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Trastuzumab and Pertuzumab in HER2-Positive Metastatic Breast Cancer in West Africa: A Retrospective Cohort Study from Côte d'Ivoire

Kouame Konan Yvon Kouassi*[a,b,c], Bitti Adde Odo[a,b,c], Yenahaban Lazare Toure[b,c,d], Amougou Felix Mbarga[a], Femi Perez Odidi[a], Petiori Gningayou Laurence Toure Spouse Kamara[a,b,c], Mohamed Kassir Agnide Madiou[a], N'Guessan Manlan Prosper Mebiala[a,b,c], Audrey Fleur Sessegnon[a,b,c], Akissi Marie Barbara Yvonne Nogbou[a], Moctar Toure[a,b,c], Innocent Adoubi[a,c,e]

[a]*Medical Oncology Department of the Treichville University Hospital Center, Abidjan, Côte d'Ivoire*

[b]*Medical Oncology Department of the Bouaké University Hospital Center, Abidjan, Côte d'Ivoire*

[c]*Félix Houphouët Boigny University, Abidjan, Côte d'Ivoire*

[d]*Alassane Ouattara University, Bouaké, Côte d'Ivoire*

[e]*National Cancer Control Program, Abidjan, Côte d'Ivoire*

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ABSTRACT

Background: Dual anti-HER2 blockade with trastuzumab plus pertuzumab combined with a taxane is the first-line treatment for metastatic HER2-positive breast cancer. However, little evidence is available on its efficacy and safety in sub-Saharan African populations. We aimed to report the effect of dual anti-HER2 blockade in Côte d'Ivoire on a cohort of patients followed up for HER2-positive metastatic breast cancer.

Methods: We conducted a retrospective analytical cohort study of female patients with HER2-positive metastatic breast cancer who were followed up in the public cancer management hospitals in Côte d'Ivoire (Treichville University Hospital Center and the National Center for Radiation Oncology) over a 2-year period from January 1, 2021, to December 31, 2022. The outcome of interest was progression-free survival, estimated by the Kaplan-Meier method. A univariable Cox regression model was used to test factors associated with progression-free survival. Variables with $P < 0.10$ were included in the multivariable model.

Results: We collected data on 30 patients. The median age was 47.2 years (interquartile range, 25 years). Common metastatic sites were the lung (63.3%), pleura (20.0%), liver (20.0%), bone (16.7%), and brain (6.7%). The most frequent adverse events were anemia (93.3%) and neutropenia (73.3%). The objective response rate was 60.0%. The median progression-free survival was 15.3 months. Median overall survival was not reached. Factors associated with better progression-free survival were the absence of brain metastasis ($P = 0.003$) and the administration of dual anti-HER2 blockade as first-line therapy ($P = 0.005$).

Conclusion: Dual anti-HER2 blockade showed therapeutic activity in terms of objective response, progression-free survival, and tolerability.

***Address for correspondence:**
Kouame Konan Yvon Kouassi,
Department of Medicine and Medical Specialties, Faculty of Medical Sciences, Félix Houphouët-Boigny University, Abidjan, Côte d'Ivoire
Email: yvonkouassi@gmail.com

INTRODUCTION

The HER2 oncogene, a major therapeutic target in HER2-positive breast cancer, is overexpressed in 21.3% of all breast cancers in Côte d'Ivoire.[1] The medical management of HER2-positive breast cancer

is well-defined and primarily relies on anti-HER2 therapies.[2] In metastatic settings, these medications have not only improved patients' prognosis but also their quality of life.[2] Trastuzumab was the first monoclonal antibody developed against HER2. At the tumor level, it works by inhibiting signaling pathways controlled by the HER2 protein and activating the antibody-dependent cellular cytotoxicity pathway by natural killer cells.[4,5] It has demonstrated clinical efficacy.[6] However, secondary resistance has been observed, necessitating the development of new drugs. Among these, pertuzumab, another anti-HER2 monoclonal antibody, works by preventing receptor dimerization, thereby complementing the action of trastuzumab.[7] The combination of these 2 molecules, known as dual HER2 blockade, along with a taxane, has become the standard first-line treatment for HER2-positive metastatic breast cancer.[7,8] However, according to the final results of the PERUSE study, only 9 of the 1436 patients (0.63%) included in the study were of African descent.[7]

Access to this therapeutic strategy remains limited in low-resource countries due to challenges in accessing specialists, diagnostic tools, and medications, both in terms of availability and cost.[9] In Côte d'Ivoire, despite these limitations, dual HER2 blockade is available and commonly used. Given the low representation of Black African populations in clinical trials on the efficacy of anti-HER2 therapies, it seemed necessary for us to conduct this study to highlight its benefits and the challenges faced in a resource-limited context.

METHODS

Study design

We conducted a retrospective analytical cohort study in the reference hospitals involved in breast cancer management in Côte d'Ivoire, which are located in Abidjan. The study period extended from January 1, 2021, to December 31, 2022, corresponding to the recruitment period.

Eligibility criteria

Patients were included if they met the following criteria: histologically confirmed breast cancer classified as metastatic; HER2-positive status determined by immunohistochemistry and/or fluorescence in situ hybridization; treated with dual anti-HER2 blockade (trastuzumab plus pertuzumab) combined with chemotherapy using a taxane; received at least 4 cycles of treatment with dual anti-HER2 blockade; and underwent regular clinical and radiological evaluations every 4 cycles.

Patients were excluded if they were male, had nonmetastatic breast cancer, had HER2-negative breast cancer or unknown HER2 status, did not receive dual anti-HER2 blockade, or had incomplete medical records.

Study variables

The parameters studied included epidemiological data, such as age, menopausal status, and medical history; clinical data, including consultation delay and type and location of metastases; anatomopathological data, such as histological type, histoprognostic grade, hormone receptor status, and HER2 expression; and therapeutic and disease evolution data, including the type of treatment received, total number of cycles received, clinical and radiological response to treatment, adverse effects, adherence, date of and reason for treatment discontinuation, and status at the last consultation.

Follow-up method

The administration of dual blockade with trastuzumab and pertuzumab was decided during a multidisciplinary tumor board meeting. Treatment was administered every 21 days. All patients had a performance status between 0 and 2 and received concomitant chemotherapy. Radiological assessment was performed after 4 cycles. All adverse events were reported on a pharmacovigilance form. Cardiac function was monitored throughout anti-HER2 therapy using transthoracic echocardiography, conducted at baseline and then every 3 months. Left ventricular ejection fraction, the primary marker of systolic function, was measured when technically feasible.

Tools and data collection process

The patients were identified from the paper and electronic databases of the centers participating in the study. An electronic form was used to collect information from the medical records.

Data analysis

Analyses were performed using the survival package of R software, version 4.3.1. Categorical variables were presented as frequencies and percentages, and continuous variables as mean (SD) or median (range). Survival curves were estimated using the Kaplan-Meier method and compared with the log-rank test. A univariable Cox regression model was used to test factors associated with progression-free survival. Variables with $P < 0.10$ were included in the multivariable model. A P value less than 0.05 was considered statistically significant.

Operational definitions

Progression-free survival (PFS) was defined as the time from initiation of dual anti-HER2 blockade to the first documented event of either disease

progression or death. Patients with no event were censored at the date of last follow-up.

Overall survival (OS) was defined as the time from initiation of treatment to the date of death from any cause. Patients who were still alive were censored at the date of their last follow-up.

Objective response refers to a quantifiable reduction in tumor burden, usually evaluated according to the Response Evaluation Criteria in Solid Tumors (RECIST), which classifies treatment response as complete response, partial response, stable disease, or progressive disease. Objective response rate (ORR) was defined as the percentage of patients who experienced either a complete response or a partial response as assessed by radiological imaging. Stable disease and progressive disease were not included in the ORR.

Treatment adherence was evaluated indirectly through the Medication Possession Ratio (MPR), defined as the ratio of the number of days for which medication was supplied to the total number of days in the treatment period. Patients with an MPR of 80% or greater were considered adherent.

RESULTS

Clinical and pathological characteristics

The study included 30 patients. The median age was 47.2 years (interquartile range, 25 years) at the time of diagnosis of metastatic disease. All patients had invasive carcinoma of no special type. The majority of patients (20 [66.7%]) had de novo metastatic disease. Pulmonary metastases were the most frequent, found in 19 patients (63.3%). Additionally, half of the tumors (15 [50.0%]) exhibited overexpression of hormone receptors. Table 1 details the clinical and pathological characteristics of the patients.

Table 1. Clinical and Pathological Characteristics of Patients (N = 30)

	No.	%
Histological Type		
Invasive carcinoma of no special type	30	100.0
Metastasis Type		
De novo metastasis	20	66.7
Metastatic recurrence	10	33.3
Time to Recurrence (n = 10)		
<6 mo	5	50.0
6–12 mo	2	20.0
>12 mo	3	30.0
Site of Metastasis		
Lung	19	63.3
Liver	6	20.0
Pleura	6	20.0
Bone	5	16.7
Brain	2	6.7
Other	4	13.3
HER2 Status		
3+	29	96.7
2+ with positive FISH result	1	3.3
Hormone Receptor Status		
Both ER and PR positive	15	50.0
ER negative and PR negative	15	50.0

ER, estrogen receptor; FISH, fluorescence in situ hybridization; PR, progesterone receptor.

Treatment and outcome characteristics

The median follow-up was 20.1 months (range, 5.8–25.0 months). The dual anti-HER2 blockade was administered as first-line therapy in 18 patients (60.0%). Paclitaxel was combined with dual HER2 blockade (trastuzumab plus pertuzumab) in 22 patients (73.3%) and docetaxel in 8 (26.7%). Approximately two-thirds of patients (20 [66.7%]) received between 6 and 12 treatment cycles. Treatment adherence was considered satisfactory in 20 patients (66.7%). Discontinuation of trastuzumab or pertuzumab was the most frequent cause of poor adherence. Objective responses were observed in 18 patients (60.0%). Table 2 details the treatment and outcome characteristics.

Regarding adverse effects, anemia was the most commonly observed (93.3%), followed by neutropenia (73.3%).

No cardiac toxicity was reported. Cutaneous reactions, in the form of rashes, were observed in 3 (10.0%).patients. Table 3 summarizes the observed side effects.

Table 2. Clinical and Pathological Characteristics of Patients (N = 30)

	No.	%
Protocol		
Dual HER2 blockade + paclitaxel	22	73.3
Dual HER2 blockade + docetaxel	8	26.7
Therapeutic Line		
First line	18	60.0
Second line	9	30.0
Third line	3	10.0
No. of Cycles Administered		
<6	3	10.0
6–12	20	66.7
12–18	6	20.0
>18	1	3.3
Treatment Adherence		
Good	20	66.7
Poor	10	33.3
Reasons for Poor Adherence (n = 10)		
Stockout of trastuzumab/pertuzumab	9	90.0
Toxic effects	1	10.0
Treatment Assessment		
Complete response	5	16.7
Partial response	13	43.3
Stable disease	7	23.3
Progressive disease	5	16.7

Table 3. Adverse Events According to the Common Terminology Criteria for Adverse Events (CTCAE) Classification System

Toxicity	Grade	Overall (N = 30)		Dual HER2 blockade + paclitaxel (n = 22)		Dual HER2 blockade + docetaxel (n = 8)	
		No.	%	No.	%	No.	%
Diarrhea							
	1–2	4	13.3	2	9.1	2	25.0
	3–4	2	6.7	0	0.0	2	25.0
Neutropenia							
	1–2	17	56.7	14	63.6	3	37.5
	3–4	5	16.7	3	13.6	2	25.0
Anemia							
	1–2	27	90.0	19	86.4	8	100
	3–4	1	3.3	1	4.5	0	0.0
Cutaneous toxicity	1–2	3	10.0	1	4.5	2	25.0
Cardiotoxicity	1–2	0	0.0	0	0.0	0	0.0

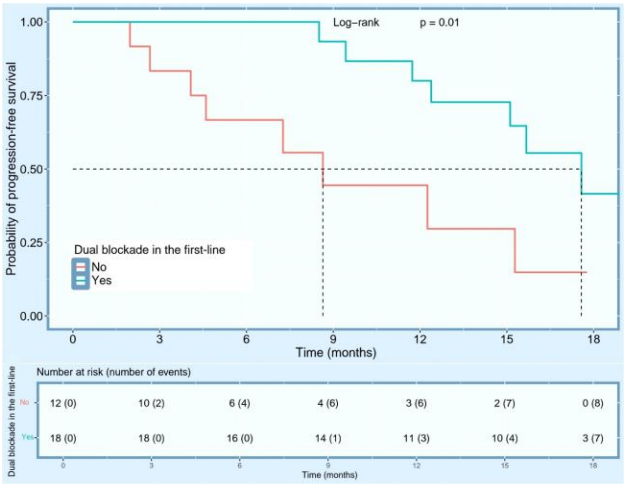

Figure 1. Progression-free survival according to line of administration of double HER2 blockade + taxane

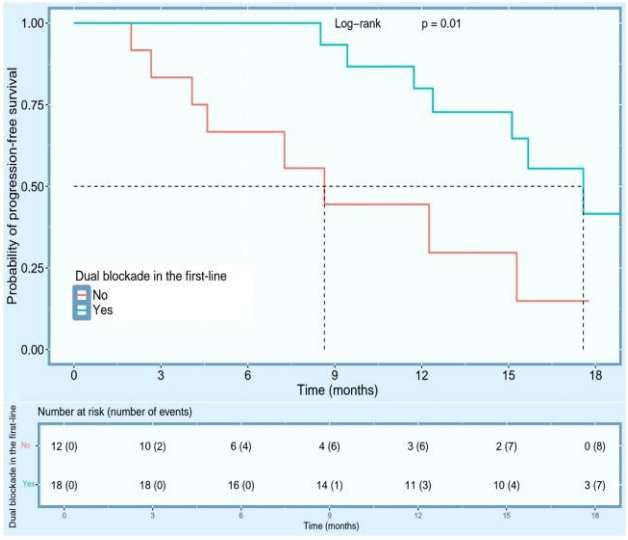

Figure 2. Progression-Free Survival According to the Presence of Brain Metastases at Diagnosis

Survival and associated factors

The median PFS was 15.3 months, while the median OS had not yet been reached at the time of the analysis (Figure 1).

No statistically significant association was found between PFS and factors such as hormone receptor status, the presence of liver or pulmonary metastases, or the de novo metastatic nature of the disease.

However, the use of dual HER2 blockade in the first line was associated with longer survival, and the presence of brain metastases was correlated with shorter survival. Patients who received dual anti-HER2 blockade as first-line treatment had a median PFS of 17.6 months, compared with 8.6 months for those who received it later ($P = 0.015$) (Figure 2).

Similarly, the median progression-free survival was 8.5 months in patients with brain metastases, compared to 15.7 months in those without brain metastases at the time of metastatic disease diagnosis ($P = 0.024$) (Figure 2). The results of regression analyses are presented in Table 4

DISCUSSION

This study provides important data on the use of dual HER2 blockade in a resource-limited country, highlighting its efficacy while underscoring the challenges related to its accessibility. The results confirmed the value of dual blockade in the treatment of HER2-positive metastatic breast cancer and identified certain prognostic factors.

However, the study has limitations. Its retrospective nature exposes it to biases, particularly in data collection and tumor response assessment.

Patient characteristics

The median age of the patients was 47.2 years, which is younger than that observed in the PERUSE study (54 years).[10] This trend is consistent with epidemiological data reported in sub-Saharan Africa, where breast cancer diagnosis is often made at an earlier age.[9,11] The most frequent metastatic sites were pulmonary (63.3%), followed by liver involvement (20.0%). These distributions are similar to those reported in the literature.[12]

Table 4. Factors Associated with Progression-Free Survival

Variable	Univariable analysis		Multivariable analysis	
	Hazard ratio (95% CI)	*P* value	Hazard ratio (95% CI)	*P* value
Lung Metastasis				
No	1.00 [Reference]			
Yes	2.53 (0.71–8.97)	0.15		
Brain Metastasis				
No	1.00 [Reference]		1.00 [Reference]	
Yes	4.65 (1.23–17.64)	0.02	55.54 (3.83–804.89)	0.003
Liver Metastasis				
No	1.00 [Reference]			
Yes	0.22 (0.03–1.69)	0.15		
First-Line Dual HER2 Blockade				
No	1.00 [Reference]		1.00 [Reference]	
Yes	0.28 (0.10–0.78)	0.02	0.15 (0.04–0.56)	0.005
Hormone Receptor Status				
Negative	1.00 [Reference]			
Positive	0.40 (0.12–1.27)	0.12		
Tumor Size				
>T3	1.00 [Reference]			
≤T3	1.57 (0.52–4.71)	0.42		
Neutropenia Grade				
1–2	1.00 [Reference]			
3–4	0.44 (0.06–3.33)	0.42		

Therapeutic response, survival, and associated factors

The ORR was 60.0%, lower than the 80.0% reported in the PERUSE study.[10] This difference could be related to several factors, notably insufficient adherence (30.0% of patients exhibiting poor treatment adherence) and a more aggressive tumor biology in younger patients.

The median PFS was 15.3 months, shorter than the 17.2 months in the CLEOPATRA trial and the 20.6 months in the PERUSE study.[6,10] However, the administration of dual blockade as first-line therapy significantly improved PFS (17.6 months vs 8.6 months; $P = 0.015$), highlighting the importance of initiating this treatment at the time of metastatic disease diagnosis. The shorter survival could be explained by the selection of more aggressive tumor clones under the pressure exerted by initial treatments.[13]

The presence of brain metastases was associated with poorer PFS (15.7 months vs 8.5 months; $P = 0.024$). This could be explained by insufficient diffusion of trastuzumab across the blood-brain barrier, with concentrations of this treatment in the central nervous system being up to 300 times lower than those observed in the bloodstream.[14,15] This result aligns with the findings of other studies that highlight the unfavorable prognosis of central nervous system involvement.[16] However, certain drugs such as tucatinib have revolutionized the medical management of brain metastases through the HER2CLIMB study.[17]

Conversely, no significant difference was found based on the presence of liver or lung metastases, which is also reported in the literature.[16]

Tolerability and accessibility

The most frequent toxic effects were hematological, with a high prevalence of anemia (93.3%) and neutropenia (73.3%). These adverse effects are comparable to those reported in the PERUSE and CLEOPATRA studies.[18,19] The absence of cardiac toxic effects could be explained by the small size of our sample or the short follow-up duration.

A major challenge highlighted in this study is accessibility to treatments. Indeed, 30.0% of the patients experienced treatment delays, mainly due to supply shortages of trastuzumab and pertuzumab. This difficulty could have affected the results and underscores the importance of improving access to treatments in our context.

CONCLUSION

Our results confirm the role and utility of dual HER2 blockade in HER2-positive metastatic breast cancer, with a particularly marked benefit when administered as first-line therapy. However, the PFS in our population is lower than the data from international clinical trials, possibly due to suboptimal adherence and difficulties in accessing treatments.

These results highlight the need to improve the availability of targeted therapies in resource-limited countries. Efforts must be undertaken to strengthen

supply chain strategies, optimize the management of toxic effects, and promote access to innovative treatments through financial aid programs or partnerships with international health organizations.

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None.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests

ETHICAL CONSIDERATIONS

The study was conducted in accordance with ethical principles and received approval from the ethics committee. Patient data were anonymized to ensure the confidentiality of medical information. Informed consent was obtained from all patients included in the study, in accordance with the recommendations of the ethics committee.

FUNDING

The research is self-funded.

DATA AVAILABILITY

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request. No access restrictions apply.

AI DISCLOSURE

The authors declare that no artificial intelligence (AI) tools were used in the generation of data, analysis, or writing of this manuscript. All work was conducted and reviewed entirely by the authors.

AUTHOR CONTRIBUTIONS

KKY: Conceptualization, Methodology, and Writing—Original Draft. OBA: Methodology and Writing—Original Draft. TYL: Data Curation and Formal Analysis. MAF: Data Curation and Formal Analysis. OFP: Methodology and Writing—Original Draft. TPGLK: Data Curation and Formal Analysis. MMKA: Data Curation and Formal Analysis. MNMP: Data Curation and Formal Analysis. SAF: Data Curation and Formal Analysis. NAMBY: Data Curation and Formal Analysis. TM: Supervision. AI: Supervision.

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