hours and received two doses of antibiotic, 8 hours apart. The analgesic inj. Ketorolac 30mg (intramuscular, every 8 hours) was used. All patients were discharged after tolerating soft diet. Patient were advised to follow-up in OPD after 48 hours of drain removal and observed for seroma formation as evident by palpation and aspiration.

Data was entered and analysed in SPSS version 24. For quantitative variables like age, mean and standard deviation was calculated. Seroma formation was compared between 2 groups by chi-square test. Frequency and percentage was calculated for stage of the disease. Effect modifiers like age and stage of the disease were controlled by stratification. Post stratification chi-square test was applied. A P-value of < 0.05 was considered statistically significant.

RESULTS

Total population included in our study was 114 divided in two equal groups. Group A (flap fixation) had 57 patients with 6 (10.5%) stage IIA, 16 (28.1%) stage IIB, 34 (59.6%) stage IIIA and 1 (1.8%) stage IV. Group B (Non flap fixation) had 57 patients with 10 (17.5%) stage IIA, 14 (24.6%) stage IIB, 32 (56.1%) stage IIIA and 1 (1.8%) stage IV. Seroma formation in both groups is shown in Table-I.

TNM staging of the patient was done and it was noted that no patient belonged to stage-I. Patients were presented with stage IIA, IIB, IIIA and IV on basis of TNM staging. More than 50% of patients were presented with TNM stage IIIA. Frequency of seroma formation was noted as 34.2% (n=39) in total study population. In group A (Flap Fixation), seroma formation was noted in 22.8% (n=13) patients, while in group B (Non-Flap Fixation) it was noted in 45.6% (n=26) patients only. No seroma formation was noted in disease stage IIA patients (n=16), so no stratification was done for this group of patient.

Our study results concluded the formation of

seroma following mastectomy as stage IIB (flap fixation 4 (25%) and non-flap fixation 2 (14.3%)), stage IIIA (flap fixation 9 (26.5%) and non-flap fixation 23 (71.9%)), stage IV (flap fixation 1 (100%) and non-flap fixation 0%). Chi-square test was employed to assess the significance of observed difference in both groups. P-value was found to be 0.010 (<0.05), indicating there was a significant difference in seroma formation among both groups with Group A (Flap Fixation) showed better results. Statistically significant difference (p-value ≤0.05) for seroma formation was noted only in disease stage IIIA. Results are shown in table 2. Results reflected that statistically significant difference (p-value ≤0.05) for seroma formation was noted only in patients with stage IIIA disease.

Seroma Formation	Study Group		P-Value
	Flap Fixation (A)	Non-Flap Fixation (B)	
Positive	13	26	0.010
	22.8%	45.6%	
Negative	44	31	
	77.2%	54.4%	
Total	57	57	
	100%	100%	

Table-I. Seroma formation in both study groups

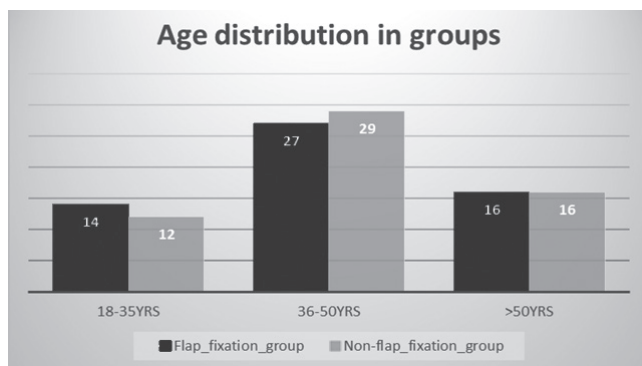


Figure-1

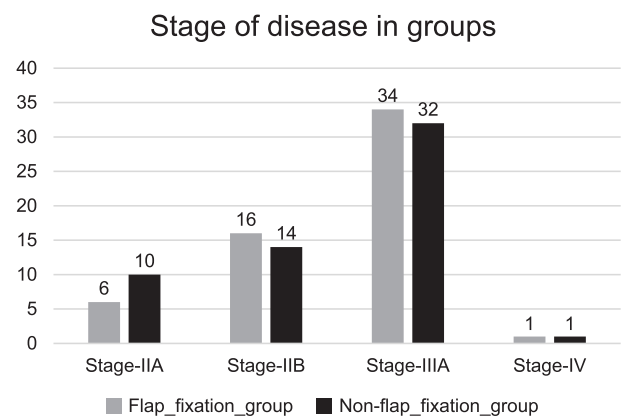


Figure-2

Disease Stage (TNM)	Seroma Formation	Group		Total	P-Value
		Flap Fixation (A)	Non-Flap Fixation (B)		
IIB	Positive	4	2	6	0.464
		25.0%	14.3%	20%	
	Negative	12	12	24	
		75.0%	85.7%	80.0%	
Total	16	14	30		
	100%	100%	100%		
IIIA	Positive	9	23	32	0.000
		26.5%	71.9%	48.5%	
	Negative	25	9	34	
		73.5%	28.1%	51.5%	
Total	34	32	66		
	100%	100%	100%		
IV	Positive	0	1	1	0.157
		0.0%	100%	50%	
	Negative	1	0	1	
		100.0%	0%	50%	
Total	1	1	2		
	100.0%	100%	100%		

Table-II. Seroma formation in both groups (stratification based on TNM disease staging)

DISCUSSION

Breast surgeries are frequently associated with post-operative seroma accumulation. Seroma is formed as a result of tissue trauma by acute inflammatory exudates during acute phase of wound healing. Moreover, there is leakage of lymph due to dissection of axillary lymphatics.⁶

It predisposes to increase incidence of wound infection and dehiscence, delays the recovery of patient, increase the frequency of hospital visits, and delays in the adjuvant treatment. However, the exact mechanism of pathogenesis is yet to be known.⁸ Postoperative seroma formation is associated with significant risk factor that was after 48 hours.¹¹ Different surgical techniques have been developed in various trials for the prevention of seroma. The most frequent practiced techniques includes minimising the dead space either using compression dressing or fixation of flaps to underlying fascia, prolonged drainage by suction and immobilisation of shoulder.¹²⁻¹⁵ Moreover, tranexamic acid, octreotide usage, tissue sealers and fibrin glue were used perioperatively to reduce the incidence of seroma formation. However, the final results of these methods for decreasing the seroma formation remain uncertain and inconclusive.¹⁶⁻¹⁹

In the recent past, mechanical closure of dead space between skin flaps and underlying pectoralis fascia has been observed for its efficiency for prevention of post-operative seroma formation. In our research, we focused on studying the effect of flap fixation technique using surgical sutures on seroma formation. Mechanical fixation between skin flap and underlying pectoralis fascia obliterates the dead space that has been resulted in decreased seroma formation. Sakkaray concluded that the technique of flap fixation mastectomy decrease the seroma incidence to 10% in comparison to 40% in non-flap fixation.¹⁴ However, the results of our study are observed to be supporting the Sakkaray study. In a study by Najeeb et. al.²⁰, it was reported that 4 (7.3%) out of 55 patients who developed seroma had stage 2 disease, whereas in stage III, 1 (6.7%) out of 15 patients had post-operative seroma. However, it was not significant difference between two stages

($p=0.936$). Whereas our study concluded seroma formation was statistically significant in stage IIIA.

Seroma incidence has been correlated with pathological tumour type, tumour stage (T-stage and N stage), along with exposure to neoadjuvant treatment or radiation.¹² Furthermore, Lumachi et al¹⁷ found out that the size of tumour is a significant factor that affect development of seroma. However, Hashemi et al.²¹ added that that tumour size, the age of patient and the axillary lymph nodes involvement were not associated with incidence of seroma. On contrary, our study supported that there is no statistical significant correlation of breast cancer stage or grade on development of seroma, comparable to Akinci et al results.⁸ On the other notes, in our study it was observed that the frequency of seroma was high ($n=39$, 34.2 %) comparing to earlier studies where frequency of 24.1% to 27.5% were described .

Raghavendra²⁴ performed a prospective study in patients of breast malignancy. He enlisted thirty patients of stage III breast cancer. All patients underwent MRM. At the time of closure, two groups were randomly formed, each containing 15 cases. Group I patients were managed by anchoring flap to underlying muscle while in Group II, flap was not stitched. In both groups, suction drains were placed and the volume of fluid calculated. It was found that although the rate of forming seroma was same in both groups but the fluid aspirated in group I was lower than group II. On the second day after surgery, there was a significant decrease in the quantity of fluid drained in Group I ($p= 0.04$). These results are comparable to our study.

Madhu et al²⁵ conducted an experimental study in patients of MRM. He segregated the operated patients in two groups on the basis of anchoring flap in first group while simple conventional closure in second group. He divided seroma into three grades depending upon the severity. It was noted that there was no patient with grade 3 seroma in flap anchoring group while there were seven patients with grade 3 seroma in the other group ($p < 0.028$). He also observed that 2 patients of the second group developed flap

necrosis while the flaps remained normal of the anchoring group. These results are similar to our study.

Dr Renjin²⁶ concluded that less than 2 weeks were required for the removal of drain in flap anchoring group while the volume of fluid (seroma) drained in non-fixing group was higher and it took 3 weeks to remove the drain.

In summary, literature reviews and the most of RCTs conducted at various clinical facilities support that the technique of flap fixation has promise in the prevention of seroma formation. The limitation of this study is that it is conducted on a small scale. Moreover, association of many comorbid conditions like hypertension and diabetes are not assessed with outcomes of both of the procedure. A large scale study of our local population is recommended to overcome these limitations.

CONCLUSION

The patients with stage IIIA undergoing mastectomy are significantly (p -value ≤ 0.05) associated with seroma formation. Whereas, flap fixation is more useful technique than non-flap fixation for minimizing post mastectomy seroma formation.




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AUTHORSHIP AND CONTRIBUTION DECLARATION

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2	Sehrish Siddique	Manuscript writing, Literature research.	
3	Sidra Mehmood Dar	Data analysis, Manuscript writing.	
4	Jahangir Sarwar Khan	Critical review.	