

To Study the Factors Influencing Seroma Formation after Modified Radical Mastectomy/Breast Conservative Surgery in MCH VIMS Ballari

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Abstract

Background: Seroma, defined as subcutaneous collection of serous fluid within the surgical cavity i.e. clinically evident, is diagnosed on clinical examination as soft/boggy swelling in the region of flaps, usually in the axilla, which can also be confirmed by wide-bore needle aspiration. Seroma is the most frequent post-operative complication following Modified Radical Mastectomy (MRM) / Breast Conservative Surgery (BCS), developing in approximately 30 % of cases. The pathophysiology and mechanism of seroma formation in breast cancer surgery remains controversial and not fully understood, as little attention has been paid in the literature to etiologic factors. Therefore, understanding of various risk factors and its proper quantification is important to predict and if possible, prevent, risk of seroma formation. The purpose of this study was to establish an association between various risk factors and seroma formation following MRM/BCS.

Materials and Methods: This prospective study was conducted among 30 patients over a period of 1 year 10 months from November 2016 to September 2018 in the Department of Surgery, Vijayanagara Institute of Medical Sciences-Ballari, after obtaining ethical committee clearance from the Institutional Ethical Committee and informed written consent from study participants.

Results: 4 out of 30 patients, accounting for 13.3 percent, developed seroma. The mean age of patients who developed seroma was 50.50 ± 9.29 (38 – 60) years. The mean volume of breast and axilla in the seroma group was 1662.50 ± 179.69 (1400 -1800 ml). This is statistically significant compared to patients without seroma formation. And drain output on post-op day 3 was 287.50 ± 25 ml (250 – 300 ml) also significant, which is a good predictor of seroma formation. 2 out of 4 were having hypertension in seroma group, which is statistically insignificant. Other variables studied had no statistical significance with respect to seroma formation.

Conclusion: The factors influencing seroma formation following MRM/BCS for carcinoma breast were found to be volume of the breast and axillary fatty-lymphatic tissue – greater the volume, higher the seroma rate. And drain output in first 72 hours is a good predictor of seroma formation.

Keywords: Seroma, Modified Radical Mastectomy, Breast Conservative Surgery.

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Introduction

Breast cancer is one of the most common malignancies in women and a leading cause of cancer death among women. More than a million cases of breast cancer are diagnosed worldwide each year. The overall incidence of breast cancer has been rising because of increase in the average life span, lifestyle changes that increase risk for breast cancer, and improved survival from other diseases. [1] It accounts for 22 % of all female cancers and is responsible for 1.6 % of the cancer related deaths in women. [2] A recent study of breast cancer risk in India revealed that 1 in 28 women develop breast cancer during her lifetime. The average age of the high-risk group in India is 43 - 46 years. [3] Incidence of breast carcinoma in India is 19.1 per 100,000 women compared to 87 in the UK and 101 in the US per 100,000 women.[4] Modern therapy has evolved to include both surgical resection for local disease and medical therapy for systemic disease. Surgery still has a central role to play but there has been a gradual shift towards more conservative techniques. [5] Modified radical mastectomy (MRM) is a safe operation with low morbidity and mortality.

Breasts are modified sudoriferous (sweat) glands, composed of glandular, adipose and connective tissues. Glandular tissue is more abundant in the upper outer portion of the breast; as a result, half of all breast cancers occur in this region. [6] The Consensus Development Conference on the treatment of breast cancer in 1979 stated that the modified radical mastectomy was the standard of treatment for stages I and II breast cancer. [7] Ever since the time of Halstead, who first carried out Radical Mastectomy in 1882, surgeons have faced several problems such as necrosis of skin

flaps, breakdown of the wound, hematoma, seroma and infection[8] Among them, seroma, which is clinically evident subcutaneous collection of serous fluid within the surgical cavity, is the most frequent post-operative complication following breast cancer surgery, [9] developing in approximately 30 % of cases [10,11]. Excessive accumulation will stretch the skin and cause it to sag, resulting in, significant morbidity, and delay in the initiation of adjuvant therapy, patient discomfort and prolongation of hospital stay [12].

With surgical ablation of the breast, during MRM/BCS, the intervening lymphatics and fatty tissues are resected en bloc, thus the vasculature and lymphatics of the gland are transected. Thereafter, transudation of lymph and the accumulation of blood in the operative field is expected. But seroma formation, although common, doesn't occur in all post-operative patients. Why it occurs in certain patients more commonly is the area, which is not fully understood, as little attention has been paid in the literature to individual etiologic factors.

To prevent seroma formation, it is important to estimate individual risk of seroma formation i.e., the identification of predictive variables. This will be helpful in designing future trials aimed at reducing the incidence of this common complication following MRM/BCS.

Aim of the Study is to establish an association between various risk factors of seroma formation.

Materials and Methods

This prospective study was conducted among 30 patients over a period of 1 year 10 months from November 2016 to

September 2018 in the Department of Surgery, Vijayanagara Institute of Medical Sciences – Ballari after obtaining ethical committee clearance from the Institutional Ethical Committee and informed written consent from study participants. Patients with breast cancer undergoing Modified Radical Mastectomy (MRM) / Breast Conservative Surgery (BCS), were included in the study.

Inclusion Criteria

All cases of breast cancer undergoing Modified Radical Mastectomy (MRM) / Breast Conservative Surgery (BCS).

Exclusion Criteria

1. Cases of breast cancer who have undergone modified radical mastectomy in some other hospital and referred to VIMS Hospital for further management.
2. Cases of mastectomy and axillary dissection for indications other than carcinoma.
3. Cases undergoing palliative mastectomies and incomplete axillary dissection.
4. Recurrent cases.

The data collected were age, body mass index (BMI), history of hypertension and diabetes mellitus, history of neo-adjuvant chemotherapy, tumour size was measured following admission to the hospital and the volume of the breast and axillary fatty-lymphatic tissue specimen was measured immediately following surgery.

The technique of measuring volume of the resected specimen was as follows. The resected specimen was carefully dropped into the container filled to the brim with water and the water displaced in a tub placed around the container was measured in millilitres.

Operative details like; use of electro-cautery, suction drains - axillary/sternal. Post-operative drain output over 72 hours, implementation of upper limb

physiotherapy (on the operated side) were noted. Following histopathological reporting, the number of lymph nodes removed was noted. All the patients were discharged with the suction drain in situ to be followed up in outpatient after teaching the patient/responsible attender as to, how to record the 24 hours drain output and thereby maintain a chart. During follow-up, wound was inspected, and suction drain was eventually removed once the output was < 20 ml over last 24 hours.

Seroma, defined as subcutaneous collection of serous fluid within the surgical cavity i. e. clinically evident, was diagnosed on clinical examination as soft/boggy swelling in the region of flaps, usually in the axilla, confirmed by wide-bore needle aspiration. In the event of seroma formation, seroma was managed by regular aspirations under aseptic precautions and applying pressure bandage.

Statistical Methods

The results were averaged (mean \pm standard deviation) for continuous data and number and percentage for dichotomous data were presented in table. Proportions were compared using Chi-square test of significance and the student's t test was used to determine the statistical difference. The data was analysed using Statistical Package for Social Sciences (SPSS) package.

Results

Demographic Data

30 consecutively admitted female patients with the diagnosis of carcinoma breast counselled for modified radical mastectomy/BCS were included in the study. Four out of 30 patients, accounting for 13.3 percent, developed seroma. The mean age of patients who developed seroma was 50.50 ± 9.29 (38 – 60), whereas the mean age of those without seroma was 51.92 ± 11.750 (28 – 72) years. The mean BMI of those with seroma was 31.88 ± 3.56

(28.04 – 36.36), the BMI for patients without seroma was 27.51 ± 3.86 (19.05 – 38.21) kg/m².

Table 1: Mean BMI (kg/m²) Distribution of the Study Population

Seroma	N	Mean BMI (kg/m ²)	SD	Min	Max	't' value	'p' value
Yes	4	31.88	3.56	28.04	36.36	0.040	0.834
No	26	27.51	3.86	19.05	38.21		
Total	30	28.09	4.70	19.05	38.21		

Table 2: Distribution of Hypertension in Study Population and Distribution of Patients Subjected to Neo-adjuvant Chemotherapy

Seroma	Hypertension		Total	Chi Square	'p' value
	Yes	No			
Yes	2 50.0 %	2 50.0 %	4 100.0 %	0.433	0.511
No	06 23.0 %	20 77.0 %	26 100.0 %		
Total	08 26.6 %	22 73.0 %	30 100.0 %		
Seroma	Neo-adjuvant Chemotherapy		Total	Chi Square	'p' value
	Yes	No			
Yes	0 .0 %	4 100.0 %	4 100.0 %	0.513	0.474
No	3 11.5 %	23 88.5 %	26 100.0 %		
Total	3 10.0 %	27 90.0 %	30 100.0 %		

Two of 4 among the seroma group, were found to be hypertensive accounting for 50 %, eleven of 26 among the non-seroma group were hypertensive accounting for 42.3 %. Of the 4 patients with seroma, none of them received neo-adjuvant chemotherapy, and 3 patients among 26 with no seroma received neo-adjuvant chemotherapy.

Table 3: Mean Value of Breast and Axilla (ml) in the Study Population

	Seroma	N	Mean	SD	Min	Max	't' value	'p' value
Volume of breast and axilla (ml)	Yes	4	1662.50	179.69	1400	1800	23.849	< 0.001
	No	26	925	358.41	150	2000		
	Total	30	1023.33	423.20	150	2000		

Table 4: Mean Drain Output (ml) Over First 3 Days in the Study Population, Mean Number of Lymph Nodes Removed in the Study Population and Mean Drain Removal Day in the Study Population

		N	Mean	SD	Min	Max	't' value	'p' value
Drain output day 1(ml)	Yes	4	212.5	25.00	200	250	0.047	0.831
	No	26	223.07	70.71	100	350		
	Total	30	221.66	72.73	100	300		

Drain output day 2 (ml)	Yes	4	250.00	40.82	200	300	2.020	0.166
	No	26	130.76	106.06	100	300		
	Total	30	146.66	64.23	100	300		
Drain output day 3(ml)	Yes	4	287.50	25.00	250	300	3.852	0.060
	No	26	113.46	35.35	50	300		
	Total	30	136.66	68.14	50	300		
		N	Mean	SD	Min	Max	't' value	'p' value
Number of lymph nodes removed	Yes	4	21.75	6.89	16	31	0.648	0.428
	No	26	16.34	6.26	7	30		
	Total	30	17.06	6.49	7	31		
		N	Mean	SD	Min	Max	't' value	'p' value
Drain removal day	Yes	4	12.75	0.957	12	14	0.942	0.340
	No	26	10.76	2.42	7	16		
	Total	30	11.03	2.37	7	16		

The mean value of breast and axilla in the seroma group was 1662.50 ± 179.69 (1400 - 1800), and that in no seroma group was 925 ± 358.41 (150 - 2000) millilitres (ml). The mean drain output on day 1 in seroma group was 212.5 ± 25.0 (200 - 250) and in no seroma group was 223.07 ± 70.71 (100 - 350) millilitres (ml); On day 2 in seroma group, 250.0 ± 40.82 (200 - 300) and in no seroma group 130.76 ± 106.06 (100 - 300) ml; On day 3 in seroma group, 287.50 ± 25 (250 - 300) and in no seroma group 113.46

± 35.35 (50 - 300) ml. The mean number of lymph nodes removed in the seroma group was 21.75 ± 6.89 (16 - 31), whereas in no seroma group was 16.34 ± 6.26 (7 - 30). The mean drain removal day in seroma group was 12.75 ± 0.95 (12 - 14), and that in no seroma group was 10.76 ± 2.42 (7 - 16). Out of 30 cases, breast conservative surgery was done on 3 patients and MRM was done on 27 patients. All 4 seroma patients had undergone MRM.

Table 5: Types of Surgery

Seroma	Type of Surgery		Total	Chi Square	'p' value
	BCS	MRM			
Yes	0	4	4	0.513	0.474
	0 %	100.0 %	100.0 %		
No	3	23	26		
	11.5 %	88.5 %	100.0 %		
Total	3	27	30		
	10.0 %	90.0 %	100.0 %		

Discussion

Our study included 30 randomly selected patients with the diagnosis of carcinoma breast undergoing modified radical mastectomy. In our study, 13.3 % of patients developed seroma. E. Hashemi et al. in their study on 158 patients with breast cancer undergoing either MRM or breast

preservation, stated that the overall seroma rate was 35 %. [13]. Gonzalez E. A. et al. in their study on 359 patients undergoing either modified radical mastectomy or wide local excision and axillary lymph node dissection showed overall seroma rate of 15.8 %, 19.9 % in MRM group and 9.2 % in BCS. [14] The mean age of presentation was 50.5 years (SD ± 9.29), no significant

association was established between age of the patient and seroma formation. Menton M. et al. opined that seroma formation increases with increasing age of the patient. [15] On the contrary, K. Kuroi et al. quoted that the existing evidence was inconclusive for age with respect to seroma formation, as did E. Hashemi et al. The mean age in E. Hashemi et al. study was 46.3 years (SD \pm 11.9). Unalp et al. reported a mean age of 53.13 years (SD \pm 13.26).

The mean BMI of patients from seroma group was 31.88 kg/mm² (SD \pm 3.56). And BMI of patients from no seroma group was 27.51. The difference was statistically not significant. Our study opines that there is no association between BMI and seroma formation.

Among the seroma group, 2 of 4 patients (50 %), were known hypertensive, while in no seroma group, 6 of 26 patients (23 %) were known hypertensive. There was no significant association between seroma formation and history of arterial hypertension in the patient. Literature shows that high BMI and arterial hypertension are considered risk factors, Douay et al. [9]. In our study, BMI and hypertension are not associated with seroma formation. In our study, none of the seroma group patients received neoadjuvant chemotherapy. Whereas 3 of 26 patients without seroma (11.5 %) had received neoadjuvant chemotherapy. No significant reduction in seroma rate could be demonstrated from the study as similarly concluded by Unalp H. R. et al. [16]

The mean volume of the breast and axillary fatty-lymphatic tissue following modified radical mastectomy in the seroma group was 1662.5 ml (SD \pm 179.69), while the volume in no seroma group was 925 ml (SD \pm 358.41). The difference between the two groups was statistically significant. Hence, seroma formation is influenced by volume of breast and axillary fatty-lymphatic tissue i.e. higher the volume, higher the seroma rate.

The mean drain output during first 24 hours in seroma group was 212.50 ml (SD \pm 25.0), that in no seroma group was 223.07 ml (SD \pm 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 \pm 40.82) and no seroma group was of 130.76 ml (SD \pm 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 \pm 25.0) in seroma group and 113.46 ml (SD \pm 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. K. Kuroi et al. suggest that a positive association between drainage volume during the initial 72 hours and seroma formation was consistent. [17]

The mean number of lymph nodes removed in seroma group was 21.75 (SD \pm 06.89) and no seroma group was 16.34 (SD \pm 06.26). The difference was not statistically significant. The mean drain removal day in seroma group was 12.75 (SD \pm 0.957) and in no seroma group was 10.76 (SD \pm 2.42), it was a statistically insignificant difference. Although K. Kuroi et al. have shown that the incidence of seroma formation was significantly higher in patients following drain removal on post-operative day 5 when compared to drain removal on post-operative day 8. In our study, patients with seroma had drain removed on days ranging from 12 – 14, while in no seroma group, drain removal was between day 7 – 30. Incidence of seroma in our study group is 13.3 %. [18]

Conclusion

Volume of the breast and axillary fatty-lymphatic tissue – greater the volume, higher the seroma rate. A higher drain output on post-operative day 3 is likely to predict the increased possibility of seroma formation. Factors like age of the patient,

hypertension, BMI, neo-adjuvant chemotherapy, number of lymph nodes removed, and the drain removal day have no bearing on seroma rate. This study is limited by its small sample size. Similar studies with larger sample size will further validate these results.

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