

Evaluation of different modalities in prevention of seroma formation post-modified radical mastectomy – An observational study from a rural tertiary care center



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ABSTRACT

Background: Seroma, a recognized complication of modified radical mastectomy (MRM) delays the administration of adjuvant therapy and also effects adverse events. **Aims and Objectives:** This study was conducted to study the sociodemographic and clinical profile of patients developing seroma post MRM and compare the effectiveness of different modalities of seroma prevention since there is a dearth of literature on this matter in our sub-Himalayan region. **Materials and Methods:** This was an observational study conducted from February 2021 to August 2022 on 60 women with carcinoma breast who underwent MRM. They were studied for sociodemographic profile, cancer characteristics, and seroma prevention techniques and followed up during the study period. Preventive modalities used were quilting, octreotide therapy, suction drains with early drain removal, passive low suction drains, sharp dissection technique, and sclerotherapy. The results were analyzed using the Statistical Package for the Social Sciences version 22. **Results:** The mean age was 49.7 ± 9.4 years, 18.3% had hypertension and 10.0% diabetes mellitus, and 58.3% presented with breast lump. Overall incidence of seroma was 23.3%; the highest was observed in sclerotherapy (50%), and the lowest was in quilting (7.1%) ($P=0.235$). The presence of hypertension ($P=0.026$) and the non-administration of neoadjuvant chemotherapy ($P=0.010$) was significantly associated with developing seroma. Sharp dissection was associated with wound infection (33.3%), sclerotherapy with flap necrosis (50%), and quilting with shoulder stiffness (21.4%). **Conclusion:** The lowest incidence of seroma was in quilting and the highest in sclerotherapy. Adverse events such as wound infection, shoulder stiffness, and flap necrosis were the lowest among patients discharged with passive drains and highest in sclerotherapy.

Key words: Seroma; Modified radical mastectomy; Neo adjuvant chemotherapy; Quilting

INTRODUCTION

Seroma is an abnormal collection of plasma or lymphatic fluid within a dead space beneath a wound that generally presents as a fluctuant swelling. Post-modified radical mastectomy (MRM), can be under the skin flaps, in the axilla after dissection, or at the donor site following latissimus dorsi harvesting. Although it has a wide variation in incidence from different studies, it is the most common

complication following MRM. It varies from 15% to 85% and its occurrence delays the administration of adjuvant chemotherapy and radiotherapy. It effects flap necrosis, wound disruption, shoulder stiffness, and arm lymphedema, notwithstanding the psychological impact on the patient.¹⁻³

Different mechanisms have been proposed regarding its causation. Some of the propositions are the dead space created after MRM, shearing off of the skin

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from the underlying pectoralis, excessive usage of electrocautery, axillary nodal harvest, metastatic axillary nodes, and extensive chest wall dissection. Release of inflammatory mediators, protein exudation, interruption of lymphovascular elements, and delayed wound healing are also contributory factors.^{1,2}

Seroma is graded 1 if asymptomatic (detected only on ultrasound), graded 2 if symptomatic but can be managed either medically or by simple aspiration, and graded 3 if symptomatic and requires surgical or radiologic intervention.³

Techniques for prevention of seroma

In quilting, skin flaps are sutured to the underlying pectoralis, reducing seroma, requiring only 10 additional minutes at surgery, facilitating day treatment, and fewer visits, culminating in reduced health care consumption.⁴ Granzier et al., found a lesser incidence of seroma after flap fixation with sutures or glue.⁵ Better results were, however, found with sutures by Van Weezenburg et al.⁶

Subcutaneous injection of octreotide had a lesser seroma incidence in patients undergoing MRM.^{7,8} In addition, it reduces the duration of hospital stay and seroma formation and its related morbidity. Suction drains are used for seroma prevention successfully² and are used by most surgeons for seroma prevention.⁹ However, there are varied observations to the contrary as well.⁹⁻¹¹

Passive drains usually had no effect on seroma formation^{12,13} while sharp scalpel dissection generally was effective in seroma prevention.^{14,15} Sclerotherapy by doxycycline is an effective preventive measure.¹⁶ External compression dressings and shoulder immobilization or physical activity, injecting tranexamic acid are also effective in many cases.^{2,3} Until date, there is a dearth of existing literature that compares between the different methods implemented to prevent seroma formation in women undergoing MRM for breast cancer in our region. This study was therefore conducted to assess the effectiveness of these different modalities in patients of breast cancer treated at a tertiary care hospital of sub-Himalayan region of Eastern India.

Aims and objectives

The specific objectives of the present study were:

1. To study the clinical profile of the patients who develop seroma after MRM
2. To calculate the incidence of seroma within various study groups created based on the modality of seroma prevention at MRM
3. To study the patient-related factors and the surgical factors that would play a role in the formation of seroma
4. To do a comparative review of the various modalities of seroma prevention and their respective outcomes.

MATERIALS AND METHODS

The study was an institution-based prospective observational study conducted from February 2021 to August 2022, in the Department of General Surgery of a rural tertiary care center of North Bengal, India, after obtaining Institutional Ethical Committee clearance.

Inclusion criteria

Women with Ca breast >18 years who underwent MRM and provided written consent were included in the study.

Exclusion criteria

Patients in whom the primary skin closure was not possible and male breast malignancies were excluded from the study. Using Cochran's formula for the sample size calculation, the sample size was 57, which was rounded off to 60. A consecutive enumeration sampling technique was adopted. Following the MRM, participants were interviewed to obtain the sociodemographic breast cancer-related characteristics, as well as the operative characteristics pertaining to the prevention of seroma. The participants were then followed up for complications during the entire study period. Seroma preventive surgical modalities used were:

1. Quilting technique is done by using fine absorbable sutures (polyglactin 3/0) and taking multiple alternating stitches 3 cm apart in rows between the subcutaneous tissues of the skin flaps and the underlying muscles at various parts of the flap and also at the wound edge, after completing the MRM. A closed suction drain of 2 limbs is then used before the closure of skin flaps (Figure 1).
2. Closed suction drain with Octreotide therapy: After completing MRM, a closed suction drain of two limbs is used, and in the post-operative period, they are administered 0.1 mg octreotide subcutaneously thrice a day for 5 days, starting from the 1st post-operative day.
3. Suction drain with early drain removal: Similar to the octreotide therapy technique, the closed suction drain is placed. However, no octreotide administration is done, and the drain is removed when the daily collection decreases below 25 mL (Figure 2).
4. Passive drain: Low-pressure suction drains are used and discharged with drains *in situ* and followed up on a twice-weekly basis.
5. Sharp dissection technique: A sharp dissection is used to raise skin flaps using scalpel and not the usual electrocautery and occasional hemostasis is achieved with non-absorbable sutures (Figure 3).
6. Sclerotherapy: Injectable doxycycline (200 mg reconstituted with 20 mL distilled water) was instilled under the skin flaps before closure.

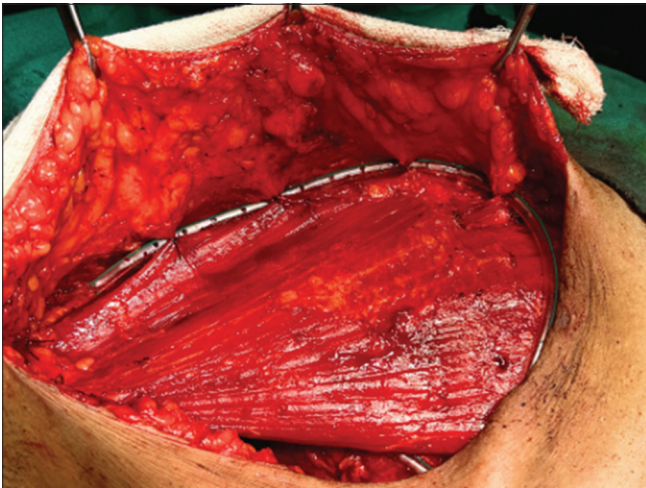


Figure 1: Quilting



Figure 2: Closed suction drain



Figure 3: Sharp scalpel dissection

Data analysis

The collected data were entered into Microsoft Excel and analyzed with the Statistical Program Statistical Package for the Social Sciences (IBM SPSS, version 22, IBM).

Data were organized and presented using the principles of descriptive and inferential statistics. The data were categorized and expressed in proportions. The continuous data were expressed as mean±SD. A $P < 0.05$ was considered to be statistically significant for the purpose of the study.

RESULTS

Most of the study participants (40.0%) were rural and aged between 40 and 49 years, with the mean age of 49.7 ± 9.4 years. Most of the women undergoing MRM in the study belonged to the poorer socioeconomic classes, that is, Class IV (26.7%) and Class V (46.7%). About 18.3% of the women had a history of hypertension. Only 10.0% of the women assessed had a history of diabetes mellitus (DM). It was seen that almost a third of the participants were obese as per the World Health Organization body mass index (BMI) classification for Asians ($>23 \text{ kg/m}^2$).

The most common presenting complaint was a lump in the breast as felt by the women (58.3%), followed by breast pain (13.3%) and discharge from the nipple(s) (10.0%). Almost equal proportions of women had tumors located in their left or their right breasts. One-third of the study participants required neoadjuvant chemotherapy (NACT) before undergoing MRM surgery.

About 91.7% of the women presenting with breast carcinoma underwent Auchincloss' type of MRM operation, while the rest (8.3%) underwent Patey's operation. Half of the MRM procedures were carried out by senior surgeons, while the other half were carried out by junior surgeons. It was observed that only in 7 patients (1.7%) level 2 nodal clearance could not be done during surgery. It was seen that the 12-month incidence of seroma was 23.3%. In the rest of the women, no seroma developed within 12 months of follow-up. Those who developed seroma required 4 aspirations. 12-month incidence of wound infection was 15.0%, the incidence of flap necrosis during this time was 13.3% and the incidence of shoulder stiffness was 13.3% during this time.

The highest incidence of post-operative seroma was observed in patients who received sclerotherapy (50%), and the lowest in those on whom quilting was done as a seroma preventive modality (7.1%). However, on analysis, the differences between the six seroma preventive modalities were not found to be statistically significant ($P=0.235$) (Table 1).

The presence of hypertension among the patients and the non-administration of NACT before MRM was associated with statistically significantly raised Odds of developing

seroma within 12 months of follow-up. The rest of the patient-related as well as clinical predictors considered were not significantly associated with the formation of seroma. When individual seroma prevention techniques were considered, it was seen that keeping all other predictors constant, quilting was associated with the least risk, and sclerotherapy was associated with the highest risk of developing seroma, although these were not statistically significant (Table 2).

On analysis, it was seen that sharp dissection was associated with the highest incidence of wound infection (33.3%), sclerotherapy was associated with the highest incidence of flap necrosis (50%), and quilting technique was associated with the highest incidence of shoulder stiffness (21.4%). Of all the seroma prevention technique, the technique of discharging the patient with the passive drain *in situ* was seen to have the overall lowest adverse event profile, with a 33.3% incidence of post-operative seroma (Table 3).

DISCUSSION

Sociodemographic characteristics of the study participants

It was observed that the mean age of the patients undergoing MRM for breast cancer was 49.7 ± 9.4 years, with most of the participants aged between 40 and 49 years of age.

The median age is 60 years in the West and 48 years in low-income nations like India.¹⁷

The prevalence of hypertension, type II DM, and obesity was found to be 18.3%, 10%, and 31.7%, respectively. Similar findings regarding the distribution of diabetes and hypertension have been reported by Heo et al., in their research exploring breast cancer among women.¹⁸ Those with a BMI >30 there is a relative risk of 1.29 in the post-menopausal age group.¹⁷

Table 1: Incidence of seroma in patients according to the seroma prevention technique employed (n=60)

Seroma prevention technique	Seroma		Total (%)	Chi-square value	P-value
	Yes	No			
Quilting (%)	1 (7.1)	13 (92.9)	14 (100)	6.807	0.235
Closed suction drain+octreotide (%)	4 (36.4)	7 (63.6)	11 (100)		
Closed suction drain (%)	1 (12.5)	7 (87.5)	8 (100)		
Passive low suction drain (%)	3 (33.3)	6 (66.7)	9 (100)		
Sharp dissection (%)	2 (16.7)	10 (83.3)	12 (100)		
Sclerotherapy (%)	3 (50)	3 (50)	6 (100)		
Total (%)	14 (23.3)	46 (76.7)	60 (100)		

Table 2: Patient and clinical predictors of seroma prevention among patients undergoing MRM (n=60)

Parameters	Adjusted odds ratio ^a	P-value
Age	1.951	0.354
Rural residence	2.447	0.358
Diabetes mellitus	0.057	0.196
Hypertension	29.539	0.026*
Obesity	1.980	0.501
Auchincloss' operation	5.209	0.451
Stage of Breast cancer		
Stage I	0.140	0.144
Stage II	0.535	0.473
Stage III	1	-
Senior surgeon	0.562	0.593
<Level 2 nodal clearance done	0.062	0.422
No Neoadjuvant chemotherapy	57.203	0.010*
Seroma prevention technique		
Quilting	0.037	0.157
Closed suction drain+octreotide	0.503	0.633
Closed suction drain	0.279	0.455
Passive drain	0.578	0.806
Sharp dissection	0.154	0.254
Sclerotherapy	1	-

^aAdjusted for age (years), urban residence, absence of DM, hypertension, obesity, Patey's operation, Stage I malignancy, MRM by junior surgeon, level 2 nodal clearance done, administration of neoadjuvant chemotherapy, and sclerotherapy as seroma prevention technique, *Statistically significant. DM: Diabetes mellitus, MRM: modified radical mastectomy

Table 3: Comparison of modalities of sclerotherapy prevention with respect to the incidence of post-operative complications among the participants (n=60)

Seroma prevention technique	Seroma	Wound infection	Flap necrosis	Shoulder stiffness
Quilting (%)	1 (7.1)	2 (14.3)	2 (14.3)	3 (21.4)
Closed suction drain+octreotide (%)	4 (36.4)	0 (0.0)	0 (0.0)	2 (18.2)
Closed suction drain (%)	1 (12.5)	2 (25.0)	0 (0.0)	1 (12.5)
Passive drain (%)	3 (33.3)	0 (0.0)	1 (11.1)	0 (0.0)
Sharp dissection (%)	2 (16.7)	4 (33.3)	2 (16.7)	2 (16.7)
Sclerotherapy (%)	3 (50)	1 (16.7)	3 (50)	0 (0.0)
Total (%)	14 (23.3)	9 (15.0)	8 (13.3)	8 (13.3)

Breast cancer-related characteristics of the study participants

It was seen in the present study that the most common complaint with which the patients presented for clinical evaluation was a breast lump (58.3%), followed by pain in the breast (13.4%) and nipple discharge (10.0%). Lumps are the most common presentation.¹⁷

In general, those who had breast conservation surgery had lesser seroma than MRM ($P=0.01$), though MRM and radical mastectomy had similar results.¹⁹

Seroma-related characteristics of the study participants

The incidence of seroma at 12 months of follow-up was 23.3%. As discussed before, seroma is a very common complication among patients undergoing MRM, with incidences as high as 85% in some studies.¹

For the prevention of seroma in the post-operative period, one of the six techniques was adopted, namely, quilting (23.3%), closed suction drain with octreotide administration (18.4%), only closed suction drains (13.3%), passive drains and discharge with drains *in situ* (15%), sharp dissection (20%) and sclerotherapy (10%). These techniques were adopted based on the individual surgeons' preference and the clinical indications of the patient. A thorough review of the existing literature did not yield any research that has compared all six of these seroma prevention techniques in a single study. Rather, any two or three techniques have been studied and compared in individual research papers.

Van Zeelst et al.,⁴ found in their study that clinically significant seroma incidence was 12.9% in the quilted versus 62.3% in the non-quilted group ($P<0.001$). In a study by Granzier et al.,⁵ a total of 187 patients were randomly assigned to Control (CON) ($n=61$), flap fixation-suture (FF-S) ($n=64$), and flap fixation-glue (FF-G) ($n=62$). Need for seroma aspirations was significantly more in the CON group ($P=0.0032$) without any difference between the flap groups; secondary outcomes, however, revealed no statistical difference. The higher number of outpatient visits in CON was clinically important (CON=27 [44.3%], FF-S=19 [30.6%] and FF-G=21 [34.4%]).

van Weezenburg et al.,⁶ observed that FF is the most promising solution. In their systematic review with network meta-analysis that included 25 articles, comprising 3423 patients, sutures, particularly running sutures, were found to be superior to tissue glue in preventing clinically significant seroma.

Prajapati et al.,⁷ found that seroma occurred in 9% of patients in the CON group and 2% of patients in the octreotide group ($P=0.010$) and thus can be used safely and effectively to decrease the volume and duration of lymphorrhea in patients undergoing MRM with axillary dissection with minimal or no complications and adverse reactions. In addition, it reduces the duration of hospital stay and seroma formation and its related morbidity.

Hirono et al.,⁸ conducted a study where six trials (738 participants) and one protocol without results were included in the study. They found somatostatin analogs reduced the volume of drained fluid (mean difference [MD] = -22.07 mL, 95% confidence interval [CI] = -42.09-2.05; $I^2=56%$) while resulting in a slight-to-no difference in the duration of drainage (MD = -0.48 days, 95% CI = -1.43-0.46; $I^2=87%$) and seroma incidence (risk ratio = 0.91, 95% CI = 0.61-1.34; $I^2=55%$). The certainty of the evidence was, however, low.

Adrien et al.,² studied fifteen randomized controlled trials (RCTs), including a total of 1766 patients undergoing radical mastectomy and axillary lymphadenectomy for breast cancer. The incidence of seroma was 24.2% (411/1698): 25.2% (232/920) in the test groups and 23.0% (179/778) in the CON groups. Neither modification of surgical technique (RR = 0.86; 95% CI [0.72, 1.03]) nor the application of a medical treatment (RR = 0.96; 95% CI [0.72, 1.29]) was effective. However, decreasing the drainage time increased the risk (RR = 1.88; 95% CI [1.43, 2.48]). There was no publication bias, but the studies were of medium-to-low quality. They concluded that despite the heterogeneity of study designs, drainage was the most effective technique. Fairhurst et al.,⁹ found that the majority of surgeons (82/97, 85%) reported using drains either routinely (38, 39%) or in certain circumstances (44, 45%).

Other methods for reducing seroma such as FF were less commonly used. Wide variation was reported in the seroma assessment and management. Over half (47/91, 52%) of respondents felt there was some uncertainty about drain use after mastectomy and axillary surgery and two-thirds (59/91, 65%) felt that a trial evaluating the use of drains vs no drains after simple breast cancer surgery was needed.

Ten Wolde et al.,¹⁰ observed that the group without a drain (n=166) had a significantly lower seroma incidence (8.4%) than the group with a drain (n=85, 21.2%) (P<0.05). Their multivariate analysis, however, found no significant predictors for seroma formation. Wound complications significantly decreased, from 31.8% in the group with a drain group to 17.5% in the group without a drain (P<0.05), concluding that post-operative drain can be omitted facilitating daycare mastectomy, eliminating drain-related care, discomfort, and related expenses.

One hundred and thirty mastectomies were performed on 119 patients by Jackson et al.¹¹ There was a significant difference in mastectomy weight between drain group patients (n=80, median: 730 g) and no drain group patients (n=50, median: 424g) (P<0.001). The mean expenses for drain group versus no drain group were £639.77 versus £365.46, respectively. Hospital stay was shorter in the no drain group (range: 1–2 days) vs drain group (range: 1–4 days). Drains did not influence complications, with no change in seroma interventions (P=0.803).

Nine randomized controlled trials were included in the review by Oyewale and Ariwoola¹² Half vacuum drains reduced both the mean hospital stay (MD: -2.30 days, 95% CI: -4.10–0.49 days, I²=97%) and the mean total effluent volume (MD: -132.61 mL, 95% CI: -207.32–-57.91 mL, I²=88%) compared with full vacuum drains. However, a statistically significant difference in the incidence of seroma between the two groups was not observed (RR: 0.67, 95% CI: 0.30–1.46, I²=65%). Likewise, there was no difference in the rate of seroma occurrence on sensitivity analysis (OR: 1.29, 95% CI: 0.72–2.33, I²=74%). Furthermore, Ivan et al.,¹³ found a significant difference (P=0.010) in the total amount of fluid collected with no significant difference in hospital stay between the full vacuum vs. half vacuum groups (P=1.000).

Bashir et al.,¹⁴ in their study observed seroma formation in a total of 14 (28%) patients in Group A (electrocautery) and 8 (16%) patients in Group B (Scalpel).

In a study of 240 patients undergoing MRM, divided between electrocautery (Group 1) and scalpel dissection (Group 2), key differences were noted in post-operative outcomes by Babar et al.,¹⁵ Group 1 showed a higher

seroma rate (31.7% vs. 18.3%, P=0.0253) and longer stays (6.3 vs. 5.7 days, P=0.024). Wound healing was slower (21.4 vs. 19.6 days, P=0.016), and pain scores were consistently higher in Group 1 at all post-operative intervals. However, the increase in infection rates in Group 1 was not statistically significant (P=0.079). Demographic factors, including age, BMI, smoking status, diabetes, hypertension, previous surgeries, and family history, were comparable between groups.

Ramkumar¹⁶ used doxycycline successfully in his cases. Doxycycline 100 mg reconstituted in 10 mL of sterile water (100 mg/vial Lyophilized) was instilled on alternate days for five sittings; each sitting had a hold time of 1 h. Seroma formation completely stopped.

To find out the predictors significantly associated with the development of seroma in patients assessed in the present study, a multivariable logistic regression was performed. The findings showed that when all other factors were kept constant, the incidence of seroma among patients undergoing MRM was statistically significantly greater among patients with hypertension (AOR = 29.539, P=0.026) and those not receiving NACT (AOR = 57.203, P=0.010). All other sociodemographic and clinical factors were not found to be statistically significantly associated with the development of seroma at 12-month follow-up.

Hypertension being an important predictor of seroma formation has been reported by Kabbash et al.³

In a study by Lorentzen et al., there was a non-significant trend towards NACT increasing the risk of seroma, wound complications, skin or nipple necrosis, flap ischemia or loss, and implant loss. A significant difference in blood loss was found, favoring NACT (MD=-75.85, 95% CI: -107.47–-44.23, P<0.00001). Heterogeneity was significant between the studies (I²>50%).²⁰

Sharp dissection was associated with the highest incidence of wound infection (33.3%), sclerotherapy was associated with the highest incidence of flap necrosis (50%), and quilting technique was associated with the highest incidence of shoulder stiffness (21.4%). Adrien et al.,² found that few studies suggested an increased risk of surgical site infection associated with drain placement and no studies attributed a decreased incidence of surgical site infection (including organ/space surgical site infection) with drain placement.

Kabbash et al.,³ had a wound infection of 10% in the quilting group with no skin flap necrosis or shoulder stiffness. Surgical site infections were lesser in the suction drain group as observed by Ten Wolde et al.¹⁰

Limitations of the study

This was a single-center study with a modest sample size. A multicentric study could not be conducted due to manpower and resource constraints, largely due to the restrictions put in place to combat the then ongoing COVID-19 pandemic. A multicenter RCT with a larger sample size can shed more light on our observations.

CONCLUSION

Although not found to be statistically significant on analysis, a clinically significant finding regarding predictive value of different seroma prevention techniques in the incidence of seroma was observed in the present study. The lowest incidence of seroma was associated with patients undergoing quilting, while the highest was for patients undergoing sclerotherapy. While the lack of statistical significance might be due to the small sample size of the study, these observations reiterate the findings of previous literature on the topic and therefore can be valuable in future seroma prevention measures.

Finally, when the adverse event profiles of each of the seroma prevention techniques were examined, it was seen that during the follow-up, apart from seromas, the incidence of adverse events such as wound infection, shoulder stiffness, and flap necrosis was the lowest among patients discharged with drain *in situ*, followed by patients with closed suction drain and octreotide administration, closed suction drain only, quilting, sharp dissection, and sclerotherapy, respectively. As each of these adverse events carry with them different sequelae, the findings of the present study, therefore, indicate that surgeons should exercise caution when choosing any one seroma prevention procedure and the incidence rates of adverse events should be kept in mind at that time.

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