



A comparative study to evaluate the effect of obliteration of dead space of mastectomy flaps

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General Note



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ABSTRACT

Background: Breast cancer has become a fast-growing cancer in India and is now the most common cancer in Indian women which has replaced cervical cancer. Multiple studies have compared operative procedure as risk factors for seroma formation. A high incidence of surgical site infection (SSI) lead to longer hospital stays, readmissions and re-operations, worse cosmetic outcomes, delays in initiating adjuvant therapy, resulting in additional costs and worse results. **Material & Methods:** A prospective interventional case control study including diagnosed cases of carcinoma breast. 72 female patients were enrolled, 36 in each limb i.e. Group A (Interventional) and Group B (Conventional), between July 2017 to August 2019. The entire patient underwent Modified Radical

Mastectomy (MRM) followed by flap fixation in group A. Post-operative total amount of seroma drained and related characteristics were assessed. *Results:* Mean age of patients was 52.79 years, majority had infiltrating ductal carcinoma with T2 lesions and in Stage II category, overall 9.72 % had seroma formation, flap necrosis was more in interventional group, the mean total drain were 39.89 ± 16.42 ml in interventional group & 50.78 ± 18.46 ml in conventional group. *Conclusion:* Dissection technique is an important factor affecting the seroma formation in post-operative period, electrocautery dissection reduces operative blood loss and postoperative drain output. Closure of the dead space by suturing mastectomy flaps reduces the total volume of drained fluid and SSI. A large, multicentric, randomized control trial of high quality is required in order to strengthen the current evidence.

Keywords: Modified Radical Mastectomy, Flap Fixation, Seroma, Surgical Site Infection (SSI).

1. BACKGROUND

Breast cancer has become a fast-growing cancer in India and is now the most common cancer in Indian women which has replaced cervical cancer. Although the early detection of breast cancer has advanced due to newer approaches, technology & awareness but its etiology is still uncertain. It remains an ongoing issue in health care. There has been minimal progress in identifying people at great risk for developing this disease (Inamdar P et al., 2011). A variety of risk factors with strong evidence have been identified like early menarche, late menopause, nulliparity and lack of history of breast feeding are risk factors for breast cancer (Ferlay J et al., 2010) Other includes smoking, alcohol drinking, use of oral contraceptive pills, lack of physical activity, poor dietary intake, obesity and exposure to radiation. Families with high incidence of breast cancer have been shown to have inherited risk of about 5-7 percent. Breast cancer is characterized by its varying prevalence, aggressive behavior and disproportionate geographical distribution (Li J et al., 2011). Breast cancer in Indian women is most prevalent cancer, accounting for 14% of all cancers (Ferlay J et al., 2015, Bray F et al., 2012). In India the incidence rates begin to increase in the early 30s and reach its peak between 50-64 years of age (Takiar R and Srivastav A, 2008). Overall incidence to develop breast cancer, one in 28 women in her lifetime, one in 22 females in urban regions whereas one in 60 females in rural fields (Chaurasia V and Pal S, 2017).

According to stage of the disease, surgical treatment includes breast conservation surgery and/or mastectomy with or without axillary dissection. Seroma formation is the most frequent post-operative complication seen after mastectomy, post-operative complications associated with seroma delays wound healing, increases susceptibility to infection, skin flap necrosis; persistent pain, dehiscence of wounds and prolongs recovery (Sakkary MA, 2012, Van Bastelaar et al., 2016). Multiple studies have compared operative procedure as a risk factors for seroma formation by comparing the various dissecting techniques used for breast surgeries like conventional dissections i.e. knife & scissors, monopolar and bipolar diathermy, harmonic scalpel (Khan S et al., 2014; Bohm D et al., 2012; Zhang Z et al., 2018; He Q et al., 2012; Deo S et al., 2002).

Several strategies and techniques have been implicated for reducing seroma formation but no single approach has consistently proven effective. Associated morbidity is not only disturbing for the patient but leads to longer hospital stays, readmissions and re-operation (Hashemi E et al., 2004), worse cosmetic outcomes, delays in initiating adjuvant therapy, resulting in additional costs and worse results. We took a case-control study to evaluate the effect of obliteration of dead space by fixation of the mastectomy flaps by sutures to the underlying chest wall, on the amount and duration of post-operative fluid drainage and its associated complication after breast surgery.

2. MATERIAL & METHODS

The present study entitled "A comparative study to evaluate the effect of obliteration of dead space of mastectomy flaps" was carried out in Department of General Surgery at JNMC allied AVBRH, Sawangi (M), Wardha. This study was conducted after the clearance from Institutional Ethics Committee (IEC). It was carried out from July 2017 to August 2019.

Inclusion criteria

Patient coming to our hospital as diagnosed cases of carcinoma breast or as undiagnosed cases & its management, who were ready to give consent for participating in study, scheduled for modified radical mastectomy were included in our study.

Exclusion criteria

Patients who were not willing to enroll in the study, patients having other breast pathologies, collagen disorder, on anticoagulant therapy, morbidly obese patient, patient with recurrence of carcinoma breast.

Study design

Prospective Interventional (Case Control Study)

Sample size

Sample size estimation

The study (Sakkary MA, 2012) observed that incidence of seroma in flap fixation group was 10% and in control group was 40%. Taking these values as reference, the minimum required sample size with 80% power of study and 5% level of significance is 29 patients in each study group. To reduce margin of error, total sample size taken is 72 (36 patients per group).

Formula used is: -

$$n \geq \frac{(pc * (1 - pc) + pe * (1 - pe)) * (Z_{\alpha} + Z_{\beta})^2}{(pc - pe)^2}$$

with

pc= incidence of seroma in flap fixation group

pe= incidence of seroma in control group

Where Z_{α} is value of Z at two sided alpha error of 5% and Z_{β} is value of Z at power of 80%.

Calculations: -

$$n \geq \frac{(.1 * (1 - .1) + .4 * (1 - .4)) * (1.96 + .84)^2}{(.4 - .1)^2}$$

$$\geq 28.75 = 29 \text{ (approximately)}$$

A total of 72 female patients were included and grouped in two containing 36 patients in each after considering the inclusion criteria. Randomization was not possible as the patient presentation was inconsistent during the study.

a) Interventional Group (Group A)

b) Conventional Group (Group B)

Preparation

All the patients underwent Modified Radical Mastectomy (MRM). Group A was subjected to intervention.

Method of intervention

Group A

In this group A patients underwent modified radical mastectomy; negative suction drain was placed and the flaps raised were tucked to the underlying Pectoralis major muscle with vicryl 3-0 sutures, sutures were placed approximately 3 cm apart. Number of sutures varied according to the size of flap. The sutures were placed in between superior flap, inferior flap to the underlying pectoralis major muscle. Axilla was also tucked to the overlying skin with the lateral chest wall preserving long thoracic and thoracodorsal nerves (Figure 1-3). This quilting was done in all the patients in interventional group. Tension less repair was done. Later the subcutaneous closure of the surgical margins and skin was closed in layers by vicryl 2-0 and nylon 3-0 or skin staplers respectively.

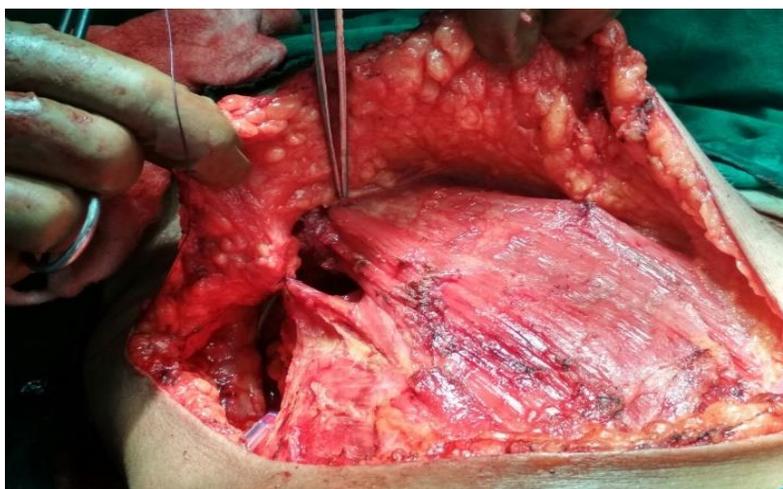


Figure 1 Representing suture fixation in pectoralis major muscle and axilla



Figure 2 Representing suture fixation in pectoralis major muscle



Figure 3 Representing suture fixation in pectoralis major muscle with superior drain placement



Figure 4 Representing post-operative partial flap necrosis

Group B

In this group of patients underwent modified radical mastectomy followed by placement of drain; subcutaneous closure of the surgical margins and skin closure without tucking the flaps. Post-operatively the amount and color of drained fluid was recorded.

The drains were removed when the amount becomes less than 30 cc for consecutive 3 days. Local chest wall ultrasound over the flaps and axilla was done on and after 10th day of removal of drains to document or exclude the presence of any collections. Drain was not kept more than 12 days in any case. The characteristics of the seroma, total amount of seroma drained, total mean amount of drained fluid, mean amount of fluid drained in last 3 days, amount of fluid drained on last day, mean day of drain removal, tumor characteristics, stage of disease, surgical site infection (SSI), flap necrosis, length of hospital stay and intervention needed for draining of seroma were recorded in master chart through coding (figure 4). The data was processed, analyzed and the results were obtained. These results were compared between the two groups.

Analysis of data

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean \pm SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was applied. Statistical tests applied; Quantitative variables were compared using Independent t test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups. Qualitative variables were correlated using Chi-Square test/Fisher's exact test. A p value of <0.05 was considered statistically significant. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

3. RESULT

Present study has majority of cases (i.e. 83%) belonging to 40-69 and least number of cases (<1%) were less than 30 years. Overall mean for age distribution was 52.79 ± 12.06 years, while for cases it was 50.97 ± 10.46 years and controls were 54.61 ± 13.46 years. Youngest participant was 25 years old while the oldest was 80 years. Overall 35 patients had right breast pathology while remaining 37 had left sided breast pathology. One patient had bilateral breast pathology. Majority of patient had infiltrating ductal carcinoma (IDC) of breast accounting for 97.22% while 2.78 % was encountered with infiltrating lobular carcinoma (ILC) and Comedo type. Majority i.e. 72 % lie in grade II in both the groups whereas 15 % were in grade I and 13 % in grade III. T2 stage remains the most common stage of presentation accounting for 41 while 2 patients were in T0 and T4 of each group in the present study. 54.17 % patient should positive lymph node metastasis in both the groups. TNM staging of the patient with 1 participant in stage 0 while stage II A & stage II B represents the bulk of patient i.e. 50 % which is followed by stage III A (table 1).

	Flap Fixation Group, n = 36	Control Group, n = 36	p-value
Patient Age			
Mean (range), Y	50.97 \pm 10.46	54.61 \pm 13.46	0.544
Side of pathology			
Left	17	20	0.479
Right	19	16	
Tumor Histology			
IDC	35	35	0.368
ILC	1	0	
Comedo	0	1	
Grade of Tumor			
Grade I	5	6	0.904
Grade II	26	26	
Grade III	5	4	
Tumor Size			
T0	1	1	0.820
T1	2	3	
T2	23	18	
T3	9	13	
T4	1	1	
Nodal Stage			

N0	19	14	0.820
N1	6	8	
N2	8	9	
N3	3	5	
TNM Stage			
0	1	0	0.539
IA	1	2	
I B	0	1	
II A	13	6	
II B	8	9	
III A	9	11	
III B	1	2	
III C	3	5	

The entire patient had seroma post-operatively. Post operatively USG showed collection of <10 ml seroma in 4 patient in interventional group while 1 patient was having <10 ml and 3 patient showed < 20 ml. Overall Surgical Site Infection (SSI) in both the groups i.e. 8.33 %, conventional group had 13.89 % of SSI whereas interventional group had 2.78 % of SSI which less than conventional group, but these results are statistically not significant. The interventional group had more partial flap necrosis as compared to the conventional group i.e. 5 and 3. These values are statistically not significant. The post-operative hospital stay was more in conventional group than interventional group i.e.8 and 5. These values are statistically not significant. Majority (i.e. 63 patient) were intervened by simple syringe aspiration i.e. G2 intervention while 7 patients needed USG guided aspiration (table 2).

Table 2 Post-Operative Complications & Intervention			
	Flap Fixation Group, n = 36	Control Group, n = 36	p-value
Seroma Formation	36	36	
Post-operative USG			
1-10 ml collection	4	1	0.238
11-20 ml collection	0	3	
Surgical Site Infection			
Present	1	5	0.199
Absent	35	31	
Flap Necrosis			
Present	5	3	0.710
Absent	31	33	
Length of Hospital Stay			
< 15 days	31	28	0.358
> 15 days	5	8	
Grade of Intervention			
G1	0	2	0.319
G2	33	30	
G3	3	4	

Mean amount of fluid drained in last 3 days was 17.77 ± 9.37 ml of drain in conventional group whereas 13.45 ± 7.37 ml. The p-value was 0.061 which is statistically not significant. Mean amount of fluid drained in last day was 11.97 ± 8.93 ml of drain in conventional group whereas 7.33 ± 5.52 ml in interventional group. The statistical p-value was 0.007* which is significant. Mean day of drain removal was removed 9 ± 1.93 day in conventional group whereas 9.33 ± 1.2 day in interventional group. The p-value is 0.227 which is statistically not significant. Mean amount of fluid drained was 50.78 ± 18.46 ml of drain in conventional group whereas 39.89 ± 16.42 ml in interventional group. The statistical p-value is 0.01* which is statistically significant. Total amount of

seroma drained was 464.58 ± 211.85 ml in conventional group whereas 377.39 ± 162.58 in interventional group, with p-value of 0.054* which is statistically significant (table 3).

	Flap Fixation Group, n = 36	Control Group, n = 36	p-value
Amount of fluid in last 3 days	13.45 \pm 7.37	17.77 \pm 9.37	0.061
Average Fluid in Last Day	7.33 \pm 5.52	11.97 \pm 8.93	0.007*
Mean drain day removal	9.33 \pm 1.2	9 \pm 1.93	0.227
Mean total fluid	39.89 \pm 16.42	50.78 \pm 18.46	0.01*
Total drain	377.39 \pm 162.58	464.58 \pm 211.85	0.054*

4. DISCUSSION

The present study was undertaken in department of general surgery and discussion is constructed on the data obtained from the study. In the present study age of patients were between 40-69 years. The youngest was of 25 years while oldest was 80 years. The mean age for cases was 50.97 ± 10.46 years while in control was 54.61 ± 13.46 (Table. 1). The overall mean age of the patients were 52.79 years in our study which is in accordance with other studies (Sakkary MA, 2012; Madhu B et al., 2017; Vilar-Compte D et al., 2004). While the study with mean early age of presentation i.e. before 50 years (Inamdar P et al., 2011; Hashemi et al., 2004; Gogia A et al., 2018; Laamiri FZ et al., 2013; Lee H et al., 2014). Whereas older age of presentation (Degnim AC et al., 2012; Gupta RK et al., 2012).

While the laterality of breast pathology was 48.61 % in right side while left side breast pathology in 51.39 % (Table 1). Study by A Gogia et al., 2018 and Ghosh S et al., 2014 is in accordance with the present study. Majority of patients were with IDC (97.22 %) while ILC (1.39 %) and other (1.39 %) (Table 1). The following study are in coherence with our study with respect to histological type of carcinoma i.e. infiltrating ductal carcinoma (Sakkary MA et al., 2012; Khan S et al., 2014; Madhu B et al., 2017; Gogia A et al., 2018; Ghosh S et al., 2014; Doval DC et al., 2015; Khater A et al., 2015). Presents data from the study reveals grade of tumor, Grade II accounts i.e. 72.22 % which dominates over other two grades. Similar findings were noted in the other studies which are in accordance with present study (Sakkary MA et al., 2012; Khan S et al., 2014; Madhu B et al., 2017; Doval DC et al., 2015; Khater A et al., 2015). Study by Ghosh S. et al., showed more patients in grade III with others (Sakkary MA et al., 2012; Khan S et al., 2014; Madhu B et al., 2017; Doval DC et al., 2015) in comparison to our study.

Present study majority of patients had T2 lesions (Table 1). Study which are in coherence with other studies which are (Sakkary MA et al., 2012; Khan S et al., 2014; Madhu B et al., 2017; Gogia A et al., 2018; Ghosh S et al., 2014) while study by Hashemi et al., 2004 had more subjects in T1 stage with 43 %, Edwards et al., 2014 showed data of T3 stage tumor that was 19.5 % whereas DC Doval et al., 2015 had 88.8 % of tumor which were > 20 mm in size. In comparative study series with positive lymph nodes (Table 1) study by Almond et al., 2010 had less than 50 % positive lymph nodes compared to present study and other study (Hashemi E et al., 2004; Gogia A et al., 2018; Doval DC et al., 2015; Sharma VM et al., 2013; Uroos Fatima and Mohammed Naim, 2014). Whereas study by Ghosh S. et al., 2014 showed 50 % of positive lymph node. Out of 54.17 % patients with positive lymph nodes showed N1 stage – 19.44 %, N2 – 23.61 % and N3 – 11.11 % respectively. This lymph node status is post-operatively diagnosed on histopathology. TNM stage in this study has majority of patients in stage II disease i.e. 50 % (Table 1) and are consistent with other studies (Khan S et al., 2014; Gupta RK et al., 2012; Ghosh S et al., 2014; Doval DC et al., 2015) while Porter KA et al., 1998 shows more number of patients of stage I group whereas A Gogia et al., 2018 had majority of patients in stage III group. Our study had 1.39 % of stage 0 patients which was less than Porter KA et al., 1998, stage I with 5.6 % and stage III with 43%.

Present study shows 13.45 ± 7.37 ml of average drain in last 3 days in cases and 17.77 ± 9.37 ml of drain in controls. These values are statistically not significant with p-value of 0.061 (Table 2). Comparing with other studies by MA Sakkary et al., 2012 and Madhu BS et al., 2017 showed similar mean drain in last 3 day measuring 207.8 (130.0-300.0) ml in cases and 213.0 (125.0-600.0) ml in controls while Ashraf Khater et al., 2015 showed 180 ± 88 [130–350] ml of drain in cases and 231 ± 134 [150–50] ml in controls. The average drain in last day before drain removal which showed 7.33 ± 5.52 ml in cases and 11.97 ± 8.93 ml in control group which is significant with a p-value of 0.007*. While in following studies i.e. MA Sakkary et al., 2012 and Madhu BS et al., 2017 had 35.0 (20.0-50.0) ml in cases and 51.5 (25.0-200.0) ml of average drain in last day. These values are very high as compared to our study.

The present study had mean drain day removal on 9.33 ± 1.2 days for cases and 9 ± 1.93 for controls respectively. These values are statistically not significant with p-value of 0.227 (Table 2). Others R G Somers et al., 1992 had 11.8 ± 9.4 days for cases and 11.2 ± 10.3 days for controls. Brian J. O’Hea et al., 1999 showed 7.0 ± 0.5 days for cases and 7.4 ± 0.8 for controls, Ruggiero R et al., 2008

shows 11.5 days for cases and 16.5 for controls, MA Sakkary et al., 2012 and Madhu BS et al., 2017 showed similar average day for drain removal i.e. 5th day for cases and 13.4th day for controls, BL. Edwards et al., 2014 had 13.4 ± 6.7 days for cases and 14.2 ± 8.2 days for controls, Ashraf Khater et al., 2015 showed 9 ± 3 days for cases and 11 ± 3 for controls. The mean total drain in our study was 39.89 ± 16.42 ml in cases and 50.78 ± 18.46 in controls which is statistically significant with a p-value of 0.01* in our study. Study by Ruggiero R et al., 2008 which utilized fibrin glue to obliterate the dead space had total mean drain of 150 ml in cases while 240 ml in control limb.

The overall total amount of drain in the present study the total drain in cases was 377.39 ± 162.58 ml and controls - 464.58 ± 211.85 ml which is statistically significant with p-value of 0.054*. Other studies by Brian J. O'Hea et al., 1999 in USA had total drain of 928 ± 94 ml in cases and 1045 ± 117 ml in controls. MA Sakkary et al., 2012 and Madhu BS et al., 2017 are similar for both cases and controls i.e. 524.8 (170.0-1525.0) and 2017.8 (445.0-5615.0), Ashraf Khater et al., 2015 showed 710 ± 290 [300–1500] ml in cases and 1160 ± 420 [500–2000] ml in controls. Post-operative seroma collection detected on USG after removal of drain, 88.89 % of patient do not show any collection post-operatively. While 11.11 % of patients showed seroma collection ranging 2 ml to 20 ml (Table 3). The present study shows SSI of 8.33 % (Table. 3) which is comparable with BL. Edwards et al., 2014 and Gao YX et al., 2010 other studies with lower SSI rates are (Khan S et al., 2014, Almond LM et al., 2010, Gong Y et al., 2010) whereas the studies with higher SSI rates were (Van Bastelaar J et al., 2016, Felipe WAB et al., 2007) respectively. About 11.11 % of patient had partial flap and marginal flap necrosis, more flap necrosis was observed in the interventional groups 13.89 % compared to conventional group 8.33 % (Table 3). Comparing the result with other studies our study had more flap necrosis compared to them (Khan S et al., 2014; Khater A et al., 2015; Gong Y et al., 2010) (Figure 4).

The study by LM Almond et al., 2010 and BL. Edwards et al., 2014 shows the post-operative hospital stay in the two groups, LM. Almond showed 2.67 ± 1.01 days more duration of hospital stay in control group while BL. Edwards showed 1.3 ± 0.6 days extra duration of hospital stay in control group. In our study the 86.11 % of cases had less than 15 days of hospital stay while 77.78 % in control group (Table 3). Patients required more than 15 % of hospital stay were 13.89 % in cases and 22.22 % in control group. The table 4 shows comparison between the studies with respect to grade of seroma formation in two groups. MA Sakkary et al., 2012 showed 90 % of patients had G1 seroma in cases while 60 % in control group, 10 % of patients had G2 seroma in cases while 35 % in control group, 0 % of patients had G3 seroma in cases while 5 % in control group, similarly Madhu BS et al., 2017 showed 80 % of patients had G0 seroma in cases while 50 % in control group, 10 % of patients had G1 seroma in cases while 10 % in control group, 10 % of patients had G2 seroma in cases while 30 % in control group, 0 % of patients had G3 seroma in cases while 5 % in control group.

In the present study showed 0 % of patients had G1 seroma in cases while 5.56 % in control group, 91.67 % of patients had G2 seroma in cases while 83.33 % in control group, 8.33 % of patients had G3 seroma in cases while 11.11 % in control group.

STUDY	YEAR	INTERVENTION REQUIRED ACCORDING TO OBSTRUCTED SEROMA							
		G0 seroma		G1 seroma		G2 seroma		G3 seroma	
		Cases	Controls	Cases	Controls	Cases	Controls	Cases	Controls
MA Sakkary et al.,	2012	-	-	90 %	60%	10%	35%	0	5 %
Madhu BS. et al.,	2017	80 %	50 %	10 %	10 %	10 %	30 %	0	5 %
PRESENT STUDY	2019	-	-	0	5.56 %	91.67 %	83.33 %	8.33 %	11.11 %

5. CONCLUSION

We conclude that dissection technique is an important factor affecting the seroma formation in post mastectomy period. We have observed that electrocautery dissection reduces operative blood loss and postoperative drain output. Closure of the dead space by suturing mastectomy flaps reduces the total volume of drained fluid and SSI. Patient care should be individualized. Further research on this very important area of breast and oncological surgery is required. A large, multicentric, randomized control trial of high quality is required in order to strengthen the current evidence. Trials should be conducted in such a manner that the effect of confounding and adjunctive procedures can be excluded.

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IEC code

DMIMS (DU)/IEC/2017-18/6639.

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