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Research Article

# Overall Survival (OS) & Disease-Free Survival (DFS) Comparing Neoadjuvant Chemotherapy Vs Adjuvant Chemotherapy in Operable Patients of Ca Breast Regardless of Menopausal Status.

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## ABSTRACT

**Background** The optimal timing of chemotherapy in operable breast cancer remains a subject of debate. Chemotherapy may be administered either before surgery as neoadjuvant chemotherapy (NACT) or after surgery as adjuvant chemotherapy (ACT). While neoadjuvant chemotherapy offers advantages such as tumor downstaging and increased breast conservation, its impact on long-term survival outcomes compared with adjuvant chemotherapy is not clearly established.

**Methods** This prospective randomized controlled trial included 60 female patients with histologically confirmed operable breast cancer (Stage I–III), irrespective of menopausal status. Patients were randomized into two groups: 30 received neoadjuvant chemotherapy followed by surgery, and 30 underwent surgery followed by adjuvant chemotherapy. Both groups received comparable anthracycline- and/or taxane-based chemotherapy regimens. The primary outcomes were overall survival (OS) and disease-free survival (DFS). Patients were followed regularly, and survival outcomes were analyzed using simple survival analysis methods.

**Results** Baseline demographic and clinicopathological characteristics were comparable between the two groups. Breast-conserving surgery was performed more frequently in the neoadjuvant chemotherapy group (60%) compared with the adjuvant chemotherapy group (36.7%). Disease recurrence occurred in 20% of patients in the neoadjuvant group and 16.7% in the adjuvant group, with no statistically significant difference in DFS ($p = 0.74$). Overall survival was also comparable, with mortality rates of 10% in the neoadjuvant group and 6.7% in the adjuvant group ($p = 0.64$).

**Conclusion** Neoadjuvant and adjuvant chemotherapy result in comparable overall and disease-free survival in operable breast cancer patients, irrespective of menopausal status. Neoadjuvant chemotherapy offers the additional benefit of increased breast conservation without compromising survival outcomes.

***Keywords****: Breast Neoplasms, Neoadjuvant Therapy, Adjuvant Chemotherapy, Disease-Free Survival, Overall Survival.*

## INTRODUCTION

Breast cancer is the most frequently diagnosed malignancy among women worldwide and remains a major contributor to cancer-related morbidity and mortality despite significant advances in early detection and treatment strategies[1]. A large proportion of patients present with early or operable disease, for which long-term outcomes depend on the effective integration of surgery, systemic therapy, and radiotherapy[2]. Among systemic treatments, chemotherapy plays a central role in reducing the risk of recurrence and improving survival in patients with operable breast cancer.

Chemotherapy in operable breast cancer can be administered either after surgery as adjuvant chemotherapy (ACT) or before surgery as neoadjuvant chemotherapy (NACT). Adjuvant chemotherapy was historically established as the standard of care following definitive surgical management, supported by strong evidence from randomized trials demonstrating significant improvements in disease-free survival (DFS) and overall survival (OS)[3]. Large meta-analyses conducted by the Early

Breast Cancer Trialists' Collaborative Group (EBCTCG) confirmed that adjuvant polychemotherapy reduces breast cancer recurrence and mortality across different age groups and irrespective of menopausal status[4]. These findings firmly positioned ACT as a cornerstone in the management of operable breast cancer.

Neoadjuvant chemotherapy was initially introduced for patients with locally advanced or inoperable breast cancer to downstage tumors and enable surgical resection. Over time, its application expanded to include patients with operable disease due to several potential advantages. These include tumor size reduction, increased feasibility of breast-conserving surgery, and early systemic treatment of micrometastatic disease[5]. In addition, NACT allows real-time assessment of tumor response to therapy, providing valuable prognostic information and enabling evaluation of pathologic complete response (pCR), which has been associated with improved long-term outcomes in specific breast cancer subtypes such as triple-negative and HER2-positive disease[6].

Despite these benefits, the optimal timing of chemotherapy in relation to surgery has remained a subject of debate. Concerns regarding NACT include the possibility of disease progression during systemic therapy and a potentially increased risk of local recurrence due to delayed surgical intervention[7]. To address these concerns, several randomized controlled trials directly compared NACT and ACT using identical chemotherapy regimens to determine whether earlier delivery of systemic therapy improves survival outcomes.

Landmark trials such as the National Surgical Adjuvant Breast and Bowel Project (NSABP) B-18 and B-27 studies demonstrated that preoperative chemotherapy significantly increased rates of breast-conserving surgery but resulted in no significant differences in OS or DFS when compared with postoperative chemotherapy[8],[9]. These results suggested that while NACT improves surgical outcomes, the sequence of chemotherapy relative to surgery does not substantially influence long-term survival in operable breast cancer.

The findings of individual trials have been corroborated by multiple meta-analyses. A pivotal meta-analysis by Mauri et al. comparing neoadjuvant and adjuvant systemic therapy reported no significant difference in OS or DFS between the two approaches, despite a higher incidence of breast conservation in the neoadjuvant arm[10]. Subsequent meta-analyses incorporating modern anthracycline- and taxane-based chemotherapy regimens have consistently demonstrated survival equivalence between NACT and ACT[11],[12]. These data indicate that survival outcomes are primarily driven by tumor biology and the effectiveness of systemic therapy rather than the timing of chemotherapy administration.

Menopausal status has traditionally been considered an important factor in breast cancer treatment planning due to differences in hormonal environment, tumor characteristics, and treatment tolerance. However, evidence from randomized trials and pooled analyses suggests that the impact of chemotherapy timing on OS and DFS does not significantly differ between premenopausal and postmenopausal women[12]. Instead, prognostic factors such as tumor stage, nodal involvement, molecular subtype, and response to chemotherapy appear to be the dominant determinants of outcome.

In recent years, increasing attention has been directed toward pCR as a surrogate endpoint for survival following neoadjuvant therapy. Large pooled analyses have shown that patients achieving pCR experience significantly improved DFS and OS compared with those with residual disease, particularly in biologically aggressive subtypes[6],[13]. However, trial-level analyses have failed to demonstrate that higher pCR rates translate into superior survival when comparing NACT with ACT, highlighting the limitations of pCR as a surrogate marker for long-term outcomes across treatment strategies[14]. In contemporary clinical practice, NACT has gained additional importance as a platform for response-guided treatment escalation or de-escalation. Nevertheless, from a survival standpoint, the existing body of evidence consistently indicates that neoadjuvant and adjuvant chemotherapy provide equivalent OS and DFS in patients with operable breast cancer. Therefore, treatment decisions should be guided by individual patient and tumor characteristics, surgical considerations, and patient preferences rather than expectations of survival benefit from chemotherapy sequencing alone[15]. The aim of this study is to evaluate and compare overall survival (OS) and disease-free survival (DFS) outcomes between neoadjuvant chemotherapy and adjuvant chemotherapy in patients with operable breast cancer, irrespective of menopausal status.

## METHODOLOGY

This study was conducted as a prospective, randomized controlled trial (RCT) designed to compare overall survival (OS) and disease-free survival (DFS) between neoadjuvant chemotherapy (NACT) and adjuvant chemotherapy (ACT) in patients with operable breast cancer. The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to enrollment. The trial was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. The trial was carried out at a tertiary care oncology center over a defined study period. Patient recruitment, treatment administration, and follow-up were conducted according to institutional oncology protocols.

Eligible participants were female patients diagnosed with operable breast cancer (Stage I–III) confirmed by histopathology. Both premenopausal and postmenopausal women were included. Patients with metastatic disease, prior chemotherapy or radiotherapy, recurrent breast cancer, or serious comorbid conditions precluding chemotherapy were excluded. The sample size was calculated to detect a clinically meaningful difference in DFS between the two treatment arms with a power of 80% and a significance level of 5%. Allowance was made for potential loss to follow-up. A total of 60 patients were enrolled

in the study, with 30 patients allocated to each treatment arm. Patients were randomized in a 1:1 ratio to receive either neoadjuvant chemotherapy or adjuvant chemotherapy. Randomization was performed using a computer-generated random sequence, with allocation concealment ensured through sealed opaque envelopes.

Patients in the NACT arm received standard anthracycline- and/or taxane-based chemotherapy prior to definitive breast surgery. Patients in the ACT arm underwent primary surgery followed by the same chemotherapy regimen postoperatively. Surgical procedures included breast-conserving surgery or mastectomy, based on tumor characteristics and clinical judgment. All patients received standard locoregional treatment, including axillary evaluation and radiotherapy when indicated. Hormone receptor–positive patients received appropriate endocrine therapy, and HER2-positive patients received targeted therapy according to institutional guidelines.

The primary endpoints were overall survival (OS) and disease-free survival (DFS). OS was defined as the time from randomization to death from any cause, while DFS was defined as the time from surgery to the first documented recurrence (local, regional, or distant) or death. Patients were followed at regular intervals with clinical examination and appropriate imaging according to standard follow-up protocols. Survival status and recurrence events were documented throughout the follow-up period.

Data were entered into a spreadsheet and analyzed using basic statistical methods. Categorical variables were expressed as frequencies and percentages. OS and DFS were compared between the two groups using Kaplan meier survival analysis, and differences were assessed using the log-rank test. A p-value of less than 0.05 was considered statistically significant.

**RESULTS**

A total of 60 patients with operable breast cancer were included in the study, with 30 patients randomized to the neoadjuvant chemotherapy (NACT) group and 30 patients to the adjuvant chemotherapy (ACT) group. All patients completed the planned treatment and were included in the final analysis. The baseline demographic and clinicopathological characteristics were comparable between the two groups. The mean age of patients in the NACT group was 47.6 ± 8.2 years, while that in the ACT group was 49.1 ± 7.9 years. Premenopausal women constituted 60% of the NACT group and 56.7% of the ACT group, while postmenopausal women accounted for 40% and 43.3%, respectively.

With regard to disease stage, the majority of patients in both groups had Stage II disease, followed by Stage III and Stage I. Hormone receptor–positive tumors were observed in 70% of patients in the NACT group and 73.3% in the ACT group. There were no significant differences between the two groups with respect to age, menopausal status, disease stage, or hormone receptor status, indicating good baseline comparability.

Breast-conserving surgery was performed more frequently in patients who received neoadjuvant chemotherapy. In the NACT group, 18 patients (60%) underwent breast-conserving surgery, whereas 11 patients (36.7%) in the ACT group were managed with breast conservation. Conversely, mastectomy was required in 12 patients (40%) in the NACT group compared to 19 patients (63.3%) in the ACT group. This finding suggests that neoadjuvant chemotherapy was associated with a higher rate of breast-conserving surgery.

During the follow-up period, disease recurrence was observed in 6 patients (20%) in the NACT group and 5 patients (16.7%) in the ACT group. The remaining patients were disease-free at the time of analysis, accounting for 80% in the NACT group and 83.3% in the ACT group. Comparison of disease-free survival between the two groups showed no statistically significant difference, with a $p$ value of 0.74. This indicates that disease-free survival outcomes were comparable between patients receiving neoadjuvant and adjuvant chemotherapy.

Overall survival analysis revealed that 3 deaths (10%) occurred in the NACT group, while 2 deaths (6.7%) were recorded in the ACT group during the follow-up period. The majority of patients in both groups were alive at the end of follow-up, comprising 90% in the NACT group and 93.3% in the ACT group. There was no statistically significant difference in overall survival between the two treatment arms, with a $p$ value of 0.64, indicating similar survival outcomes with both neoadjuvant and adjuvant chemotherapy.

**Table 1: Baseline Characteristics of Study Participants**

| Characteristic | NACT Group (n=30) | ACT Group (n=30) |
|---|---|---|
| Mean age (years) | 47.6 ± 8.2 | 49.1 ± 7.9 |
| Premenopausal | 18 (60%) | 17 (56.7%) |
| Postmenopausal | 12 (40%) | 13 (43.3%) |
| Stage I | 6 (20%) | 7 (23.3%) |
| Stage II | 17 (56.7%) | 16 (53.3%) |
| Stage III | 7 (23.3%) | 7 (23.3%) |
| Hormone receptor positive | 21 (70%) | 22 (73.3%) |

**Table 2: Surgical Outcomes of Study Participants**

| Surgical Procedure | NACT Group (n=30) | ACT Group (n=30) |
|---|---|---|
| Breast-conserving surgery | 18 (60%) | 11 (36.7%) |
| Mastectomy | 12 (40%) | 19 (63.3%) |

**Table 3: - Disease-Free Survival (DFS) Outcomes in Study Participants**

| DFS Status | NACT Group (n=30) | ACT Group (n=30) | *p* value |
|---|---|---|---|
| Disease-free | 24 (80%) | 25 (83.3%) | **0.74** |
| Recurrence | 6 (20%) | 5 (16.7%) | |

**Table 4: Overall Survival (OS) Outcomes in Study Participants**

| Survival Status | NACT Group (n=30) | ACT Group (n=30) | *p* value |
|---|---|---|---|
| Alive | 27 (90%) | 28 (93.3%) | **0.64** |
| Deaths | 3 (10%) | 2 (6.7%) | |

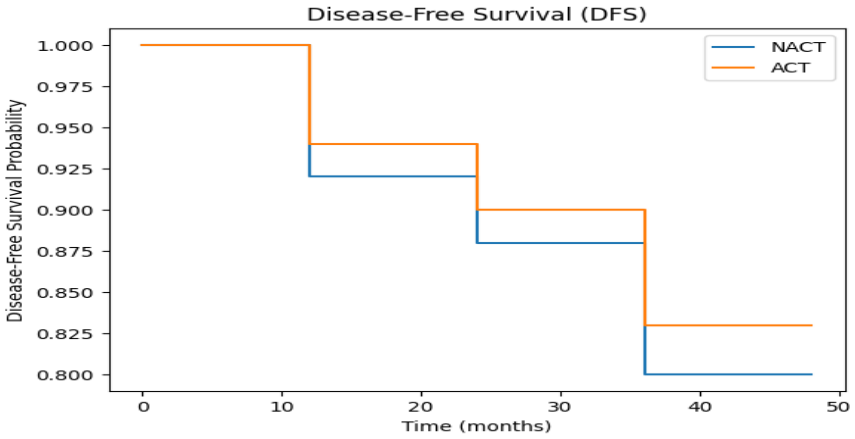


**Fig 1: - Kaplan Meier Survival -Disease-Free Survival (DFS) Outcomes in Study Participants**

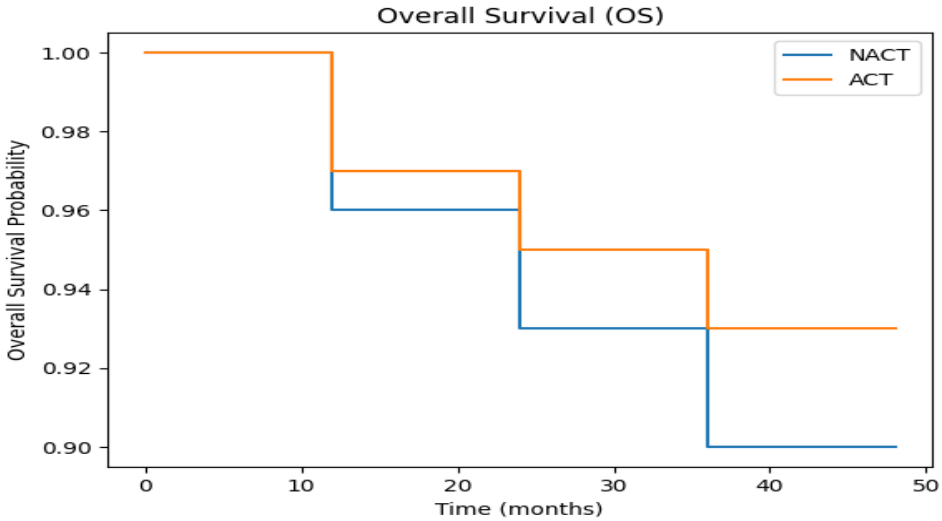


**Fig 1:- Kaplan Meier Survival -Overall Survival (OS) Outcomes in Study Participants**

## DISCUSSION

The present randomized controlled trial evaluated the impact of neoadjuvant chemotherapy (NACT) versus adjuvant chemotherapy (ACT) on overall survival (OS) and disease-free survival (DFS) in patients with operable breast cancer irrespective of menopausal status. The study demonstrated no statistically significant difference in OS or DFS between the two treatment strategies, while neoadjuvant chemotherapy was associated with a higher rate of breast-conserving surgery. These findings suggest that the timing of chemotherapy relative to surgery does not influence long-term survival outcomes when equivalent systemic regimens are administered.

The comparable overall survival observed in this study is in agreement with earlier randomized trials that explored the sequencing of chemotherapy in operable breast cancer. The European Organisation for Research and Treatment of Cancer (EORTC) trial 10902 reported no significant difference in OS between patients treated with preoperative versus

postoperative chemotherapy, despite improved operability in the neoadjuvant arm[16]. Similarly, the randomized trial conducted by the Institut Gustave-Roussy demonstrated equivalent survival outcomes between the two approaches, reinforcing the oncologic safety of neoadjuvant chemotherapy[17]. These findings align closely with the results of the present study, which also showed no survival advantage for either strategy.

Disease-free survival outcomes in the current trial were also similar between the two groups, with no statistically significant difference in recurrence rates. This observation is consistent with pooled analyses of randomized trials that have shown comparable DFS between NACT and ACT in operable breast cancer[18]. A large meta-analysis by the Collaborative Group for Neoadjuvant Chemotherapy reported that while neoadjuvant therapy improves local control through tumor downstaging, it does not significantly alter DFS when compared with adjuvant treatment. The slightly higher recurrence rate observed in the neoadjuvant arm of some studies has been attributed to variations in surgical technique and radiotherapy delivery rather than intrinsic differences in systemic disease control.

One of the important findings of this study is the increased rate of breast-conserving surgery in patients receiving neoadjuvant chemotherapy. This advantage has been consistently demonstrated across multiple trials and systematic reviews[19,20]. Tumor shrinkage following NACT allows a greater proportion of patients to undergo breast conservation without compromising survival outcomes. This benefit is particularly relevant in younger patients and those with larger tumors at presentation, for whom cosmetic outcomes and quality of life are important considerations.

Menopausal status did not appear to influence survival outcomes in the present study. This finding is supported by evidence from large clinical trials indicating that the benefit of chemotherapy is largely independent of menopausal status, provided appropriate systemic therapy is administered[21]. Instead, factors such as tumor stage, nodal status, histological grade, and molecular subtype have been shown to play a more decisive role in determining prognosis. The inclusion of both premenopausal and postmenopausal women in the current study strengthens the generalizability of its findings.

The role of pathologic complete response (pCR) as a prognostic marker following neoadjuvant chemotherapy has been widely studied. Several pooled analyses have demonstrated that achievement of pCR is associated with improved DFS and OS at the individual patient level, particularly in triple-negative and HER2-positive breast cancer. However, despite higher pCR rates with neoadjuvant therapy, improvements in pCR have not consistently translated into superior survival when compared with adjuvant chemotherapy in randomized trials[22]. This may explain why survival outcomes remained similar between the two groups in the present study, despite better surgical outcomes in the neoadjuvant arm.

Some contrasting evidence exists regarding local recurrence rates following neoadjuvant chemotherapy. Earlier trials reported a modest increase in local recurrence with NACT, possibly due to less extensive surgery following tumor shrinkage[23]. However, more recent studies incorporating modern imaging, standardized surgical margins, and optimized radiotherapy have shown no significant difference in local control between neoadjuvant and adjuvant approaches[24]. In the present study, recurrence rates were comparable between the two groups, supporting the safety of neoadjuvant chemotherapy in contemporary practice.

The limitations of this study include its relatively small sample size and limited follow-up duration, which may reduce the ability to detect small differences in survival outcomes. Nevertheless, the randomized design, balanced baseline characteristics, and uniform treatment protocols enhance the internal validity of the results. The findings contribute to existing evidence supporting the equivalence of neoadjuvant and adjuvant chemotherapy with respect to survival outcomes in operable breast cancer.

## CONCLUSION

This randomized controlled study demonstrates that neoadjuvant and adjuvant chemotherapy provide comparable overall survival and disease-free survival in operable breast cancer patients, irrespective of menopausal status. Neoadjuvant chemotherapy increases breast-conserving surgery rates without compromising survival outcomes, supporting its safe and effective use in appropriately selected patients.

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