

PROSPECTIVE STUDY ON EFFICACY OF MECHANICAL OBLITERATION OF DEAD SPACE FOLLOWING AXILLARY CLEARANCE FOR CARCINOMA BREAST IN REDUCING THE INCIDENCE OF SEROMA FORMATION

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ABSTRACT

BACKGROUND

Seroma formation and its sequelae including infection, flap necrosis, delayed wound healing and patient discomfort form one of most commonly encountered complication following mastectomy and axillary dissection. Mechanical closure of dead space by flap fixation is a simple surgical procedure that eliminates dead space after mastectomy by decreasing the movement of flap over chest wall and thereby reducing the exudate.

The aim of this study is to evaluate the effect of mechanical closure of dead space after mastectomy in prevention of seroma formation.

MATERIALS AND METHODS

A total of 80 patients of carcinoma breast who underwent modified radical mastectomy in Department of General Surgery, Government Rajaji Hospital, Madurai, during the period from March 2016 to August 2016, were included, randomised into two groups based on inpatient number. 42 patients with odd IP number in conventional simple wound closure (Group A) and 38 patients with even IP number in flap fixation (Group B). Patients were evaluated for day 1 drain volume, total drain volume, drain removal day, seroma and wound complications.

RESULTS

Of the 80 women, 42 women with mean age 48 ± 8 years belongs to group A and 38 women with mean age 46 ± 7 years belongs to group B. Average size of the tumour at presentation was 3.4 cm. 36 (45%) women presented with stage IIA disease and 44 (55%) with stage IIB disease. Drain volume in first postoperative day varied from 100 to 200 mL with average of 170 mL in group A and 163 mL in group B. There was no statistically significant difference in the drain volume in first postoperative day ($p > 0.05$). The average total drain volume in the postoperative period in group A was 1426 mL and 932 mL in group B. P value was found to be significant (< 0.001). The average day of drain removal in group A was 13 days and 8 days in group B. P value was found to be significant (< 0.001). 8 patients developed seroma in group A vs. none in group B. P value was found to be significant (> 0.05). One patient developed wound complication (cellulitis) vs. none in group B. There was no statistically significant difference in the incidence of wound complications in both groups.

CONCLUSION

The present prospective study demonstrated that the mechanical obliteration of dead space by flap fixation significantly decreases the incidence of seroma formation. So, when performing modified radical mastectomy, the flap fixation technique is a valuable technique for reducing seroma formation allowing early drain removal and increased patient satisfaction.

KEYWORDS

Carcinoma Breast, Modified Radical Mastectomy, Axillary Clearance, Seroma, Flap Fixation.

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BACKGROUND

"Seroma formation and its sequelae including infection, flap necrosis, delayed wound healing and patient discomfort form one of most commonly encountered complication following mastectomy and axillary dissection varying in incidence from 3 to 85%.¹ Seroma formation after breast cancer surgery is a persistent problem much to the annoyance of surgeon and patient alike, in spite of advances in surgical techniques and haemostasis.

Pathophysiology of seroma is not clear and it is widely discussed in literature. Seroma is formed by acute

inflammatory exudates in response to surgical trauma and acute phase of wound healing or fibrinolytic activity in serum or lymph drainage.²

Seroma is influenced by large dissection area, dead space under the skin flaps and axillary region, shoulder movement, which affects attachment of skin flaps. The incidence of seroma is correlated with obesity, hypertension, breast volume, early shoulder exercise and use of heparin and tamoxifen.³⁻⁵ Seroma accumulation elevates the flaps from the chest wall and axilla thereby hampering their adherence to the tissue bed. It thus can lead to significant morbidity such as wound haematoma, delayed wound healing, wound infection, wound dehiscence, prolonged hospitalisation, delayed recovery and initiation of adjuvant therapy.

Number of techniques have been employed in an attempt to reduce or prevent seroma formation among mastectomy patients using mechanical and chemical approaches. However, there is heterogeneity in their benefits and there is paucity of uniform evidence for their use.

Mechanical closure of dead space by flap fixation is a simple surgical procedure that eliminates dead space after mastectomy. The objective of this study is to evaluate the effect of mechanical closure of dead space after mastectomy in prevention of seroma formation.

Aims and Objectives

To evaluate the efficacy of mechanical obliteration of dead space following axillary clearance for carcinoma breast in reducing the incidence of seroma formation.

MATERIALS AND METHODS

Source of Data- This is a prospective study comprising 80 patients of carcinoma breast over a period of six months from March 2016 to August 2016. In this present study, the clinical material consists of patients admitted with carcinoma breast in the Department of General Surgery at Government Rajaji Hospital, Madurai.

Method of Collection of Data

Sample Size- The size of sample work is 80 cases.

Patients with odd inpatient number underwent modified radical mastectomy with conventional simple wound closure. Patient with even inpatient number underwent modified radical mastectomy with obliteration of dead space by flap fixation.

Inclusion Criteria

All the patients admitted in general surgical ward, aged more than 18 years with carcinoma breast requiring modified radical mastectomy. Patients consented for inclusion in the study according to the designated proforma.

Exclusion Criteria

Patients with carcinoma breast undergoing breast conservation surgery.

Patients with carcinoma breast undergoing radiotherapy.

Patients with carcinoma breast undergoing modified radical mastectomy after neoadjuvant chemotherapy.

Patients with carcinoma breast undergoing palliative surgery/toilet mastectomy.

Patients with carcinoma breast undergoing completion mastectomy.

Patients not consented for inclusion in the study.

The data will be collected in prescribed proforma where in it contains particulars of the patient, clinical history, clinical examination and diagnosis, relevant investigations and details of surgery.

The patients were followed for three weeks in postoperative period.

Day 1 drain volume, total drain volume, drain removal day, seroma and wound complication were all recorded.

Ethical clearance has been obtained from ethical committee of Government Rajaji Hospital, Madurai, prior to conducting the study.

Statistical Analysis- In this study, the results of the two groups were compared and analysed by using Chi-square test.

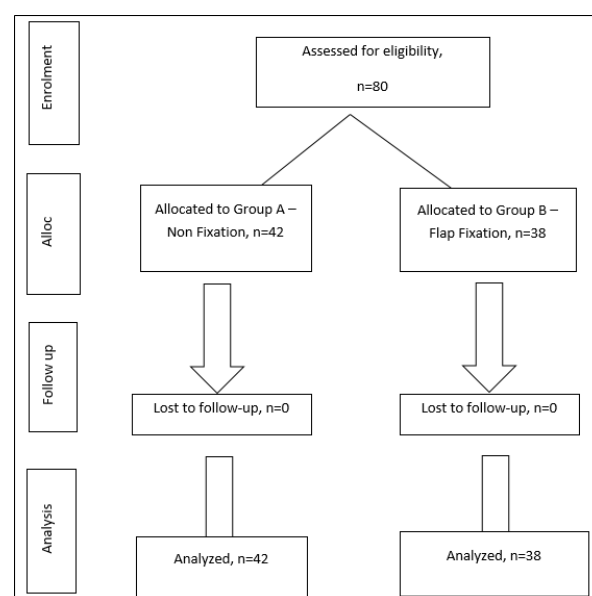


Figure 1. Consort Diagram

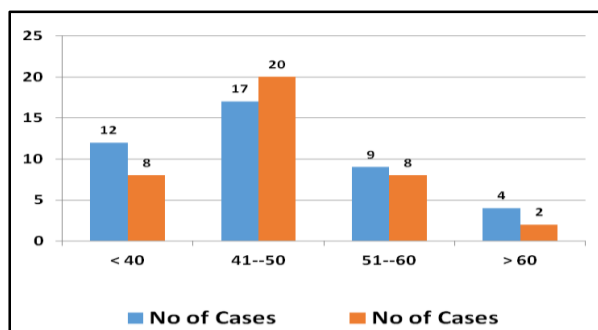
RESULTS AND OBSERVATION

In this "Prospective study on efficacy of mechanical obliteration of dead space following axillary clearance for carcinoma breast in reducing the incidence of seroma formation" conducted in Department of General Surgery at Government Rajaji Hospital, Madurai, from March 2016 to August 2016, a total of 80 patients of carcinoma breast who underwent modified radical mastectomy were included in this prospective study and randomised into two groups based on inpatient number. 42 patients with odd IP number in conventional simple wound closure (Group A) and 38 patients with even IP number in flap fixation (Group B) were considered for the study.

Patients Demography

Age Group (in Years)	Number of Patients	Percentage	Group A (%) n=42	Group B (%) n=38
<40	20	25	12 (28)	8 (21)
41-50	37	46	17 (40)	20 (52)
51-60	17	21	9 (21)	8 (21)
>60	6	7	4 (9)	2 (5)

Table 1. Age at Presentation



Graph 1. Age at Presentation

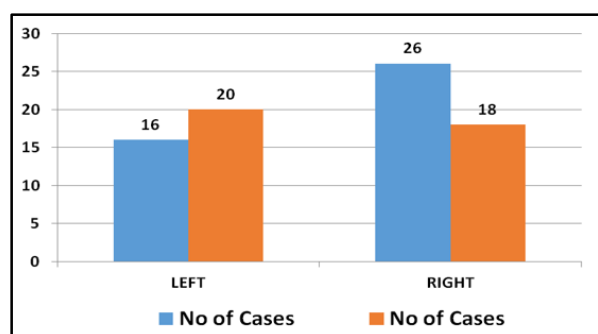
In this study, age of the patients were more than 18 years. The youngest patient included in this study series was 30 years and the eldest was 69 years old. Almost, 46% of the patients were in 41-50 age group. This includes 40% in group A and 52% in group B.

Average age in this study series is 47 years.

Side	Number of Patients		Percentage
	Group A	Group B	
Right	26	18	55
Left	16	20	45

Table 2. Location of the Tumour

The present study showed that carcinoma affects both side breast equally with slight preponderance for right side.

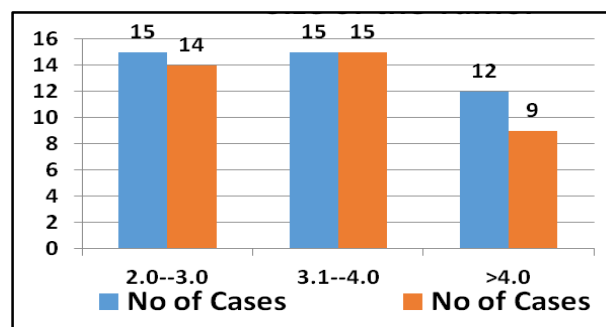


Graph 2. Location of Tumour

Size in cm	Number of Patients		Total
	Group A	Group B	
2.0-3.0	15	14	29
3.0-4.0	15	15	30
4.0-5.0	12	9	21

Table 3. Size of the Tumour

In the study, the size of tumour at presentation varied from 2 cm to 4.8 cm with average size being 3.4 cm.

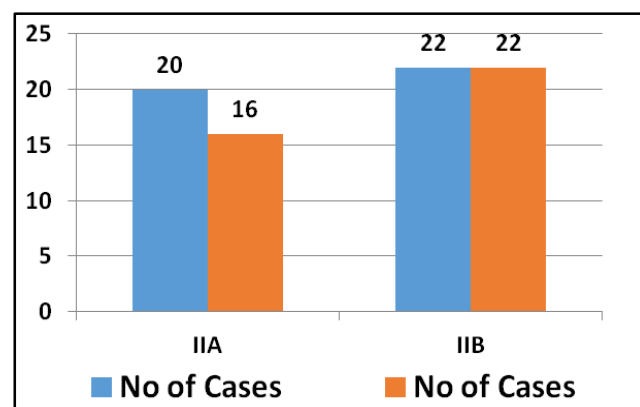


Graph 3. Size of the Tumour

Stage	Number of Patients		Total
	Group A	Group B	
IIA	20	16	36
IIB	22	22	44

Table 4. Stage of the Patient

In the study, 36 women presented with stage IIA disease and 44 women presented with stage IIB disease.



Graph 4. Stage of the Patient

COMPARISON OF STUDY GROUPS

Comparison of Study Groups	Flap Non-Fixation Group A (n=42) (%)	Flap Fixation Group B (n=38) (%)
Demography		
Mean age	48 ± 9	46 ± 7
Location		
Right	26 (62)	18 (47)
Left	16 (38)	20 (52)
Tumour size		
Mean tumour size	3.46	3.43
Stage of the patient		
IIA	20 (47)	16 (42)
IIB	22 (52)	22 (58)

Table 5. Comparison of Study Groups

In the present study, modified radical mastectomy with conventional simple wound closure was performed in 42 women with mean age 48 ± 9 years.

Of the 42 women, 26 (62%) had right-sided breast carcinoma and 16 (38%) had left-sided breast carcinoma.

Average size of the tumour at presentation was 3.46 ± 0.8 cm.

Of the 42 women, 20 (47%) women belonged to stage IIA at presentation and 22 (52%) women belonged to stage IIB.

Modified radical mastectomy and wound closure with flap fixation was performed in 38 women with mean age 46 ± 7 years.

Of the 38 women, 18 (47%) had right-sided breast carcinoma and 20 (52%) had left-sided breast carcinoma.

Average size of the tumour at presentation was 3.43 ± 0.8 cm.

Of the 38 women, 16 (42%) women belonged to stage IIA at presentation and 22 (57%) women belonged to stage IIB.

POSTOPERATIVE FOLLOW UP

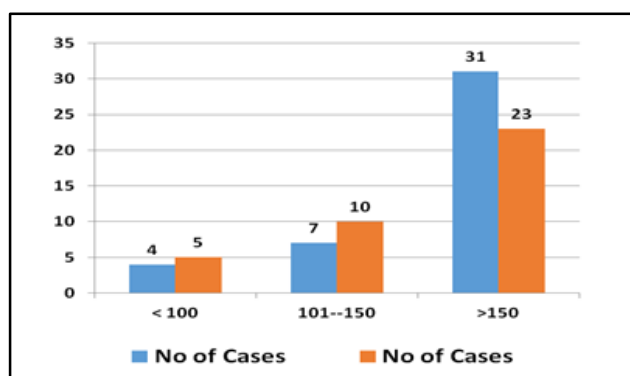
Postoperative drain volume on day 1, total drain volume, day of drain removal, seroma formation and wound complications has been compared between two groups (A and B). The results were compared with 'p' value using Chi-square test.

Day 1 Drain Volume (mL)	Number of Patients		Total
	Group A	Group B	
<100	4	5	9
100-150	7	10	17
>150	31	23	54
Mean Volume (mL)	170.2	163.8	
'p' value = 0.41 NS			

Table 6. Day 1 Drain Volume

In the present study, the drain volume in first postoperative day in Group A (flap non-fixation) was compared with Group B (flap fixation) after modified radical mastectomy.

Drain volume in first postoperative day varied from 100 to 200 mL with average of 170 mL in group A and 163 mL in group B. There was no statistically significant difference in the drain volume in first postoperative day ($p > 0.05$).



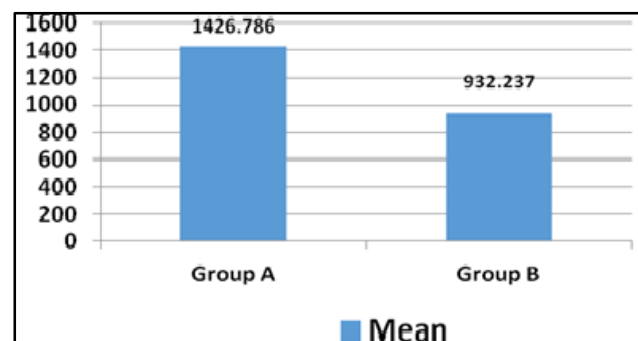
Graph 6. Day 1 Drain Volume

	Mean Total Volume (mL)	SD
Group A	1426	240
Group B	932	216
'p' value <0.001 S		

Table 7. Total Drain Volume

In the present study, the total drain volume in the postoperative period in Group A was compared with Group B.

The average total drain volume in the postoperative period in group A was 1426 mL and 932 mL in group B. P value was found to be significant (< 0.001).



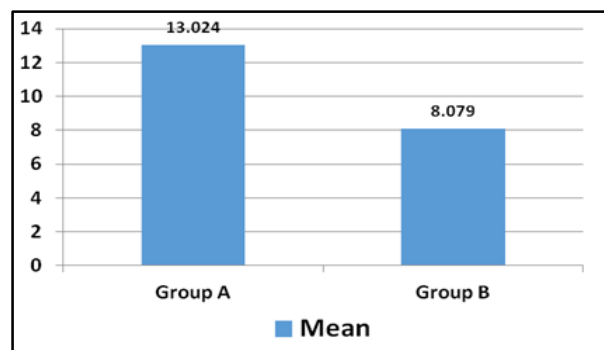
Graph 7. Total Drain Volume

	Mean Day of Removal	SD
Group A	13	2.3
Group B	8	1.6
'p' value <0.001 S		

Table 8. Drain Removal Day

In the present study, drain removal day in Group A was compared with Group B.

The average day of drain removal in group A was 13 days and 8 days in group B. P value was found to be significant (< 0.001).



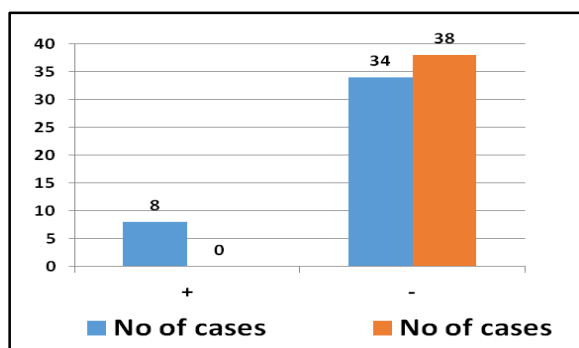
Graph 8. Drain Removal Day

Seroma	Group A	Group B	Total
Present	8	0	8
Absent	34	38	72
'p' value=0.027 S			

Table 9. Incidence of Seroma

In the present study, the incidence of seroma formation in Group A was compared with Group B.

8 patients developed seroma in group A vs. none in group B. P value was found to be significant (> 0.05).



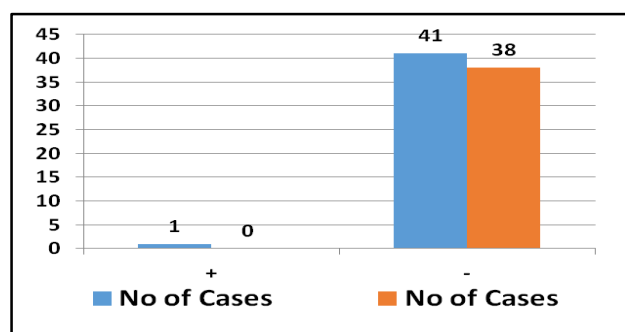
Graph 9. Incidence of Seroma

Wound Complications	Group A	Group B	Total
Present	1	0	1
Absent	41	38	79
'p' value=0.95 NS			

Table 10. Incidence of Wound Complications

In the present study, wound complications in Group A was compared with Group B.

One patient developed wound complication (cellulitis) vs. none in group B. There was no statistically significant difference in the incidence of wound complications in both groups.



Graph 10. Incidence of Wound Complications

SUMMARY

Prospective study on efficacy of mechanical obliteration of dead space following axillary clearance for carcinoma breast in reducing the incidence of seroma formation conducted in Department of General Surgery at Government Rajaji Hospital, Madurai, from March 2016 to August 2016.

- Data collected in a prescribed proforma, analysed and evaluated for day 1 drain volume, total drain volume, seroma formation and wound complications.
- Sample size was 80 women in two groups, group A - 42 (flap non-fixation) and group B - 38 (flap fixation). All 80 women completed study protocol.
- Of the 80 women, 42 women with mean age 48 ± 8 years belongs to group A and 38 women with mean age 46 ± 7 years belongs to group B.
- Average size of the tumour at presentation was 3.4 cm.
- 36 (45%) women presented with stage IIA disease and 44 (55%) with stage IIB disease.
- Drain volume in first postoperative day varied from 100 to 200 mL with average of 170 mL in group A and 163 mL in group B. There was no statistically significant

difference in the drain volume in first postoperative day ($p > 0.05$).

- The average total drain volume in the postoperative period in group A was 1426 mL and 932 mL in group B. P value was found to be significant (< 0.001).
- The average day of drain removal in group A was 13 days and 8 days in group B. P value was found to be significant (< 0.001).
- 8 patients developed seroma in group A vs. none in group B. P value was found to be significant (> 0.05).
- One patient developed wound complication (cellulitis) vs. none in group B. There was no statistically significant difference in the incidence of wound complications in both groups.
- The present prospective study demonstrated that the mechanical obliteration of dead space by flap fixation significantly decreases the incidence of seroma formation.

DISCUSSION

Seroma is a significant problem following axillary dissection for breast cancer, which is now considered as sequelae rather than complication.

Mechanical obliteration of dead space by flap fixation in an attempt to reduce incidence of seroma formation has been proposed by many studies with inconsistent results. So, the present study was undertaken to evaluate the effect of mechanical obliteration of dead space by flap fixation in reducing incidence of seroma formation.

In this study, 80 women with breast cancer who underwent modified radical mastectomy were evaluated for total drain volume, drain removal time, seroma formation and wound complications in two study groups (group A - 42 women and group B - 38 women).

There were no significant differences between the two groups with regard to age, stage and tumour size.

In group A, 42 women who underwent modified radical mastectomy had their wound closed in two layers-subcutaneous tissue with 2-0 Vicryl and skin with 2-0 Ethilon.

In group B, 38 women who underwent modified radical mastectomy had their wound closed by fixation of skin flap to underlying pectoralis major muscle with multiple rows of intermittent 2-0 Vicryl followed by skin closure with 2-0 Ethilon.

In all the patients, 214F suction drain were kept in axilla and in front of pectoral muscles.

Drain volume on first postoperative day was recorded. Drain was removed when the output was less than 30 mL for 24 hours. Total drain volume was recorded. The patients were followed for three weeks. The patients who developed seroma by clinical examination were recorded. Wound was observed for any complications like infection, cellulitis and necrosis.

In the present study, we found that the flap-fixation technique significantly decreased the drainage period ($P < 0.001$; significant), which agrees with the results of Inwang et al.⁶

Our mean number of days for drain removal was 8 days in the flap-fixation group versus 13 days in the no-flap-fixation group; this disagrees with the results of Kopelman et al⁷ who said that most surgeons remove the drain when the drainage volume is less than 50 mL in the preceding 24 hrs., which usually takes about 10 days if the flap-fixation technique is not used.

In the present study, we found that the flap-fixation technique significantly decreased the total amount of fluid drained ($P < 0.001$; highly significant), which agrees with the results of Alaa Eldin et al.⁸

The mean amount of serous fluid drained was 932 mL in the flap-fixation group versus 1426 mL in the no-flap-fixation group, whereas the mean amount of serous fluid drained was 262.2 mL in the flap-fixation group versus 763.5 mL in the no-flap-fixation group in the study conducted by Natalie et al. This may be due to the fewer number of patients in their study.

The overall clinical incidence of seroma in the whole study was about 10% (8/80).

Woodworth et al⁹ reported that the incidence of seroma fell within the range of 10-81% and this agrees with our result.

Our study showed that the flap-fixation technique was associated with no incidence of clinically symptomatic seroma (0%) after mastectomy as compared with the control group (19%) with P value less than 0.001, which was highly significant. Purushotham et al¹⁰ also found that flap fixation was useful in decreasing seroma formation after drain removal.

In our study, one patient developed cellulitis in the no flap-fixation technique vs. none in flap-fixation technique, which was treated medically and improved later on.

Flap fixation obliterates the dead space and reduces the incidence of seroma formation probably by decreasing movement of flap over the chest wall and thereby reducing the exudate.

CONCLUSION

In the present study of the 80 women who completed the study protocol, 42 women were in group A (flap non-fixation) and 38 women were in group B (flap fixation) underwent modified radical mastectomy.

After analysing the data and observations, the present prospective study demonstrated that the mechanical obliteration of dead space by flap fixation significantly decreases the incidence of seroma formation.

The sample size in the current study is relatively smaller, so a larger study sample maybe needed before any further conclusion can be made.

However, when performing modified radical mastectomy, the flap-fixation technique is still a valuable technique for reducing seroma formation allowing early drain removal and increased patient satisfaction.

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