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Original Research Article

EFFECT OF NEOADJUVANT CHEMOTHERAPY ON SEROMA FORMATION AFTER MODIFIED RADICAL MASTECTOMY: AN EXPERIMENTAL STUDY

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ABSTRACT

Background: Breast cancer is the single most common type of cancer among women around the world, and is now the leading cause of cancer deaths. Recently, neoadjuvant chemotherapy (NACT) is applied more commonly to treatment of locoregionally advanced breast cancer in order to downstage the tumor to help the surgical benefits. However, the effects of NACT on some postoperative complications, such as seroma formation after modified radical mastectomy (MRM), remain unclear. **Objective:** The objective of the study was to assess the impact of NACT on seroma formation, hospitalization duration and time to remove surgical drain after modified radical mastectomy (MRM) surgery.

Materials and Methods: A randomized control trial was conducted on 50 patients with breast cancer who had undergone modified radical mastectomy at PGIMS, Rohtak. These patients were divided into 2 groups: 25 in Group A (NACT) & 25 in Group B (Non-NACT). In each group, postoperative parameters like blood loss, time to drain removal, duration of hospital stay, and development of seroma were evaluated. The results were assessed by means of t-tests, chi-square tests, and logistic regression analysis.

Results: Patients with NACT had statistically significant prolonged axillary drain retention (p=0.026) and increased duration of hospital stays (p=0.008) compared with non-NACT group. However, there was no significant difference between the two groups in intraoperative blood loss, flap drain removal time, or overall postoperative complications. Seroma formation was observed in 22% of patients with no significant difference between NACT and non-NACT groups (p=0.306).

Conclusion: NACT does not significantly increase the seroma formation, but does increase postoperative drain retention and hospital stay. These results indicate the need for tailored perioperative strategies for breast cancer people on NACT to improve the surgical and recovery outcomes.

Keywords: Modified Radical Mastectomy, Breast Cancer, Seroma Formation, Neoadjuvant Therapy.

INTRODUCTION

In 2020, female breast cancer is expected to be the main cause of cancer in the world, accounting for 2.3 million new cases and 11.7% of total cases. It is the sixth highest cause of cancer mortality globally, accounting for 685,000 fatalities. Breast cancer affects one in every four cancer cases and one in every six cancer deaths in women. It is the leading cause of cancer incidence in 159 out of 185 nations and mortality in 110. Developed countries have 88% higher incidence rates than developing countries (55.9 and 29.7 per 100,000, respectively). The highest rates (>80 per 100,000) are found in Australia/New Zealand, Western Europe (with Belgium having the highest incidence), Northern America, and Northern Europe, while the lowest rates (<40 per 100,000) are found in Central

America, Eastern and Middle Africa, and South Central Asia.[1]

Higher HDI countries have a higher prevalence of reproductive and hormonal risk factors (e.g. early menarche, later menopause, advanced age at first birth, fewer children, less breastfeeding, menopausal hormone therapy, oral contraceptives), lifestyle risk factors (e.g. alcohol intake, excess body weight, physical inactivity), and increased detection through organized or opportunistic mammograph.[2]

As shown, breast cancer is the most common malignancy in women, and surgery is the primary treatment. Common surgical procedures includes modified radical mastectomy with or without reconstruction or breast preservation, as well as axillary lymph node dissection.[3]

Breast cancer staging is based on tumor size, nodal involvement, metastasis presence, and particular biomarkers such as oestrogen receptors, progesterone receptors, and the ERBB2 receptor (previously HER2). Ductal carcinoma in situ (DCIS) is a stage 0 noninvasive breast cancer. Stages I, IIa, and IIb define early invasive cancer, while stages IIIa, IIIb, and IIIc characterize locally progressed disease. All of these phases of breast cancer are not metastatic. The stage IV of breast cancer is metastatic.[4]

Nonmetastatic breast cancer is treated with preoperative and postoperative systemic therapies that include chemo¬therapy, endocrine therapies, immunotherapy with mono¬clonal antibodies directed at tumor receptors, and surgery and radiation.[5]

Neoadjuvant chemotherapy was initially intended to be utilized in patients with locally advanced illness in order to turn inoperable tumors into operable ones. Neoadjuvant chemotherapy is now widely used to treat early-stage, operable breast cancer patients. Neoadjuvant chemotherapy is now used to treat locally advanced breast cancer, inflammatory breast cancer, and big tumor downstaging, allowing for breast conservation treatment.[6]

The most common consequence after mastectomy and/or ALND is seroma development, Excessive buildup stretches the skin, causing stiffness and irritation.[7]

Although it is rarely a life-threatening consequence, it considerably increases hospitalization days and impairs patient quality of life, eventually increasing disease burden and stretching the health-care budget. The reported incidence of seroma development ranges greatly from 15% to 18%. There are various views on the specific cause of seroma development. Several variables have been linked to seroma development, including the amount of lymph node clearance, the number of positive nodes, the use of postoperative radiation, and whether intraoperative lymphatic channel ligation was performed or not.[8] Researchers discovered a link between neo-adjuvant treatment prior to MRM and seroma development.[9]

In this regard, several researches produced inconsistent results, with some concluding that NAC causes modest amounts of seroma development while others finding no such link. This component must thus be confirmed by more research in order to generate greater evidence.

We want to study or evaluate whether NACT influences the development and severity of seroma formation. So, seroma formation was compared between patients following modified radical mastectomy with or without previous NACT.

MATERIALS AND METHODS

This prospective study took place over one year at our Surgery Department after obtaining institutional ethical approval from Institutional Ethical. There were 50 female breast cancer patients with modified radical mastectomy undergoing the study in two separate NACT and Non-NACT groups consisting of n=25 patients each. The research participants had their breast cancer tumors classified into either 5 cm or smaller categories resulting in Group A and Group B. Data collection was carried out via convenience sample to the two groups. Several perioperative and postoperative parameters were assessed, such as intraoperative blood loss, flap drain removal day, axillary drain removal day, hospital stay duration, postoperative complications, and histopathological findings. Seroma development was evaluated clinically.

Statistical Analysis

Data analysis was performed using SPSS v23, Descriptive statistical analysis was done for continuous and categorical variables. Independent t-tests were used for continuous variables and chi-square tests for categorical variables were used. Logistic regression analysis was done to find predictors of seroma formation. For the results to be significant, p-value≤0.05 was considered.

RESULTS

Table 1: Sociodemographic, clinical Information and pathological characteristics of breast cancer patients undergoing modified radical mastectomy

Characteristics		Frequency	Percentage (%)
Age (Years)	**30-45**	16	32%
	45-60	19	38%
	>60	15	30%
BMI (kg/cm^2)	**<18.5**	9	18%
	18.5-22.5	16	32%

		22.5-25	18	36%
		>25	7	14%
Comorbidities		**No morbidity**	37	74%
		Hypertension	6	12%
		Hypothyroidism	1	2%
		Tuberculosis	2	4%
		Type 2 Diabetes Mellitus	2	4%
		Type 2 Diabetes Mellitus and Hypertension	2	4%
Size of tumor (cm)		**<2**	9	18%
		2-5	36	72%
		5	5	10%
Skin Involvement		**Yes**	8	16%
		No	42	84%
Axillary Lymph Node		**No**	38	76%
		Single	11	22%
		2-3 lymph nodes	1	2%
TNM Staging	**T**	**T1**	3	6%
		T2	26	52%
		T3	17	34%
		T4	4	8%
	N	**N0**	39	78%
		N1	11	22%
	M	**M0**	48	96%
		M1	1	2%
		Mx	1	2%

Table 2: Comparison of various peri-operative and post-operative parameters between both groups using chi-square and independent t-test

Variables		**Group A (NACT)**	**Group B (Non-NACT)**	**χ^2/t-value**	**p-value**
Blood Loss	<200 ml	11	10	0.359	0.836
	200-400 ml	9	11		
	>400 ml	5	4		
Flap drain removal (POD)	< 3 days	2	4	0.767	0.682
	3-5 days	21	19		
	>5 days	2	2		
Axillary drain removal (POD)	<10 days	5	11	7.284	0.026*
	10-15 days	15	14		
	>15 days	5	0		
Hospital stay (days)	<5 days	2	6	11.885	0.008*
	5-10 days	10	16		
	10-15 days	5	3		
	>15 days	8	0		
Postoperative complications	No complication	21	23	3.091	0.378
	Fever	3	1		
	Loose stools	1	0		
	Flap Necrosis	0	1		
Type	Invasive Ductal cell carcinoma	24	25	1.020	0.312
	Lobular carcinoma	1	0		
Grade	1	8	6	2.118	0.347
	2	16	15		
	3	1	4		
ER	Positive	12	19	4.160	0.041*
	Negative	13	6		
PR	Positive	10	17	3.945	0.047*
	Negative	15	8		
HER2NEU	Positive	6	5	0.117	0.733
	Negative	19	20		
Lymphovascular Invasion	Present	12	11	0.081	0.777
	Absent	13	14		
Seroma Formation	Positive	4	7	1.049	0.306
	Negative	21	18		
Regional Lymph Nodes		12.28±3.23**	11.96±3.49**	0.336	0.738

Significant at $p \leq 0.05$
****Mean±SD***

Table 3: Logistic regression analysis to predict seroma formation by blood loss, flap drain removal, axillary drain removal and post-operative hospital stay in Group A (NACT)

Outcome	Predictor	B	S.E.	Wald $\chi 2$	df	p-value	Exp(B)
Seroma Formation	Blood Loss	-.002	.008	.058	1	.810	.998
	Flap drain removal	-.816	.741	1.213	1	.271	.442
	Axillary drain removal	.253	.202	1.565	1	.211	1.288
	Post-operative hospital stay	.048	.162	.089	1	.765	1.050

The p-value significant at <0.05

B: Beta (Unstandardized regression weight)

S.E.: Standard Error

Wald $\chi 2$: Statistical test value of individual predictor variables for logistic regression analysis

Table 5.4.2: Logistic regression analysis to predict seroma formation by blood loss, flap drain removal, axillary drain removal and post-operative hospital stay in Group B (Non-NACT)

Outcome	Predictor	B	S.E.	Wald $\chi 2$	df	p-value	Exp(B)
Seroma Formation	Blood Loss	-.003	.003	.827	1	.363	.997
	Flap drain removal	-.103	.417	.062	1	.804	.902
	Axillary drain removal	-.073	.197	.138	1	.711	.930
	Post-operative hospital stay	-.016	.209	.006	1	.939	.984

The p-value significant at <0.05

B: Beta (Unstandardized regression weight)

S.E.: Standard Error

Wald $\chi 2$: Statistical test value of individual predictor variables for logistic regression analysis.

Table 1 shows demographic data and clinical characteristics of study population. 38% participants belong to the age range from 45 to 60 years old. A BMI falling within 22.5-25 kg/m² is observed among 36% of those who took part in the study. Among the study population, 74 percent have no morbidity and hypertension affects 12 percent. The dimension of tumors mostly lies within the 2-5 cm range (72%). The occurrence of skin involvement cases are found to be 16%. Lymph node involvement in the axilla occurs in 24% of patients but 76% of those with breast cancer do not have affected lymph nodes. The results show 52% of patients have T2 tumors and 78% without nodal involvement (N0) with 96% presenting with no metastasis. A comparison between both groups' peri-operative and post-operative parameters is shown in Table 2. Results showed a statistically significant difference between both groups in terms of their hospital stay and hormone receptor status (ER & PR). However, no difference was found between the groups in intraoperative blood loss, flap drain removal, axillary drain removal, postoperative complications, histopathological reports (type, grade, HER2NEU, lymphovascular invasion, seroma formation and reginal lymph node. Table 3 shows predict seroma formation by blood loss, flap drain removal, axillary drain removal and postoperative hospital stay in Group A (NACT). There is no statistically significant probability of predicting outcome i.e. seroma formation by blood loss, flap drain removal, axillary drain removal, and postoperative hospital stay in Group A. Table 4 shows predict seroma formation by blood loss, flap drain removal, axillary drain removal, and postoperative hospital stay in Group B (Non-NACT). There is no statistically significant probability of predicting outcome i.e. seroma formation by blood loss, flap drain removal, axillary drain removal, and postoperative hospital stay in Group B.

DISCUSSION

Breast cancer remains a dangerous worldwide health issue with increased prevalence in India during the recent years. The researchers investigated whether seroma development together with additional surgical outcomes varied after modified radical mastectomy (MRM) following neoadjuvant chemotherapy (NACT). The research investigations provide insight into how NACT affects key surgical outcomes both before and after breast cancer procedures and contributes to ongoing assessments of breast cancer treatment strategies.

The study population consisted of 50 individuals, with the majority falling into the 45–60 years age group (38%). These results are similar with a study by Benz in which they found that Most participants had a BMI in the normal to slightly overweight range, with 36% having a BMI between 22.5–25 and 32% between 18.5–22.5.10 A significant portion of the participants (74%) reported no comorbidities, while hypertension was the most common comorbidity (12%), consistent results were found by Ng et al.11 The majority of tumors were between 2 and 5 cm (72%), and most participants had no lymph node involvement (76%). The TNM staging indicated that most participants had T2 tumors (52%) with no lymph node involvement (78%) and no distant metastasis (96%). Most cases

experienced blood loss of less than 400 ml in present study with similar findings found by Clegg-Lamptey & Dakubo that intra-operative blood loss with majority losing less than 300 grams.[12] Flap drains were typically removed between 3–5 days post-operative day which is inconsistent with a study by Stoyanov et al. according to which drains are removed on the second or third postoperative day.[13] Axillary drains between 10–15 days. Contrasting results by Parikh et al. randomized 100 patients who underwent mastectomy with axillary clearance to drain removal at either 3 or 6 days post¬operatively.[14] Invasive ductal carcinoma was the most common tumor type (98%), and most tumors were grade 2 (62%), similar findings by Badowska-Kozakiewicz et al.[15] Seroma formation was observed in 22% of the participants. Comparable results were found in a study by Woodworth et al. in which Seromas developed in 39 of the 252 operations for an incidence of 15.5 %.[16] The findings indicate that NACT does not significantly impact intraoperative blood loss, with no statistically significant difference observed between the NACT and non-NACT groups (p=0.836). These results align with previous study by Zhang et al. reported no significant differences in intraoperative blood loss.[17] Conversely, by McCool et al. done a study in which they found that patients undergoing interval cytoreductive surgery after NACT had a higher risk of blood transfusion, suggesting increased intraoperative blood loss in this cohort.[18] Flap drain removal timing indicated that NACT does not influence early postoperative fluid drainage. However, a significant difference was observed in axillary drain removal timing. This suggests that NACT might affect lymphatic drainage patterns, leading to prolonged drainage requirements. Contrasting study by Jung et al. demonstrated that NACT did not affect the duration of axillary drainage, suggesting that other factors, such as surgical technique and individual patient characteristics, may play more substantial roles in determining drainage duration.[19]

Hospital stay duration was notably longer in the NACT group, with significantly more patients requiring extended hospitalization. Contrasting results were found by Glassgow et al. in which they reported that patients undergoing NACT experienced shorter postoperative hospital stays compared to those receiving adjuvant chemotherapy.[20] Also conflicting results by Zhang et al. in which neoadjuvant group significantly reduced postoperative hospital stay.[17]

Histopathological analysis revealed a significant difference in estrogen receptor (ER) and progesterone receptor (PR) positivity between the two groups, with the non-NACT group showing higher hormone receptor positivity. This observation is consistent with previous study by Jin et al. reported alterations in ER and PR expression following NACT, emphasizing the importance of reassessing hormone receptor status post-therapy to optimize adjuvant treatment strategies.[21] Similarly Rey-Vargas et al. observed statistically significant decrease in PR expression values between biopsy and surgical specimens after NACT.[22]

Other histopathological parameters, including tumor type, grade, HER2NEU status, and lymphovascular invasion, did not show significant differences between the NACT and non-NACT groups. This aligns with prior research by Schettini et al. in which they did not identify significant differences between the two groups.[23] Similarly, a study by Kang et al. investigated the prognostic implications of HER2 changes after NACT and reported that HER2 status remained stable in the majority of cases.24 These findings suggest that while NACT is effective in reducing tumor size, it does not significantly impact intrinsic tumor characteristics such as HER2 status, tumor grade, or lymphovascular invasion. Seroma formation was not significantly different between the NACT and non-NACT groups. This finding in line with a study by Narasimhappa in which they found NACT has no effect on seroma rate. This indicates that factors beyond NACT, particularly the type of surgical procedure, may have a greater influence on seroma development.[25] Likewise, a systematic review and meta-analysis by Lorentzen et al. concluded that NACT does not significantly affect the incidence of postoperative complications, including seroma formation.26 Furthermore, the number of regional lymph nodes involved did not significantly differ between the two groups. This suggests that while NACT may reduce overall tumor burden, its effect on nodal involvement remains variable. aligns with findings from existing literature by Chen et al.[27] For instance, a study by Mandic et al. indicated that while NACT effectively reduced tumor size, its impact on lymph node metastasis was inconsistent, with no significant reduction in lymph node positivity observed across the studies analyzed.[28] However, contrasting evidence by Cabioglu et al. who analyzed recurrence rates in clinically node-positive breast cancer patients who underwent sentinel lymph node biopsy after NACT. The study found that achieving node-negative status post-NACT was associated with lower recurrence rates, suggesting that NACT can effectively reduce nodal disease in certain patient populations.[29]

Overall, these findings contribute to the ongoing discourse on the effects of NACT on tumor biology and postoperative outcomes. Future research with larger cohorts and molecular analyses is warranted to better understand the mechanisms underlying these observations.

The results of present study show that seroma formation can't be predicted by blood loss, flap drain removal, axillary drain removal, or post-operative hospital stay in either NACT and Non-NACT Group. For instance, a retrospective study by Hashemi et al. found that seroma formation was significantly associated with the type of surgery performed, particularly modified radical

mastectomy, but not with other variables such as age, tumor size, nodal involvement, preoperative chemotherapy, surgical instrument used, use of pressure garments, or duration of drainage.[8] Similarly, a study by Purushotham et al. analyzed 375 patients and reported that there is no evidence in difference between seroma rates, volume of seroma fluid aspirated and wound sepsis.[30] These studies support the observation that seroma formation is influenced more by the type of surgical procedure rather than by perioperative factors such as blood loss, drain management, or length of hospital stay.

Contrasting result in a prospective study done on 108 patients by Somers et al. found that earlier drain removal was associated with a higher incidence of seroma formation, suggesting that the timing of drain removal can influence seroma development.[31] Also, Kuroi et al. identified a significant association between postoperative drainage volume and seroma formation, indicating that higher drainage volumes may predict increased risk of seroma.[32]

CONCLUSION

This study examined the impact of neoadjuvant chemotherapy (NACT) on post-mastectomy outcomes, focusing on drain duration and hospital stay. Findings indicate that while NACT influenced axillary drain removal time and hospital stay ($p < 0.05$), it did not significantly affect seroma formation ($p > 0.05$). Additionally, factors like tumor size, blood loss, and histopathology showed no significant differences between groups. Logistic regression confirmed that seroma risk was not predicted by surgical parameters. These results suggest that concerns about seroma formation should not deter the use of NACT, while its influence on drain duration and hospital stay warrants further investigation.

Limitations of The Study

The study has few shortcomings because of its restricted subject count that affects detection of slight changes in postoperative results including seroma development. The research only took place at a single medical facility thus limiting the practicality of its findings for broader surgical populations or diverse situations. The brief duration of follow-up hinders the proper evaluation of long-term surgical outcomes brought about by neoadjuvant chemotherapy. Access to proper randomization in research design would reduce chances of selection bias thereby weakening final result validity.

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