

## Seroma Formation Between Flap and Non-flap Fixation Following Mastectomy in Term of Age and Type of Surgery in Breast Cancer Patients in A Tertiary Care Hospital

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### Abstract

**Objection:** To compare the adequacy of flap fixation and non-flap fixation for preventing seroma formation, depending upon age and type of surgery in patients undergoing mastectomy, at RMU Allied Hospitals following mastectomy.

**Method:** Randomized controlled trial setting of this study was Surgical units of Rawalpindi medical university (RMU) & Allied Hospital. Duration of this study was conducted from October 2019 to April 2020. Sample size of 114 cases was enlisted in the study. Non probability, consecutive sampling. Patients were equally randomized to flap-fixation (Group A) and non-flap fixation (Group B). Patients of both groups were followed up 48 hours postoperatively for seroma formation as evident by palpation and aspiration. Results were analysed using SPSS software and p-value  $\leq 0.05$  considered significant.

**Results:** 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 (p-value 0.010). In group A, mean aspirated fluid found to be 28.46 ml  $\pm$  15.19SD while it was noted as 30.00 ml  $\pm$  13.78SD in group B.

**Conclusion:** The patients undergoing modified radical mastectomy and above 50 years of age are significantly (p-value  $\leq 0.05$ ) associated with seroma formation following mastectomy. Whereas, flap fixation is more useful technique than non-flap fixation for minimizing post mastectomy seroma formation.

**Keywords:** seroma, modified radical mastectomy, flap fixation

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### Introduction

Breast carcinoma is one of the commonest malignancy in Pakistan. According to an estimate, about 1 in every 9 Pakistani women develops breast cancer at some part of her life.<sup>1</sup> As most patients present late, the commonest surgical procedure performed is Modified Radical Mastectomy (MRM). In MRM, two approaches can be used for wound closure i.e. Non-Flap Fixation or conventional approach and Flap fixation. In the Non-

Flap fixation, skin flaps are sutured using interrupted skin sutures while in flap fixation approach the subcutaneous tissue of skin flap is first sutured to the underlying pectoral muscle and then skin is closed conventionally. One of the common complications associated with MRM is seroma formation. Seroma is defined as the accumulation of serous fluid at the site of surgery. The frequency of seroma ranges between 15 and 81%.<sup>2</sup> As a result of its accumulation, many post-op complications including surgical site infection (SSI), delayed healing and skin flap necrosis occur.<sup>3</sup> Many factors contribute in the formation of seroma like age, body mass index and use of electrocautery.<sup>4</sup> In a recent systemic review, chances of forming seroma can be reduced by aspirating the collection along with fixing the skin flaps to underlying structures.<sup>5</sup> It is hypothesized that flap fixation reduces seroma formation by reduction in dead space.

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In a study carried out by James Van Bastelaar et al, incidence of seroma formation was 35.9% in patients who underwent flap fixation as compared to 59.1% in patients in whom flap fixation was not done; with a p-value of 0.0023. Similarly, in a retrospective study, incidence of seroma formation reduced to 80.5% in non-flap fixation group as compared to 22.5% in flap fixation ( $p < 0.01$ ).<sup>6</sup> The objective of this research proposal is to opt better surgical procedure among Flap Fixation and Non-Flap Fixation to reduce post-operative complication mainly in terms of forming seroma in patients undergoing mastectomy at RMU and allied hospital.

### Material and Methods

Randomized controlled trial setting of this study was Surgical units of Rawalpindi medical university (RMU) & Allied Hospital. Duration of this study was conducted from October 2019 to April 2020. Sample size of 114 cases was enlisted in the study. Non probability, consecutive sampling. After permission from the concerned authorities and ethical committee total of 114 patients 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 confirmed by detailed history, thorough clinical examination and relevant investigations. Hospital registration numbers and 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.

### Results

Mean age of the total study population found to be 45.47 years  $\pm 9.49$ SD. In group A, mean age of patients was 45.35 years  $\pm 10.15$ SD while it was noted as 45.60 years  $\pm 8.85$ SD in group B. 22.8% (n=26) of total study population were belonged to age group less than 35 years, 49.1% (n=56) were of age 36-50 year while 28.1% (n=32) patient were presented with age more than 50 years. Group wise distribution of age groups is presented in table 1. 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%

**Table 1:** Distribution of study population in different age groups.

Age Groups	Study Group		Total
	Flap Fixation (A)	Non-Flap Fixation (B)	
18-35 Years	14	12	26
	24.6%	21.1%	22.8%
36-50 Years	27	29	56
	47.4%	50.9%	49.1%
>50 Years	16	16	32
	28.1%	28.1%	28.1%
Total	57	57	114
	100.0%	100.0%	100.0%

**Table 2:** Seroma formation in both groups (stratification based on age groups)

Age Groups	Seroma Formation	Group		Total	P-Value
		Flap Fixation (A)	Non-Flap Fixation (B)		
18-35 Years	Positive	4	4	8	0.793
		28.6%	33.3%	30.8%	
	Negative	10	8	18	
		71.4%	66.7%	69.2%	
Total	14	12	26		
	100.0%	100.0%	100.0%		
36-50 Years	Positive	6	12	18	0.125
		22.2%	41.4%	32.1%	
	Negative	21	17	38	
		77.8%	58.6%	67.9%	
Total	27	29	56		
	100.0%	100.0%	100.0%		
>50 Years	Positive	3	10	13	0.012
		18.8%	62.5%	40.6%	
	Negative	13	6	19	
		81.3%	37.5%	59.4%	
Total	16	16	32		
	100.0%	100.0%	100.0%		

(n=13) patients, while in group B (Non-Flap Fixation) it was noted in 45.6% (n=26) patients only. 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. Results are shown in table 2 and 3. Furthermore, mean value of the aspirated fluid was noted as 29.49ml ±14.08SD among

**Table 3:** Seroma formation in both groups (stratification based on type of surgery)

Type of Surgery	Seroma Formation	Group		Total	P-Value
		Flap Fixation (A)	Non-Flap Fixation (B)		
Mastectomy	Positive	2	0	2	0.076
		18.2%	0.0%	7.4%	
	Negative	9	16	25	
		81.8%	100.0%	92.6%	
Mastectomy + SNE	Total	11	16	27	0.248
		100.0%	100.0%	100.0%	
	Positive	0	1	1	
		0.0%	50.0%	25.0%	
MRM	Negative	2	1	3	0.000
		100.0%	50.0%	75.0%	
	Total	2	2	4	
		100.0%	100.0%	100.0%	
MRM	Positive	11	25	36	0.000
		25.0%	64.1%	43.4%	
	Negative	33	14	47	
		75.0%	35.9%	56.6%	
MRM	Total	44	39	83	0.000
		100.0%	100.0%	100.0%	

the total study sample who were positive for seroma formation. In group A, mean aspirated fluid found to be 28.46 ml ±15.19SD while it was noted as 30.00 ml ±13.78SD in group B. Effect modifiers like age was controlled by the stratification. Post stratification chi-square test was applied. Results reflected that statistically significant difference (p-value ≤0.05) for seroma formation was noted only in >50 years of age group.

## Discussion

Seroma formation is one of the commonest complication seen after breast surgery with a frequency of 3% to 85%.<sup>7</sup> Gonzalez et al. in their research analysed cases who underwent MRM (modified radical mastectomy) along with WLE (wide local excision) for breast carcinoma and found that the only predictor of formation of seroma

was the type of procedure performed; however tumour size, age, weight of patient, involvement of axillary lymph nodes and use of chemotherapy were not significantly associated with the seroma formation<sup>8</sup>. Whereas our study showed that as the age is a significant contributor of seroma; as age advances, the percentage of seroma in non-flap fixation increases i.e. 33.3% in 18-35 age group, 41.4% in 36-50 year age group and 62.5% in above 50 years age group respectively. The rate of seroma formation declined with flap Fixation as the age group increases.

Management of breast cancer has been adapted from mastectomy to breast conservation surgery during the last decade. It is now concluded that radical mastectomy including MRM increases the incidence of forming seroma as compared to simple mastectomy<sup>9,10</sup>. Moreover, probability of its accumulation is lesser in breast conservation surgery (BCS)<sup>11</sup>. Since there are conflicting results in the literature, this study was conducted to assess the efficacy of flap fixation for preventing seroma formation in comparison with non-flap fixation, so that better treatment may be recommended to our local population.

Mohammed A et al<sup>12</sup> in his prospective interventional study found that the quantity of serous fluid drained after MRM was greater in patients who were not managed with flap anchoring technique (p-value < 0.001). Moreover drains of the flap fixing patients were removed earlier than the control group (p-value <0.001). Similar study was conducted by Arafa et al<sup>13</sup> and found that 22 patients develop seroma in suture group while 39 in the control group (p-value < 0.001).

Hashemi et al conducted a retrospective observational study and found that type of breast surgery has significant impact in forming seroma as it was two and a half times higher in patients of MRM<sup>14</sup>. Moreover the rate of seroma was two and a half times greater in non-flap fixing technique. This is consistent with our results where rate of seroma formation is significantly higher after MRM.

Ten Wolde and Kuroi in their study found that the span of anatomical planes formed during surgery play a vital role in seroma formation, therefore during mastectomy, occlusion of dead space is an essential tool. This was not be achieved by wearing pressure garments or bandages however, quilting of the skin flaps or skin flap fixation was much more effective<sup>15,16</sup>.

Coveney et al, evaluated the effect of closing dead space on seroma formation after mastectomy. The complication rate was lower in the flap fixation group, two patients (10%) developed cellulitis; in the control group,

2 patients developed cellulitis and 2 developed partial flap necrosis (20%).<sup>17</sup>

Larsen et al, found that this technique not only fastened the recovery process but it also enhanced the range of shoulder motion among patients underwent MRM<sup>18</sup>.

Chilson TR et al, in their publication described that the flap anchoring procedure reduced the frequency of seroma (p value < 0.03). As a result, the number of office visits were also markedly decreased by the patients (p-value < 0.0001).<sup>19</sup>

In another study, Ahmed M et al evaluated the outcomes of anchoring flaps to anterior chest wall for abutting space with drainage as an alternative to the classic form of mastectomy closure with closed suction drain for MRM. Sixty patients of breast cancer after completing metastatic workup, underwent modified radical mastectomy (MRM). Patients were segregated into two groups; group A (n=30) were flap fixing group and group B (n=30) were non flap fixing group. All patients were presented with breast cancer with age range of 32 to 75 years. Postoperative patients were followed and their data was collected and compared. Patients' demographics were not different in the two groups. They reported less overall complication in group A than group B, also reduced total seroma volume in group A and reduced number of drain days in group A than B. They concluded that anchoring skin flaps to chest wall lessens the formation of seroma.<sup>20</sup>

In summary, most of the carried out RCTs indicate that flap fixation prevents 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 undergoing modified radical mastectomy and above 50 years of age are significantly (p-value ≤ 0.05) associated with seroma formation following mastectomy. Whereas, flap fixation is more useful technique than non-flap fixation for minimizing post mastectomy seroma formation.

## Conflict of Interest

*None*

## Funding Source

*None*

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### **Authors Contribution**

**AZ, SS:** Conceptualization of Project

**AZ, RS:** Data Collection

**SMD:** Literature Search

**SMD:** Statistical Analysis

**JSK:** Drafting, Revision

**SS:** Writing of Manuscript