Original Research Article

Observational study on the incidence and risk factors for seroma formation following modified radical mastectomy

Mohammed Ribin.S[1], Jayan. N.P[2*], Abdul Basith[3], E.V.Gopi[4]

[1]Junior Resident, Department of General Surgery, Government Medical College, Calicut, Kerala, India
[2]Associate Professor, Department of General surgery, Government Medical College, Calicut, Kerala, India
[3]Assistant Professor, Department of General surgery, Government Medical College, Calicut, Kerala, India
[4]Professor and Head of the Department, Department of General Surgery, Government Medical College, Calicut, Kerala, India

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Abstract

Introduction: Breast cancer is the most common malignancy in women and second leading cause of cancer death among women. The surgical treatment of choice for these patients is either modified radical mastectomy or breast preservation depending upon stage of the disease. Seroma formation is the most frequent postoperative complication after breast cancer surgery, of which the pathogenesis has not been fully understood. In view of this, we collected data to determine the incidence and risk factors related to seroma formation in our patients and increase its scope and hence attempt to prevent it. **Materials and methods:** An observational study was conducted in 126 female patients who have undergone MRM from the Department of General Surgery, Government Medical College, Kozhikode from November 2020 to November 2021. Those who are having seroma clinically within 4 weeks of surgery are sent for radiological evaluation (USG), size measured accordingly. Statistical analysis of the data performed and Pearson Chi-square test and Fisher's Exact test were used for comparing categorical variables between groups. **Results:** The threshold age of development of seroma formation after MRM was ≥56.The threshold BMI of development of seroma formation after MRM was ≥27.50kg/m2.The threshold tumour size of development of seroma formation after MRM was ≥4cms. Out of 26 patients who underwent level 3 axillary dissection, 13 patients (81.2%) developed seroma. Level 2 axillary dissection was performed in 110 patients and only 26 (23.6%) patients developed seroma. >12 lymph nodes were removed in 33 patients and 25(75.8 %) developed seroma. In 93 patients with < 12 lymph nodes removed only 14 (15.1%) patients developed seroma. **Conclusion: 1.** 31% of patients in the study population who had undergone MRM developedseroma within four weeks after surgery. **2.** Seroma formation after MRM showed positive correlation with age, BMI, tumour size, level 3 axillary dissection and >12 lymph nodes removed during surgery. **3.** There was no correlation between seroma formation and day of drain removal, neoadjuvant chemotherapy, usage of breast bandage and shoulder exercises.

Keywords: Breast cancer, MRM, seroma

Introduction

Breast cancer is the most common malignancy in women and second leading cause of cancer death among women[1]. The surgical treatment of choice for these patients is either modified radical mastectomy or breast preservation depending upon stage of the disease. Seroma formation is the most frequent postoperative complication after breast cancer surgery[2].

Seroma is defined as a subcutaneous collection of serous fluid post-mastectomy under the skin flap, in the dead space of the axilla or the breast [3]. The incidence documented ranges from 15-81%. Seroma formation increases chances of infection, delays wound healing, flap necrosis, persistent pain, dehiscence of the wound and thus prolong the convalescence period[1]. It occurs in most patients after mastectomy and is now increasingly being considered side effect of surgery rather than a complication however, all patients are not clinically symptomatic[2]. Seroma may prolong patient recovery and hospital stay, increase health care costs and possibly delay the administration of systemic treatment where required.There are several factors implicated in seroma formation like the extent of lymph node clearance, number of positive nodes, the use of postoperative radiation and whether intraoperative lymphatic channel ligation was done or not, but opinion differs as to their individual role in its pathogenesis[4]. The pathogenesis of seroma has not been fully understood. Seroma is formed by acute inflammatory exudates in response to surgical trauma and acute phase of wound healing. Extensive dissection in mastectomy and axillary lymphadenectomy damages several blood vessels and lymphatics with subsequent oozing of blood and lymphatic fluid from a larger raw surface area when compared with breast- conserving procedures leads to seroma formation. Fluid accumulation elevates the flaps from the chest wall and axilla thereby hampering their adherence to the chest wall bed and delay healing[5]. Another common complication post-mastectomy is hematoma[6].

The optimal ways to reduce the incidence of seroma formation are unknown. The morbidity associated with post mastectomy seroma has led to efforts in identifying risk factors so that they can be modified thereby reducing the incidence of seroma, but none of these risk factorshave been universally accepted [7]. In order to reduce seroma formation a number of procedures have been proposed. They include drainage of the operative wound, external compression dressing , diathermy performed during surgery, ultrasound, argon, laser, harmonic scalpel, endoscopic procedures, various techniques of axillary space closure, fibrin glue, sclerotherapy using tetracyclines and tranexamic acid application. However, no standard resulting in effective diminution of seroma formation incidence following axillary dissection has yet been established[8].

Materials and methods

The present prospective cohort study was conducted in the Department of general surgery, government medical college, Calicut,

*Correspondence
Dr. Jayan. N.P
Associate Professor, Department of General surgery, Government Medical College, Calicut, Kerala, India
E-mail: dr_jayan81@yahoo.com

Kerala, India from November 2020 to November 2021.Those who are having seroma clinically within 4weeks of surgery were sent for radiological evaluation (USG) and size was measured accordingly.

Inclusion criteria

All female patients undergoing modified radical mastectomy getting admitted in the general surgery department from 1 year after the approval of IRC& IEC

Exclusion criteria

1. Patients with uncontrolled diabetes mellitus chronic liver disease chronic kidneydisease, Tuberculosis
2. Patients on anticoagulants with altered coagulation profile.
3. Patients who are not willing to give consent.
4. Hypoalbuminemia

Sample size

126

Statistical analysis

All the data collected were analysed using SPSS statistical software version 22. Quantitative variables were summarised using mean and standard deviation (SD). Categorical variables were represented using frequency and percentage. Independent sample t test was used to test statistical significance of difference between means of variables among different independent groups. Pearson Chi-square test and Fisher's Exact test were used for comparing categorical variables between groups.

Results

Seroma was identified in 39 of 126 patients (31%). The data are presented in Table 1-5. Factorsidentified to be significantly related to the seroma are the age ≥56 years , tumor size ≥4cms , BMI ≥27.50, removal of >12 lymph nodes and level 3 axillary dissection.

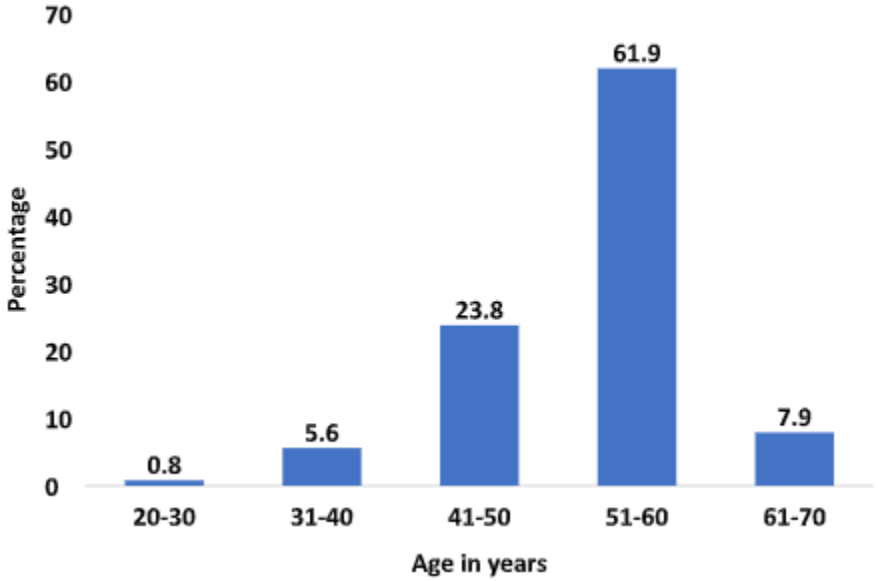

Figure 1: Distribution of age in years

Table 1: Age (n = 126)

Age	Seroma present (39)	Seroma absent (87)
≥56	23	25
<56	16	62

P value 0.001

In the patients with seroma , 58.97 % was having age ≥56 and 41.02% was having age <56.This data is suggestive that increasing age is a risk factor for seroma formation.

Table 2: BMI (n=126).

BMI	Seroma present (39)	Seroma absent (87)
≥27.50	23	30
<27.50	16	57

P value 0.010

Seroma formation was significantly higher in patients with higher BMI. 23 patients out of 39patients who developed seroma was having BMI of ≥27.50.

Table 3: Tumor size (n=126).

Tumour size	Seroma present (39)	Seroma absent (87)
≥4cms	31	32
<4cms	8	55

p value <0.001

Larger the tumour size, greater was the prevalence of seroma. Out of 39 patients who developed seroma 31 patients (79.4%) had a tumour size ≥4cms. Rest of the 8 patients(20.5%) who had seroma post MRM was having tumour size of <4cms

Table 5: Type of axillary dissection(n=126).

Type of axillary dissection	Seroma present (39)	Seroma absent (87)
Level 2	26	84
Level 3	13	3

p value <0.001

In patients who have underwent level 3 axillary dissection, 13 out of 39 patients (81.2 %) developed seroma indicating that level 3 axillary dissection increased the incidence of seromaformation.

Table 4: Number of lymph nodes removed (n=126).

Number of lymph nodes removed	Seroma present (39)	Seroma absent (87)
<12	14	79
>12	25	8

p value <0.001

Out of 33 patients in which more than 12 lymph nodes were removed, 25 patients (75.7%) developed seroma. Only 15.1% with <12 lymph nodes involvement had developed seroma. This substantiates that when larger number of lymph nodes are removed the chance of seroma formation is higher.

Discussion

Seroma formation is the most common complication of breast cancer surgery. To prevent seroma formation, it is important to identify individual risk factors of seroma formation and identification of predictive variables which will be vital in designing future trails aimed at reducing the incidence of this common complications of breast cancer surgery.

Seroma delays wound healing and prolongs the hospital stay, delays adjuvant radiotherapy and chemotherapy. Besides the economic loss due to the prolonged hospital stay and delay inrehabilitation, seroma formation also adds to psychological trauma. This is often an to the embarrassment of the operating surgeon, whose experience in surgery does not influence the incidence of seroma after mastectomy.

Seroma formation is influenced by an array of surgical techniques and devices[9]. In the past decades, many authors identified the application of suction drainage as the only effective solution to the problem of seroma. More recently, research has focused on the approach of closing the dead space and the studies favouring flap fixation after mastectomy has shown a substantial gain[10]. Despite substantial heterogeneity, there is evidence that drainage can safely be omitted without exacerbating seroma formation and its complications[11].

In patients affected by breast cancer requiring axillary lymph nodes dissection, the use of advanced hemostasis devices is highly desirable. Among the non-traditional tools, Thunder beat resulted to be superior in terms of reduction of intra-operative blood loss and post- operative drainage output, moreover associated to a substantial reduction of postoperative seroma incidence[12]. The use of drains did not prevent seroma formation. On the other handit was associated with a longer postoperative hospital stay and more pain after surgery for breast cancer [13]. The use of Ligasure reduced drainage amount and duration of drain till removal, but increased operative time[14].

The results of our study, are almost comparable to the studies of:

In a study of Suresh B.P et.al[1] a retrospective study factors influencing seroma formation after breast cancer surgery at tertiary care centre was carried out. A total number of 83 patientsdiagnosed to have carcinoma breast who underwent breast cancer surgery were considered. The overall seroma formation arte was estimated to be 27%.Factors identified to be significantly related to the formation of seroma were age >45years, tumour size, number of positive lymphnodes, BMI>30, type of surgery, total lymph nodes removed.

In a study of Jacek Zielinski et.al[8] a prospective study was carried out to analyze the impact of selected factors on the incidence of seroma formation in breast cancer patients undergoing mastectomy.A total number of 150 breast cancer patients were enrolled in the study. The cumulative total seroma volume collected by the end of treatment was higher and the overall time of seroma treatment was longer in patients over the age of 60 years (p = 0.001 and p = 0.001 respectively). Duration of seroma was significantly longer in obese patients (p = 0.036).

In a study of Mohammed Faisal et. Al[15] a prospective case control study was carried out to study the efficacy of axillary exclusion on seroma formation after modified radical mastectomy. This study contains 64 patients, the study group contains 32 patients, and the control group contains 32 patients. Age, BMI (mean control = 31.7 and study = 30.2), and tumor size were of no significant differences to be more concise on the effect of axillary exclusion. The mean of day of drain removal in the control group was 17.8 day (15–19) with a mean of total drain output of 4525.6 ml (4430–3660 ml) while the mean in the study group of day of drain removal was 11.3 (10–13) with a mean of total drain output of 1476.2 ml (620– 2200 ml), $p < 0.001$.

Conclusions

The incidence of seroma formation within four weeks post MRM was found to be 31%. Parameters like age, BMI, tumour size, level 3 axillary dissection and >12 lymph nodes removed during surgery showed positive correlation with seroma formation after MRM. No correlation was found between seroma formation and day of drain removal, neoadjuvant chemotherapy, usage of breast bandage and shoulder exercises.

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