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Real-World Outcomes of Palbociclib Plus Anastrozole in Postmenopausal HR+ HER2- Recurrent, Unresectable or Metastatic Breast Cancer: A Retrospective Study from Central India

Dr. Diksha Mathu[1], Dr. Praghnya Tejale[2], Dr. Ashok Kumar Diwan[3], Dr. Vijay Kumar Mahobia[4], Dr. Pooja Gangharia[5]

[1]Junior Resident, Department of Radiation Oncology, Government Medical College and Hospital, Nagpur
Email: *dmathu87[at]gmail.com*

[2]Assistant Professor, Department of Radiation Oncology, Government Medical College and Hospital, Nagpur
Email: *drpraghnyatejale[at]gmail.com*

[3]Professor and Head, Department of Radiation Oncology, Government Medical College and Hospital, Nagpur
Email: *tinuad76[at]gmail.com*

[4]Associate Professor, Department of Radiation Oncology, Government Medical College and Hospital, Nagpur
Corresponding Author Email: *drvijay_mahobia[at]yahoo.com*

[5]Junior Resident, Department of Radiation Oncology, Government Medical College and Hospital, Nagpur
Corresponding Author Email: *ganghariapooja123[at]gmail.com*

Abstract: ***Background: According to GLOBOCAN 2022, breast cancer accounts for 13.6% of all cancer cases in India, leading to a mortality rate of 10.7%. Current treatment guidelines recommend combining Cyclin-Dependent Kinase 4/6 (CDK4/6) inhibitors with endocrine therapy for patients with HR+/HER2− MBC, based on evidence from multiple phase III trials. Palbociclib, the first approved CDK4/6 inhibitor, has shown improved outcomes when combined with aromatase inhibitors in postmenopausal women with advanced disease, as demonstrated in the PALOMA-1 and PALOMA-2 trials. Objective: This study aims to observe the effect of treating post-menopausal HR+ Her2- recurrent, unresectable or metastatic breast cancer with a combination of Palbociclib plus Anastrozole by assessing progression-free survival (PFS) rates, adverse events and objective response. Methods: This was a retrospective observational study conducted at a tertiary care center in Central India. Sixty postmenopausal women with HR+ HER2- recurrent, unresectable, or metastatic breast cancer received either Anastrozole alone or a combination of Palbociclib and Anastrozole. Treatment was continued until disease progression or the development of unacceptable adverse events. Results: This retrospective observational study evaluates the combination of Palbociclib and Anastrozole in postmenopausal women with HR-positive, HER2-negative recurrent, unresectable, or metastatic breast cancer at a tertiary care center in Central India. Sixty patients were divided equally into two treatment groups: Anastrozole alone and Anastrozole plus Palbociclib. The combination therapy group demonstrated a longer progression-free survival (median not reached at 24 months) compared to the Anastrozole-only group (9 months, 95% CI: 7–11 months). While the combination treatment was associated with higher rates of adverse events, particularly neutropenia and anemia, no therapy discontinuations occurred due to toxicity. The study suggests that Palbociclib plus Anastrozole offers improved disease control with manageable side effects in real-world clinical practice. Conclusion: Palbociclib plus Anastrozole exhibited favourable effectiveness and manageable toxicities with better median PFS.***

Keywords: Palbociclib, Anastrozole, metastatic breast cancer, hormone receptor-positive, real-world study

1. Introduction

Breast cancer accounts for nearly one-third of all cancer cases among women. (1) As per the GLOBOCAN data 2022, in India, Breast Cancer accounted for 13.6% (192020) of all cancer cases and 10.7% (98337) of all deaths with a cumulative risk of new cases being 2.90. Approximately 6% of cases are diagnosed at the metastatic stage (MBC), meaning the disease has already spread to distant tissues. The 5-year survival rate for de novo MBC is only 29.0%. (2)

Estrogen receptor-positive breast cancer accounts for approximately 70–80% of all diagnosed breast cancers. The vast majority of these cancers depend on estrogen receptor activation or estrogen synthesis, or both, for tumour growth and progression. Endocrine therapy, a therapeutic mainstay for estrogen receptor-positive breast cancer, targets estrogen receptor activation, estrogen synthesis, or both. Standard-of-care endocrine therapies for post-menopausal patients include selective estrogen receptor modulators (eg, Tamoxifen), aromatase inhibitors (eg, Letrozole, Anastrozole, and Exemestane), and the first generation selective estrogen receptor antagonist and degrader (SERD) Fulvestrant. (3)

However, many patients have treatment resistance, even in the curative setting, and approximately 30% of patients with high-risk disease who receive adjuvant endocrine therapy will relapse with metastatic disease. In addition, some patients receiving endocrine therapies have persistent adverse events that negatively affect quality of life and often lead to early discontinuation of treatment. (3)

Also, patients from the low-middle income category (LMIC) face financial constraints. Indeed, only around 60% of patients complete 5 years of adjuvant endocrine therapy. Therefore, more effective and better-tolerated therapies are needed to improve adherence and further improve outcomes for patients with estrogen receptor-positive breast cancer. (3)

Hence, this study aims to shed light on PFS, efficacy, and cost-effectiveness of the drug for patients undergoing treatment at our tertiary care centre.

The cyclin-dependent kinases (CDKs) are a large family of serine–threonine kinases that play an important role in regulating cell-cycle progression. (4) Palbociclib (Ibrance, Pfizer) is a small-molecule inhibitor of CDK4 and CDK6.4 Preclinical studies of Palbociclib have shown its ability to preferentially inhibit the growth of estrogen receptor (ER) – positive breast cancer cells, act synergistically with anti-estrogens, and reverse endocrine resistance. (5)

Multiple trials have shown that cyclin-dependent kinases 4/6 (CDK4/6) inhibitors in combination with ET significantly improve progression-free survival (PFS) and overall survival (OS) compared with ET alone, with manageable safety profiles and maintained quality of life (QoL) under therapy. (6) With this rationale, the study aims to evaluate the outcomes of treating postmenopausal HR-positive, HER2-negative recurrent, unresectable, or metastatic breast cancer with a combination of Palbociclib and Anastrozole at our centre.

This study is particularly significant because it provides real-world evidence from a tertiary care setting in Central India, addressing the gap in data for treatment outcomes in resource-constrained healthcare environments.

Purpose: This study aims to evaluate the progression-free survival, treatment response, and adverse events associated with Palbociclib plus Anastrozole compared to Anastrozole alone in postmenopausal women with HR+ HER2- recurrent, unresectable, or metastatic breast cancer in a real-world clinical setting.

Aims and Objectives

1) Primary Objective
- To assess progression-free survival (PFS) in postmenopausal patients with HR-positive, HER2-negative recurrent, unresectable, or metastatic breast cancer.

2) Secondary Objectives
- To assess the objective response rate (ORR) based on RECIST 1.1 criteria.
- To assess adverse events according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

2. Material and methods

Study Design

This is a **retrospective observational study** conducted at Department of Radiation Oncology at a tertiary care center in Central India.

Study Population and Sample Size

The study population comprises postmenopausal women with biopsy-confirmed hormone receptor-positive (HR+), HER2-negative breast cancer that is recurrent, unresectable, or metastatic. All eligible patients who received treatment at the tertiary care centre between January 2023 and January 2025 were included. The study included 30 patients in the Anastrozole monotherapy group and 30 patients in the Palbociclib plus Anastrozole combination therapy group.

Inclusion Criteria for Study:

1) Postmenopausal women
2) Histologically confirmed Infiltrating Ductal Carcinoma
3) Hormone receptor-positive (HR+), HER2-negative status
4) Recurrent disease
5) Unresectable disease
6) Metastatic disease
7) ECOG Performance Status 0, 1, 2, or 3
8) Willingness to provide written informed consent

Exclusion Criteria for Study:

1) Presence of visceral crisis
2) ECOG Performance Status of 4
3) History of any other malignancy (double malignancy)

Ethical considerations

- Approval was taken from the Institutional Ethics Committee (IEC). (No.: 3699).
- Title and synopsis approved from Board of Research Studies (BORS), MUHS, Nashik.
- Informed written consent in subject's vernacular language was taken after apprising them of the nature and purpose of study.

Data Collection Parameters

a) Baseline Demographic and Clinical Data

The following variables were recorded:
- Age
- ECOG Performance Status (PS)
- Stage at initial diagnosis
- Type of recurrence: Local / Regional / Distant metastasis
- Site (s) of metastasis: Bone / Lung / Liver / Brain
- Prior chemotherapy: Adjuvant / Neoadjuvant

b) Adverse Events Assessment

Treatment-related adverse events will be assessed and graded according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. The following adverse effects will be evaluated:
- Fatigue
- Anemia
- Febrile neutropenia
- Thrombocytopenia
- Nausea
- Vomiting
- Arthralgia
- Alopecia
- Backache
- Diarrhea
- Headache
- Stomatitis
- Reduced appetite

- Upper respiratory tract infection (URTI)
- Hot flushes
- Dry skin
- Dysgeusia
- Urinary tract infection (UTI)

Intervention given
Patients were categorized into two treatment groups:

Group A:
Tablet Anastrozole 1 mg orally once daily (OD), continuous dosing

Group B (Control Group):
- **Tablet Anastrozole** 1 mg orally once daily (OD), continuous dosing
- **Tablet Palbociclib** 125 mg administered orally once daily (OD) for 21 consecutive days, followed by 7 days break, completing a 28 day cycle (i. e., Days 1–21 of a 28-day cycle)

Statistical Analysis-Data analysis was done using Microsoft Excel 2019. Statistical test performed was Kaplan-Meier.

A p-value of less than 0.05 was considered statistically significant.

Primary Endpoint Analysis

a) Progression-Free Survival (PFS):
PFS was analysed using the **Kaplan-Meier survival method**.

b) Secondary Endpoint Analysis
- Objective Response Rate (ORR): Evaluated using RECIST 1.1 criteria.
- Baseline demographic, clinical characteristics and adverse events:
- **Continuous variables:** Summarized as mean with standard deviation.
- **Categorical variables:** Summarized in terms of proportion, frequency and percentage

3. Results

Table 1: Distribution of study subjects according to Age

Age	Number of Subjects	Percentage
40-49	18	30%
50-59	20	33.30%
60-69	9	15%
70-79	12	20%
80-89	1	1.70%
TOTAL	60	100%

Table 01: The above table shows distribution of study subjects according to their age. In the present study, a total of 60 subjects were included. Majority of the study participants, 20 (33.3%), belonged to the age group of 50–59 years, followed by 18 (30.0%) participants in the 40–49 years age group. Subjects in the age group of 70–79 years constituted 12 (20.0%), while 9 (15.0%) were in the 60–69 years age group. Only 1 (1.7%) participant belonged to the age group of 80–89 years. This distribution indicates that the majority of the study participants were in the middle age groups of 40–59 years.

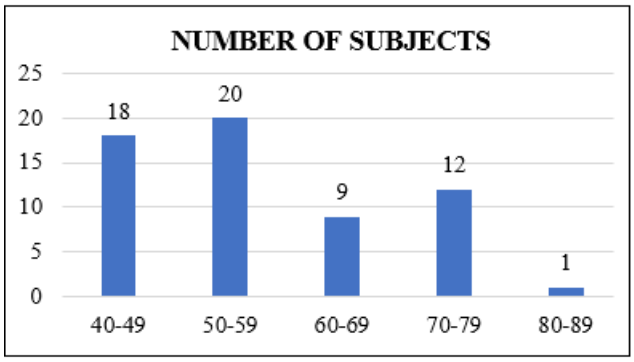


Table 2: Distribution of study subjects according to ECOG

ECOG	Number of Subjects	Percentage
Grade 0	1	1.70%
Grade 1	44	73.30%
Grade 2	10	16.70%
Grade 3	5	8.30%
TOTAL	60	100%

Table 02 shows distribution of study subjects according to their ECOG performance status. Majority of the study participants, 44 (73.3%), had an ECOG grade of 1, indicating they were restricted in physically strenuous activity but ambulatory and able to carry out light work. Grade 2 was observed in 10 (16.7%) subjects, suggesting they were ambulatory and capable of all self-care but unable to carry out any work activities. Grade 3 was noted in 5 (8.3%) participants, who were capable of only limited self-care and confined to bed or chair more than 50% of waking hours. Only 1 (1.7%) subject had a Grade 0 performance status, indicating full activity without restriction.

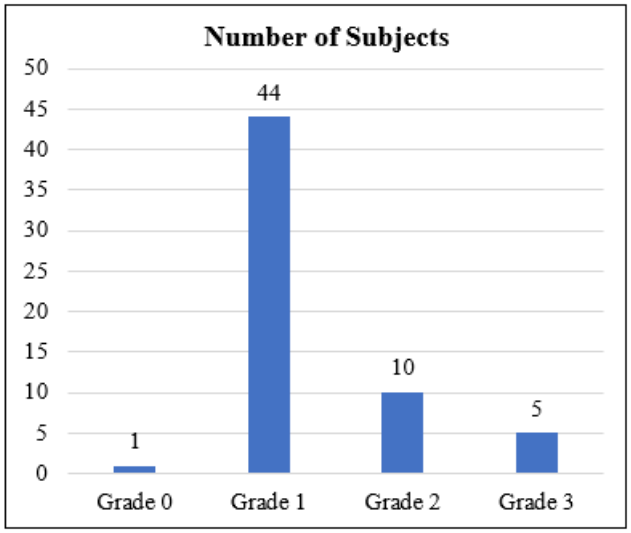


Table 3: Distribution of study subjects according to Stage of disease

Stage of Disease	Number of Subjects	Percentage
CLINICAL CLASSIFICATION		
cT2N1M1	1	1.60%
cT3N1M1	3	5%
cT3N2M1	1	1.60%
cT4aN1M1	1	1.60%
cT4aN2aM0	1	1.60%

cT4aN2aM1	2	3.30%
cT4bN0M1	2	3.30%
cT4bN1M0	2	3.30%
cT4bN1M1	2	3.30%
cT4bN2aM1	1	1.60%
cT4bN3cM0	1	1.60%
cT4bN3cM1	3	5%
cT4cN0M1	1	1.60%
cT4cN1M0	1	1.60%
cT4cN1M1	1	1.60%
cT4cN2aM0	2	3.30%
cT4cN2M1	1	1.60%
cT4cN2aM1	1	1.60%
PATHOLOGICAL CLASSIFICATION		
PT0N2aMx	1	1.60%
PT1NxMx	1	1.60%
PT1N0Mx	1	1.60%
PT1N2aMx	1	1.60%
PT2N0Mx	6	10%
PT2N0M0	3	5%
PT2N1aM0	1	1.60%
PT2N1Mx	3	5%
PT2N1M0	5	8.30%
PT2N2Mx	1	1.60%
PT2N2M0	2	3.30%
pT2N2aMx	1	1.60%
PT2N2aM0	1	1.60%
PT2N3aMx	1	1.60%
pT3N1Mx	1	1.60%
PT3N2aMx	1	1.60%
PT3N2aM1	1	1.60%
PT3N3Mx	1	1.60%
PT4N3aMx	1	1.60%
TOTAL	60	100%

Table 03 shows distribution of study subjects according to the stage of disease, based on clinical and pathological classification. In the present study, the most frequently observed clinical stage was cT3N1M1 and cT4bN3cM1, with 3 (5%) subjects each. This was followed by stages such as cT4aN2aM1, cT4bN0M1, cT4bN1M0, cT4cN2aM0, each comprising 2 (3.3%) subjects. Other clinical stages like cT2N1M1, cT3N2M1, cT4aN1M1, cT4aN2aM0, cT4bN2aM1, cT4bN3cM0, cT4cN0M1, cT4cN1M0, cT4cN1M1, and cT4cN2M1 were seen in 1 (1.6%) subject each. The most common pathological stage was PT2N0Mx, seen in 6 (10%) subjects. This was followed by PT2N1M0, reported in 5 (8.3%) subjects. Other frequently observed pathological stages included PT2N0M0 and PT2N1Mx, with 3 (5%) subjects each. Less frequently observed stages were PT2N2M0 and PT2N2aM0, each in 2 (3.3%) subjects, and various other individual stages such as PT0N2aMx, PT1NxMx, PT1N0Mx, PT1N2aMx, PT2N1aM0, PT2N2Mx, pT2N2aMx, PT2N3aMx, pT3N1Mx, PT3N2aMx, PT3N2aM1, PT3N3Mx, and PT4N3aMx, each reported in 1 (1.6%) subject.

Table 4: Distribution of study subjects according to Recurrence or Upfront Metastasis

Recurrence or Upfront Metastasis	Number of Subjects	Percentage
Recurrence	22	36.70%
Recurrence with metastasis	11	18.30%
Upfront metastasis	20	33.30%
Unresectable	7	11.70%
TOTAL	60	100%

Table 04 shows the distribution of study subjects according to recurrence or upfront metastasis. In this study, 22 (36.7%) had recurrence, and 11 (18.3%) had recurrence with metastasis. Upfront metastasis was observed in 20 (33.3%) subjects, while 7 (11.7%) were found to have unresectable disease.

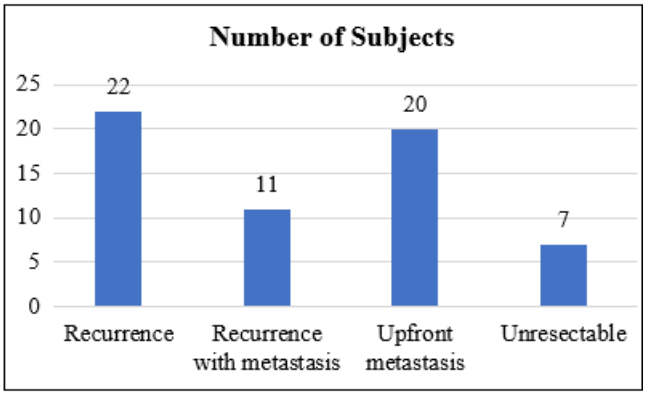


Figure 1: Distribution of study subjects according to site of metastasis

Figure 01 shows the distribution of study subjects according to the site of metastasis.28 (46.6%) study subjects had no metastasis. Among those with metastasis, the most common site was the bone, seen in 18 (30%) subjects, followed by the lungs in 13 (21.6%), liver in 8 (13.3%), and brain in 3 (5%). This indicates that the bone was the most frequently involved metastatic site in the study population.

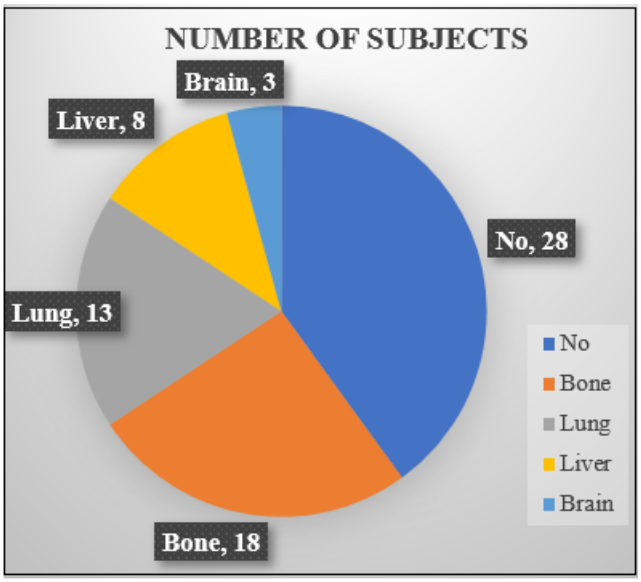


Table 5: Distribution of study subjects according to prior chemotherapy

Table 05 shows the distribution of study subjects according to the type of treatment received.44 (73.3%) of the study subjects received adjuvant therapy, while 16 (26.6%) received neoadjuvant therapy.

Table 06: Distribution of study subjects according to Treatment group

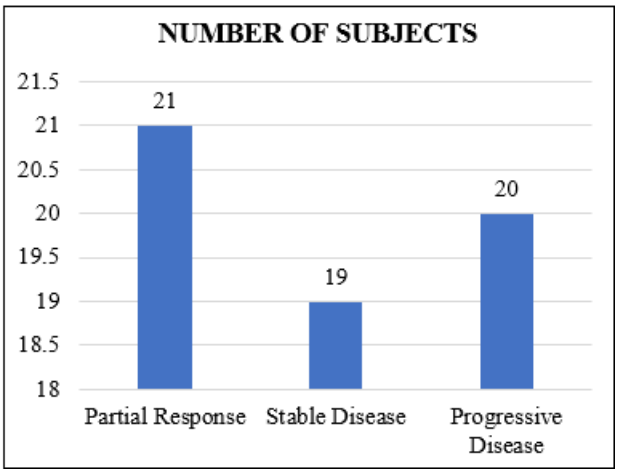
Treatment Group	Number of Subjects	Percentage
Anastrozole	30	50%
Anastrozole plus Palbociclib	30	50%
Total	60	100%

Table 06 shows the distribution of study subjects according to the treatment group. Out of 60 subjects, 30 (50%) received Anastrozole alone, while the remaining 30 (50%) were treated with a combination of Anastrozole and Palbociclib.

Table 7: Distribution of study subjects according to RECIST criteria 1.1

RECIST Criteria 1.1	Number of Subjects	Percentage
Partial Response	21	35%
Stable Disease	19	31.70%
Progressive Disease	20	33.30%
Total	60	100%

Table 07 shows the distribution of study subjects according to treatment response as per RECIST criteria 1.1.21 (35%) study subjects showed a partial response, 19 (31.7%) study subjects had stable disease and 20 (33.3%) study subjects experienced progressive disease.



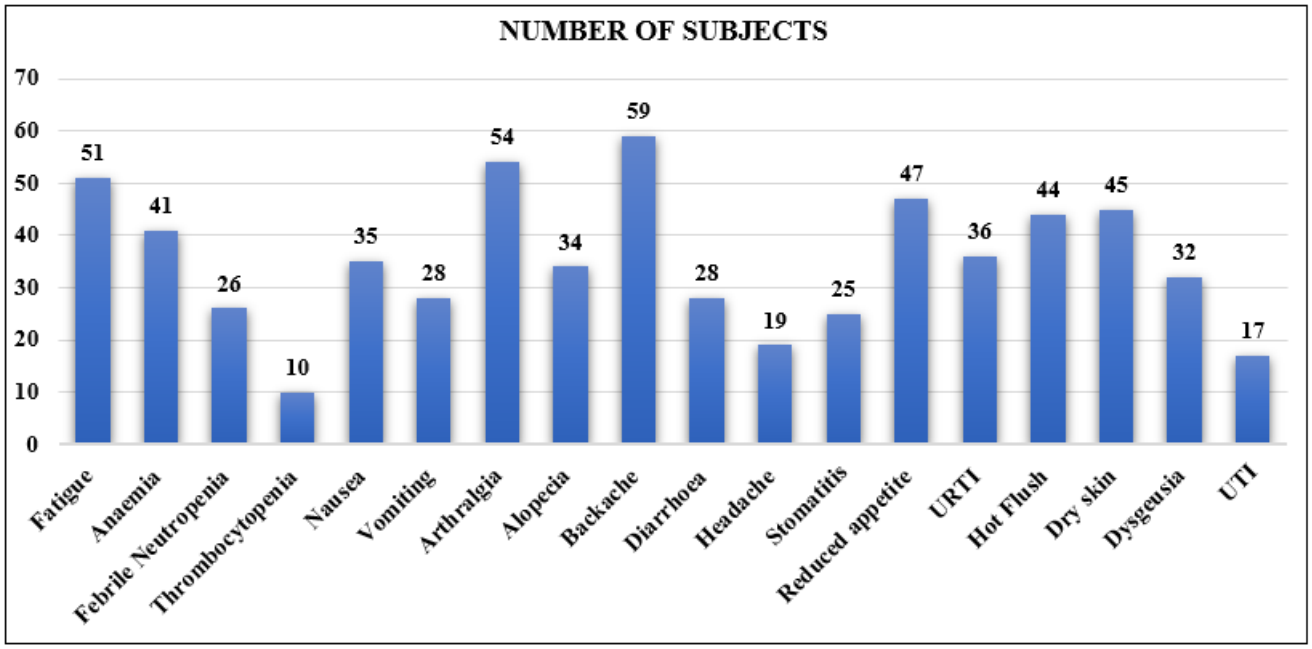


Figure 2: Distribution of study subjects according to Adverse Events

Figure 02 shows the distribution of study subjects according to the adverse effects experienced during treatment. The most commonly reported side effect was backache, observed in 59 (98.3%) subjects, followed by arthralgia in 54 (90%) and fatigue in 51 (85%). Other frequently reported adverse effects included dry skin in 45 (75%), hot flush in 44 (73.3%), anaemia in 41 (68.3%), and upper respiratory tract infections (URTI) in 36 (60%). Nausea was seen in 35 (58.3%), alopecia and backache each in 34 (56.7%), and dysgeusia (altered taste) in 32 (53.3%) subjects. Vomiting and diarrhoea were experienced by 28 (46.7%) subjects each. Febrile neutropenia was noted in 26 (43.3%), reduced appetite in 25 (41.7%), stomatitis and headache in 19 (31.7%) each, and urinary tract infection (UTI) in 17 (28.3%). The least reported adverse effect was thrombocytopenia, seen in 10 (16.7%) subjects.

Table 8: Distribution of study subjects according to Grades of adverse events

Adverse Events	Anastrozole (n = 30)			Anastrozole + Palbociclib (n = 30)		
	Any grade	Grade 3	Grade 4	Any grade	Grade 3	Grade 4
Fatigue	22 (73.3)	0	0	29 (96.6)	0	0
Anaemia	15 (46.6)	0	0	26 (86.6)	10 (33.3)	0
Febrile Neutropenia	0	0	0	26 (86.6)	25 (83.3)	1 (3.33)
Thrombocytopenia	2 (6.66)	0	0	8 (26.6)	0	0
Nausea	9 (30)	0	0	26 (86.6)	0	0
Vomiting	2 (6.66)	0	0	24 (80)	0	0
Arthralgia	24 (80)	0	0	30 (100)	0	0

Alopecia	4 (13.3)	0	0	30 (100)	0	0
Backache	29 (96.6)	0	0	30 (100)	0	0
Diarrhoea	2 (6.66)	0	0	26 (86.6)	0	0
Headache	16 (53.3)	0	0	3 (10)	0	0
Stomatitis	10 (33.3)	0	0	14 (46.4)	0	0
Reduced appetite	18 (60)	0	0	28 (93.3)	0	0
URTI	8 (26.6)	0	0	27 (90)	15 (50)	0
Hot Flush	19 (63.3)	0	0	24 (80)	0	0
Dry Skin	21 (70)	0	0	23 (76.6)	0	0
Dysgeusia	15 (50)	0	0	16 (53.3)	0	0
UTI	9 (30)	0	0	8 (26.6)	0	0

Table 08 shows the distribution of adverse events observed among study subjects receiving Anastrozole alone and those receiving Anastrozole combined with Palbociclib. In the present study, 30 subjects were enrolled in each treatment group. Among the Anastrozole group, the most common adverse events of any grade were backache (29, 96.6%), arthralgia (24, 80%), and fatigue (22, 73.3%). In comparison, the Anastrozole plus Palbociclib group experienced a higher incidence of adverse events, with 30 (100%) subjects reporting arthralgia, alopecia, and backache, and 29 (96.6%) reporting fatigue. Notably, severe (Grade 3) adverse events such as anaemia (10, 33.3%) and febrile neutropenia (25, 83.3%) were predominantly observed in the combination therapy group, while no Grade 3 or Grade 4 events were reported in the Anastrozole alone group. Febrile neutropenia of Grade 4 severity occurred in 1 (3.33%) subject receiving combination therapy.

Table 9: Association between treatment group and RECIST Criteria

Treatment Group	Stable disease	Progressive disease	Partial Response	P – value
Anastrozole	12 (40)	17 (56.7)	1 (3.3)	< 0.00001
Anastrozole plus Palbociclib	8 (26.7)	3 (10)	19 (63.3)	
TOTAL	20	20	20	

Table 09 shows the distribution of treatment responses among study subjects receiving Anastrozole alone and those receiving Anastrozole combined with Palbociclib. In the present study, 30 subjects were enrolled in each treatment group. Among the Anastrozole group, the most common response was progressive disease (17, 56.7%), followed by stable disease (12, 40%) and partial response (1, 3.3%). In comparison, the Anastrozole plus Palbociclib group showed a markedly better response profile, with partial response observed in 19 (63.3%) subjects, stable disease in 8 (26.7%), and progressive disease in only 3 (10%). A statistically significant difference ($P < 0.00001$) was observed between the two treatment groups, indicating that the combination therapy achieved superior clinical responses compared to Anastrozole alone.

Kaplan-Meier survival curve

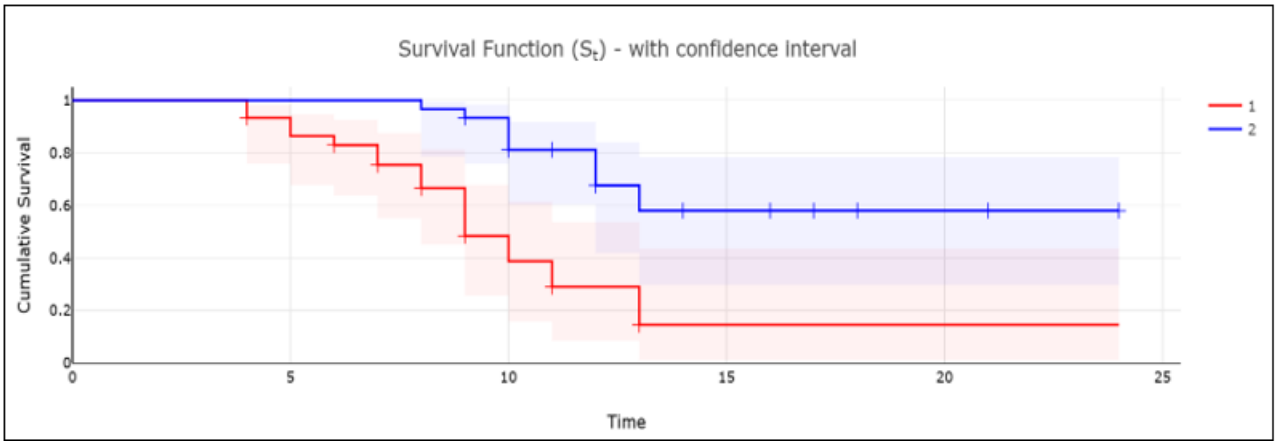


Figure 03 shows that the blue curve, representing group Anastrozole combined with Palbociclib never dropped to 0.5 (50%) on the Y-axis throughout the observed follow-up period. This indicates that half of the patients remained progression-free at the last follow-up (24 months). In contrast, the red curve representing Group 1 (Anastrozole alone) indicates a median progression-free survival of 9 months, with a 95% confidence interval of 7 to 11 months.

4. Discussion

In this study, majority of the study subjects 33.3% belonged to the age group of 50–59 years, followed by 30.0% participants in the 40–49 years age group. Study done by **Rugo et al. [5] (2022)** showed that 35.4% of the study subjects belonged to the age group of 50 to 64 years.

In our study, 73.3% of the study participants had an ECOG grade of 1 and 16.7% of the study participants had an ECOG

grade of 2 and it is similar to study done by **Yang et al. [7] (2023)** where 61.6% of the study participants had an ECOG grade of 1 but in contrast to study done by **Finn et al. [4] (2016)** where 46.4% of the study participants had an ECOG grade of 1.

The present study shows that 36.7% of the subjects presented with recurrence and 33.3% had upfront metastasis and it is similar to study done by **Finn et al. [4] (2016)** where 31.6% of the subjects presented with recurrence and 37.1% had metastasis. Our study shows that in 30% of the study participants most common site of metastasis was bone followed by 21.6% in lungs. This was in contrast to the study done by **Yang et al. [7] (2023)** where 37% of the study participants had lung involvement and 34.1% had liver involvement.

In our study, 73.3% of the study subjects received adjuvant therapy, while 26.6% received neoadjuvant therapy. Study done by **Finn et al. [4] (2016)** showed that 40.3% of the study subjects received adjuvant therapy while 13.3% received neoadjuvant therapy.

Based on RECIST 1.1 criteria, 35% of patients had a partial response, while 31.7% maintained stable disease, and 33.3% experienced progression. This indicates that a significant proportion of patients 66.7% achieved clinical benefit either through disease regression or stabilisation. These findings are consistent with those reported in the PALOMA-2 trial by **Finn et al. [4] (2016),** where clinical benefit rate was 77.5%.

The present study showed that among the Anastrozole group, the most common adverse events of any grade were backache in 96.6%, arthralgia in 80% and fatigue in 73.3%. In comparison, the Anastrozole plus Palbociclib group experienced a higher incidence of adverse events, with 100% subjects reporting arthralgia, alopecia, and backache, and 96.6% reporting fatigue. Study done by **Hurvitz et al. [3] (2023)** showed that in the Anastrozole plus Palbociclib group, the most common adverse event was neutropenia, occurring in 40% of patients. Asthenia was reported in 25%, followed by decreased neutrophil count in 22%, and arthralgia in 19% study subjects. Our study showed that severe (Grade 3) adverse events such as anaemia in 33.3% and febrile neutropenia in 83.3% were predominantly observed in the combination therapy group, while no Grade 3 or Grade 4 events were reported in the Anastrozole alone group. This is similar to study done by **Finn et al. [4] (2016)** where 39.2% of patients reported events of grade 3 or higher in Palbociclib–Letrozole group with neutropenia occurring in 66.4% of the study subjects and leucoplakia occurring in 28.4% of the study subjects. In our study, half of the patients in Anastrozole plus Palbociclib group remained progression-free at the last follow-up and Anastrozole group had a median progression-free survival of 9 months, with a 95% confidence interval of 7 to 11 months. Study done by **Finn et al. [4] (2016)** showed that the median progression free survival was 24.8 months (95% CI, 22.1 to not estimable) in the Palbociclib–Letrozole group and 14.5 months (95% CI, 12.9 to 17.1) in the Placebo–Letrozole group. Our findings align with those from the **PALOMA-2 trial**, where Palbociclib plus endocrine therapy improved progression-free survival compared to endocrine therapy alone.

5. Conclusion

In conclusion, this retrospective analysis suggests that the combination of Palbociclib and Anastrozole offers superior progression-free survival compared to Anastrozole alone in postmenopausal HR+ HER2- metastatic breast cancer patients in Central India. While adverse events were more common in the combination group, these were largely manageable without therapy discontinuation. Future prospective studies with longer follow-up are needed to validate these findings and assess overall survival benefits.

Conflict of Interest
The authors declare no conflict of interest

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