

# Effectiveness Of Multidrug Regimen (Ac) Vs Single Agent (Paclitaxel) Neo Adjuvant Chemotherapy In Labc- A Prospective Study

Pradeep Kumar M<sup>1</sup>, Ramprasath E<sup>2\*</sup>, Manibalan S<sup>3</sup>, Rajesh Kumar<sup>4</sup>, Lalith Kumar D<sup>5</sup>

<sup>1</sup>Postgraduate, Department of General Surgery, Chettinad Hospital and Research Institute, Chettinad Academy of Research and Education, Kelambakkam-603103, Tamil Nadu, India. Email: pradeepkumar.m19@gmail.com

<sup>2</sup>Assistant Professor, Department of General Surgery, Chettinad Hospital and Research Institute, Chettinad Academy of Research and Education, Kelambakkam-603103, Tamil Nadu, India. Email: valaram.941@gmail.com

<sup>3</sup>Assistant Professor, Department of General Surgery, Chettinad Hospital and Research Institute, Chettinad Academy of Research and Education, Kelambakkam-603103, Tamil Nadu, India. Email: manibal27@gmail.com

<sup>4</sup>Senior Resident, Department of Pharmacology, Northern Eastern Indhira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS), Mawdiangdiang, Shillong, Meghalaya-793018. Email: raj07b@gmail.com

<sup>5</sup>Postgraduate, Department of General Surgery, Chettinad Hospital and Research Institute, Chettinad Academy of Research and Education, Kelambakkam-603103, Tamil Nadu, India. Email: dr.lalith2322@gmail.com

Received: 20th Oct, 2025; Revised: 22th Dec, 2025; Accepted: 22th Jan, 2026; Available Online: 17th Feb, 2026

## ABSTRACT

**Background:** Neoadjuvant chemotherapy is an integral component in the management of locally advanced breast cancer, facilitating tumor downstaging and improving surgical outcomes. Anthracycline-based multidrug regimens are commonly used; however, single-agent taxane therapy may be a suitable alternative in selected patients. This study compared the effectiveness and tolerability of an anthracycline-based multidrug regimen versus single-agent Paclitaxel as NACT in LABC.

**Methods:** This prospective comparative study included 20 patients with LABC, divided into two groups: AC regimen (n = 10) and single-agent Paclitaxel (n = 10). Baseline clinicopathological characteristics, treatment response, adverse events (grade  $\geq 2$ ), surgical outcomes, and postoperative axillary nodal status were assessed. Clinical and pathological responses were evaluated following completion of NACT.

**Results:** The overall clinical response rate was 80% in both groups. Pathological complete response was achieved in 30% of patients in the AC group and 20% in the Paclitaxel group. Breast conservation surgery was performed in 60% of patients receiving AC and 50% receiving Paclitaxel. Hematologic toxicities, including neutropenia and anemia, were more frequent in the AC group, whereas non-hematologic toxicities such as peripheral neuropathy and myalgia/arthralgia were significantly higher in the Paclitaxel group.

**Conclusion:** Both AC and single-agent Paclitaxel demonstrated comparable efficacy as neoadjuvant chemotherapy in LABC. While AC showed a slightly higher pathological complete response, Paclitaxel offered similar clinical and surgical outcomes with reduced hematologic toxicity. Treatment selection should be individualized based on patient tolerance and clinical profile.

**Keywords:** Locally advanced breast cancer; Neoadjuvant chemotherapy; Anthracycline-based regimen; Paclitaxel; Pathological complete response

**How to cite this article:** Kumar PM, Ramprasath E, Manibalan S, Kumar R, Kumar DL, Effectiveness Of Multidrug Regimen (Ac) Vs Single Agent (Paclitaxel) Neo Adjuvant Chemotherapy In Labc- A Prospective Study...Int J Drug Deliv Technol. 2026; 16(2): 322-326; DOI: 10.25258/ijddt.16.2.35

**Source of support:** Nil.

**Conflict of interest:** None

## INTRODUCTION

Locally advanced breast cancer (LABC) is a serious clinical issue that has not yet been studied sufficiently because of its high progression rate and the potential spread to other locations. Necessitating to minimise the size of the tumour, to make it resectable by surgery, and to increase survival outcomes in the long term, neoadjuvant chemotherapy (NAC) has become an essential part of the LABC treatment (1,2).

Due to its efficacy in adjuvant and neoadjuvant care, the combination of Adriamycin and Cyclophosphamide (AC) as a multidrug is widely accepted as a typical regimen of chemotherapy. Due to the various researches conducted on

their comparative efficacy and toxicity profile, single agent treatment, such as Paclitaxel, have emerged as potential alternatives (3).

Despite much research, no universally accepted chemotherapy regimen of LABC has been established yet. Sequential administration of taxanes such as paclitaxel and anthracyclines such as AC might also increase the overall outcome and pathological complete response rates according to some clinical studies (4). Factors that should be considered when making a decision include treatment tolerability, side effects, and quality of life used by patients, yet no consistent results have been presented when

Effectiveness Of Multidrug Regimen (Ac) Vs Single Agent (Paclitaxel) Neo Adjuvant Chemotherapy In Labc- A Prospective Study

comparing AC and single-agent Paclitaxel as neoadjuvant therapy (5,6).

This is a prospective study that would directly compare the efficacy of multidrug AC regimen and the single agent Paclitaxel one in the neoadjuvant setting in patients with LABC. The study aims to offer the optimal evidence to inform the best therapeutic selection and enhance prognostic results in this group of patients by assessing clinical response, pathology results, and treatment toxicities. Finally, the results will be useful to add knowledge to improve chemotherapy treatments and to aid individualized approaches to treatment in locally advanced breast cancer.

**Methodology:**

This prospective, observational, comparative study was conducted in the Department of Surgery, Chettinad Hospital and Research Institute, Chennai, over eight months following approval by the Institutional Ethics Committee. Written informed consent was obtained from all participants. Twenty patients with locally advanced breast cancer (LABC) were enrolled. Patients with early-stage disease or distant metastasis were excluded. Baseline assessment included clinical examination, imaging, tumor staging, menopausal status, and estrogen/progesterone receptor (ER/PR) status.

Patients received neoadjuvant chemotherapy and were categorized into two groups (n = 10 each) based on the regimen administered. Group A received doxorubicin (60 mg/m<sup>2</sup>) and cyclophosphamide (600 mg/m<sup>2</sup>) every 21 days for four cycles, while Group B received a paclitaxel-based regimen as per institutional protocol. Clinical response was evaluated using RECIST version 1.1 criteria before and after chemotherapy. Following neoadjuvant treatment, patients underwent definitive surgery (breast conservation surgery or modified radical mastectomy). Pathological response was assessed on surgical specimens, with pathological complete response (pCR) as the primary outcome, and tumor regression graded using the Miller–Payne system. Postoperative axillary lymph node status was documented.

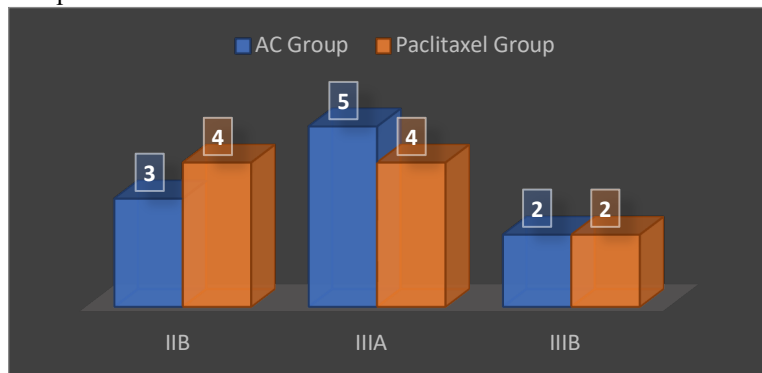
Adverse events were prospectively recorded and graded; toxicities of Grade ≥2 were included. Hematologic and non-hematologic adverse events, treatment delays, dose reductions, and hospitalizations were analyzed. Data were analyzed using IBM SPSS Statistics version 21. Chi-square test or Fisher’s exact test is used as a statistical test to compare two groups. A p-value <0.05 was considered statistically significant.

**RESULTS:**

**Table 1: Clinical characteristics of Patients**

Variables		AC group (n =10)	Paclitaxel Group (n=10)
Age (years)		48.2 ± 9.5	52.4 ± 8.7
Menstrual status	Premenopausal	6	4
	Postmenopausal	4	6
ER/PR Status	Positive	7	7
	Negative	3	3

The mean & SD of age among AC group and Paclitaxel Group are 48.2 ± 9.5 and 52.4 ± 8.7 years respectively. Among the Participants 4 patients in the AC group and 6 patients in the Paclitaxel Group were Postmenopausal women. In both the groups 7 participants showed positive to ER/PR Status.



**Figure 1: Tumor Staging**

The distribution of tumor stages shows a broadly comparable pattern between the AC group and the Paclitaxel group, with stage IIIA emerging as the most common presentation in both cohorts. In the AC group, the highest number of patients were classified as stage IIIA, followed by stage IIB, with the fewest patients in stage IIIB. A similar trend was observed in the Paclitaxel group, where stage IIIA again predominated, while stage IIB and IIIB were less frequently represented. Notably, stage IIB cases were slightly more common in the Paclitaxel group compared to the AC group, whereas stage IIIA cases were marginally higher in the AC group. Stage IIIB distribution was identical in both groups.

**Table 2: Outcome**

Outcome	AC Regimen (n=10)	Paclitaxel (n=10)
Pathological Complete Response (pCR)	3 (30%)	2 (20%)
Partial Response (PR)	5 (50%)	6 (60%)
Stable Disease (SD)	2 (20%)	1 (10%)
Progressive Disease (PD)	0	1 (10%)
Clinical Response (CR+PR)	8 (80%)	8 (80%)

Both treatment groups demonstrated comparable overall clinical response rates, with 80% of patients in each group achieving either complete or partial clinical response. In the AC regimen group, pathological complete response was observed in 3 patients, while 2 patients in the Paclitaxel group achieved pCR. Partial response constituted the most

frequent outcome in both groups, occurring slightly more often in the Paclitaxel group compared to the AC group. Stable disease was more commonly observed in the AC group, whereas 1 patient in the Paclitaxel group experienced progressive disease, which was not seen in the AC group.

**Table 3: Treatment Tolerability and Adverse Events (≥ Grade 2)**

Adverse Event	AC Group (n=10)	Paclitaxel Group (n=10)	p-value
<b>Hematologic</b>			
Neutropenia	6 (60%)	2 (20%)	0.07
Febrile Neutropenia	1 (10%)	0 (0%)	0.50
Anemia	5 (50%)	1 (10%)	0.06
<b>Non-Hematologic</b>			
Alopecia	10 (100%)	9 (90%)	0.50
Nausea/Vomiting	8 (80%)	3 (30%)	0.03*
Peripheral Neuropathy	1 (10%)	6 (60%)	0.03*
Myalgia/Arthralgia	2 (20%)	7 (70%)	0.03*
<b>Treatment Modifications</b>			
Dose Reduction	3 (30%)	2 (20%)	0.50
Cycle Delay (>7 days)	4 (40%)	1 (10%)	0.14
Hospitalization (Related to AE)	2 (20%)	0 (0%)	0.23

Hematologic adverse events were more common in the AC group, with neutropenia observed in 60% patients compared to 20% patients in the Paclitaxel group and anemia in 5 patients versus 1 patient respectively. Febrile neutropenia occurred in 1 patient in the AC group and in none of the patients receiving Paclitaxel.

Non-hematologic toxicities were comparatively higher in the Paclitaxel group. Nausea and vomiting were reported in 8 patients in the AC group and 3 patients in the Paclitaxel group, a difference that was statistically significant (p = 0.03). Peripheral neuropathy was seen in 1 patient in the AC group versus 6 patients in the Paclitaxel group (p = 0.03),

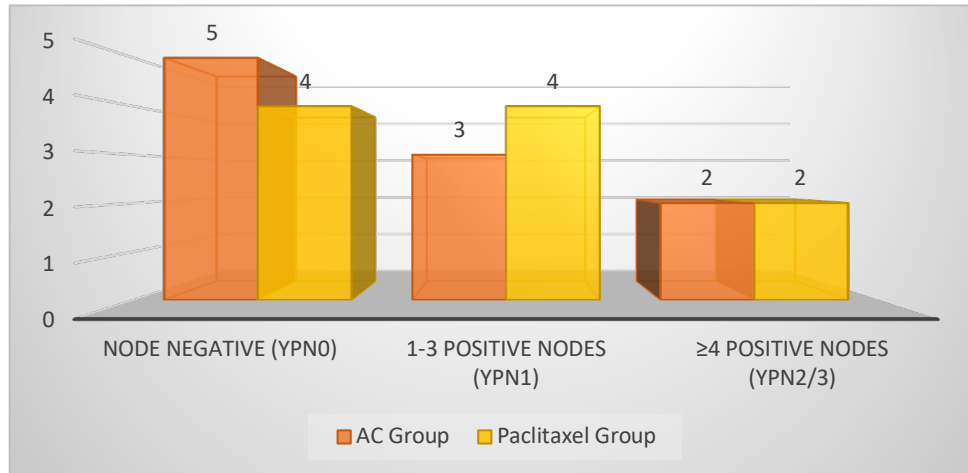
while myalgia/arthralgia occurred in 20% patients receiving AC and 70% patients receiving Paclitaxel (p = 0.03). Alopecia was frequent in both groups, affecting all patients in the AC group and 90% patients in the Paclitaxel group. Regarding treatment modifications, dose reduction was required in 3 patients in the AC group and 2 patients in the Paclitaxel group. Cycle delay of more than 7 days was noted in 4 patients receiving AC compared to 1 patient in the Paclitaxel group (p = 0.14). Hospitalization related to adverse events occurred in 2 patients in the AC group, while no such events in the Paclitaxel group (p = 0.23).

**Table 4: Surgical Outcomes Post-NACT**

Variable	AC Group (n=10)	Paclitaxel Group (n=10)	p-value
<b>Type of Surgery Performed</b>			
- Breast Conservation Surgery (BCS)	6 (60%)	5 (50%)	0.50
- Modified Radical Mastectomy (MRM)	4 (40%)	5 (50%)	0.50

Following neoadjuvant chemotherapy, breast conservation surgery was performed in 6 patients (60%) in the AC group and in 5 patients (50%) in the Paclitaxel group, with no statistically significant difference between the two regimens

(p = 0.50). Modified radical mastectomy was required in 4 patients (40%) receiving the AC regimen and 5 patients (50%) treated with Paclitaxel, again showing comparable distribution across groups (p = 0.50).



**Figure 2: Axillary Lymph Node Status (Post-op)**

Overall, node-negative status was slightly more frequent in the AC group, whereas limited nodal involvement (ypN1) was marginally higher in the Paclitaxel group. Advanced nodal disease (ypN2/3) occurred at an equal frequency in both groups. These findings indicate similar postoperative axillary nodal outcomes following neoadjuvant chemotherapy in the two treatment groups.

## DISCUSSION

This prospective study compared a standard anthracycline-based multidrug regimen (AC) with single-agent Paclitaxel as neoadjuvant chemotherapy in patients with locally advanced breast cancer (LABC). The findings indicate that both treatment approaches achieved similar levels of tumor response and comparable surgical outcomes, while differing mainly in their toxicity profiles.

In our study the predominance of ER/PR-positive tumors in both study showed 70% and similar study by Onitilo AA et al showed ER/PR+, Her2- is 68.9% which is closer to our study findings (7). In terms of efficacy, the overall clinical response rate was identical in both groups, with 80% of patients achieving either complete or partial response. Although the pathological complete response rate was numerically higher in the AC group (30%) compared to the Paclitaxel group (20%), the difference was modest. Anthracycline-based combination chemotherapy has historically been associated with pCR rates of approximately 20–30% in LABC, as demonstrated in the studies by Fisher B et al and Bear HD et al (8,9).

A study by Dodiya HG et al demonstrated the patients underwent TAC chemotherapy had pCR 20.8% whereas FAC/FEC chemotherapy patients had pCR 13% which is different from our study results and its mainly due to the usage of different drugs (10). Green MC et al reported that Patients receiving weekly paclitaxel had a higher pCR rate (28.2%) whereas in our study patients with paclitaxel had pCR of 20% (11).

Hematologic adverse events, including neutropenia and anemia, were more frequent in patients receiving AC, reflecting the well-known myelosuppressive effects of anthracycline-based chemotherapy (7,12). Non-hematologic toxicities were more pronounced in the

Paclitaxel group, with significantly higher instances of peripheral neuropathy and myalgia or arthralgia, aligning with the known toxicity profile of taxanes. In contrast, nausea and vomiting were more frequent in the AC group, reflecting the increased emetogenic potential of anthracycline-containing treatments, despite the use of standard antiemetic measures. Although there were more treatment interruptions and hospitalizations in the AC arm, these differences were not statistically significant, consistent with previous comparative studies. Our study results are consistent with previous studies (13,14).

Both regimens equally facilitated surgical downstaging, with significant breast conservation surgery achieved in both groups. No significant differences were observed between AC and Paclitaxel, aligning with large neoadjuvant trial evidence indicating that effective chemotherapy enhances breast-conserving procedure feasibility without sacrificing oncological safety. Postoperative axillary nodal status was also comparable, indicating similar regional disease control (9,15).

Overall, the study indicates that AC-based multidrug chemotherapy has a slightly higher pathological complete response rate compared to single-agent Paclitaxel, which offers similar clinical response and surgical outcomes with less hematologic toxicity. Paclitaxel monotherapy is recommended for selected patients, especially older individuals or those with comorbidities, though the risk of neuropathy should be considered. Our study's small sample size highlights the need for larger randomized trials to validate these results and identify the best patient population for each treatment regimen.

## CONCLUSION:

In our study, both anthracycline-based multidrug AC regimen and single-agent Paclitaxel were found to be comparably effective as neoadjuvant chemotherapy for locally advanced breast cancer. They showed similar overall clinical response rates, tumor downstaging, feasibility of breast-conserving surgery, and postoperative axillary outcomes. While the AC regimen had a higher pathological complete response rate, it also resulted in more hematologic toxicity. Conversely, single-agent Paclitaxel provided equivalent clinical outcomes with a better hematologic safety profile, though it had a higher occurrence of non-

hematologic side effects such as peripheral neuropathy. This supports the use of Paclitaxel in selected patients, particularly those with lower tolerance for combination chemotherapy. Further research with larger trials is needed to confirm these findings and improve patient selection for optimal treatment

#### REFERENCE

1. Moon YW, et al. Neoadjuvant chemotherapy with infusional 5-fluorouracil, adriamycin and cyclophosphamide in locally advanced breast cancer. *Breast Cancer Res Treat.* 2005;92(1):89-97.
2. Papademetriou K, et al. Neoadjuvant therapy for locally advanced breast cancer. *Cancer Treat Rev.* 2010;36(8):645-53.
3. Kayal S, et al. Comparison of neoadjuvant chemotherapy (NACT) with AC+D in LABC. *J Clin Oncol.* 2015;33(Suppl):1122.
4. eviQ Cancer Treatments Online. Breast neoadjuvant/adjuvant AC followed by paclitaxel. 2024.
5. Gupta S, et al. Single agent weekly paclitaxel as neoadjuvant chemotherapy in LABC: feasibility and toxicity. *Radiother Oncol.* 2012;102(1):e65-e69.
6. O'Shaughnessy JA. Current status of paclitaxel in the treatment of breast cancer. *Semin Oncol.* 1995;22(3 Suppl 6):1-7.
7. Onitilo AA, Engel JM, Greenlee RT, Mukesh BN. Breast cancer subtypes based on ER/PR and Her2 expression: comparison of clinicopathologic features and survival. *Clin Med Res.* 2009;7(1-2):4-13.
8. Fisher B, Brown A, Mamounas E, et al. Effect of preoperative chemotherapy on local-regional disease in women with operable breast cancer: findings from NSABP B-18. *J Clin Oncol.* 1997;15(7):2483-2493.
9. Bear HD, Anderson S, Smith RE, et al. Sequential preoperative or postoperative docetaxel added to preoperative doxorubicin plus cyclophosphamide for operable breast cancer: NSABP B-27. *J Clin Oncol.* 2006;24(13):2019-2027.
10. Dodiya HG, Brahmabhatt AP, Khatri PK, Kaushal AM, Vijay DG. Neoadjuvant chemotherapy in patients with locally advanced breast cancer: a pilot-observational study. *Journal of cancer research and therapeutics.* 2015 Jul 1;11(3):612-6.
11. Green MC, Buzdar AU, Smith T, et al. Weekly paclitaxel improves pathologic complete remission in operable breast cancer when compared with paclitaxel once every 3 weeks. *J Clin Oncol.* 2005;23(25):5983-5992.
12. Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Comparisons between different polychemotherapy regimens for early breast cancer: meta-analyses of long-term outcome. *Lancet.* 2012;379(9814):432-444.
13. Jones SE, Savin MA, Holmes FA, et al. Phase III trial comparing doxorubicin plus cyclophosphamide with docetaxel in the adjuvant treatment of breast cancer. *J Clin Oncol.* 2006;24(34):5381-5387.
14. Park SB, Goldstein D, Krishnan AV, et al. Chemotherapy-induced peripheral neurotoxicity: a critical analysis. *CA Cancer J Clin.* 2013;63(6):419-437.
15. Smith IC, Heys SD, Hutcheon AW, et al. Neoadjuvant chemotherapy in breast cancer: significantly enhanced response with docetaxel. *J Clin Oncol.* 2002;20(6):1456-1466