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Original Article

Assessment Of The Total Volume Of Seroma Aspirated And Early Drain Removal Following The Use Of Injection Methylprednisolone In Patients Undergoing Modified Radical Mastectomy

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Abstract

Background: Between 30% and 92 percent of people are affected. After the suction drain is removed, it is common for the seroma to reappear, necessitating repeated skin punctures. This results in a higher risk of infection, as well as a delay in adjuvant therapy of several weeks.

Objectives: Assessment of the Total volume of the Seroma aspirated and Early Drain removal.

Method: The study was conducted on a total of 62 patients undergoing Modified Radical Mastectomy at KARNATAKA INSTITUTE OF MEDICAL SCIENCES, HUBLI from December 2019 to January 2022. In the study period, 62 patients fulfilled the inclusion criteria and were randomized, 31 in the methylprednisolone intervention group and 31 in the control group.

Results: The age of the subjects varied from 25 years to 75 years. The average age cases of carcinoma breast were >45 years. Out of 62 patients, 7 patients (22.6%) in the test group had seroma, and 11 patients (35.5%) in the control group had seroma which was statistically insignificant.There is a significant difference in the drain removal days between the test and control groups. The post-operative drain removal within 5 days in the test group is 77.4% compared to the control group 16.1%.

Conclusion: Various factors implicated to be predisposing factors for seroma formation such as the age of the patient, BMI of the patient, stage of the tumour, the role of neoadjuvant therapy, number of lymph nodes dissected, lymph node ratio, stage of the tumour, total drain output, drain removal day and molecular subtype were analyzed and age of the patient >45yrs, BMI>25, were found have a statistically significant association with seroma formation. The total volume of seroma aspirated was lower in the test group. Test group also favours the early drain removal and reduced drain output.

Keywords: Seroma formation, Age, BMI, stage of the tumour, lymph node ratio, total drain output

INTRODUCTION

Female breast cancer has now surpassed lung cancer as the leading cause of global cancer incidence in 2020, with an estimated 2.3 million new cases, representing 11.7% of all cancer cases. Breast cancer is much less common in India than it is in Western countries. Still, breast cancer is the most common cancer among Indian females, with an age-adjusted rate of 25.8 per 100,000 women and a mortality rate of 12.7 per 100,000.women.[1].In India, the incidence of breast cancer ranges from 5 to 10 per 100,000 people. Female population per year in rural areas to 30 female population per 100,000 population per year in towns and cities.

A study of the burden of cancer and their variation across the states of India- global burden of disease 1990-2016 estimated that in India there were 1,18,0000 breast cancer cases 98.1% of these were in females the prevalent number of cases was 5,26,000.

In these patients, surgery is the standard of care, with modified radical mastectomy being the most commonly performed procedure for carcinoma breast. Seroma formation is the most common complication after modified radical mastectomy, with incidence ranging from 15% to 85%,[2]. A seroma is a collection of serous fluid that forms after the formation of skin flaps during mastectomy or in the axillary dead space after axillary dissection.[3] Seroma causes significant morbidity in the patient, as well as a prolonged hospital stay and a delay in starting adjuvant treatment, interfering with the treatment of the systemic component of the disease and reducing survival. The formation of a seroma increases the likelihood of infection, delays wound healing, flap necrosis, persistent pain, wound dehiscence, and thus lengthens the convalescence period. Hence this study was conducted to assess the total volume of seroma aspirated in reducing post-mastectomy seroma.

MATERIALS AND METHODS:

The study was conducted on patients admitted in the inpatient department of General Surgery in Karnataka Institute of Medical Sciences, Hubli with the diagnosis of carcinoma breast who underwent primary modified radical mastectomy and those who received neoadjuvant chemotherapy followed by modified radical mastectomy during the study period from December 2019 to January 2022. Institutional ethical committee clearance was obtained before the starting of present study

All patients who were admitted under the Department of General Surgery in Karnataka Institute of Medical Sciences, Hubli with the diagnosis of carcinoma breast and underwent Modified Radical Mastectomy during the study period from December 2019 to January 2022 satisfying the inclusion criteria were enrolled for the study. Patient details were documented including history and clinical examination(Sex, Age, BP, BMI, Stage of the disease).

Patients were randomized alternatively in both test and control groups.

All the patients in the Test group undergoing modified radical mastectomy received injection methylprednisolone 125mg bolus intravenously before induction. Postoperatively total drain output is recorded and the drain removal day is noted. The patients are followed up till POD-10 and the seroma if present is aspirated and total seroma volume is recorded.

In our study seroma is defined as collection of serous fluid after mastectomy on POD-10 after the drain removal (<50 ml on POD-3) which requires aspiration.

INCLUSION CRITERIA

- All patients of Carcinoma Breast undergoing Modified Radical Mastectomy.
- Patients with carcinoma breast who received neoadjuvant chemotherapy followed by Modified Radical Mastectomy.

EXCLUSION CRITERIA

- Patients with Diabetes mellitus
- Patients treated with glucocorticoids within 1 month before surgery
- Patients unwilling for study
- Carcinoma Breast Patients who didn't undergo surgery

STATISTICAL ANALYSIS:

Data were entered into a Microsoft Excel datasheet and analyzed by using SPSS software version 22. Data was represented in the form of proportions and frequencies.

RESULTS:

The age of the subjects varied from 25 years to 75 years. The average age cases of carcinoma breast were >45 years. The peak incidence of breast cancer in female patients attending our hospital was found to be >45 years with an incidence of 50% followed by 36-45 years with an incidence of 38.7%

Table1: Age Distribution of study subjects

Age group (years)	Test		Control	
	N	%	N	%
26-35	5	16.1	2	6.5
36-45	8	25.8	16	51.6
>45	18	58.1	13	41.9
Total	31	100	31	100
Chi square p value=0.09 (Not significant)				

The age of the subjects varied from 25 years to 75 years. The average age cases of carcinoma breast were >45 years. The peak incidence of breast cancer in female patients attending our hospital was found to be >45 years with an incidence of 50% followed by 36-45 years with an incidence of 38.7%

Table2: Occurrence of seroma between the study groups

Seroma	Test		Control	
	N	%	N	%
Present	7	22.6	11	35.5
Absent	24	77.4	20	64.5
Total	31	100	31	100
Chi-square p value=0.26 (Not significant)				

Out of 62 patients,7 patients (22.6%) in the test group had seroma, and 11 patients (35.5%) in the control group had seroma which was statistically insignificant.

Table 3: Comparison of drain output at 48hrs between the study groups

Drain volume (ml)	**Test**		**Control**	
	N	**%**	**N**	**%**
≤50	9	29	2	6.5
>50	22	71	29	93.5
Total	31	100	31	100
Chi square p value=0.02 (Significant)				

Out of 31 patients in the test group 9 patients(29%) had seroma volume less than 50ml in 48 hrs compared to the control group 2 patients(6.5%) which was statistically significant.

Table 4: Aspirated seroma between the groups

Groups	**Number**	**Mean**	**SD**	**p-value**
Test	7	70	11.5	**0.01**
Control	11	88.2	15.4	
Independent t-test, p value-Significant				

Of the total 62 patients in the study, 31 patients in the test group only 7 patients(70%) required intervention in form of seroma aspiration when compared to the control group of 11 patients(88.2%).

Table 5: Total drain output between the study groups

Groups	**Number**	**Mean**	**SD**	**p-value**
Test	31	386.1	350.2	0.02
Control	31	644.5	467.0	
Independent t-test, p-value- Significant				

Out of 62 patients, 7 patients (22.6%) in the test group had seroma, and 11 patients (35.5%) in the control group had seroma which was statistically insignificant.

Table 6: Comparison of removal of drain across the study groups

Drain removal (Days)	Test		Control	
	N	%	N	%
0 - 3	7	22.6	1	3.2
4-5	17	54.8	4	12.9
6-7	5	16.1	13	41.9
>7	2	6.5	13	41.9
Total	31	100	31	100
Chi square p value=<0.001 (Highly significant)				

There is a significant difference in the drain removal days between the test and control groups. The post-operative drain removal within 5 days in the test group is 77.4% compared to the control group 16.1%.

DISCUSSION:

Seroma formation is by far the most common complication following breast surgery, and there are a plethora of studies on the issue. There is sufficient evidence that preventative actions are effective. There isn't a single method that works in every case. Although the pathophysiology of seroma production is still being studied, various triggering events have been linked to it. Numerous studies have postulated several predisposing characteristics for seroma formation. Various surgery-related factors have been theorized to boost seroma formation, but there is inadequate evidence to support each of these factors, necessitating our investigation.

The mechanism behind the formation of a seroma is not known in detail. The immunoglobulin G, granulocyte and lymphocyte counts in the mastectomy cavity have been compared in patients with and without seroma formation.[4] The levels of immunoglobulin G, leucocytes, and granulocytes were higher immediately postoperatively and then declined steadily, whereas the opposite pattern was found for the lymphocyte count which increased steadily over time. It was concluded that a seroma was not just an accumulation of serum, but probably formed part of the postoperative inflammatory response involved in wound healing. Furthermore, the presence of proteinases, proteinase inhibitors and cytokines (tissue plasminogen activator (tPA), urokinase-type plasminogen activator (uPA), urokinase receptor (uPAR), plasminogen activator inhibitor (PAI)-1 and 2, interleukin 6 (IL-6), and interleukin (IL) 1β) in seroma fluid was demonstrated.[5]

Steroids inhibit the inflammatory response through the inhibition of cytokine function.[6] In our study, we found that injecting 125 mg of bolus i/v methylprednisolone 1hour before surgery was a convenient mode of application, which helped decrease the average drain output and also decreased the days for which drainage was needed. This intervention also reduced the total incidence of seromas on the 2nd postoperative day as compared to the nonintervention group (i.e., 29% vs 6.5%). Total seroma volume during days 1-5 and the number of seroma punctures were also reduced. There was no incidence of wound infection complications between the groups.

In our study, the mean age group of carcinoma breast patients in the test group was 48.1% and in the control group was 47.9% which was comparable with the other studies.[6,7,8]

In our study, there was an association of mean BMI with seroma formation with a high BMI value higher the incidence of seroma formation (p-value 0.02) which was comparable with other studies.[6]

Table 7: Drain removal among various studies

Studies	p-value
Maryam khan	0.005
Ayman A. Albatanony et al	0.01
Our study	0.001

In our study, drain removal within 5 days was observed in 77.4% of patients in the test group when compared to the control group 16.1% which was comparable with other studies. [8,9]

Table 8: Seroma aspiration among various studies

Studies	p-value
G Qvamme et al	0.001
S Vijayalakshmi	0.007
Shyamsundar	0.015
Our study	0.01

In our study, out of 31 patients in the test group, 7 patients had seroma and requires aspiration with a mean of 70% compared to the control group where 11 patients had seroma which required aspiration with a mean of 88.2% which was comparable with other studies.[7, 10,11]

CONCLUSION:

Seroma formation following mastectomy is a common problem and identification of its predisposing factors helps in understanding its pathophysiology better aiding in better preventive methods and early identification and management of seroma thus decreasing the morbidity and complications.

Various factors implicated to be predisposing factors for seroma formation such as the age of the patient, BMI of the patient, stage of the tumour, the role of neoadjuvant therapy, number of lymph nodes dissected, lymph node ratio, stage of the tumour, total drain output, drain removal day and molecular subtype were analyzed and age of the patient >45yrs, BMI>25, were found have a statistically significant association with seroma formation.

The total volume of seroma aspirated was lower in the test group when compared with the control group and the study signifies the early drain removal in the test group compared to the control group.

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