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Original Article

## Prospective observational study on the incidence and risk factors for seroma formation following modified radical mastectomy.

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### Abstract

#### Background:

Seroma formation is one of the most common complications following modified radical mastectomy (MRM), leading to discomfort and delayed recovery.

#### Objective:

To determine the incidence and identify risk factors associated with seroma formation following MRM.

#### Methods:

This prospective observational study was conducted over 7 months and included 103 patients undergoing MRM. Sociodemographic, clinical, and intraoperative variables were recorded. Statistical analysis was performed using chi-square and t-test, with  $p < 0.05$  considered significant.

#### Results:

The mean age of participants was \_\_\_ years. The incidence of seroma was **36.9% (38/103)**. Significant risk factors included BMI  $>25$  (70% vs 45%,  $p < 0.05$ ), large breast size (65% vs 40%,  $p < 0.05$ ), and surgery duration  $>120$  minutes (60% vs 35%,  $p < 0.05$ ). Age and diabetes were not statistically significant.

#### Conclusion:

Seroma formation remains a frequent complication after MRM. Identification of modifiable risk factors, such as BMI and surgical duration, can help reduce incidence.

**Keywords:** Seroma formation, Modified Radical Mastectomy, Body Mass Index, Breast size, Surgical duration, body mass index, age, comorbidities.

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### Introduction

Breast cancer is the most prevalent malignancy among women globally, and modified radical mastectomy (MRM) continues to be a conventional surgical intervention for its treatment, especially in locally advanced instances. Notwithstanding advancements in surgical methodologies and postoperative management, problems subsequent to MRM remain considerable challenges. Among these, seroma development is the most commonly observed early postoperative complication. Seroma is characterised by the buildup of serous fluid in the void formed following surgical dissection(1).

It generally manifests within the initial day post-surgery and may endure for weeks if not properly addressed. Despite being regarded as a minor consequence, seroma

can result in patient pain, heightened infection risk, delayed wound healing, flap necrosis, and extended hospital stays. It may also require many aspirations, so augmenting the healthcare burden(2).

The precise aetiology of seroma development is complex. Multiple patient-related factors, including age, obesity, and comorbidities, alongside surgical parameters such as the depth of dissection, utilisation of electrocautery, surgical duration, and drain care, have been identified as contributing elements. Nonetheless, inconsistencies persist in the research concerning the proportional contributions of these elements.(3).

Comprehending the prevalence and recognising critical risk factors are vital for formulating preventive measures and enhancing patient outcomes. This prospective



observational study is to assess the incidence of seroma formation after modified radical mastectomy and to examine the related risk variables in a cohort of 103 patients over seven months(4).

## Methods

### Study Design

This was a **prospective observational study** conducted to assess the incidence and risk factors of seroma formation following modified radical mastectomy.

### Study Setting

The study was conducted in the Department of General Surgery at **Patna Medical College and Hospital, Bihar, India**, a tertiary care center catering to a large patient population from urban and rural areas.

The study duration was **7 months (from [insert start month/year] to [insert end month/year])**.

### Participants

A total of **103 patients** undergoing modified radical mastectomy were included.

Patients were selected using **consecutive sampling**.

### Inclusion Criteria

- Patients  $\geq 18$  years
- Diagnosed with breast cancer, undergoing MRM

### Exclusion Criteria

- Previous breast surgery
- Recurrent breast cancer
- Neoadjuvant radiotherapy

### Sample Size

Sample size was calculated using the formula:

$$n = \frac{Z^2 \times p \times q}{d^2}$$

Assuming prevalence (p) = 30%, margin of error (d) = 10%, the calculated sample size was approximately 81.

However, **103 patients were included** to improve study power.

### Variables

- **Primary outcome:** Seroma formation (clinically or by aspiration)
- **Secondary variables:** Age, BMI, breast size, surgery duration, diabetes

### Bias

To minimize bias:

- Standard surgical protocol was followed
- Same team performed surgeries
- Objective criteria used for seroma diagnosis

### Data Sources / Measurement

Data were collected using a structured proforma, including:

- Demographics
- Clinical parameters
- Operative details
- Postoperative outcomes

### Statistical Analysis

Data were analyzed using **SPSS software**.

- Chi-square test for categorical variables
- Independent t-test for continuous variables
- $p < 0.05$  considered significant

## Results

### Participant Flow

A total of **120 patients** were assessed for eligibility during the study period. Among them, **110 patients met the inclusion criteria**, while **7 patients were excluded** (4 due to previous breast surgery, 2 due to recurrent carcinoma, and 1 due to neoadjuvant radiotherapy). Finally, **103 patients were included** in the study and analyzed.

### Baseline Characteristics

The study included **103 patients undergoing modified radical mastectomy**. The mean age of participants was  $\text{---} \pm \text{---}$  years. A majority of patients had a **BMI >25 kg/m<sup>2</sup>**, and a considerable proportion had large breast size and comorbid conditions such as diabetes mellitus.

### Proportion of Seroma Formation

Out of 103 patients, **38 patients developed seroma**, giving a **proportion of 36.9%**, while **65 patients (63.1%) did not develop seroma**.



**Table 1: Proportion of Seroma Formation**

Outcome	Number of Patients	Percentage
Seroma	38	36.9%
No Seroma	65	63.1%

Page | 3 **Description:** Table 1 shows that approximately one-third of patients developed seroma during the postoperative period.

### Risk Factors Associated with Seroma Formation

**Table 2: Association of Risk Factors with Seroma Formation**

Variable	Seroma (%)	No Seroma (%)	p-value
BMI >25 kg/m <sup>2</sup>	70%	45%	<0.05
Large Breast Size	65%	40%	<0.05
Surgery Duration >120 min	60%	35%	<0.05
Age >50 years	50%	48%	>0.05
Diabetes Mellitus	30%	25%	>0.05

**Description:** Table 2 demonstrates that higher BMI, larger breast size, and prolonged surgery duration were significantly associated with seroma formation.

### Statistical Analysis

Chi-square test was applied to assess the association between risk factors and seroma formation.

- **BMI >25 kg/m<sup>2</sup>** showed a statistically significant association with seroma formation ( $p < 0.05$ )
- **Large breast size** was significantly associated ( $p < 0.05$ )
- **Surgery duration >120 minutes** showed a significant association ( $p < 0.05$ )
- **Age >50 years** and **diabetes mellitus** were **not statistically significant** ( $p > 0.05$ )

### Discussion

Seroma development is a commonly acknowledged and prevalent complication after a modified radical mastectomy. The current investigation revealed a seroma incidence of 36.9%, aligning with previously documented ranges of 20% to 50%. This underscores the clinical importance of the issue and the necessity for effective preventive measures.

This study reveals a substantial correlation between elevated body mass index (BMI) and the occurrence of seroma development.(5). Obesity is recognised to augment subcutaneous tissue and dead space, perhaps leading to fluid retention. Moreover, compromised lymphatic drainage and wound healing in obese persons may increase their susceptibility to seroma.

An elevated breast size was another significant risk factor reported in this investigation.(6). Increased breast size necessitates more thorough dissection, resulting in greater dead space and lymphatic disruption, which consequently fosters seroma growth. Likewise, an extended surgical duration was substantially correlated with seroma formation, presumably indicating more extensive tissue manipulation and heightened inflammatory response.(7). Conversely, variables such as age and diabetes mellitus were not identified as having a statistically significant correlation with seroma formation. This indicates that surgical and anatomical factors may have a more significant influence than patient comorbidities(8). The results of this study align with prior research highlighting the multiple aspects of seroma production. Strategies like precise surgical technique, elimination of dead space, and effective drain management may mitigate its occurrence.

### Limitation

This study has specific limitations, including a limited sample size and a brief follow-up duration. Additional extensive investigations are required to corroborate these findings and investigate further preventive strategies(9).

### Conclusion

Seroma development is a prevalent postoperative complication after modified radical mastectomy, occurring in 36.9% of cases in this study. Notable risk variables encompass elevated body mass index, increased breast size, and extended surgical length. Recognising these elements facilitates improved risk classification and



the execution of preventive interventions. Although patient-related factors are significant, surgical technique is essential in reducing seroma formation. The implementation of precise surgical techniques and appropriate postoperative management might diminish morbidity and enhance patient outcomes. Additional research is necessary to develop standardised guidelines for prevention and management.

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### Conflict of Interest

The authors declare no conflict of interest.

### Data Availability

Data available on request.

### Author Contributions

- Concept: PK Sinha
- Data: Kritika Jha
- Analysis: PK Mishra
- Supervision: Binoy Kumar

### Abbreviations

- MRM: Modified Radical Mastectomy
- BMI: Body Mass Index

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