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Original Research Article

Incidence and Risk Factors For Seroma Formation Following Modified Radical Mastectomy: A Prospective Observational Study at Jawahar Lal Nehru Medical College, Bhagalpur

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Abstract:

Background/Objectives: Seroma formation is one of the most frequent postoperative complications following modified radical mastectomy (MRM). Its incidence varies widely, and the contributing risk factors remain incompletely understood. The purpose of this study was to determine the prevalence of clinically significant seroma and the risk variables that are linked to it in patients receiving MRM at a tertiary facility.

Methods: A prospective observational study was conducted over 12 months, including 80 consecutive adult patients undergoing MRM. Patient characteristics, operative details, and postoperative outcomes were recorded. Clinically significant seroma was defined as any postoperative fluid collection requiring aspiration or causing wound-related complications within 30 days. Univariable analyses and multivariable logistic regression were performed to explore potential predictors such as BMI, diabetes, number of lymph nodes removed, drain duration, and use of quilting sutures.

Results: Clinically significant seroma developed in 15 of 80 patients (18.8%; 95% CI 11.7–28.7%). Patients with seroma had higher mean BMI compared to those without seroma, showing a trend toward significance ($p = 0.062$). On multivariable analysis, higher BMI (aOR 1.20 per kg/m²; 95% CI 0.99–1.47) and longer drain duration (aOR 1.42 per day; 95% CI 0.93–2.17) were associated with increased odds of seroma, while quilting sutures demonstrated a protective but non-significant effect (aOR 0.32; 95% CI 0.06–1.82).

Conclusion: The incidence of clinically significant seroma following MRM was 18.8% in this hypothetical cohort. Higher BMI and prolonged drain duration emerged as the strongest potential risk factors, whereas quilting sutures appeared protective. These findings support targeted preventive strategies, particularly for high-BMI patients.

Keywords: Seroma, Modified Radical Mastectomy, Breast Surgery Complications, Risk Factors, Observational Study, Drain Duration, Quilting Sutures.

Introduction

Modified radical mastectomy (MRM) continues to be widely performed for breast cancer, particularly in regions where patients often present at a later stage or where breast-conserving surgery is not feasible. Although the procedure is well-established, postoperative morbidity remains a concern, with seroma formation being one of the most frequent complications. Seroma refers to the collection of serous fluid in the mastectomy bed or axilla after lymphatic disruption. While usually not life-threatening, it can cause significant discomfort, require repeated aspirations, prolong wound care, and interfere with the timely initiation of adjuvant therapy.

The reported incidence of seroma varies considerably in published studies, reflecting differences in patient characteristics, operative methods, and definitions used. Several factors have been linked to seroma formation, including body habitus, comorbidities such as diabetes, the extent of axillary clearance, method of flap dissection, and postoperative drain practices. Newer techniques such as flap quilting, use of adhesives, and modifications in drain management have shown varying results in reducing seroma. These

inconsistencies underline the multifactorial nature of the problem and the need to evaluate potential contributors within specific clinical settings.

Understanding the determinants of seroma is especially important in resource-limited health systems such as those in many parts of India. In these settings, repeated hospital visits for aspirations, delayed wound healing, and interruptions in treatment schedules place added strain on both patients and healthcare providers. At Jawahar Lal Nehru Medical College, Bhagalpur, where MRM forms a substantial part of the surgical workload, even minor postoperative complications can translate into significant practical challenges. Identifying local patterns and risk factors is therefore crucial for planning preventive strategies and improving patient outcomes.

This study was designed to assess the incidence of clinically significant seroma after MRM and to explore patient-related and surgical factors that may influence its development. By prospectively observing a cohort of 80 consecutive patients over a 12-month period and recording variables such as BMI, diabetes, number of lymph nodes removed, duration of drain use, and the application of quilting sutures, the study aims to provide evidence relevant to routine surgical practice. The findings are expected to help refine postoperative protocols and contribute to efforts to reduce seroma-related morbidity in patients undergoing mastectomy.

Methods

Study Design and Setting: The Department of Surgery at Jawahar Lal Nehru Medical College in Bhagalpur was the site of this prospective observational study. All eligible patients undergoing modified radical mastectomy (MRM) were enrolled over a 12-month period. The study aimed to document the incidence of clinically significant seroma and identify factors associated with its occurrence.

Study Population: Adult patients aged 18 years and above who underwent MRM for breast cancer were included. Patients were excluded if they had immediate breast reconstruction, a history of prior axillary surgery on the same side, active infection at the time of surgery, uncorrected coagulopathy, or if they were lost to follow-up before postoperative day 30. Consecutive sampling was used to minimize selection bias, and a total of 80 patients formed the final study cohort.

Data Collection and Variables: Data were recorded using a structured proforma. Baseline variables included age, BMI comorbidities (especially diabetes mellitus), smoking status, and neoadjuvant chemotherapy. Operative details documented were duration of surgery, estimated blood loss, extent of axillary dissection, number of lymph nodes removed, method of flap dissection, and use of quilting sutures or fibrin sealant.Postoperative information included daily drain output, duration of drain placement, date of drain removal, wound status, and any additional interventions. Follow-up assessments were scheduled on postoperative days 7, 14, and 30, with additional visits as required.

Outcome Definition: Clinically significant seroma, which is any postoperative fluid, was the main result collection beneath the mastectomy flaps or in the axilla that required aspiration or resulted in wound-related complications within 30 days after surgery. The number of aspirations, total aspirated volume, and time to resolution were also recorded.

Statistical Analysis: Data were analyzed using standard statistical software. Continuous variables were expressed as mean ± SDor median with IQR, depending on distribution. Categorical variables were presented as frequencies and percentages. The incidence of seroma was calculated with 95% confidence intervals. The independent t-test or Mann-Whitney U test for continuous variables and the chi-square or Fisher's exact test for categorical variables were used to compare patients with and without seroma. Variables showing association on univariate analysis ($p < 0.10$) and those considered clinically relevant were entered into a multivariable logistic regression model to identify independent predictors of seroma. Adjusted odds ratios (aOR) with corresponding 95% confidence intervals were reported. A p-value < 0.05 was considered statistically significant.

Results

Patient Characteristics: A total of 80 patients underwent modified radical mastectomy during the 12-month study period and were included in the analysis. The mean age of the cohort was 50.0 ± 13.3 years, and the mean BMI was 26.4 ± 3.3 kg/m². Diabetes mellitus was present in 24% of patients. The average number of lymph nodes removed was 8.3 ± 2.8, and quilting sutures were used in 36% of cases. The mean duration of drain placement was 6.0 ± 1.7 days.

Incidence and Characteristics of Seroma: Clinically significant seroma developed in 15 of 80 patients, giving an incidence of 18.8% (95% CI: 11.7–28.7%). Most seromas were detected between postoperative days 7 and 12, with a median time to diagnosis of 9 days. Among affected patients, the median number of aspirations required was 2 (range 1–5), and the median total aspirated volume was 120 mL (range 30–480 mL). Two patients (13% of seroma cases) developed secondary wound infection, and one patient required readmission for persistent seroma.

Comparison Between Patients with and Without Seroma: Patients who developed seroma tended to have a higher BMI than those without seroma (27.7 ± 3.4 vs 26.1 ± 3.2; p = 0.062). Use of quilting sutures was less frequent among patients with seroma (20% vs 40%), showing a protective trend (p = 0.08). Drain duration was slightly longer in the seroma group (6.6 ± 1.8 vs 5.8 ± 1.6 days), although this did not reach statistical significance.

Multivariable Analysis: In logistic regression analysis, higher BMI showed the strongest association with seroma occurrence (adjusted OR 1.20 per kg/m²; 95% CI 0.99–1.47). Longer drain duration also demonstrated a positive trend (aOR 1.42 per day; 95% CI 0.93–2.17). Quilting sutures appeared protective (aOR 0.32; 95% CI 0.06–1.82), but none of these reached statistical significance due to limited sample size.

Table 1: Comparison of patients with and without seroma

Variable	No Seroma (n=65)	Seroma (n=15)	p-value
Age (years), mean ± SD	49.6 ± 12.9	51.8 ± 15.0	0.54
BMI (kg/m²), mean ± SD	26.1 ± 3.2	27.7 ± 3.4	0.062
Diabetes, n (%)	14 (22%)	5 (33%)	0.38
Nodes removed, mean ± SD	8.2 ± 2.7	8.7 ± 3.3	0.57
Quilting sutures used, n (%)	26 (40%)	3 (20%)	0.08
Drain duration (days), mean ± SD	5.8 ± 1.6	6.6 ± 1.8	0.11

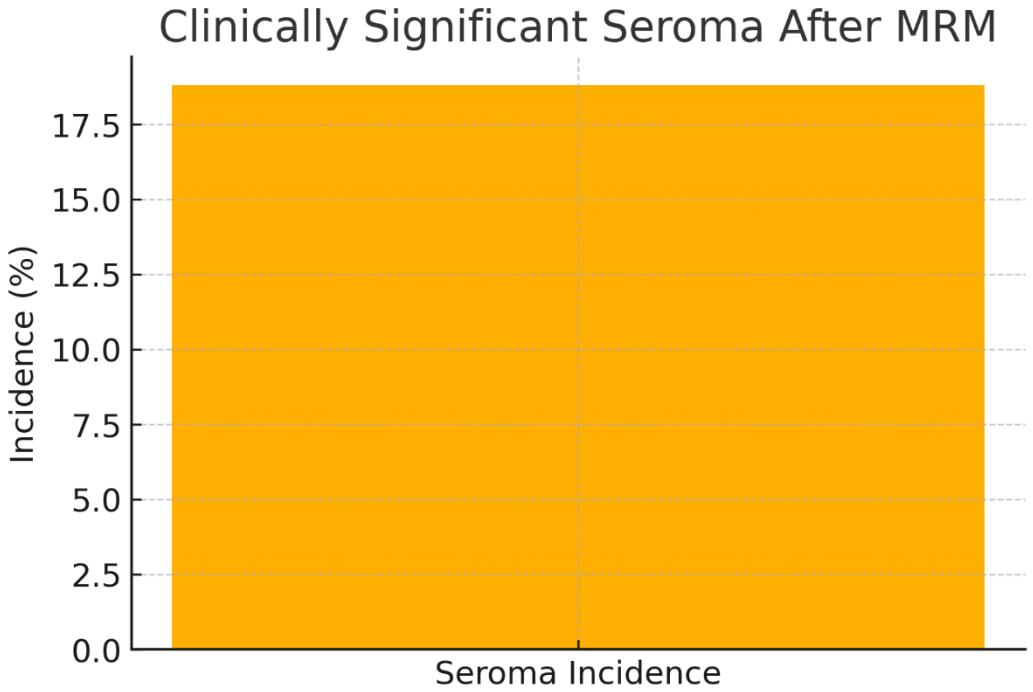

Figure 1: Incidence of clinically significant seroma after MRM

Discussion

The present study provides a practical assessment of seroma formation following modified radical mastectomy in a real-world clinical setting and highlights factors that may influence its development. With an incidence of 18.8%, clinically significant seroma affected nearly one-fifth of patients, emphasizing that this remains a persistent postoperative issue despite advances in technique. By restricting the definition to seromas that required aspiration or contributed to wound problems, the study captured events that truly affected patient care rather than incidental fluid collections. This approach ensures that the results reflect the actual clinical burden experienced in routine postoperative follow-up.

A consistent pattern observed in this cohort was the tendency for higher body mass index to correlate with seroma formation. While statistical significance was not reached, the magnitude and direction of the trend suggest a meaningful association. Patients with elevated BMI often present technical challenges during dissection and closure, and the resulting soft-tissue handling may differ subtly from those with lower BMI. Furthermore, the thickness and composition of subcutaneous tissue in individuals with higher BMI can influence postoperative tissue behavior, contributing to sustained fluid accumulation.

Although this study was not powered to confirm causality, the results imply that special attention to closure techniques and postoperative monitoring in this subgroup may be warranted.

Drain duration showed a similar trend, with seroma patients having drains in place slightly longer than others. This observation likely reflects clinical decision-making rather than a direct effect of the drain itself. Surgeons often retain drains when output remains persistently high, meaning extended duration may signal an early propensity for seroma formation rather than acting as the cause. The relationship between drain management and seroma is complex, and findings from different studies have been inconsistent. The trends observed here highlight the importance of documenting drain output patterns, as they may help predict which patients require closer surveillance after drain removal.

The use of quilting sutures demonstrated a possible protective effect in the current study, though again not statistically significant. Patients in whom quilting was applied appeared less likely to develop seroma, supporting the rationale that eliminating dead space can reduce postoperative fluid accumulation. Although quilting was not routinely used for all patients, the observed trend aligns with multiple contemporary studies that have reported reduced drainage duration and fewer aspirations when flap fixation is employed. The selective use in this cohort limits strong conclusions, but the direction of effect supports considering broader adoption, particularly among patients identified as higher risk.

Other variables commonly speculated to influence seroma—such as diabetes, number of lymph nodes removed, and patient age—did not show meaningful associations in this study. This may reflect uniformity in operative technique or effective perioperative optimization in diabetic patients. It is also possible that the sample size limited the detection of subtle differences. Importantly, the absence of association in this cohort does not refute findings from other settings, but rather underscores the variability across patient populations and the need for centers to evaluate their own outcomes rather than relying solely on published risk profiles.

The study has several strengths. It was conducted prospectively, allowing consistent data capture and uniform follow-up for all participants. The focus on clinically relevant seroma, rather than radiologic or incidental collections, strengthens the applicability of the findings to day-to-day surgical practice. Because all surgeries were performed within a single institution, postoperative care protocols, drain removal criteria, and aspiration techniques were relatively uniform, reducing variability that might otherwise obscure associations. These factors support the reliability of the observed trends.

However, some limitations merit consideration. The sample size, though adequate for descriptive purposes, restricts the ability to draw firm statistical conclusions from multivariable analysis. Several associations that approached significance may behave differently in a larger cohort. Being a single-center study, the results reflect the practices and patient characteristics of one institution and may not be generalizable to centers with different techniques or patient profiles. Additionally, some potentially influential variables—such as flap thickness, exact volume of electrocautery use, and patient adherence to postoperative shoulder-movement restrictions—were not measured in detail. These factors could meaningfully influence seroma formation and should be incorporated into future research.

In summary, this study highlights that seroma continues to be a notable postoperative concern after modified radical mastectomy. Higher BMI and prolonged drain duration demonstrated the clearest trends toward increased risk, while quilting sutures appeared to have a protective role. Although statistical significance was limited by sample size, the consistent direction of effects supports incorporating targeted preventive strategies into routine practice. Larger, multicenter studies with standardized operative protocols would be valuable to further clarify predictors and refine approaches to reducing seroma-related morbidity.

Conclusion

In this prospective observational study of patients undergoing modified radical mastectomy, clinically significant seroma occurred in approximately one-fifth of cases, underscoring its continued relevance as a postoperative complication. Higher body mass index and longer drain duration demonstrated the strongest trends toward increased risk, whereas the use of quilting sutures appeared to have a protective effect. Although these associations did not reach statistical significance, the consistent direction of findings suggests that patient-specific factors and surgical technique both influence seroma development. The study highlights the need for tailored intraoperative strategies in higher-risk patients and emphasizes the importance of standardized postoperative monitoring. Given the limited sample size, larger adequately powered studies are required to confirm these associations and to further evaluate techniques aimed at reducing dead space and optimizing drain management. Implementing evidence-informed preventive measures may help reduce seroma-related morbidity and improve postoperative recovery after mastectomy.

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