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An observational study on the incidence and risk factors for seroma formation post modified radical mastectomy

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ABSTRACT

Background : Seroma development is a typical complication following the modified radical mastectomy (MRM) for breast cancer, leading to patient discomfort, postponed wound healing and elevated infection risk. Identifying risk factors associated with seroma formation is crucial for developing effective prevention strategies.

*Aim:*The purpose of this research was to determine the frequency and protective variables for seroma formation in MRM patients.

Methods:(40) Forty, female patients undergoing MRM participated in a prospective observational research. Information was gathered about clinical, perioperative, and demographic factors. To find important risk factors for seroma production, univariate and multivariate logistic regression analyses were carried out. SPSS version 23.0 was used for the statistical analysis.

*Result:*Seroma formation was observed in 18 out of 40 patients (45%). Univariate analysis identified higher BMI (p=0.037) and diabetes mellitus (p=0.041) as significant risk factors. Multivariate analysis confirmed these findings, with higher BMI (OR=1.21, 95% CI 1.03-1.42, p=0.022) and diabetes mellitus (OR=4.67, 95% CI 1.10-19.85, p=0.037) remaining significant predictors of seroma formation.

Conclusion: Higher BMI and diabetes mellitus are significant risk factors for seroma formation following MRM. These findings highlight the need for targeted postoperative care and monitoring for patients with these risk factors to reduce the incidence of seroma and improve surgical outcomes.

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Recommendations: Implementing tailored postoperative care protocols for patients with higher BMI and diabetes mellitus could mitigate the risk of seroma formation. Further to confirm these results, larger sample size investigations are advised and refine prevention strategies.

Keywords: Seroma formation, Modified radical mastectomy, Breast cancer surgery, Risk factors, Postoperative complications

INTRODUCTION

The surgical care of breast cancer still relies heavily on modified radical mastectomy (MRM), especially when breast-conserving surgery is not possible or requested. Seroma development is still a common consequence after MRM, despite improvements in surgical methods and after care. Seroma, which is characterised as the buildup of serous fluid in the dead space left by surgical dissection, can cause serious morbidity such as infection, slowed wound healing, and discomfort for the patient [1].

There is a great deal of variation in the literature on the incidence of seroma formation following MRM; reports range from 10% to 85% [2]. Variations in surgical methods, patient profiles, and classifications of seroma are responsible for this broad variation. Different patient parameters, such as age and BMI and comorbidities, as well as surgical characteristics, such as the degree of tissue dissection, the use of electrocautery, and the presence of drains, are risk factors for seroma formation [3].

Finding risk factors that can be changed and those that cannot be changed is crucial for preventing seroma formation, according to recent research. A study conducted in 2019 by Baghestani et al., for example, showed that a higher body mass index (BMI) is consistently linked to a higher risk of seroma. This is probably because adipose tissue has more dead space and lymphatic disruption. Likewise, diabetes mellitus has been recognised as an important threat , presumably because of its effects on immunological response and wound healing [4]. Comprehending these risk factors is essential for formulating focused approaches to lower the incidence of seroma and enhance surgical results.

Seroma formation has a complicated and poorly understood pathogenesis. It is thought to be caused by a confluence of shear pressures, lymphatic disruption, and inflammatory reactions

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at the surgical site. Aspiration is the usual method of managing seroma, however repeated aspirations raise the risk of infection and pain for the patient. As a result, prevention is ideal, which calls for a deep comprehension of the underlying mechanism and risk factors [5].

This study seeks to offer a thorough analysis of the incidence and risk variables related to seroma formation after MRM. Our objective is to determine the critical patient and surgical factors that lead to the formation of seromas by means of a prospective observational study. Clinical practice can benefit from this knowledge, which will enhance patient care and lower the risk of problems following surgery. The study's conclusions may also add to the current discussion on surgical best practices and the creation of recommendations meant to reduce seroma formation after breast cancer surgery.

METHODOLOGY

Study Design

This research employed a prospective research using observations and designs to assess the occurrence rate and contributing variables associated with seroma formation following modified radical mastectomy.

Study Setting

The study was done at the Department of Surgery at Nalanda medical college & hospital , Patna , a tertiary care centre, over a period of 12 months from (1-03-22) to (30- 02-24)

Participants

In all, forty people took part in this study. Female patients who gone through the modified radical mastectomy for breast cancer were included in study.

Inclusion Criteria

1. Female patients above 18 years.

2. Patients diagnosed with breast cancer and scheduled for modified radical mastectomy.

3. Patients who provided written informed agreement to take part in the research.

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Exclusion Criteria

1. Patients with a history of previous breast surgery or radiation therapy.

2. Patients with coagulation disorders or on anticoagulant therapy.

3. Patients with pre-existing conditions that might affect wound healing (e.g., uncontrolled diabetes mellitus, severe malnutrition).

4. Patients unwilling or unable to provide informed consent.

Bias

To minimize selection bias, all eligible patients meeting the inclusion criteria were consecutively recruited. Data collection was standardized, and researchers involved in data analysis were blinded to patient identifiers to reduce observer bias.

Data Collection

1. Demographic information (age, BMI, comorbidities).

2. Clinical information (tumor stage, type of mastectomy).

3. Perioperative details (duration of surgery, type of anesthesia, use of drains).

4. Postoperative outcomes (incidence of seroma, time to seroma formation, volume of seroma).

Procedure

1. All patients underwent modified radical mastectomy as per standard surgical protocols.

2. Postoperative care included routine wound management and follow-up visits.

3. Seroma formation was assessed clinically and, if necessary, confirmed via ultrasound.

4. Seromas were managed according to the hospital's clinical guidelines, including aspiration and/or drainage as needed.

Statistical Analysis

SPSS version 23.0 was utilized for data entry and analysis. To compile the data, descriptive statistics were employed. The proportion of seroma formation incidence was determined.

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Potential risk factors were determined using uni-variate analysis, and confounding factors were taken into account by including variables in a multivariate logistic regression model with a p-value of less than 0.05. Odds ratios and 95% confidence intervals were given for each risk factor identified by the multivariate analysis.

RESULTS

Participant Characteristics

This study includes 40 female patients who underwent modified radical mastectomy. The participants' mean BMI was 27.6 kg/m² (SD ± 4.3) and their mean age was 53.2 years (SD ± 10.4). Table 1 provides an overview of the participants' clinical and demographic details.

Table 1: Demographic and Clinical Characteristics of Participants

Characteristic	Value
Mean Age (years)	53.2 ± 10.4
Mean BMI (kg/m²)	27.6 ± 4.3
Comorbidities	
- Hypertension	12 (30%)
- Diabetes Mellitus	8 (20%)
Tumor Stage	
- Stage I	10 (25%)
- Stage II	20 (50%)
- Stage III	10 (25%)
Duration of Surgery (min)	145 ± 30
Type of Anesthesia	
- General Anesthesia	40 (100%)
Use of Drains	40 (100%)

Incidence of Seroma Formation

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Seroma formation was observed in 18 out of 40 patients, resulting in an incidence rate of 45%. The time to seroma formation ranged from 2 to 10 days postoperatively, with a mean of 5.3 days (SD ± 2.1).

Risk Factors for Seroma Formation

By using univariate analysis, several potential risk factors for seroma formation were identified. A variable was included in the multivariate logistic regression model if its p-value was less than 0.05.

Table 2: Univariate Analysis of Risk Factors for Seroma Formation

Variable	Seroma (n=18)	No Seroma (n=22)	p-value
Mean Age (years)	54.7 ± 9.8	51.9 ± 11.0	0.342
Mean BMI (kg/m²)	29.1 ± 4.5	26.4 ± 3.9	0.037
Hypertension (%)	8 (44.4%)	4 (18.2%)	0.053
Diabetes Mellitus (%)	6 (33.3%)	2 (9.1%)	0.041
Tumor Stage (%)			
- Stage I	2 (11.1%)	8 (36.4%)	0.045
- Stage II	10 (55.6%)	10 (45.5%)	0.314
- Stage III	6 (33.3%)	4 (18.2%)	0.087
Duration of Surgery (min)	150 ± 28	140 ± 32	0.296

Table 3: Multivariate Logistic Regression Analysis of Risk Factors for Seroma Formation

Variable	Odds Ratio (OR)	95% Confidence Interval (CI)	p-value
Mean BMI (kg/m²)	1.21	1.03 - 1.42	0.022

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Diabetes Mellitus (%)	4.67	1.10 - 19.85	0.037
Tumor Stage (%)			
- Stage I	0.29	0.06 - 1.36	0.117
- Stage II	Reference		
- Stage III	2.20	0.50 - 9.60	0.292

Discussion

A 45% observed incidence of seroma development was noted among the 40 female patients in the research who had undergone modified radical mastectomy. Participants had a mean age of 53.2 years and a mean BMI of 27.6 kg/m2. An average of 5.3 days after surgery, seroma development happened throughout the first week. It is evident from the high incidence that post-mastectomy patients frequently experience this problem.

According to univariate study, diabetes mellitus and a higher BMI are two possible risk factors for seroma production. Patients with a higher BMI, in particular, were statistically significantly more likely to have seromas (p=0.037). A noteworthy risk factor that also surfaced was diabetes mellitus (p=0.041). Although this finding was not statistically significant in multivariate analysis, tumour stage I demonstrated a protective trend against seroma production.

Higher BMI and diabetes mellitus were observed to be significant independent risk variables for seroma development by multivariate logistic regression. The odds ratio (OR) for patients with higher BMIs was 1.21, meaning that for every unit increase in BMI, there was a 21% increase in the risk of having seroma. A more than four-fold increase in the likelihood of seroma development was linked to diabetes mellitus (OR=4.67). These results imply that in order to reduce the risk, people with these traits need to be closely monitored and may benefit from proactive interventions.

One common postoperative consequence after modified radical mastectomy (MRM) is seroma development. Numerous investigations have examined the frequency, contributing variables, and mitigation strategies for seroma development. According to a study, the size of the breast mass, place, afflicted breast side, age, and body weight were not significant predictors of the formation of seroma after breast cancer surgery [6].

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Hypertension, obesity, and electrocautery use were found to be major risk factors for seroma formation following Modified Radical Mastectomy (MRM).It was demonstrated the relationship between serum albumin levels and seroma formation, showing that a lower level of serum albumin (<3.5 g/dl) was linked to a higher incidence of seroma formation following MRM [7].

Preventive measures have also been extensively studied. It was demonstrated that the use of ultrasonic scalpels significantly reduces the incidence of seroma compared to traditional electrocautery. This finding supports the adoption of ultrasonic scalpels in surgical practice to mitigate seroma risk.

CONCLUSION

In conclusion, the study finds that after a modified radical mastectomy, a higher BMI and diabetes mellitus are significant predictors of seroma formation. These findings emphasise the necessity of customised postoperative treatment and management plans to address these risk factors and perhaps lower the likelihood of seroma and enhancing the results for patients. It is advised that bigger, multicenter cohorts be used in future research to confirm these results and improve risk-reduction tactics. Clinical procedures and further study in this field can be informed by the thorough understanding of the patient profile and risk factors linked to seroma production that these data provide.

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