A Study of Factors Influencing Seroma Formation after Radical Modified Mastectomy

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ABSTRACT

BACKGROUND
Breast cancer is the second most common cancer in the world and, most frequent cancer among women with an estimated 1.67 million new cancer cases diagnosed in 2012. Breast cancer is the fifth most common cause of death from cancer overall and while it is the most frequent cause of cancer death in women in less developed regions it is now the second cause of cancer death in more developed regions deaths after lung cancer. Most of the cases in India present in locally advanced stage and surgery (Modified Radical Mastectomy) is a major part of the treatment the others being chemotherapy and Radiotherapy. The complications of modified radical mastectomy are numbness, paraesthesia, seroma formation and shoulder immobility. Seroma formation increases the morbidity, repeated aspirations, infection and hospitalization. The incidence of seroma formation varies between 5% and 85%. Its formation depends on the type of surgery, the operating surgeon, preoperative radiation or chemotherapy, the amount of postoperative physical activity, use of cautery use of closed suction drains and closure of dead space have been implicated as potential factors influencing the likelihood of seroma formation.

METHODS
It is a prospective study of 50 patients. The incidence of seroma formation and the factors influencing it were analysed.

RESULTS
50 patients who underwent modified radical mastectomy were studied. 18 patients (36%) developed seroma. Out of 18 patients who developed seroma, 10 patients (55.56%) had diabetes 14 patients (70%) had hypertension, 10 patients (55,56%) had received NACT. The mean BMI of those with seroma was 26.55 (20-34); the mean drain removal day of those with seroma was 13.28 days (7-19), whereas the mean for patients without seroma was 6.38 days (4-10).

CONCLUSIONS
DM, hypertension have significant association with seroma formation. Higher BMI has strong association for seroma formation. With larger tumour size, chances of seroma formation is high. High drain output on post-operative day 1, POD 2, POD 3 is likely to predict increased seroma formation. Age of the patient, tumour side, NACT, preoperative RT, number of lymph nodes removed, have no bearing on seroma rate.

KEYWORDS
Carcinoma Breast, Modified Radical Mastectomy, Breast Conservation Surgery, Axillary Lymph Node Dissection, Seroma, NACT, Radiotherapy

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DOI: 10.18410/jebmh/2020/162

Financial or Other Competing Interests: None.

How to Cite This Article:
Narasimhappa R, Bobburi V. A study of factors influencing seroma formation after radical modified mastectomy. J. Evid. Based Med. Healthc. 2020; 7(14), 743-747. DOI: 10.18410/jebmh/2020/162

Submission 31-01-2020,
Peer Review 07-02-2020,
Acceptance 20-02-2020,
Published 06-04-2020.

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Breast cancer is the second most common cancer in the world and, most frequent cancer among women with an estimated 1.67 million new cancer cases diagnosed in 2012. Breast cancer ranks as the fifth cause of death from cancer overall and while it is the most frequent cause of cancer death in women in less developed regions and it is now the second cause of cancer death in more developed regions after lung cancer.  

Most of the cases in India present in locally advanced stage and surgery (Modified Radical Mastectomy) is a major part of the treatment the others being Chemotherapy and Radiotherapy. The complications of Modified radical mastectomy are numbness, paraesthesia, seroma formation and shoulder immobility, seroma formation increases the morbidity, repeated aspirations, infection and hospitalization the incidence of seroma formation varies between 5% and 85%, its formation depends on the type of surgery, the operating surgeon, preoperative radiation or chemotheraphy, the amount of postoperative physical activity, use of cautery use of closed suction drains and closure of dead space have been implicated as potential factors influencing the likelihood of seroma formation. Constant chest wall movement due to respiration and shoulder use creates shearing forces that delay flap adhesion. For this, several techniques of flap fixation or wound drainage, limitation of postoperative shoulder movement and the use of adhesive glue have been investigated to improve primary healing and minimize seroma formation. To reduce incidence of seroma formation, it is essential to estimate individual risk for seroma formation, and future trials should be aimed at identifying predictive variables and thus reduce the incidence of seroma.

This is a prospective study conducted among patients undergoing modified radical mastectomy during October 2015 to October 2017 in Dr B.R. Ambedkar Medical College.

**METHODS**

Modified radical mastectomy: removal of the Breast with nipple. Areola complex and the tumour and dissection of level 1, 2 and 3 an elliptical skin incision is planned to include the nipple and areola and any previous excisional biopsy scar upper flap raised till clavicle, lower flap till sub mammary fold dissection extended medially till medial border of sternum and laterally till latissimus dorsi. The breast tissue along with tumour is excised along with level 1, 2 and 3 clearance in axilla, drain placed in axilla and breast and skin closed with Ethylon 2.0

**Definitions**

A seroma is defined as any palpable fluid collection in the axilla. Any seroma aspirated once a week or earlier if required and Sample sent for culture and sensitivity. Wound infection was defined as erythema, cellulitis, purulent drainage, wound Gaping, skin necrosis, or positive microbiology, at the incision site that needed Antibiotics. All patients were followed up in the outpatient clinics. Data was collected and recorded longitudinally, output, cumulative postoperative day 7 drain output, total drain output, duration of drainage. Outcome measures: The primary endpoint of the study was the incidence of seroma formation the other parameters were measured were postoperative day 1 drain output, cumulative postoperative day three drain.

**Statistical Analysis**

Descriptive statistical analysis has been carried out in the present study results on continuous measurements are presented on Mean SD and results on categorical measurements are presented in percentage (%). Chi square test has been used to find significance of study Parameters on categorical scale between two groups. Student ‘t’ test has been used to determine the significance between two group means. All analyses were two tailed and p & t < 0.05 was considered significant. SPSS version 16.0 was used for data analysis.

**RESULTS**

50 Consecutively admitted patients with the diagnosis of locally advanced Carcinoma breast and who underwent MRM were included in the study., 18 out of 50 Patients (36%) developed seroma, 10 among the seroma group were found to be Diabetic, accounting for 55.56%, 8 among non-seroma group were diabetic (44.44%), p value 0.031 (significant). 14 (70%) among the seroma group were found to be hypertensive, 6(30%) among non-seroma group were diabetic, p value 0.000043 (significant). 10 patients who had receive NACT developed seroma, and 8 patients who received no NACT developed seroma, p value 0.145, 1 patient who had received RT developed seroma, and 17 patients who received no RT developed seroma, The mean tumour size of the patients who developed seroma was 5.56 (2-11), whereas the mean tumour size of those without seroma was 4.38 (2-10) cm, p value is 0.08 (significant). The mean Age of those with seroma was 44.17 (28-64), whereas the mean age for patients without seroma was 45.69 (32-68). The mean BMI of those with seroma was 26.55(20-34), whereas the mean BMI for patients without seroma was 24.31(20-30) p value was significant 0.02. 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 <0.001.
The Mean drain output of those with seroma on day 2 was 211.1 mL (100-280), whereas the mean for patients without seroma was 130.4 mL (75-200). p Value was significant <0.001. The Mean drain output of those with seroma on day 3 was 177.8 mL (100-250), whereas the mean for patients without seroma was 103.44 (50-150). p Value was significant <0.001. The Mean Total drain output of those with seroma was 1215 mL (550-1750), whereas the mean for patients without seroma was 569 mL (250-950). p Value was significant <0.001. The Mean Drain removal day of those with seroma was 13.28, (7-19) whereas the mean for patients without seroma was 6.38 (4-10). p Value was significant <0.001. The Mean number of lymph nodes removed in seroma group was 17.72 (9-32), whereas the mean for patients without seroma was 18.0 (8-40). p Value was significant <0.001. 14 patients who underwent Electrocautery dissection developed seroma, and 4 patients developed seroma without the use of EC. p Value was significant 0.016. 3 patients who underwent Ultrasonic dissection developed seroma, and 15 patients developed seroma without the use of EC. p Value was significant 0.0004.

7 patients who received CB+AP developed seroma, and 11 patients developed seroma without the use of AP. p Value was Insignificant 0.163. 10 patients who received sealants developed seroma, and 8 patients developed seroma without the use of Sealants. p Value was Insignificant 0.568.

**DISCUSSION**

Breast cancer is the most common cancer in woman and surgical management remains the main line of management. The most common types of breast surgeries are MRM & BCS. Seroma is the commonest sequel following breast cancer surgery. Seroma accumulation elevates the flaps from the chest wall and axilla thereby hampers their adherence to tissue bed. Although it usually resolves within few weeks, excessive fluid accumulation will stretch the skin and cause it to sag, resulting in patient discomfort and prolongation of hospital Stay. It can thus lead to significant morbidity such as wound hematoma, wound Infection, flap necrosis, wound break down, prolonged hospitalization, delayed recovery, psychological distress and delay in starting chemotherapy. Thus, although a number of factors have been correlated with seroma formation, strong data on factors associated with seroma formation are still rare, and it is difficult to identify patients who will ultimately suffer from seroma. Various studies have shown that suturing of skin flaps is a successful means of reducing seroma formation. The success of external compression dressings has not yet been validated adequately through randomized studies Early drain removal has also been shown not to significantly affect seroma formation while reducing duration of drainage and other postoperative morbidity.8,12 Complications due to these methods are not much different from the standard drain method and are not frequent or serious. Our study included 50 patients with the diagnosis of carcinoma breast undergoing modified radical mastectomy. In our study, 36% of patients developed seroma. E Hashemi et al in their study on 158 patients with breast cancer undergoing modified radical mastectomy or breast preservation, over all seroma rate was 35%.13 Gonzalez E A et al in their study on 159 either undergoing modified radical mastectomy or wide local excision and axillary lymph node excision showed over all seroma rate of 15.8%, 19.9% in modified radical mastectomy group and 9.2% in breast conserving group.14 Seroma rate in the study by Unalp H R et al was 14.28%. The mean age of presentation was 44.17 years (SD11.56), p value was 0.61, No significant association was established between the age of the patient and seroma formation. Menton Met opine that seroma formation increases with increasing age of the patient. In the contrary, K. kuroi et al quoted that existing evidence was inconclusive for age with respect to seroma formation,15 as did E.Hashemi et al. The mean age in E. Hashemi et al study was 46.3 year (SD+11.9)13 Unalp et al reported a mean age of 53.13 (SD +13.26) which is comparable to the mean age of patients in studies from India like Nadkarni et and Chintamani et al.16 The mean age is lower than the patients in studies from other parts of the world like Gupta et al, Purushotham et al, Jain et al, Lumachi et al, Galatius et al, O'Hea et al and Ruggerio et al.17-22

This underlines the fact that breast cancer occurs at an earlier age in Indian than in Western countries. Mean BMI was 26.55 of Kg/m² (SD 3.3). In our study BMI in patients from no seroma group has low BMI (24.31), p Value is 0.02, the difference was statistically significant. Our study opines that there is association between BMI and seroma formation. Among the seroma group, 14 of 18 patients, were hypertensive, while in non-seroma group, 6 of 32 patients were known hypertensives. p Value is 0.000043. There was highly 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, Kumar et al found a significant association b/w and HTN with seroma. Among the seroma group, 10 of 18 patients, were Diabetic, while in non-seroma group, 8 of 32 patients were known Diabetics. p Value is 0.031. There was significant association between seroma formation and history of Diabetes in the patient in the study, 10 of the seroma group patients received neoadjuvant.

Chemotherapy, whereas 8 patients who had not received neoadjuvant chemotherapy developed seroma. p Value is 0.145. Significant reduction in seroma rate could not be demonstrated from the study as similarly concluded by Unalp H R et al. 1 patient who had received RT developed seroma, and 17 patients who received no RT developed seroma. p Value was Insignificant 0.632. 14 patients who underwent Electrocautery dissection developed seroma, and 4 patients developed seroma without the use of EC p value was significant 0.016 3 patients who underwent Ultrasonic dissection developed seroma, and 15 patients developed seroma without the use of US. p Value was significant 0.0004 7 patients who received CB+AP developed seroma,
and 11 patients developed seroma without the use of AP. p Value was Insignificant 0.163 10 patients who received sealants developed seroma, and 8 patients developed seroma without the use of Sealants. p Value was Insignificant 0.568. The mean drain output during first 24 hours in seroma group was 264.44 (SD +76.79), that in no seroma group was 171.25 mL (+36.49), there was significant difference between both the groups, p value was <0.001. The Mean drain output of those with seroma on day 2 was 211.1 mL (100-280), whereas the mean for patients without seroma was 130.4 mL (75-200). p Value was significant <0.001. The Mean drain output of those with seroma on day 3 was 177.8 mL (100-250), whereas the mean for patients without seroma was 103.44(50-150). p Value was significant <0.001. It suggests that the difference was statistically significant, suggesting the probability of seroma formation in those patients with higher drain output on post op day 3. K. Kuroi et al, suggested that a positive association between drainage volume during the initial 72 hrs and seroma formation was consistent. The Mean Total drain output of those with seroma was 1215 mL (550-1750), whereas the mean for patients without seroma was 569 mL (250-950).

p Value was significant <0.001. The Mean day of drain removal in patients with seroma was 13.28 (7-19), whereas the mean for patients without seroma was 6.38 (4-10) p value was significant <0.001. Although Kuroi et al showed the seroma formation rate was significantly high in patients following drain removal on post day 5 when compared to drain removal on post op day 8. In our study, patients with seroma had drain removed on days ranging from (7-19) and in non-seroma group (4-10) The Mean number of lymph nodes removed in seroma group was 17.72 (9-32), whereas the mean for patients without seroma was 18.0 (8-40). p Value was significant <0.001.

**CONCLUSIONS**

The factors influencing seroma formation following modified radical mastectomy for carcinoma breast are DM, HTN, high BMI, large tumour, high drain output on POD 1, POD 2, POD 3, age of the patient, tumour side, NACT and preoperative RT. Number of lymph nodes removed has no bearing on seroma rate.

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