

Impact of the CDK4/6 Inhibitor Line of Use on Progression-Free Survival in HR+/HER2- Metastatic Breast Cancer: Real-Life Experience in Morocco

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ABSTRACT Introduction Hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer represents the most common molecular subtype. The introduction of cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors in combination with endocrine therapy has profoundly changed the therapeutic paradigm. However, real-world data from low- and middle-income countries remain limited, and the optimal timing for CDK4/6 inhibitor initiation is still debated, particularly following the publication of the SONIA trial. Methods We conducted a retrospective cohort study at the Department of Medical Oncology of Hassan II University Hospital in Fez. Forty-one patients with de novo or recurrent HR+/HER2- metastatic breast cancer treated with palbociclib or ribociclib in combination with endocrine therapy between January 2018 and December 2024 were included. CDK4/6 inhibitors were administered in either the first-line or second-line setting. The primary endpoint was progression-free survival (PFS). Secondary endpoints included overall survival (OS), objective response rate (ORR), clinical benefit rate (CBR, defined as partial response or stable disease \geq 24 weeks), safety, and tolerability. Cox proportional hazards models were used for univariate and multivariate analyses of prognostic factors. Results The median age was 55.2 years (range, 31–92). CDK4/6 inhibitors were administered as first-line therapy in 63.4% of patients and as second-line therapy in 36.6%. The median progression-free survival was 29.2 months (95% CI: 23.5–34.9), while the median overall survival had not been reached at the time of analysis. A partial response was observed in 48.78% of patients, and the clinical benefit rate was high. Patients treated in the first-line setting showed a longer progression-free survival compared with those treated in the second line (29.2 vs. 10.4 months); however, this difference was not statistically significant ($p = 0.248$). Toxicities were mainly hematological, dominated by grade 3–4 neutropenia (58.5%). Conclusion In this real-world cohort, the combination of CDK4/6 inhibitors with endocrine therapy demonstrated meaningful clinical efficacy with manageable toxicity. First-line use of CDK4/6 inhibitors may provide a relevant clinical benefit in resource-limited settings. Further prospective studies adapted to local realities are needed to optimize therapeutic sequencing strategies.

Keywords: Breast cancer; Metastasis; Targeted therapy; Antcdk4/6

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INTRODUCTION

Breast cancer represents one of the major public health challenges worldwide. It is the most common cancer among women and the second leading cause of cancer overall when both sexes are combined. In 2022, approximately 2.3 million new cases were diagnosed, accounting for 11.6% of all newly diagnosed cancers [1].

In Morocco, data from the Greater Casablanca Cancer Registry indicate that breast cancer accounts for 39.1% of all female cancers, confirming its substantial public health impact [2].

Despite considerable advances in the diagnosis and management of early-stage breast cancer, a significant proportion of patients eventually develop metastatic disease. Breast cancer is a biologically heterogeneous entity and can be classified into several molecular subtypes based on immunohistochemically analysis, allowing for more targeted therapeutic strategies [3].

Approximately 70–80% of breast cancers belong to the hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2-) subtype. In this population, endocrine therapy alone long represented the cornerstone of treatment [4].

However, tumor progression inevitably occurs in the majority of patients, highlighting the existence of multiple mechanisms of endocrine resistance. Among these, activation of the cyclin D1–CDK4/6–retinoblastoma (Rb) pathway has been implicated in resistance to endocrine therapy [5]. This biological insight led to the development of cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors, namely palbociclib, ribociclib, and abemaciclib.

Over the past decade, the integration of CDK4/6 inhibitors in combination with endocrine therapy has transformed the therapeutic landscape of luminal/HER2- metastatic breast cancer. Nevertheless, real-world data remain limited, particularly in low- and middle-income countries. Furthermore, the publication of the SONIA trial has reignited the debate regarding the optimal timing of CDK4/6 inhibition, questioning the benefit of first-line use compared with initiation in the second-line setting. This issue is of particular relevance in contexts characterized by limited access to and high costs of these treatments.

Within this framework, we conducted a retrospective real-world evaluation of CDK4/6 inhibitors at the Department of Medical Oncology of Hassan II University Hospital in Fez. This study included 41 women with HR+/HER2- metastatic breast cancer, either de novo or recurrent, treated between 2018 and 2024. The primary endpoint was progression-free survival in the first- and second-line settings, assessed by the investigator according to RECIST v1.1 criteria. Secondary endpoints included overall survival, objective response rate (ORR), duration of response, clinical benefit rate (CBR), and safety. In addition, univariate and multivariate analyses were performed to identify prognostic factors influencing survival outcomes.

MATERIALS AND METHODS

Study Design

This was a retrospective, descriptive, and analytical cohort study conducted in the Department of Medical Oncology at Hassan II University Hospital of Fez. The study included patients with hormone receptor-positive and HER2-negative (HR+/HER2-) metastatic breast cancer, either de novo or recurrent, diagnosed between January 2018 and December 2024.

Patient Recruitment

A total of 41 patients with HR+/HER2- metastatic breast cancer was included. Eligibility criteria were: histologically confirmed HR+/HER2- metastatic breast cancer; treatment with a CDK4/6 inhibitor (palbociclib or ribociclib) in combination with endocrine therapy, administered either as first-line treatment or as second-line therapy following progression on endocrine monotherapy; and availability of adequate clinical and radiological follow-up data. Patients with incomplete clinical or outcome data or those who received other targeted therapies were excluded. Abemaciclib was not available in Morocco during the study period and was therefore not used.

Data Collection

Clinical, pathological, and therapeutic data were collected from electronic medical records and paper-based patient files. Collected variables included demographic characteristics, tumor-related parameters, treatment modalities, treatment responses, survival outcomes, and treatment-related toxicities.

Tumor response and disease progression were assessed using standard imaging modalities according to routine clinical practice and evaluated in accordance with the Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1.

Statistical Analysis

Descriptive statistical analyses were used to summarize patient characteristics. The primary endpoint was progression-free survival (PFS), defined as the time from initiation of CDK4/6 inhibitor therapy to radiologically confirmed disease progression or death from any cause, according to RECIST version 1.1.

Secondary endpoints included overall survival (OS), objective response rate (ORR), clinical benefit rate (CBR), defined as partial response or stable disease lasting at least 24 weeks, as well as treatment tolerability and safety.

Univariate and multivariate prognostic analyses were performed using Cox proportional hazards regression models. Variables included in the models were age, tumor size, nodal status, Scarf-Bloom-Richardson (SBR) histological grade, Ki-67 proliferation index, metastatic pattern, type of CDK4/6 inhibitor, and line of treatment. Missing data were not imputed. All statistical analyses were performed using SPSS software version 26 (IBM Corp., Armonk, NY, USA). A two-sided p-value < 0.05 was considered statistically significant.

RESULTANTS

Characteristics patient

The cohort included 41 patients, with a median age of 55.2 years (range: 31–92). Among them, 70.7 % (n = 29) were older than 45 years, and 29.3 % (n = 12) were younger than 45 years. The majority of patients, 61 % (n = 25), were postmenopausal. Comorbidities were present in 19.5 % (n = 8) of patients, mainly hypertension and diabetes. The predominant histological types were invasive ductal carcinoma (IDC) and invasive mammary carcinoma, accounting for 46.3 % (n = 19) and 43.9 % (n = 18) of cases, respectively. At diagnosis, 39 % of tumors was classified as cT4, and 60.9 % of patients had at least one positive lymph node. According to the Scarf-Bloom-Richardson (SBR) grading system, modified by Elston and Ellis, grade II was the most frequent, representing 73.2 % of cases. Regarding metastatic presentation, 78.0 % (n = 32) of patients had de novo metastatic disease, while 22 % (n = 9) represented relapses. Among relapsed patients, 4.9 % (n = 2) occurred within 12 months and 17.1 % (n = 7) after more than 12 months. The most frequent metastatic sites were bone (73.2 %, n = 30), lung (43.9 %, n = 18), and liver (36.6 %, n = 15). In molecular analysis, Ki-67 was notably high at 75.8 %. Regarding HER2 expression, 36.6 % (n = 15) of patients had HER2-low tumors, and 63.4 % (n = 26) had HER2-ultra-low tumors [Tables 1 and 2 summarize these demographic, clinical, and biological characteristics].

CDK: CYCLIN-dependent kinase, Her2: HUMAN epidermal Growth factor receptor2

This table summarizes the demographic, clinical, comorbid, and histopathological features of the 41 included patients. Characteristics include age, menopausal status, comorbidities, family history of cancer, tumor histopathological type, clinical tumor size, lymph node status, and histological grade. Data are presented as absolute numbers and percentages. The table provides an overview of baseline risk factors, clinical severity, and histopathological profile within the cohort. No comparative statistical analysis is included; the table serves solely for descriptive purposes to characterize the study population. CDK4/6: Cyclin-dependent kinase, Her2: Human epidermal Growth factor receptor 2. This table describes the baseline clinical presentation, metastatic patterns, and prior systemic treatments of 41 patients with

Table 1: Descriptive characteristics of patients monitored for hormone receptor-positive/HER2 negative metastatic breast cancer treated with anti-CDK4/6. Values are expressed as numbers and PERCENTAGE (%).

Features	Number of patients (N=41)	Frequency%
Age in Years		
≥45 ψεαρσ	29	70,73
<45ψεαρσ	12	29,26
Menopausal Status		
Menopausal	25	61,0
Premenopausal	16	39,0
Comorbidities		
Arterial Hypertension	6	14,6
Diabetes	2	4,9
Cardiac disease	0	0,0
Family history of cancer		
Breast	3	7,3
Ovarian	1	2,4
Histopathological type		
Invasive ductal Carcinoma	19	46,3
Invasive breast carcinoma	18	43,9
Invasive lobular carcinoma	2	4,9
Adenocarcinoma	2	4,9
Tumor size		
cT1	4	9,8
cT2	13	31,7
cT3	8	19,5
cT4(abcd)	16	39,0
Lymph node status		
N0	16	39,0
N1	19	46,3
N2	3	7,3
N3	3	7,3
SBR Grade		
I	3	7,3
II	30	73,2
III	8	19,5

Table 2: Characteristics of previous metastatic disease and treatment. Values are expressed as numbers and percentages (%).

Features	Number of patients (N=41)	Frequency%
Clinical presentation		
De novo metastatic	32	78,0
Recurrent metastatic	9	22,0
Relapse interval		
≥12μοντησ	7	17,1
<12μοντησ	2	4,9
Sites of metastasis		
Pleuro-pulmonary	18	43,9
Hepatic	15	36,6
Cerebro-meningeal	0	0,0
Peritoneal	1	2,4
Osseuses	30	73,2
Ganglion	25	61,0
Others	2	4,9
Previous treatments received		
Neoadjuvant chemotherapy	7	17,1
Adjuvant chemotherapy	7	17,1
Palliatives chemotherapy	9	22,0
Adjuvant hormone therapy	9	22,0

hormone receptor-positive and HER2-negative (HR+/HER2-) metastatic breast cancer included in this retrospective cohort study. Clinical presentation is classified as de novo or recurrent metastatic disease, and the disease-free interval is reported for patients with recurrent disease only. Metastatic sites were assessed using standard imaging modalities according to routine clinical practice; multiple metastatic sites could be present in the same patient; therefore, percentages may exceed 100%. Prior treatments include neoadjuvant, adjuvant, and palliative chemotherapy, as well as adjuvant endocrine therapy administered before initiation of CDK4/6 inhibitor-based treatment. Data are presented as absolute numbers and percentages calculated based on the total study population (N=41). No inferential statistical comparisons were performed for this descriptive table.

Therapeutic Management

CDK4/6 inhibitors were administered as first-line therapy in 63.4 % (n=26) of patients and as second-line therapy in 36.6 % (n = 15). Palbociclib was used in 90.2 % of patients (n=37), while ribociclib was administered in 9.7 % (n=4) [Table 3].

In terms of treatment response, 29.3 % (n=12) of patients had stable disease, 48.8 % (n=20) achieved a partial response, and 22 % (n=9) experienced disease progression. At the time of analysis, 87.8 % of patients was alive, and 12.2 % had died. The main hematologic toxicities were grade [3, 4] neutropenia (58.5%), followed by anemia and thrombocytopenia. Non-hematologic adverse events were primarily fatigue. In our cohort, 29.3 % (n=12) of patients had stable disease, and 48.8 % (n=20) achieved a partial response. This table summarizes the therapeutic characteristics and clinical outcomes of the 41 breast cancer patients treated with CDK4/6 inhibitors. It includes the line of therapy (first- or second-line), type of CDK4/6 inhibitor administered (Palbociclib or Ribociclib), treatment response assessed according to standard RECIST criteria (partial response, stable disease, or progressive disease), and patient status at the time of analysis (alive or deceased). Data are presented as absolute numbers and percentages. This descriptive table provides a clear overview of treatment distribution, efficacy, and short-term survival in the

Table 3: Therapeutic MODALITIES, REONSE and progression of metastatic patients undergoing treatment. Values are expressed as numbers and percentages (%).

Features	Number of patients (N=41)	Frequency%
Line of CDK 4/6 inhibitor therapy		
First line	26	63,4
Second-line	15	36,6
CDK4/6 inhibitor Used		
Palbociclib	37	90,2
Ribociclib	4	9,8
Reponse to treatment		
Partial response	20	48,78
Stable disease	12	29,27
Progressive disease	9	22,0
Status at the time of analysis		
Alive	36	87,8
Deceased	5	12,2

cohort. No inferential statistical comparisons are included; the table is intended for descriptive purposes.

Survival

The median progression-free survival (PFS) was 29.2 months (95 % CI: 23.5–34.9). Median overall survival (OS) was not reached at the time of analysis. The response duration was 78 %, and the clinical benefit rate was high [Figure 1].

This figure shows the progression-free survival (PFS) of 41 patients stratified by CN status. PFS, expressed in months, was defined

as the time from treatment initiation to documented disease progression or death from any cause. The median PFS for the cohort was 29.2 months (95 % CI: 23.5–34.9). Univariate analysis showed that only lymph node involvement was significantly associated with shorter progression-free survival (PFS) ($p = 0.033$). Neither the type of CDK4/6 inhibitor, age, tumor size, Ki-67 percentage, nor hormone receptor status had a significant impact on survival outcomes [Figure 2].

This Figure Illustrates The Progression-Free Survival (Pfs) Of Patients Stratified By Cn Status. Pfs Was Defined As The

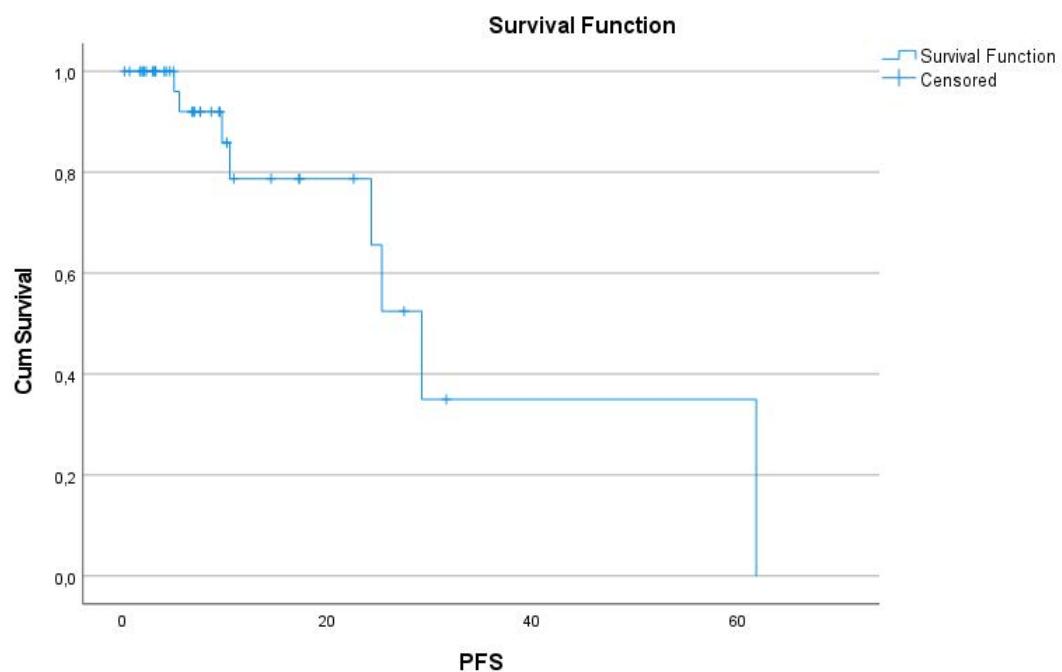


Figure 1: Kaplan-Meier curve of progression-free survival (PFS).

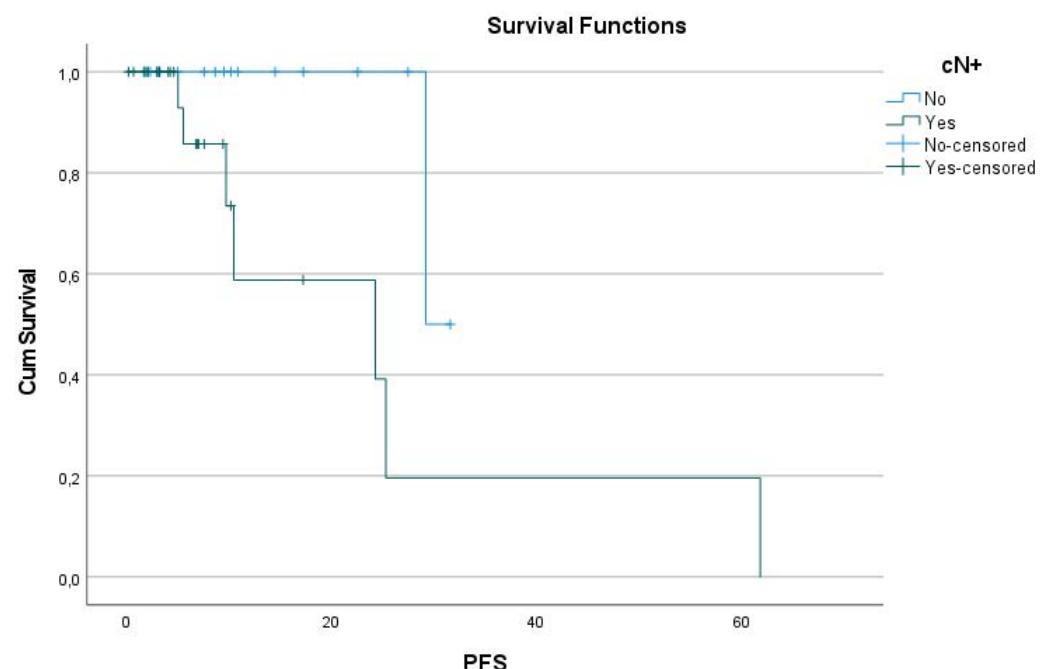


Figure 2: Kaplan-Meier curves of progression-free survival according to clinical nodal status.

Time From Initiation Of Treatment To Documented Disease Progression Or Death From Any Cause. Patients With Cn-Positive Disease (Green Curve) Showed Shorter Pfs Compared With Cn-Negative Patients (Blue Curve). The Kaplan-Meier Method Was Used To Estimate Survival Probabilities Over Time, And Differences Between Groups Were Evaluated Using The Log-Rank Test ($P = 0.033$). Censored Data Points Are Indicated By Tick Marks On The Curves. This Analysis Demonstrates That Cn Positivity Is Associated With A Poorer Prognosis In Terms Of Disease Progression. Furthermore, our analysis showed that first-line administration of CDK4/6 inhibitors in patients with HR+/HER2– breast cancer was associated with an improved progression-free survival compared to second-line use (PFS = 29.2 months vs. 10.4 months); however, this difference was not statistically significant ($p = 0.248$).

DISCUSSION

In this single-center retrospective study conducted in a real-world setting, the combination of a CDK4/6 inhibitor with endocrine therapy in patients with HR+/HER2– metastatic breast cancer demonstrated notable clinical efficacy, with a median progression-free survival (PFS) of 29.2 months and median overall survival (OS) not reached at the time of analysis. These findings are broadly consistent with those reported in pivotal phase III clinical trials, confirming the translatability of CDK4/6 inhibitor benefits outside the strict context of randomized trials [6-11]. The observed PFS in our cohort is particularly comparable to that reported in PALOMA-2, MONALEESA-2, and MONARCH-3, where median PFS ranged between 27 and 33 months in the first-line setting [6,8,11]. This similarity is remarkable considering several unfavorable factors in our population, including high Ki-67 proliferation indices, a substantial proportion of de novo metastatic patients, and a non-negligible frequency of visceral involvement. These data support the hypothesis that inhibition of the cyclin D-CDK4/6-Rb axis remains effective even in biologically more aggressive subgroups, as suggested in prior exploratory analyses [12, 13]. A central point of our analysis concerns the sequence of CDK4/6 inhibitor administration. Although the comparison between first- and second-line uses did not reach statistical significance, a clinically relevant difference in favor of first-line administration was observed (PFS 29.2 vs. 10.4 months). This trend partially contrasts with the SONIA trial, which did not demonstrate a significant PFS benefit for a systematic first-line introduction of CDK4/6 inhibitors [14]. However, several contextual factors may explain this discrepancy. Unlike SONIA, our population was treated in a resource-limited setting, where access to subsequent lines of therapy is often restricted. In this context, delaying the introduction of CDK4/6 inhibitors could expose some patients to a loss of the optimal therapeutic window, an aspect that deserves particular attention in low- and middle-income countries.

Our study also has several limitations, including a small sample size and imbalance in the distribution of patients according to line of therapy, with the majority receiving CDK4/6 inhibitors

as first-line treatment. This imbalance may introduce selection and indication biases, potentially affecting the interpretation of observed PFS differences. Our results are consistent with other real-world evidence reporting objective response rates, PFS durations, and tolerability profiles comparable to those in randomized trials [15-17]. In our cohort, the partial response rate approached 50 %, and the overall clinical benefit was high, confirming the sustained efficacy of these treatments in daily practice. Furthermore, most patients were still alive at the time of analysis, consistent with the prolonged OS observed in the MONALEESA trials, particularly with ribociclib [9, 10].

Regarding tolerability, hematologic adverse events, especially grade [3-4] neutropenia, predominated, with no unexpected severe toxicities. This safety profile aligns with data from PALOMA and MONALEESA trials and underscores the feasibility of managing CDK4/6 inhibitors in non-academic settings [6-10]. The absence of abemaciclib in our therapeutic arsenal remains a limitation, given its distinct toxicity profile and demonstrated continuous activity in the MONARCH studies [11, 18]. From a prognostic perspective, only lymph node involvement was significantly associated with shorter PFS in our univariate analysis, while age, CDK4/6 inhibitor type, Ki-67, and line of therapy did not significantly influence survival. These findings illustrate the current limitations of conventional Clinico-biological factors for predicting CDK4/6 inhibitor benefit. Although progesterone receptor (PR) expression and Ki-67 have been proposed as potential biomarkers, data remain heterogeneous and inconclusive, with hormone receptor positivity—particularly estrogen receptor (ER) status—still being the only validated criterion for eligibility [13]. Our results should be interpreted in light of inherent limitations of retrospective design, modest sample size, and lack of randomization. Nevertheless, this study provides original data from a North African context, still underrepresented in the literature, highlighting the potential benefit of early CDK4/6 inhibitor use in settings with limited access to innovative therapies. Additional limitations include the single-center design, heterogeneous management, absence of centralized review of immunohistochemically markers and detailed molecular data, and unavailability of certain CDK4/6 inhibitors, all of which may confound interpretation. These limitations emphasize the need for prospective, multicenter studies incorporating standardized biological assessments and a comprehensive biomolecular approach to identify robust predictive factors and optimize therapeutic sequencing strategies, particularly in resource-limited settings.

CONCLUSION

This study confirms the efficacy and tolerability of CDK4/6 inhibitors in the treatment of HR+/HER2– metastatic breast cancer in real-world practice. It suggests that first-line use may provide a tangible clinical benefit in resource-limited countries, despite the results of the SONIA trial. Prospective studies tailored to local socio-economic realities are needed to optimize therapeutic sequencing strategies and ensure equitable access to innovative treatments.

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