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Original Research Article

Factor Associated with Post-operative Seroma Formation after Modified Radical Mastectomy

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Abstract: Breast cancer remains the second leading cause of cancer death among women worldwide. It is significantly contributing to the cancer surgical load. Though various advancement in therapies, surgery remains the primary treatment, particularly modified radical mastectomy (MRM]. However, the most common postoperative complication is noticed as seroma formation which affects 3-85% of cases. This study aims to identify patient and surgery specific risk factors influencing seroma formation. The prospective observational study was conducted at Bangabandhu Sheikh Mujib Medical University (BSMMU], Dhaka, Bangladesh. Study included women aged >20 years with stage I or II breast carcinoma undergoing MRM with Level II axillary dissection. Key findings include a significant association between increased age, high BMI, diabetes mellitus, shorter drain duration, and increased postoperative drain output with seroma formation. Electrocautery dissection showed a higher seroma incidence compared to sharp dissection. The tumor characteristics did not significantly impact seroma risk. Axillary lymph node dissection (ALND] emerged as a major driver. Optimized postoperative care, including individualized drain management, is critical for reducing seroma-related complications. The study underscores the necessity for tailored postoperative strategies to improve patient outcomes and calls for further research to establish standardized seroma prevention protocols in breast cancer surgery.

Keywords: Breast cancer, Seroma Formation, Radical Mastectomy.

INTRODUCTION

Breast cancer has remained the second leading cause of cancer death among women worldwide over the past decades and contributes significantly to cancer surgical load[1]. While advancements in chemotherapy, radiotherapy, hormonal therapy and immunotherapy have emerged, surgery remains the primary treatment for breast carcinoma [2]. Modified radical mastectomy

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(MRM] continues to be widely performed with high success. However, seroma formation, occurring in 3–85% of cases, remains the most common postoperative complication following MRM or breast-conserving surgery (BCS] [1].

A precise definition of seroma as "the accumulation of primarily sterile tissue fluid in a wound cavity" remains unclear. However, its development is influenced by inflammatory, exudative, and transudative processes in surgically compromised soft tissue, along with impaired lymphatic vessels.[3] The severance of lymphatic vessels during surgery, combined with postoperative limb mobilization and reduced lymphatic drainage, further promotes fluid accumulation, contributing to seroma formation[4].

Seroma is classified into three grades;
Grade I: if asymptomatic and detected only on ultrasound;
Grade II: if symptomatic but manageable with medication or aspiration; and
Grad III: if symptomatic requiring surgical or radiologic intervention.[5]

Postoperative seromas usually resolve within a month without intervention, but in up to 15% of cases, they persist, leading to complications such as delayed healing, infections, necrosis, lymphedema, pain, and functional or aesthetic concerns. These issues can hinder recovery and delay subsequent adjuvant therapy. [6]

Seroma risk factors vary , but key contributors include the type of surgery (mastectomy or breast-conserving surgery with or without lymph node removal], surgical technique (scalpel vs. electrocautery] and patient factors such as age, BMI, hypertension, DM, tumor size, lymph node involvement , neoadjuvant chemotherapy, and drain use [7] .

Suction drains are widely used but their effectiveness remains debated. Other strategies include sharp scalpel dissection, compression dressings, shoulder immobilization, and tranexamic acid injections has been tried in different studies to reduce incidence of seroma formation. [8].

Alternative methods focus on reducing dead space using fibrin or polyurethane adhesives, quilting sutures, and ultrasound dissection, preoperative steroids, intraoperative cyanoacrylate adhesives and postoperative somatostatin analogs also show potential. However, further research is needed to establish standardized seroma prevention protocols in breast cancer surgery. [9,10]

Aims and objectives

This study aims to identify and analyze patient and surgery specific risk factors affecting postoperative seroma formation after MRM. Given the limited comparative literature on these interventions, further research is essential to develop evidence-based strategies for understanding seroma incidence and improving patient outcomes in breast cancer treatment.

The specific objectives of the present study were:

- To study the clinical profile of the patients who develop seroma after MRM.
- To study the patient-related factors and the surgical factors that would play a role in the formation of seroma.

MATERIALS & METHODS

The study employed a prospective observational design in the Department of Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU], Dhaka, Bangladesh from January to December 2022. Institutional Ethical Committee and IRB approvals were obtained prior to commencement Patients were recruited based on predefined inclusion and exclusion criteria, ensuring a controlled study population.

Women aged >20 years with carcinoma of the breast (stage I or II] who underwent modified radical mastectomy (MRM] with Level II axillary dissection and provided informed consent were included, while patient having age less than 20 years, BMI <18kg/m^2 or >35kg/m^2, carcinoma of breast (stage more than II], recurrent breast carcinoma, patient received neo-adjuvant therapy, bilateral carcinoma of breast and male breast malignancies were excluded.

Both verbal and written consent were secured from participants, and confidentiality was strictly maintained. Patients who declined participation received equal standard of care. The study adhered to ethical guidelines and ensured systematic data collection for statistical analysis.

Modified radical mastectomy with level II axillary dissection was done in every case. During surgery, the skin incision was made by scalpel. Skin flaps were raised either by sharp (scissors or scalpel] or electrocautery dissection (Monopoler diathermy, Vallylab Force Fx, manufactured by Covidien Medtronic] depending upon the operating surgeon's choice and was not randomized. Control of small bleeding vessels with cautery was allowed for either group. Sharp dissection of the axilla was performed in all patients. Two closed suction drains were kept, one in the axilla and another under the lower flap. Drains

were removed when the draining amount was less than 50 ml in preceding 24 hours. The operating time, amount of drainage and pattern, time of drain removal was recorded and surgical site complications like seroma, drainage, wound infection, wound gap and flap necrosis were observed. Data were collected in a predesigned data collection sheet. Statistical analysis of the results was done by using computer based statistical software, SPSS 23.0 version. Comparative analysis employed Student's t-test or Mann–Whitney U test for continuous variables and chi-square or Fisher's exact test for categorical variables. A p-value <0.05 was considered significant at 95% confidence interval.

RESULT & ANALYSIS

This study analyzed various patient and surgery related factors contributing to seroma formation following modified radical mastectomy (MRM]. Continuous data were recorded in inclusive method. Some of the previous works show interrelation of variables with the outcome.

Patient demographics revealed that the majority were within the 35-50 years age group (mean age: 46.6 ± 9.4 years]. It was observed that, among the patient who developed seroma, a significant proportion were in higher age group. Our study found a strong correlation between increasing age and higher drainage output, making it a significant independent predictor of seroma (OR ≈ 29, P = 0.026].

Table 1: Age Distribution and Seroma Formation

Age Range	Seroma (Yes]	Seroma (No]	Total	Seroma Rate (%]
20–35 years	0	6	6	0.0%
35–50 years	5	22	27	18.5%
>50 years	5	8	13	38.5%

The mean BMI was 25.19±3.29 Kg/m^2. It was observed that BMI has a strong correlation with seroma formation. Overweight and obese patients (BMI >25 kg/m^2] exhibiting a significantly higher incidence of drainage output and seroma formation (p = 0.002]. Specifically, those within the 30-35 kg/m^2 range had an increased risk (OR: 2.31, 95% CI: 1.41–3.78, p = 0.004] compared to patients with normal BMI.

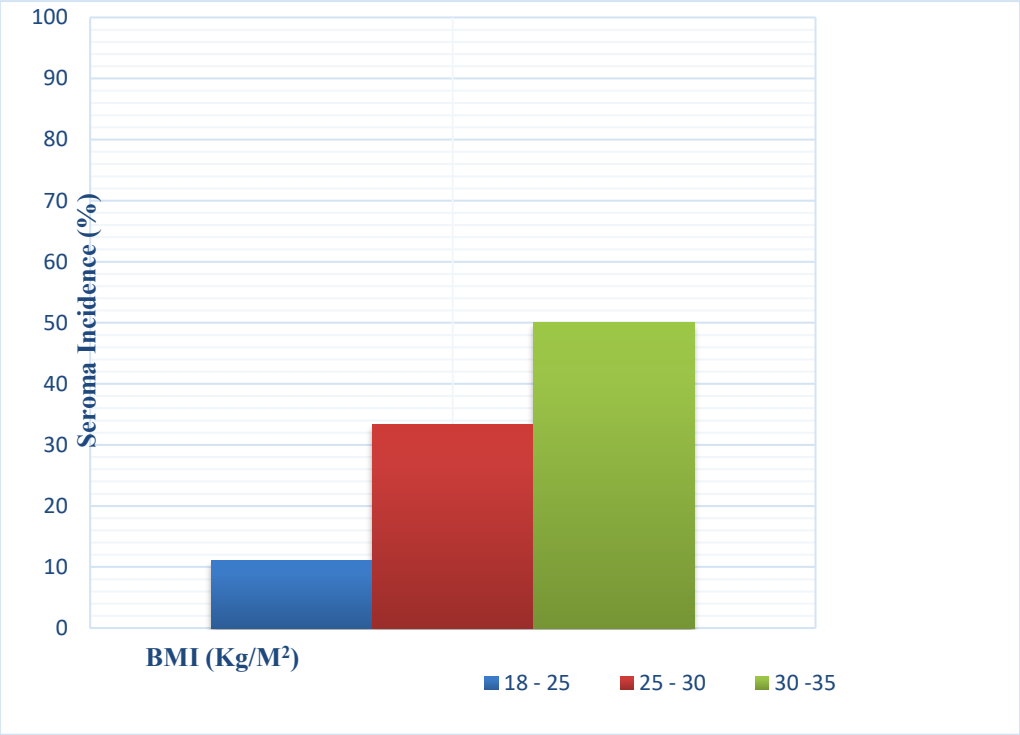

Figure 1: BMI and Seroma formation

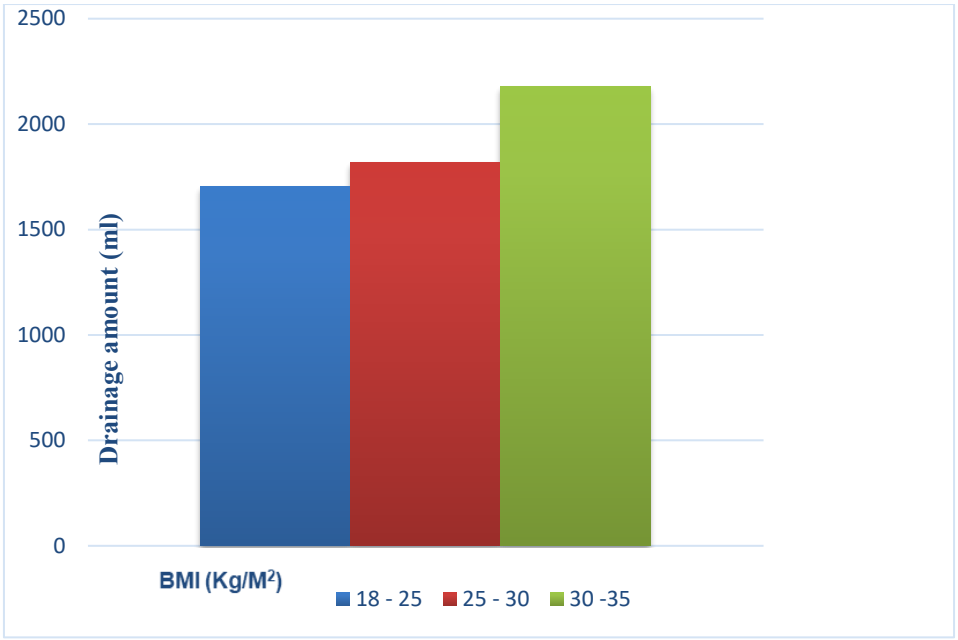

Figure 2: BMI and Drainage amount

Table 2: Correlation of Diabetes (DM] and Hypertension (HTN] with Seroma Formation

DM	HTN	Seroma (Yes]	Seroma (No]	Total Patients	Seroma Rate (%]
No	No	3	29	32	9.4%
No	Yes	3	0	1	100.0%
Yes	No	4	4	8	50.0%
Yes	Yes	3	4	7	42.9%

Seroma formation occurred in 21.7% of the study population. A chi-square test showed a statistically significant association between comorbidities (DM, HTN] and seroma formation (*p < 0.001*], with the highest risk seen in patients having both conditions or HTN alone (though based on a single case].

Seroma formation was analyzed in relation to dissection technique, tumor stage, tumor location, and axillary lymph node dissection (ALND]. Electrocautery dissection had a higher seroma incidence than sharp dissection (p=0.004]. Tumor location and size was not a definitive predictor (p = 0.287]. However, ALND showed a significant relationship with seroma formation (p=0.035], suggesting that lymph node dissection may contribute to increased seroma risk.

Table 3: Frequency of complication in Electrocautery and Sharp Dissection group (n = 46]

Complication	Electrocautery Dissection (N = 23] = 23	Sharp Dissection (N = 23] = 23	P value*
Seroma Formation	7 (30.4]	3 (13.0]	0.004

**'t' test of proportion was done to measure the level of significance. Value within the parenthesis indicates percentage.*

Drainage factors also played a crucial role. Patients whose drains removed before 7th postoperative day had a significantly higher likelihood of developing seroma (eight out of 10 cases] (OR: 2.89, 95% CI: 1.73–4.82, p < 0.001], and those with drain outputs exceeding 1000 mL were also at increased risk (p = 0.0009]. Notably, two out of 10 seroma cases were observed in patients whose drains were removed after POD 7 (p < 0.001], emphasizing the correlation of seroma development with early removal of drain tube.

Table 4: Seroma Status, Drain Duration, and Output

Seroma Status	Mean Drain Duration (days]	SD Drain Duration	Mean Drain Output (ml]	SD Drain Output	Number of Patients	p-value*
No	8.70	1.10	810.28	288.65	36	0.0000
Yes	6.64	0.67	1165.00	232.82	10	0.0009

**Independent samples t-tests were used to compare mean drain duration and total drain output between patients with and without seroma.*

The column explanation (table 4]:

- Seroma (Yes]: Number of patients with seroma who also had the complication.
- Seroma (No]: Number of patients with seroma who did not have the complication.
- No Seroma (Yes]: Number of patients without seroma who had the complication.
- No Seroma (No]: Number of patients without seroma who did not have the complication.

The findings highlight BMI, DM, Electrocautery Dissection, prolonged drain duration and increased postoperative drain output as significant predictors of seroma formation. Optimized perioperative care, including individualized drain management, is critical for reducing seroma related complications.

Seroma formation occurred in 10 patients (21.7%], with eight patients requiring aspiration and two patient's seroma regressed spontaneously. It was observed an associated with an increased risk of wound-related complications, including flap necrosis, wound infection, and wound dehiscence or wound gap in patients with seroma formation.

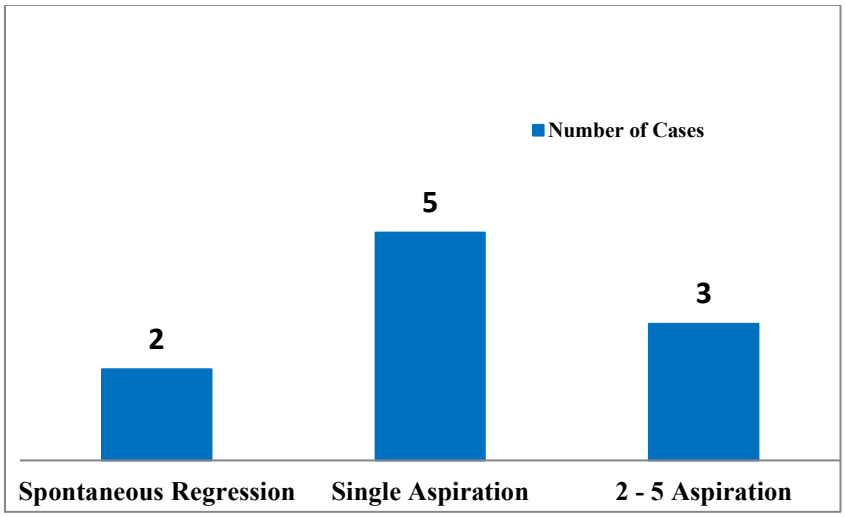

Figure 3: Number of seroma aspiration

Table 5: Association of seroma formation with wound complications

Complication	Seroma (Yes]	Seroma (No]	No Seroma (Yes]	No Seroma (No]	p-value*
Flap Necrosis	5	0	5	36	0.000089
Wound Infection	4	0	6	36	0.000846
Wound Gaping	7	0	3	36	0.0000007

Statistical test** (chi-square and Fisher's exact test] done to calculate the **p-value.

This study reinforces the multifactorial nature of seroma formation and underscores the necessity for tailored postoperative strategies to improve patient recovery outcomes.

DISCUSSION

Surgical care prioritizes optimizing outcomes while balancing risk and benefit. Seroma formation remains one of the most prevalent post-mastectomy complications, with incidence rates varying between 3% and 85%. [1] Our study investigated patient-specific and surgical factors influencing seroma formation and compared our findings with existing literatures.

Age and BMI in Seroma Formation

Age as a risk factor for seroma formation has been widely debated. Our study found a strong correlation between increasing age and higher drainage output, making it a significant independent predictor of seroma (OR ≈ 29, P = 0.026]. This aligns with prior literature suggesting that aging

contributes to delayed wound healing, reduced lymphatic drainage, and weakened tissue integrity, all of which elevate seroma risk [10]. However, other studies have not found a statistically significant link between age and seroma formation, indicating variability based on study design and population characteristics [4].

Our study also demonstrated a strong correlation between high BMI and seroma formation, with obese patients exhibiting increased drainage volumes. These findings are consistent with research indicating that pre-obesity and higher BMI significantly increase seroma formation (P = 0.016].[1] However, the Expanding Scope About Factor study did not establish BMI as a significant predictor, suggesting that its impact may depend on statistical modeling and patient demographics. [10]. Additionally, our data confirm that patients with higher BMI, particularly those in the electrocautery dissection (ED] group, had increased total drainage output, supporting previous studies linking ED to prolonged inflammatory response and greater tissue damage [11,12].

Diabetes, Hypertension and Seroma Formation

The correlation analysis identified a moderate positive correlation between diabetes mellitus and seroma formation (p=0.034], suggesting DM as a risk factor. [13] In contrast, hypertension (17.4% prevalence] showed no significant association with seroma (p=0.097]. This aligns with known physiological mechanisms where both conditions impair wound healing and disrupt lymphatic drainage, increasing seroma risk [6]. Garzali et al. identified hypertension as a significant predictor of seroma formation. However, they did not establish diabetes as a significant factor, whereas our dataset demonstrated a clear correlation.[8] Similarly, the Expanding Scope About Factor study found increased postoperative fluid retention in patients with metabolic disorders but did not establish diabetes or hypertension as independent seroma predictors, highlighting inconsistencies across studies. [4]

Dissection Technique and Seroma Risk

Our analysis identified a significantly higher seroma rate in the ED group (30.4%] compared to the sharp dissection (SD] group (13.0%]. Additionally, ED patients exhibited greater total drainage volumes (1082.17 mL vs. 692.61 mL in the SD group] and prolonged drainage duration (7.78 vs. 6.39 days]. These findings support prior studies associating ED with increased seroma risk due to greater thermal injury and inflammatory response [5]. However, some studies have not established dissection method as an independent predictor of seroma formation, reflecting variability in surgical techniques and sample sizes [4, 14].

Tumor Size, Location, Stage and ALND

Tumor characteristics did not significantly influence seroma formation in our study. Stage 1 tumors exhibited negligible seroma incidence (0.0%], while Stage 2 tumors showed slightly higher rates (31.8% in the left breast, 21.4% in the right breast]. However, these differences were likely driven by surgical extent rather than tumor factors alone. This is consistent with prior literature stating that tumor size and location do not significantly impact seroma risk [4].

Conversely, axillary lymph node dissection (ALND] emerged as a major driver of seroma formation, reinforcing prior findings. Studies indicate that patients undergoing ALND experience higher seroma rates (88.9%] compared to those without node removal (79.6%] [1]. Additionally, the Without Drain study identified MRM with ALND as an independent predictor of increased seroma volume (P < 0.001], consistent with our findings that ALND patients exhibited higher drainage volumes and prolonged seroma presence [3].

Drain Management and Seroma Prevention

Our study highlights drain management as a key factor in seroma prevention**.** Premature drain removal (3–7 days] resulted in a significantly higher seroma incidence (75%], while prolonged drainage beyond 7 days reduced it to 8%. These findings are consistent with previous research demonstrating that shorter drain duration leads to increased fluid accumulation due to unobliterated dead space [4]. Similarly, Kabbash *et al.,* reported that a 5-day drainage period resulted in more frequent seromas than an 8-day duration, further reinforcing the importance of adequate drainage time. [7].

Despite these findings, some studies question whether prolonged drainage truly prevents seroma or merely delays fluid accumulation post-removal**.** Additionally**,** the Without Drain study suggested that omitting drains entirely did not significantly increase seroma rates, challenging the necessity of routine drainage after mastectomy [3]. These inconsistencies highlight the need for individualized drain management strategies rather than a one-size-fits-all approach.

CONCLUSION

Our study highlights key factors influencing seroma formation, including age, BMI, surgical technique, drain duration, and total drainage output. Both patient factor and surgical technique influence post-operative outcome following breast cancer

surgery. Optimizing surgical techniques, drain management, and perioperative adjuncts—such as controlled mobility and compression therapy—may help reduce seroma-related complications.

Despite some inconsistencies in the literature, our findings underscore the need for individualized surgical planning. Future research should focus on evaluating seroma prevention strategies to refine evidence-based guidelines for breast cancer surgery.

Limitations of the Study:

The small sample size, lack of randomization, and uncontrolled confounders like surgeon experience and postoperative care variations are the key limitations of the study. It focused on short-term seroma formation, excluding long-term complications such as bleeding, pain, strength and range of motion of muscles and lymphoedema. However, these important gaps to be filled up by future studies.

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