Section: General Surgery

Original Research Article

EVALUATION OF RISK FACTORS FOR SEROMA FORMATION FOLLOWING MODIFIED RADICAL MASTECTOMY AT A TERTIARY CARE CENTER IN JHARKHAND

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Received : 17/07/2025
Received in revised form : 05/09/2025
Accepted : 28/09/2025

Keywords:
Modified radical mastectomy, seroma, age, BMI, drain output, neoadjuvant chemotherapy.

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DOI: 10.47009/jamp.2025.7.5.227

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2025; 7 (5); 1199-1202

ABSTRACT

Background: Breast cancer is the most frequent cancer among women with surgery as the primary mode of management. Modified Radical Mastectomy is the most preferred approach. Seroma formation is most common problem occurring after mastectomy. So the aim of this study was to evaluate the incidence of seroma formation in post modified radical mastectomy with relation to age, body mass index, drain output on post operative day 1,2,3 and total drain output and effect of neoadjuvant chemotherapy so that further episodes of seroma formation could be decreased. **Materials and Methods:** An observational prospective study on 116 patients was done. Seroma formation was considered the primary end point. Statistical analysis was done with help of student 't' test in case of continuous data and Chi square test was used for categorical data. **Result:** 38 out of 116 patients had seroma formation giving incidence rate of 32.76%. Age, body mass index, mean drain output on postoperative day 1 and 3 and total drain output was significant with p value of <0.005 while mean drain output on post operative day 2 and effect of neoadjuvant chemotherapy on seroma formation was not significant. **Conclusion:** Seroma formation has strong correlation with higher age, high body mass index, high drain output on pod 1,3 and total drain output, while it is not related to mean drain output on postoperative day 2. It also has no relation with use of neoadjuvant chemotherapy.

INTRODUCTION

Breast cancer remains the most commonly diagnosed cancer among women globally, with approximately 2.3 million new cases reported in 2020, accounting for around a quarter of all female cancers. The incidence shows significant regional variation, ranging from 27 per 100,000 women in regions like Middle Africa and East Asia to as high as 92 per 100,000 in North America. In Western Europe, the lifetime risk of developing breast cancer is estimated at one in nine women, contributing to 3–5% of all female deaths.[1]

Treatment for breast cancer typically involves a combination of local and systemic therapies. The chosen modality depends on the clinical staging and individual patient factors.[2] For non-metastatic cases, surgery remains the cornerstone of treatment. Among the surgical options, modified radical mastectomy (MRM) is frequently preferred due to its favorable outcomes in terms of long-term survival and reduced local recurrence.[3]

However, MRM is not without complications. Common postoperative issues include hematoma, wound infection, and particularly seroma formation. A seroma is the buildup of serous fluid in the space beneath the skin flaps or within the axillary area following mastectomy. Reported rates of seroma formation range widely from 4.8% to over 50%.[4-7] This condition can disrupt wound healing, increase the risk of infection, and delay the initiation of adjuvant treatments, thereby extending the patient's recovery period.

Multiple factors are thought to influence the development of seromas. These include patient-related aspects such as age, body mass index (BMI), and history of neoadjuvant chemotherapy, as well as surgical variables like drain output and technique.

The present study seeks to explore the association between these potential risk factors and the incidence of seroma following MRM, with the aim of identifying strategies to minimize its occurrence and improve postoperative outcomes.

MATERIALS AND METHODS

A hospital-based prospective observational study was done from June 2023 to December 2024. A total

ISSN (O): 2687-5365; ISSN (P): 2753-6556

116 female patients undergoing modified radical mastectomy in Department of General surgery, Rajendra Institute of Medical Sciences, Ranchi were observed. Approval from the Institutional Ethics Committee was taken and prior informed consent was obtained from the patient.

Inclusion Criteria

- Participants undergoing modified radical mastectomy.
- Females of all age group.

Exclusion Criteria

- Patient who was hypoproteinemic.
- Patients with other co-morbidities like diabetes mellitus and hypothyroidism.

The primary endpoint was the incidence of seroma formation. Analysis for seroma formation was done on selected factors like age, BMI, neoadjuvant chemotherapy and drain output. Seroma was managed by regular aspiration under aseptic precautions and the drain removal was delayed until the resolution of seroma. Descriptive statistical analysis had been carried out in this study. Results on continuous measurements were presented on Mean±SD and results on categorical measurements were presented in percentage (%). Chi-square test had been used to find the significance of study parameters on categorical scale between two groups. Student 't' test had been used to determine the significance between two group means. All analyses were two tailed and p value 0.05 was considered significant. SPSS version 16.0 was used for data analysis.

RESULTS

We had a total of 116 patients who underwent modified radical mastectomy during our study period. Out of 116 patients, 38 developed seroma which constitutes 32.76 percent of total population under study. [Table 1]

Among 116 patients with age ranging from minimum of 21 years to maximum of 80 years and mean age of 50.87 years, mean age of patients who developed seroma was 54.32±12.45 years while the patients who did not develop seroma had a mean age of 49.20±11.23 years. p value for this come out as 0.0280, which was statistically significant.

BMI of patients included in this study ranges from 18.20 to 31.10 with mean BMI of 23.86. The mean BMI of those with seroma was 25.77±2.43 while the BMI for patients without seroma formation was 22.92±1.99 with p value of < 0.0001 which was highly significant.

Table 1: Distribution of seroma in study population

Seroma	Frequency	Percentage
Yes	38	32.76
No	78	67.24
Total	116	100.0

Table 2: Association of risk factors with seroma formation

Parameters	Seroma group (n=38)	No seroma group (n=78)	p value	Significance
Age (years)	54.32±12.45	49.20±11.23	0.0280	Significant
Body Mass Index (kg/m2)	25.77±2.43	22.92±1.99	<0.0001	Highly significant
Neoadjuvant chemotherapy (NAC)	10/36 (27.8%)	28/80 (35%)	0.0580	Not significant
Drain Output (ml) on POD 1	199.89±52.71	154.38±37.11	<0.0001	Highly significant
Drain Output (ml) on POD 2	152.36±49.55	136.73±41.58	0.077	Not significant
Drain Output (ml) on POD 3	153.42±54.0	116.17±43.22	0.001	Significant
Total drain output (ml)	787.78±194.38	525.88±165.44	<0.0001	Highly significant

Out of 116 patients 36 of them got neoadjuvant chemotherapy while rest 80 of them directly went for modified radical mastectomy. 10 of the people who got neoadjuvant chemotherapy developed seroma while 28 of the people who did not get the therapy had seroma formation. The p value came out to be 0.0580 which was not significant.

Patients who developed seroma had significantly higher mean drain outputs on postoperative day 1 (199.9 ± 52.71ml vs. 154.38 ± 37.11 ml, $p < 0.0001$) and day 3 (153.42 ± 54.0 ml vs. 116.17 ± 43.22 ml, $p = 0.001$), as well as higher mean total drain output (787.78 ± 194.38 ml vs. 525.88 ± 165.44 ml, $p < 0.0001$) compared to patients without seroma. While total drain output on postoperative day 2 (152.36±49.55 vs. 136.73±41.58 ml, p= 0.077) was not significant.

DISCUSSION

Breast cancer is the second most common cancer among humans. It is the most frequent cancer among women, with an estimated 2.3 million cases diagnosed worldwide in 2020, representing about 25% of all cancers in women. According to stage of disease, a multimodal treatment plan is allotted and among surgeries, breast conserving surgery and modified radical mastectomy are commonly done. Due to higher recurrence rates and need for radiotherapy, Modified Radical Mastectomy (MRM) is still the most common type of surgery performed in our institution. Among many other complications like wound infection, flap necrosis, hematoma formation, seroma formation is commonest among all and causes significant morbidity to the patient. Seroma formation is still an elusive topic, its pathophysiology, predisposing factors and preventive methods remain unclear.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Reported incidence of seroma formation is ranging from 4.5–51% as shown in different studies.[4-7] In our study, we selected 116 patients undergoing modified radical mastectomy in our institute, out of which 38 patients had seroma formation which accounts for 32.76%. Gurushantappa et al (2020) had done a prospective study among 86 patients undergoing MRM and had incidence of seroma formation as 28.39%.[8] Ribin S M et al (2022) did a prospective study among 126 patients undergoing MRM and had incidence rate of 31%.[9] Chandrakala et al (2024) suggested the seroma formation among 86 patients was 31%.[10]

In our study, the mean age of presentation was 54.32±12.45. p value between age of the patient and seroma formation was 0.028, which was significant. Thus we can say that there is an association between increasing age of the patient and seroma formation. Ribin S M et al (2022) with p value of 0.001 in the patients with seroma, 58.97 % was having age ≥56 and 41.02% was having age 45 yrs have higher incidence of seroma (33%) which is statistically significant with p-value of 0.011.[9]

Mean BMI for patients with seroma formation were 25.77±2.43 in our study. It has a highly significant p value of <0.0001, suggestive of very strong association between high BMI of the patient and seroma formation. Kurnia et al (2016) also suggested that BMI has a positive linear correlation with seroma formation, and it has been predicted that those with high BMI produce seroma more than those with lower BMI.[10,11] Ribin SM et al (2022) (p value 0.010) said that seroma formation was significantly higher in patients with higher BMI. 23 patients out of 39 patients who developed seroma having BMI >27.50.[9]

In our study, 10 patients out of 36 who had received neoadjuvant chemotherapy developed seroma postoperatively, while 28 patients out of 80 who had not received neoadjuvant chemotherapy had seroma formation. p value for this study came out to be 0.0580, thus use of neoadjuvant chemotherapy is not significant with seroma formation. Gonzalez et al (2003) did a retrospective study for factors affecting seroma formation after breast surgery, out of which one was neoadjuvant chemotherapy; he suggested that use of neoadjuvant chemotherapy is not significant with rates of seroma formation.[12]

The mean drain output in our study on post operative day 1 was 199.89±52.71 ml in patients with seroma formation while in patients without drain output was 154.38±37.11 ml. p value for association between seroma formation and drain output on day 1 was <0.0001, which was again very highly significant. Thus it is suggestive of drain output in first 24 hour of surgery is an important predictor for seroma formation. Narsimhappa R et al (2020) did a similar study among 50 patients and found out that the mean drain output of those with seroma on day 1 was 264.4 ml (150-400), whereas the mean for patients without seroma was 171.25 ml (100-250 mL). p value was significant with value of <0.001.[13]

In our study, the mean drain output on post operative day 3 was 153.42±54.0 ml in patients with seroma formation while in patients without seroma formation the mean drain output on day 3 was 116.17±43.22 ml. The p value for association between them was 0.001 which was statistically significant. Kuroi S et al (2006) suggested that high drainage volume in first 72 hours is an important risk factor seroma formation.[14] Muqueem et al (2022) did a prospective observational study among 30 patients and found out that the mean drain output during first 24 hours in seroma group was 212.50 ml (SD± 25.0), that in no seroma group was 223.07 ml (SD ±70.71), although there was difference between the two groups, it was not statistically significant. In following 24 hours, seroma group was of 250.0 ml (SD± 40.82) and no seroma group was of 130.76 ml (SD± 106.06). The observed difference between the two groups was not statistically significant. The drain output on post operative day three was 287.50 ml (SD± 25.0) in seroma group and 113.46 ml (SD± 35.35) in no seroma group. The difference was close to statistical significance, suggesting the possibility of seroma formation in those patients with higher drain out-put on post-operative day three.[15]

The mean total drain output in seroma group was 787.78±194.38 (185-1050 ml) and in no seroma group was 525.88±165.44 (215-920 ml), p value was 0.0001, statistically significant. Lumachi F et al (2004) suggested that total higher drain output is an independent risk factor for seroma formation.[16]

CONCLUSION

The factors affecting seroma formation following modified radical mastectomy for breast carcinoma are as follows:

- Age of the patient is statistically significant with seroma formation. Higher the age of patient, more is the chance of seroma formation.
- BMI of the patient is very strongly associated with seroma formation. High BMI patients are more prone to develop seroma in their post operative period.
- High drain output on day 1 acts as strong predictor for seroma formation.
- Higher drain output on post operative day 3 is associated with more chances of seroma formation.
- High total drain output acts as an independent risk factor for seroma formation.
- Neoadjuvant chemotherapy is not significantly associated with seroma formation.

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