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RESEARCH ARTICLE
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A PROSPECTIVE EVALUATION OF SEROMA FREQUENCY AND DETERMINANTS FOLLOWING MODIFIED RADICAL MASTECTOMY IN A TERTIARY HOSPITAL OF NORTH INDIA

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Abstract

Background: Seroma formation is one of the most frequent early postoperative complications following modified radical mastectomy (MRM). Although often self-limiting, seroma can contribute to delayed wound healing, increased risk of infection, prolonged hospitalization, and postponement of adjuvant therapy. Identifying factors associated with seroma is essential to improve postoperative outcomes.

Aim: To determine the incidence of seroma following MRM and assess patient- and surgery-related risk factors associated with its development.

Methods: A prospective observational study was conducted over 18 months at a tertiary-care teaching hospital. Sixty female breast cancer patients undergoing MRM were consecutively enrolled. Demographic variables, comorbidities, tumor stage, and operative details were recorded. Seroma occurrence within 30 postoperative days was assessed clinically and confirmed by aspiration or ultrasonography when indicated. Statistical analysis was performed using SPSS v26. Variables with $p < 0.05$ on univariate analysis were included in multivariate logistic regression to determine independent predictors.

Results: Seroma developed in 24 of 60 patients, yielding an incidence of 40%. Mean time to seroma detection was 6.0 ± 2.4 days. On univariate analysis, BMI ≥ 28 kg/m² ($p = 0.018$) and hypertension ($p = 0.041$) were significantly associated with seroma. Both BMI ≥ 28 kg/m² (OR = 1.15; 95% CI: 1.01–1.32; $p = 0.027$) and hypertension (OR = 3.85; 95% CI: 1.05–14.15; $p = 0.042$) remained independent predictors in multivariate analysis. Age, diabetes mellitus, tumor stage, and duration of surgery showed no significant associations.

Conclusion: Seroma formation is common after MRM, occurring in 40% of cases. Elevated BMI and hypertension are significant independent predictors. Identifying high-risk patients preoperatively may guide tailored peri-operative strategies to reduce seroma incidence and enhance postoperative outcomes.

Keywords: Seroma, Modified Radical Mastectomy, Breast Cancer Surgery, Postoperative Complications, Risk Factors, Body Mass Index, Hypertension

INTRODUCTION

Breast cancer is the most commonly diagnosed malignancy among women worldwide and continues to represent a major cause of morbidity and mortality. Surgery remains the cornerstone of management, either in the form of breast-conserving techniques or via modified radical mastectomy (MRM). Postoperative complications are not uncommon, and among these, seroma formation is frequently encountered after breast surgery, particularly following axillary lymph node dissection (ALND) [1].

Seroma is defined as the postoperative accumulation of serous fluid within the dead space created by tissue dissection. It may present as swelling, discomfort, tension, and sometimes pain at the surgical site. Although often self-limiting, seroma can cause delayed wound healing, infection, prolonged drainage, extended hospital stay, and postponement of adjuvant systemic or radiation therapy—thus adversely affecting patient outcomes [1,2].

The incidence of seroma following MRM varies markedly across studies, ranging from 15% to as high as 85% [1,3]. Variability arises from differences in patient populations, surgical technique, extent of axillary dissection, use of electrocautery, and criteria used for defining seroma. In some cases, repeated aspirations may be needed, increasing the risk of discomfort and secondary infection.

The pathophysiology of seroma formation remains incompletely understood. It is believed to result from a combination of lymphatic disruption, inflammatory exudation, creation of dead space, and shearing forces between skin flaps and underlying tissues [4]. Identified or proposed risk factors include older age, higher body mass index (BMI), breast size, hypertension, diabetes mellitus, and extent of nodal dissection, though evidence remains inconsistent across studies [3–5]. Some authors have suggested that obesity predisposes patients to seroma because of increased fatty tissue, which results in greater disruption of lymphatics and formation of larger dead space [6].

Hypertension and other comorbidities have also been suggested to impair postoperative wound-healing response and therefore favour fluid accumulation [7]. Similarly, use of electrocautery in tissue dissection has been associated with increased seroma owing to thermal damage of lymphatic channels [3]. On the other hand, several surgical modifications—quilting sutures, ultrasonic scalpels, fibrin sealants—have been studied to reduce seroma incidence, though evidence has been heterogeneous and not clearly conclusive [8].

Considering the burden posed by seroma in delaying recovery and complicating postoperative care, it is essential to better define its incidence and related determinants within local patient populations. This becomes particularly important in resource-limited settings, where prolonged drainage and repeated aspirations may impose additional constraints. The present study therefore aims to evaluate the frequency of postoperative seroma formation among patients undergoing modified radical mastectomy in our tertiary care center and to assess patient- and surgery-related risk factors associated with its development. A clearer understanding of predictive parameters could guide risk stratification, targeted peri-operative management, and improved postoperative outcomes.

METHODOLOGY

Study Design: This study employed a prospective observational design to determine the incidence of seroma formation following modified radical mastectomy (MRM) and to identify associated risk factors.

Study Setting and Duration: The study was conducted at a tertiary-care teaching hospital over an 18-month period from Jan 2023 to June 2024.

Study Population: Female patients diagnosed with breast carcinoma and scheduled for MRM were consecutively recruited. Recruitment continued until the predetermined sample size of 60 was achieved.

Inclusion Criteria

1. Female patients ≥18 years of age
2. Histologically confirmed breast carcinoma

3. Planned for modified radical mastectomy with or without axillary dissection
4. Ability to provide informed consent

Exclusion Criteria
1. Previous breast or axillary surgery
2. Prior radiotherapy to the breast or axilla
3. Known coagulation disorders or ongoing anticoagulation therapy
4. Active wound infection or systemic sepsis at time of surgery
5. Severe uncontrolled diabetes mellitus
6. Patients not consenting to participate

Sample Size: A total of 60 patients were enrolled based on feasibility and the average procedural volume at the study site during the study period.

Sampling Technique: A consecutive sampling method was used. Eligible patients fulfilling inclusion criteria were enrolled until the sample size was met.

Data Collection Tool: A pre-structured case record form was utilized to document:
- Demographic characteristics
- Clinical history
- Tumor staging
- Operative details
- Post-operative follow-up and outcomes

The data collection team remained blinded to the subsequent risk analysis, ensuring unbiased acquisition.

Operational Definitions
Seroma: A clinically detectable, fluctuant fluid collection at the mastectomy site, occurring within 30 days of surgery, confirmed by aspiration and/or ultrasound when required.

Study Procedure
1. All participants underwent MRM under general anaesthesia following standard operative protocol.
2. Number of drains, surgical duration, type of axillary dissection, and use of cautery were documented.
3. Postoperative management, including drain monitoring, mobilization, and analgesia, followed standard institutional protocols.
4. Patients were evaluated clinically on postoperative days 2, 5, 7, and then weekly up to 4 weeks. Additional assessments were performed if symptoms suggested seroma formation.
5. If seroma was suspected, diagnosis was confirmed clinically or by ultrasonography. Aspiration was performed if clinically indicated.

Variables Assessed and Outcome Measures: Independent variables included age, body mass index (BMI), comorbidities such as hypertension and diabetes mellitus, tumor stage, duration of surgery, use of electrocautery, and number of drains, while the dependent variable was the development of postoperative seroma. Data quality assurance was ensured through prior training of data collectors, double-entry and cross-checking to minimize entry errors, and blinded analysis by investigators. The primary outcome measure was the incidence of postoperative seroma within 30 days of modified radical mastectomy (MRM), and the secondary outcome was the identification of associated risk factors.

Ethical Considerations: The study was conducted in accordance with the Declaration of Helsinki, and ethical approval was obtained from the Institutional Ethics Committee. Written informed consent

was obtained from all participants prior to enrolment. To maintain confidentiality, patient identifiers were removed from all records, individual data were coded and stored in password-protected files, and only study investigators had access to the coded data.

Statistical Analysis: Statistical analysis was performed using SPSS (version 26). Descriptive statistics were presented as means ± standard deviation and percentages. Categorical variables were analyzed using the Chi-square test or Fisher's exact test, while quantitative variables were compared using the independent t-test. Variables with $p < 0.05$ in univariate analysis were included in a multivariate logistic regression model to identify independent predictors of seroma. A p-value < 0.05 was considered statistically significant, and results were reported as Odds Ratios (OR) with 95% Confidence Intervals (CI).

RESULTS

A total of 60 female patients undergoing modified radical mastectomy (MRM) were included in the study. The mean age of the participants was 52.1 ± 11.3 years, and the mean BMI was 27.8 ± 4.6 kg/m². Comorbidities included hypertension in 14 (23.3%) patients and diabetes mellitus in 10 (16.7%) patients. Most patients presented with Stage II disease (45%), followed by Stage III (35%) and Stage I (20%).(Table 1)

Table 1: Demographic & Clinical Characteristics (N = 60)

Variable	**Mean ± SD / n (%)**
Age (years)	52.1 ± 11.3
BMI (kg/m²)	27.8 ± 4.6
Hypertension	14 (23.3%)
Diabetes Mellitus	10 (16.7%)
Tumor Stage	
— Stage I	12 (20%)
— Stage II	27 (45%)
— Stage III	21 (35%)
Duration of Surgery (minutes)	145 ± 29
Use of Electrocautery	60 (100%)
Drains placed	60 (100%)

Seroma developed in 24 out of 60 patients (40%). The mean time at which seroma was detected was 6.0 ± 2.4 days post-operatively, ranging from days 4 to 11. On univariate analysis, higher BMI (≥28 kg/m²) and hypertension were significantly associated with seroma formation ($p < 0.05$). Age, diabetes mellitus, tumor stage, and duration of surgery did not show statistically significant association. (Table 2)

Table 2: Comparison of Variables Between Seroma and Non-Seroma Groups

Variable	**Seroma (n=24)**	**No Seroma (n=36)**	**p-value**
Age (years)	53.4 ± 10.8	51.3 ± 11.7	0.410

Table 2: Comparison of Variables Between Seroma and Non-Seroma Groups

BMI (kg/m²)	29.3 ± 4.7	26.9 ± 4.2	**0.018**
Hypertension	9 (37.5%)	5 (13.9%)	**0.041**
Diabetes Mellitus	5 (20.8%)	5 (13.9%)	0.620
Tumor Stage			
— Stage I	4 (16.7%)	8 (22.2%)	0.600
— Stage II	10 (41.7%)	17 (47.2%)	0.680
— Stage III	10 (41.7%)	11 (30.6%)	0.390
Duration of Surgery (min)	148 ± 31	142 ± 29	0.380

($p < 0.05$ considered significant)

Variables found significant on univariate analysis (BMI and hypertension) were entered into multivariate logistic regression. Both BMI ≥28 kg/m² and hypertension remained independent predictors of seroma formation. (Table 3)

Table 3. Multivariate Logistic Regression Analysis of Factors Associated with Seroma Formation

Variable	**Odds Ratio (OR)**	**95% CI**	**p-value**
BMI ≥ 28 kg/m²	1.15	1.01 – 1.32	**0.027**
Hypertension	3.85	1.05 – 14.15	**0.042**

($p < 0.05$ considered significant)

DISCUSSION

In this prospective study, the incidence of seroma formation after modified radical mastectomy (MRM) was 40%, which aligns with the broad incidence reported in the literature ranging between 15–85% [1,3]. Seroma continues to be among the most commonly encountered early postoperative complications following breast cancer surgery, with potential consequences such as delayed wound healing, local infection, repeated aspirations, prolonged hospital stay, and delayed initiation of adjuvant therapy [1,2].

Body mass index (BMI ≥ 28 kg/m²) was found to be an independent predictor of seroma formation. Prior studies have also demonstrated higher seroma frequency among obese patients [3,5,6]. The mechanism likely involves increased disruption of lymphatic channels and creation of a larger dead space in patients with greater adipose tissue volume, thereby facilitating postoperative fluid accumulation [4,6]. Obesity is also known to alter immune response and wound-healing capacity, further increasing risk [6].

Hypertension was another significant independent risk factor in our analysis, consistent with reports suggesting its detrimental impact on microcirculation and wound repair processes [7]. Impaired capillary function may contribute to increased tissue edema and accumulation of inflammatory exudate, making fluid collection more likely [9]. Although hypertension has been less frequently studied compared to BMI and diabetes, its association in this cohort highlights the need for enhanced perioperative blood pressure control.

In contrast, age did not show significant association with seroma development. This finding agrees with multiple studies reporting no correlation between patient age and risk of seroma [5]. Similarly, diabetes mellitus did not significantly affect seroma formation in our cohort. Although diabetes is widely recognized as a risk factor for impaired wound healing, other studies have noted conflicting results [4,6]. Improved perioperative glycemic control in the present cohort may partially explain this lack of association.
Tumor stage and operative duration were not significantly associated with seroma formation in this study. Some authors have noted increased seroma rates with more extensive surgical dissection associated with advanced tumor stage; however, evidence remains inconsistent [6,10].

Strategies to reduce seroma formation have included quilting sutures, flap fixation, sealing agents, and minimizing cautery usage [8]. Quilting sutures have demonstrated benefit by reducing dead space, thereby lowering the seroma rate [8]. However, universal consensus is lacking, and practice varies widely depending on surgeon preference and resource availability.

The findings of this study underscore the importance of identifying high-risk individuals preoperatively—particularly those with elevated BMI and hypertension—to inform clinical decision-making. Tailored perioperative interventions such as optimized weight and comorbidity management, meticulous surgical handling, and focused postoperative surveillance may help reduce complication rates.

CONCLUSION

This prospective observational study found that seroma formation is a frequent postoperative complication following modified radical mastectomy, with an incidence of 40%. Although often self-limiting, seroma can delay wound healing, increase infection risk, prolong hospital stay, require repeated aspirations, and postpone adjuvant therapy. Higher body mass index (BMI ≥ 28 kg/m^2) and hypertension were identified as significant independent predictors, emphasizing the need for careful preoperative assessment and individualized peri-operative management, including weight optimization, blood pressure control, meticulous surgical technique, and closer monitoring. Other variables—such as age, diabetes mellitus, tumor stage, and duration of surgery—showed no significant association with seroma. As seroma formation is multifactorial, larger multicenter studies with longer follow-up and exploration of additional risk factors (e.g., breast size, smoking, axillary dissection level) are warranted. Overall, recognizing high-risk characteristics can guide targeted interventions to reduce postoperative seroma and improve patient outcomes.

Declarations
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REFERENCES

1. Srivastava V, Basu S, Shukla VK. Seroma formation after breast cancer surgery: what we have learned in the last two decades. J Breast Cancer. 2012;15(4):373–380. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC3542843/
2. Kazzam ME, Ng P. Postoperative Seroma Management. [Updated 2023 Aug 14]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK585101/
3. Spiekerman van Weezelenburg MA, Daemen JH, van Kuijk SM, et al. Seroma formation after mastectomy: A systematic review and network meta-analysis of different flap fixation techniques. Journal of Surgical Oncology. 2024 May;129(6):1015-24. Available at:

https://cris.maastrichtuniversity.nl/files/185433178/Beets-2024-Seroma-formation-after-mastectomy.pdf

4. Pogson CJ, Adwani A, Ebbs SR. Seroma following breast cancer surgery. European Journal of Surgical Oncology (EJSO). 2003 Nov 1;29(9):711-7. Available at: https://pubmed.ncbi.nlm.nih.gov/14602488/
5. Gonzalez EA, Saltzstein EC, Riedner CS, Nelson BK. Seroma formation following breast cancer surgery. The breast journal. 2003 Sep;9(5):385-8. Available at: https://pubmed.ncbi.nlm.nih.gov/12968958/
6. Pan XF, Huan JL, Qin XJ. Potential risk factors for the development of seroma following mastectomy with axillary dissection. Molecular and clinical oncology. 2015 Jan 1;3(1):222-6. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4251103/
7. Guo SA, DiPietro LA. Factors affecting wound healing. Journal of dental research. 2010 Mar;89(3):219-29. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC2903966/
8. Morarasu S, Clancy C, Ghetu N, et al. Impact of quilting sutures on surgical outcomes after mastectomy: a systematic review and meta-analysis. Annals of Surgical Oncology. 2022 Jun;29(6):3785-97. Available at: https://pubmed.ncbi.nlm.nih.gov/35103890/
9. Jain PK, Sowdi R, Anderson AD, MacFie J. Randomized clinical trial investigating the use of drains and fibrin sealant following surgery for breast cancer. Journal of British Surgery. 2004 Jan;91(1):54-60. Available at: https://pubmed.ncbi.nlm.nih.gov/14716794/
10. Kuroi K, Shimozuma K, Taguchi T, et al. Evidence-based risk factors for seroma formation in breast surgery. Japanese journal of clinical oncology. 2006 Apr 1;36(4):197-206. Available at: https://academic.oup.com/jjco/article-abstract/36/4/197/824107?redirectedFrom=fulltext