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Study of Early Post Operative Complications of Modified Radical Mastectomy and Assessment of Risk Factors with Specific Reference to Neoadjuvant Chemotherapy

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ABSTRACT

In India, breast cancer is the most frequent cancer to affect women. For females, it ranks as the second most frequent cause of death. Breast cancer is the most frequent cancer among Indian women in urban areas and the second most common among those in rural areas, with increased incidence and awareness of the disease. To enumerate the early post-operative complications of Modified Radical Mastectomy, calculate the incidence of the complications and the risk factors and its association with the complications. It was an Institutional based prospective observational study from January-June 2021-2022 Indoor patients in Department of General Surgery in Medical College and Hospital Kolkata. 60 patients were included in this study. We found that, in most of the patients seroma formation was seen in T3 (8(29.6%)) which was statistically significant ($p = 0.0120$) 9 (30.0%) patients had seroma formation when duration of operation was 1-2 hrs but it was not statistically significant and 8 patients (26.7%) with nodal status N1 had seroma formation but it was not statistically significant ($p = 0.5849$) and the mean Post Op Pain (VAS) 3rd day was more (2.6522 ± 0.6473) in patients without NACT compared to with NACT (2.3784 ± 0.3784) but this was not statistically significant ($p = 0.1699$). The mean Post Op Pain (Vas Score) 7th day was more (0.8108 ± 0.7760) in patients with NACT compared to without NACT (0.7826 ± 0.5184) though it was not statistically significant ($p = 0.8781$). We discovered that, albeit not statistically significant the mean Post Op Pain (Vas Score) on day 14 was lower in the non-intervention group when compared to the intervention group. Similarly the mean Post Op Pain (Vas Score) on day 30 was lower in the non-intervention group when compared to the intervention group. Breast cancer outcomes, modified radical mastectomy (mrm) and breast conservation therapy.

INTRODUCTION

In India, breast cancer is the most frequent cancer among women^[1]. For women, it ranks as the second most frequent cause of death^[2]. Breast cancer is now the most frequent cancer among Indian women living in cities and the second most common among those living in rural areas, thanks to increased knowledge and incidence^[3]. There aren't many population-based research on breast cancer patients to learn about their health-seeking habits. The majority of breast cancer patients in poor nations continue to receive their diagnosis at a somewhat late stage over 50% of cases have locally progressed malignancy^[4]. It has been noted that patients with lower incomes (48%) and educational status tend to receive a delayed diagnosis of breast cancer, which is associated with a lower survival rate^[5,6].

Large primary tumors (>5 cm) tumors involving the chest wall, skin involvement, ulceration or satellite skin nodules, inflammatory carcinoma, bulky or fixed axillary nodes and clinically evident internal mammary or supraclavicular nodal involvement (stages IIB, IIIA and IIIB disease) are among the characteristics of patients with locally advanced breast cancer. Depending on the disease's stage a number of therapy options are available for breast cancer. Although total tumor excision is the best course of action, it is not always feasible, hence other therapeutic approaches have also been discussed. Neo adjuvant chemotherapy therapy is a course of treatment that is often appropriate for a subset of patients within the Indian patient population.

Breast conserving treatment (BCT) frequently replaces modified radical mastectomy (MRM) in high-income nations. As radiation therapy a necessary part of bone marrow transplantation (BCT) is not easily accessible, MRM remains the treatment of choice in low-and middle-income countries (LMICs). It has been discovered that the patient's quality of life did not significantly differ after undergoing these operations^[7].

MATERIALS AND METHODS

Experiment design: Institutional based prospective observational study.

Study setting: Indoor patients in Dept. of General Surgery in Medical College and Hospital Kolkata.

Time line: Study was conducted for 18 months. 14 months was provided for data collection. Next 2 months for statistical analysis and another 2 months for thesis writing and submission.

Place of study: Medical College and Hospital, Kolkata

Time of study: January-June 2021-2022

Study population: Patients who will undergo modified radical mastectomy in medical college Kolkata.

Sample size: Using the census approach, their unit performs one modified radical mastectomy on average per week. There were 35 MRM instances in all in 2020. There were 48 and 56 total MRM cases in 2019 and 2018, respectively. They chose to conduct the trial on 60 patients, taking into account the 10% exclusion criterion the length of the study and the practical feasibility of the 66 total MRM cases that would occur over the study time. So, my sample size is 60 patients.

Study design: Institutional based non randomized prospective, observational study.

Inclusion criteria:

- Patients who have undergone Modified Radical Mastectomy
- Patients who have received neoadjuvant chemotherapy before Modified Radical Mastectomy
- Patients willing to give written informed consent and to follow study procedure

Exclusion criteria:

- Refusal to join study
- Presence of any neurological/psychiatric disease/skin diseases
- Class 3 and 4 surgical patients as per ASA
- Pregnancy

RESULT

Clinical tumour (T) status: In our study, 22 (36.7%) patients had T2, 27 (45.0%) patients had T3,4 (6.7%) patients had T4, 3 (5.0%) patients had T4a and 22 (36.7%) patients had T4b.

Clinical nodul (N) status: In our study, 25 (41.7%) patients had N0, 30 (50.0%) patients had N1 and 4 (6.7%) patients had N2a.

NACT: In our study, 37 (61.7%) patients had NACT. Seroma Formation 3rd day. In patients with NACT, 12 (32.4%) patients had Seroma Formation. Association of Seroma Formation with NACT was statistically significant ($p = 0.0102$). Wound Infection 3rd day. In patients with NACT, 4 (10.8%) patients had Wound Infection. Association of Wound Infection with NACT was not statistically significant ($p = 0.1026$).

Haematoma: In with NACT, 2(5.4%) patients had Haematoma. Association of Haematoma with NACT was not statistically significant ($p = 0.2567$).

Table 1: Distribution with all parameter

Clinical tumour (T) status	Frequency	Percent
T2	22	36.7
T3	27	45.0
T4	4	6.7
T4a	3	5.0
T4b	4	6.7
Total	60	100.0
Clinical nodul (N) status		
N0	25	41.7
N1	30	50.0
N2a	4	6.7
No	1	1.7
Total	60	100.0
NACT		
No	23	38.3
Yes	37	61.7
Total	60	100.0

Distribution of mean Post Op Pain (VAS) 3rd Day with Group was not statistically significant ($p = 0.6233$). Distribution of mean Post OP Pain (VAS SCORE) 7th Day with Group was not statistically significant ($p = 0.2691$). Distribution of mean Post OP Pain (VAS SCORE) 14th Day with Group was statistically significant ($p = 0.0075$). Distribution of mean POST OP Pain (VAS SCORE) 30th Day with Group was not statistically significant ($p = 0.0784$).

DISCUSSIONS

The present study was an Institutional based prospective observational study. This study was conducted from January-June 2021-2022 at Department of General Surgery in Medical College and Hospital Kolkata. 60 patients were included in this study. We found that, most of the patients had Seroma Formation (3rd day) (12(32.4%)) who received NACT compared to those who did not (1(4.3%)) which was statistically significant ($p = 0.0102$).

We found that, in most of the patients seroma formation was seen in T3 (8(29.6%)) which was statistically significant ($p = 0.0120$) 9 (30.0%) patients had seroma formation when duration of operation was 1-2 hrs but it was not statistically significant and 8 patients (26.7%) with nodal status N1 had seroma formation but it was not statistically significant ($p = 0.5849$).

Uslukaya *et al.*^[8] discovered that the most popular method for preventing seroma formation a common complication following axillary and breast surgery is the use of preventive surgical drains. The DIT, treatment protocols, tumor histopathologic features, size of removed breast tissue (BS) tumor size (TS) number of totally removed lymph nodes (TLN) and metastatic lymph nodes (MLN) treatment methods and whether or not the patients received neoadjuvant chemotherapy were all retrospectively recorded from the hospital database. The patient's mean DIT was 4.8 days and their mean age was 48.9 years. Bowen *et al.*^[9] demonstrated that using 1:1 matching, one could

assess the risk of neoadjuvant chemotherapy for surgical morbidity following mastectomy with or without reconstruction. For patients with breast cancer having mastectomy, postoperative surgical problems are still a possibly avoidable occurrence. One factor that has been linked to increased risk is neoadjuvant chemotherapy however, it has not undergone a thorough analysis to determine its primary causal impact.

Suresh *et al.*^[10] discovered that, among women, breast cancer is the most common cancer and ranks second in terms of cancer-related mortality. The mainstay of treatment is still surgical intervention. One of the most common side effects of breast cancer surgery is seroma production its etiology is still unknown and has several sporadic origins. Information about the following factors was compared with the patient's age, BMI, neoadjuvant chemotherapy, tumor size, amount of lymph nodes excised, postoperative exercises and physiotherapy, use of cautery and initial and 72 hrs wound drainage. For their study's statistical data analysis, they employed the t-test and chi square approaches. Research revealed that only 4 individuals experienced wound infection on the third day, however the difference was not statistically significant ($p = 0.1026$). Patients with wound infections in T3 19 (42.2%) did not have statistically significant wound infections ($p = 0.1130$). It was not statistically significant that just 2 individuals experienced wound infection for the entire 1-2 hrs operation. The fact that just 1 patient (100.0%) who chewed tobacco experienced a wound infection was statistically significant ($p = 0.0001$).

Bawoke *et al.*^[11] In facilities with limited or no radiotherapy services, modified radical mastectomy is the preferred technique. AOR 6.2 (CI 1.5-8.7) for diabetes and AOR 8.9 (CI 1.2-14.2) for neoadjuvant chemotherapy were substantially correlated with the 17.2% seroma rate. 14.9% of surgical site infections were related to retroviral infections (AOR 4.2 (CI 2.1-5.8) and neoadjuvant chemotherapy (AOR 1.8 (CI 1.3-3.9)). Throughout the research, there was not a single in-hospital death. While the rate of surgical site infections was higher the rate of seroma was lower than in published studies.

Our study showed that, 7 patients who had received developed Mastectomy Skin Flap Necrosis (3rd day) which was statistically significant ($p = 0.0264$). 1 (00.0%) patient with chewing tobacco had mastectomy skin flap necrosis which was statistically significant ($p = 0.0055$). We showed that, 2 patients had Haematoma who received NACT though it was not statistically significant ($p = 0.2567$). In T4b 2 (50.0%) patients had haematoma which was statistically significant ($p < 0.0001$). Duration of

Table 2: Association between seroma formation NACT
NACT

Seroma formation 3rd day	No	Yes	Total
No	22	25	47
Row %	46.8	53.2	100.0
Col %	95.7	67.6	78.3
Yes	1	12	13
Row %	7.7	92.3	100.0
Col %	4.3	32.4	21.7
TOTAL	23	37	60
Row %	38.3	61.7	100.0
Col %	100.0	100.0	100.0
Wound infection 3rd day	No	23	3053
Row %	43.4	56.6	100.0
Col %	100.0	81.1	88.3
Yes	0	7	7
Row %	0.0	100.0	100.0
Col %	0.0	18.9	11.7
Total	23	37	60
Row %	38.3	61.7	100.0
Col %	100.0	100.0	100.0
Haematoma	No	23	3558
Row %	39.7	60.3	100.0
Col %	100.0	94.6	96.7
Yes	0	2	2
Row %	0.0	100.0	100.0
Col %	0.0	5.4	3.3
TOTAL	23	37	60
Row %	38.3	61.7	100.0
Col %	100.0	100.0	100.0

Table 3: Distribution of mean Post Op Pain (VAS) at different time interval

Post Op Pain(VAS) 3rd Day	Number	Mean	SD	Minimum	Maximum	Median	p- value
T2	22	2.5909	0.5903	1.0000	3.0000	3.0000	0.6233
T3	27	2.4815	0.7530	1.0000	4.0000	3.0000	
T4	4	2.2500	1.2583	1.0000	4.0000	2.0000	
T4a	3	2.6667	1.1547	2.0000	4.0000	2.0000	
T4b	4	2.0000	0.8165	1.0000	3.0000	2.0000	
POST OP pain (vas score) 7th day							
T2	.7727	.5284	0.0000	2.0000	1.0000	1.0000	0.2691
T3	.7037	.5417	0.0000	2.0000	1.0000	1.0000	
T4	1.0000	1.4142	0.0000	3.0000	0.5000	0.5000	
T4a	.6667	.5774	0.0000	1.0000	1.0000	1.0000	
T4b	1.5000	1.2910	0.0000	3.0000	1.5000	1.5000	
Post OP pain (VAS score)14th day							
T2	22	.0909	.2942	0.0000	1.0000	0.0000	0.0075
T3	27	.2222	.4237	0.0000	1.0000	0.0000	
T4	4	.5000	1.0000	0.0000	2.0000	0.0000	
T4a	3	.0000	.0000	0.0000	0.0000	0.0000	
T4b	4	1.0000	.8165	0.0000	2.0000	1.0000	
T2	22	.0455	.2132	0.0000	1.0000	0.0000	0.0784
T3	27	.0370	.1925	0.0000	1.0000	0.0000	
T4	4	.2500	.5000	0.0000	1.0000	0.0000	
T4a	3	.0000	.0000	0.0000	0.0000	0.0000	
T4b	4	.5000	1.0000	0.0000	2.0000	0.0000	
Post OP pain (VAS score) 30th day							
T2	22	.0455	.2132	0.0000	1.0000	0.0000	0.0784
T3	27	.0370	.1925	0.0000	1.0000	0.0000	
T4	4	.2500	.5000	0.0000	1.0000	0.0000	
T4a	3	.0000	.0000	0.0000	0.0000	0.0000	
T4b	4	.5000	1.0000	0.0000	2.0000	0.0000	

operation >2hrs, 2 (25.0%) patients had haematoma which was statistically significant ($p = 0.0012$). In diabetic patients 2 (100.0%) had haematoma which was statistically significant ($p = 0.0081$). In N1 1 patient and N2a 1 patient had haematoma formation which was statistically significant ($p = 0.0347$).

In our study the mean Post Op Pain (VAS) 3rd day was more ($2.6522 \pm .6473$) in patients without NACT compared to with NACT (2.3784 ± 2.3784) but this was not statistically significant ($p = 0.1699$). The mean Post Op Pain (Vas Score) 7th day was more ($.8108 \pm .7760$) in

patients with NACT compared to without NACT ($.7826 \pm .5184$) though it was not statistically significant ($p = 0.8781$).

Obadiel *et al.*^[12] noted that the most prevalent malignancy among women worldwide is breast cancer. roughly 13% of all new cancer cases, both male and female, occur each year and in Yemen, breast cancer accounts for roughly 22.8% of cancer cases among female patients. To assess certain risk factors and related comorbidities, as well as investigate the early problems that follow a modified radical mastectomy in

patients who have been diagnosed with breast cancer. The current prospective and observational study, carried out at the Al-Gomhori Teaching Hospital, detailed the problems experienced by fifty patients diagnosed with breast cancer who underwent modified radical mastectomy between January 2019 and January 2020. The cases had a mean age of 45.6% and a standard deviation of 12.4% years.

We found that the mean Post Op Pain (Vas Score) 14th day was lower ($.0870 \pm .2881$) in without NACT compared to with NACT ($.3243 \pm .5799$) it was not statistically significant ($p = 0.0733$) and the mean Post Op Pain (Vas Score) 30th day was lower ($.0435 \pm .2085$) in without NACT compared to with NACT ($.1081 \pm .3933$) though it was not statistically significant ($p = 0.4709$).

CONCLUSION

Most of the patients had Seroma Formation (3rd day) who received NACT compared to those who did not, which was statistically significant. In most of the patients seroma formation was seen in T3 which was statistically significant. Only 4 patients had Wound Infection (3rd day). One patient with chewing tobacco had wound infection which was statistically significant 7 patients had Mastectomy Skin Flap Necrosis (3rd day) which was statistically significant.

One patient with chewing tobacco had mastectomy skin flap necrosis which was statistically significant. Two patients had Haematoma who received NACT though it was not statistically significant. In T4b 2 patients had haematoma which was statistically significant.

Duration of operation: >2 hrs, 2 patients had haematoma which was statistically significant. Two diabetic patients had haematoma which was statistically significant. In N1 1 patient and N2a 1 patient had haematoma formation which was statistically significant. In our study the mean Post Op Pain (VAS) 3rd day was more in patients without NACT compared to those who received NACT but this was not statistically significant. The mean Post Op Pain (Vas Score) 7th day was more in patients with NACT compared to without NACT though it was not statistically significant.

We found that the mean Post Op Pain (Vas Score) 14th day was lower in without NACT compared to with NACT it was not statistically significant and the mean Post Op Pain (Vas Score) 30th day was lower in without NACT compared to with NACT though it was not statistically significant. We concluded that the early post-operative complications were less in patients who did not receive neoadjuvant chemotherapy in Modified Radical Mastectomy. We also concluded that large tumour size, nodal status, diabetes, hypertension

chewing tobacco are the risk factors of early post-operative complications of modified radical mastectomy.

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