

HER2 Overexpression in Invasive Breast Carcinoma in the Democratic Republic of Congo and its Association with Selected Clinicopathological Characteristics

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Background: Breast cancer is a heterogeneous disease and HER2 overexpression identifies a subgroup of tumors associated with aggressive behavior and targeted therapy response. Although HER2 expression has been widely studied worldwide and in some African countries, data remain limited in the Democratic Republic of the Congo, where access to molecular diagnostic techniques is still restricted.

Objective: This study aimed to determine the frequency of HER2 protein overexpression and its association with clinicopathological characteristics of breast carcinoma in the Democratic Republic of the Congo in order to provide local evidence to support diagnostic and therapeutic strategies.

Methods: We conducted a cross-sectional analytical study from 2014 to 2016 in Kinshasa and Lubumbashi including 86 invasive breast carcinoma cases. HER2 expression was assessed by immunohistochemistry and scored according to standard guidelines. Associations were analyzed using odds ratios with 95% confidence intervals.

Results: HER2 overexpression was observed in 25.6% of cases. No statistically significant association was found between HER2 status and age, tumor size, histological type, tumor grade, or estrogen receptor status. The absence of statistical significance may be related to the limited sample size.

Conclusion: Approximately one quarter of breast carcinomas showed HER2 overexpression in this Congolese population. These findings support the importance of routine HER2 testing in breast cancer management in resource-limited settings. Although no statistically significant associations were found, this study provides additional data on HER2 expression in the Congolese context and highlights the need for larger studies with longer study periods to better assess clinicopathological associations.

Keywords: breast cancer, HER2, immunohistochemistry, Democratic Republic of Congo, biomarkers

Introduction

Breast cancer remains the most frequently diagnosed cancer among women worldwide and represents a major public health challenge, particularly in low- and middle-income countries (LMICs), where mortality rates remain disproportionately high.¹ In sub-Saharan Africa, breast cancer is often characterized by late-stage diagnosis, aggressive biological behavior, and limited access to molecular diagnostics and targeted therapies, resulting in poor survival outcomes.^{2,3}

Breast carcinoma is a biologically heterogeneous disease, and its classification based solely on histopathological features is insufficient to guide optimal management. Molecular biomarkers have therefore become essential for prognostic stratification and therapeutic decision-making. Among these biomarkers, the human epidermal growth factor

receptor 2 (HER2) plays a central role. HER2 is a transmembrane tyrosine kinase receptor involved in cell proliferation and survival, and its overexpression or gene amplification is associated with aggressive tumor behavior and poor prognosis in the absence of targeted therapy.⁴

HER2-positive breast cancer accounts for approximately 15–30% of invasive breast carcinomas worldwide.⁵ The introduction of anti-HER2 targeted therapies has markedly improved survival outcomes in this subgroup, making accurate assessment of HER2 status a critical component of breast cancer management.⁶ International guidelines therefore recommend routine evaluation of HER2 status in all newly diagnosed invasive breast cancers using immunohistochemistry (IHC), with in situ hybridization techniques recommended for equivocal (2+) cases.⁷

In African settings, recent studies have reported considerable variability in the prevalence of HER2-positive breast cancer, reflecting differences in population characteristics, laboratory practices, and access to standardized testing methods.⁸ Despite the growing burden of breast cancer in the Democratic Republic of Congo (DRC), data on HER2 expression and its association with clinicopathological characteristics remain limited. Furthermore, access to confirmatory molecular techniques such as fluorescence in situ hybridization (FISH) remains a major challenge in many pathology laboratories across the country, potentially leading to under- or misclassification of HER2 status.⁹

Several studies have evaluated the immunohistochemical characteristics of breast cancer in the Democratic Republic of Congo. A retrospective study conducted in Kinshasa reported HER2 positivity in approximately one quarter of breast cancer cases and highlighted the importance of immunohistochemistry in tumor classification.¹⁰ Earlier studies in Congolese populations have also reported variable frequencies of HER2 overexpression depending on laboratory practices and diagnostic capacity.^{11,12} However, most of these studies primarily focused on receptor distribution and molecular subtypes rather than on the association between HER2 expression and clinicopathological characteristics. In the Democratic Republic of the Congo, access to immunohistochemistry and molecular diagnostic techniques has historically been limited, and HER2 testing has not been systematically performed in all pathology laboratories. During the study period, most immunohistochemical analyses were performed outside the Democratic Republic of the Congo due to the lack of local technical facilities. Most available studies have mainly described receptor distribution and molecular subtypes, with limited analysis of clinicopathological associations. The clinicopathological variables included in this study (age, histological type, tumor size, histological grade, and hormone receptor status) were selected because they are routinely available in pathology reports and are commonly used in studies evaluating HER2 expression and breast cancer prognosis.

In addition, access to confirmatory molecular techniques such as fluorescence in situ hybridization remains limited in many pathology laboratories in the Democratic Republic of the Congo, which may affect the accuracy of HER2 classification and limit the comparability of results across studies. Therefore, there is a need for additional studies to better characterize HER2 expression and its clinicopathological correlations in the Congolese context, particularly in settings with limited diagnostic resources.

Although previous studies have described the immunohistochemical profile of breast cancer in the Democratic Republic of the Congo, few studies have specifically analyzed the association between HER2 overexpression and clinicopathological characteristics such as age, tumor size, histological grade, and hormone receptor status. In addition, most previous studies were conducted in a single city, whereas the present study includes cases from both Kinshasa and Lubumbashi, providing broader data on HER2 expression in the Congolese context. This study therefore contributes additional information on HER2 expression patterns and their clinicopathological correlations in a resource-limited setting.

Understanding the frequency of HER2 protein overexpression and its relationship with clinicopathological parameters is essential to inform diagnostic strategies, support rational use of targeted therapies, and contribute to evidence-based breast cancer management in the Congolese context. In the Democratic Republic of the Congo, HER2 testing is not systematically performed in all pathology laboratories due to limited access to immunohistochemistry and molecular diagnostic techniques. Most available studies have mainly described receptor distribution and molecular subtypes, with limited analysis of clinicopathological correlations. The clinicopathological variables included in this study were selected because they are routinely available in pathology reports and are commonly used in studies evaluating HER2 expression and breast cancer prognosis. The objective of this study was therefore to determine the frequency of HER2 protein

overexpression in invasive breast carcinoma in the Democratic Republic of Congo and to evaluate its association with selected clinicopathological characteristics.

Methodology

Type and Study Setting

It was an analytical cross-sectional study conducted over a three-year period, from 2014 to 2016, in the cities of Kinshasa and Lubumbashi, in the Democratic Republic of the Congo. The study was carried out within anatomopathology departments involved in the histopathological diagnosis of breast cancer.

Study Population

The study population consisted of patients with a histological diagnosis of invasive breast carcinoma. All patients for whom usable paraffin blocks and adequate histological slides were available allowing immunohistochemical analysis of the HER2 marker were included. Cases with insufficient or non-exploitable histological material for immunohistochemical analysis were excluded. In total, 86 cases of invasive breast carcinoma were retained and analyzed.

Clinical and Histopathological Data

Clinical and histopathological data were collected from medical records and pathology reports. The variables studied included:

- Patients' age at the time of diagnosis;
- Histological type of the tumor;
- Tumor size, classified according to the TNM classification (T1 to T4);
- Histological grade, grouped into grades I, II, and III;
- Estrogen receptor (ER) status, when available.

Immunohistochemical Analysis of HER2

HER2 protein expression was evaluated by immunohistochemistry on formalin-fixed, paraffin-embedded tissue sections.

HER2 immunohistochemical staining was performed on formalin-fixed, paraffin-embedded tissue sections using standard immunohistochemical techniques. Antigen retrieval was performed using heat-induced epitope retrieval. Slides were incubated with primary antibodies against HER2, followed by secondary antibody and chromogen visualization. HER2 expression was scored according to ASCO/CAP guidelines using a four-tier scoring system (0, 1+, 2+, 3+). Scores of 0 and 1+ were considered negative, 3+ was considered positive, and cases scored as 2+ were considered equivocal. Confirmation by fluorescence in situ hybridization (FISH) was not performed due to limited availability of molecular diagnostic facilities. HER2 immunohistochemical scoring was performed by a trained pathologist according to ASCO/CAP guidelines. Quality control procedures were followed according to standard laboratory practices, including the use of control tissue samples and independent slide review to ensure consistency in HER2 scoring.

Confirmation of Equivocal Cases

Confirmation of equivocal HER2 cases (score 2+) by in situ hybridization (FISH or another equivalent technique) was not performed due to technical constraints and limited resources at the time of the study.

Statistical Analysis

Data was entered and analyzed to assess the association between HER2 expression and clinicopathological characteristics.

Statistical analysis was performed using SPSS software version 19 (IBM Corp., Armonk, NY, USA). Associations between categorical variables were tested using the Chi-square test or Fisher's exact test when appropriate. Odds ratios with 95% confidence intervals were calculated to measure the association between HER2 overexpression and clinicopathological variables. A p-value < 0.05 was considered statistically significant. P-values were calculated using the Chi-square test or Fisher's exact test depending on expected cell counts.

Results

Table 1 shows that HER2 oncoprotein overexpression (score 3+) was observed in 22 patients, corresponding to 25.6% of all breast carcinomas analyzed. Cases with equivocal HER2 expression (score 2+) accounted for 4 patients (4.7%), whereas 75.3% of tumors showed no HER2 overexpression (scores 0 and 1+). Thus, in this series, most of the breast carcinomas studied were characterized by the absence of HER2 oncoprotein overexpression.

In this series, HER2 oncoprotein overexpression was observed only in patients with invasive ductal carcinoma of no special type (NST), with 22 HER2-positive cases, representing 26.2% of this subgroup. The majority of NST carcinomas did not show HER2 overexpression (73.8%) (Table 2).

No HER2 overexpression was observed among mixed invasive ductal and lobular carcinomas or invasive papillary carcinomas, all of which were HER2 negative.

Table 3 shows that no statistically significant association was identified between HER2 overexpression and patients' age, tumor size, histological grade, or estrogen receptor status ($p > 0.05$ for all comparisons).

Table 1 HER2 Oncoprotein Expression by Immunohistochemistry

HER2 Score	Number (n=86)	Percentage
0	50	58.1
1+	10	11.6
2+	4	4.7
3+	22	25.6

Table 2 Distribution of HER2 Overexpression According to Histological Type

Histological Type	HER2+ n (%)	HER2- n (%)
Invasive ductal carcinoma, no special type (NST)	22 (26.2)	62 (73.8)
Mixed invasive ductal and lobular carcinoma	0 (0)	1 (100)
Invasive papillary carcinoma	0 (0)	1 (100)

Table 3 Association Between HER2 Overexpression and Clinicopathological Characteristics

Variable	Category	HER2+ n (%)	HER2- n (%)	OR (IC95%)	p
Age (years)	> 45	15 (31.3)	33 (68.7)	2.01 (0.72–5.60)	0.18
	≤ 45	7 (18.4)	31 (81.6)		
Tumor size	T1–T2	6 (28.6)	16 (71.4)	1.13 (0.38–3.37)	0.83
	T3–T4	16 (25.0)	48 (75.0)		
Histological grade	III	15 (32.0)	32 (68.0)	2.14 (0.77–5.96)	0.13
	I–II	7 (20.0)	32 (80.0)		
Estrogen receptors	RE–	13 (59.1)	25 (39.1)	0.44 (0.17–1.19)	0.10
	RE+	9 (40.9)	39 (60.9)		

However, some descriptive trends were observed, including a higher proportion of HER2-positive tumors among patients older than 45 years, in grade III tumors, and among estrogen receptor–negative tumors. The lack of statistical significance may be related to the limited sample size.

Discussion

The present study analyzed the expression of the HER2 oncoprotein and its relationship with clinicopathological characteristics in a series of breast carcinomas diagnosed in the Democratic Republic of the Congo. HER2 overexpression was observed in 25.6% of patients, while most tumors did not show overexpression of this marker. This distribution highlights the biological heterogeneity of breast cancer in the study population. A finding widely reported in recent reviews addressing molecular phenotypes of breast cancer in Africa.^{13–15}

Frequency of HER2 Overexpression

The proportion of HER2-positive tumors observed in this study falls within the range reported in recent African series. A study conducted in Cameroon on HER2 oncoprotein expression in breast carcinomas reported a substantial proportion of tumors overexpressing HER2, confirming the existence of biological heterogeneity of breast cancer in Central Africa.¹⁶

Furthermore, multicenter analyses in East Africa have shown that the frequency of HER2-positive tumors varies considerably according to the populations studied, immunohistochemical practices, and interpretation criteria used highlighting the impact of methodological differences on prevalence estimates.¹⁴ These studies indicate that variations observed between African studies do not solely reflect biological differences, but also technical constraints such as tissue fixation quality, lack of standardization of procedures, and limited access to molecular confirmation techniques for equivocal cases.

In this context, the results of the present study provide complementary data from the Democratic Republic of the Congo, a setting characterized by limited diagnostic resources. They contribute to enriching the available data from Central Africa and confirm that direct comparison of HER2 prevalence across African studies should be interpreted with caution, considering the specific methodological and technical contexts of each country.^{14,16}

HER2 and Patients' Age

In this series, no HER2 overexpression was observed among so-called “special-type” carcinomas; however, the small number of these subtypes limits the significance of this observation. Although a higher proportion of HER2-positive tumors was observed among patients older than 45 years. This difference did not reach statistical significance, indicating that age at diagnosis is not a discriminating factor for HER2 status in the study population.

These findings are consistent with those reported by Lee et al¹⁷ who showed that HER2-positive tumors can occur at different ages in adulthood, without evidence of a specific age profile. The authors emphasize that HER2 overexpression mainly reflects intrinsic biological characteristics of the tumor rather than a direct effect of chronological age.¹⁷

More recently, a large cohort study did not identify a consistent association between age at diagnosis and HER2 status after adjustment for clinicopathological characteristics. The authors reported that age-related variations were weak and heterogeneous and did not allow identification of a reproducible age gradient for HER2 overexpression.¹⁸ Studies combining several African populations have also reported a lack of a consistent relationship between age at diagnosis and HER2 status, suggesting that HER2 overexpression may occur at different ages in adult life.^{14,19}

Taken together, these results suggest that age, when considered alone, is not a reliable determinant of HER2 status. HER2 overexpression appears to be a biological characteristic that may occur at different stages of adult life, reinforcing the need for systematic assessment of HER2 status in all patients with invasive breast carcinoma, regardless of age at diagnosis.

HER2 and Histological Type

In this study, HER2 overexpression was observed exclusively in invasive ductal carcinomas of no special type (NST), whereas no overexpression was identified among so-called “special-type” carcinomas. This distribution highlights the

intrinsic biological heterogeneity of NST carcinomas, which represent a broad morphological group encompassing tumors with diverse molecular profiles, including both HER2-positive and HER2-negative subtypes.

These findings are consistent with those reported in a large pathological series combining immunohistochemistry and *in situ* hybridization (SISH) that invasive ductal carcinoma NST is the histological subtype most frequently associated with HER2 amplification and overexpression.²⁰ The authors noted that, among the different histological types studied, NST accounted for the majority of HER2-amplified cases, while special histological carcinomas generally exhibited a low frequency of HER2 overexpression or even absence of confirmed amplification.

Similarly, recent comparative analyses of HER2 expression according to histological subtypes have shown that special carcinomas—such as mucinous, tubular, or papillary carcinomas—are more often characterized by distinct biological profiles, generally associated with low HER2 expression and more favorable clinical behavior.²¹ These data support the hypothesis that HER2 distribution reflects the intrinsic biology of each histological type rather than a random phenomenon.

In the African context, recent systematic reviews also confirm this trend, as some authors report that NST breast carcinomas represent the majority of HER2-positive tumors in sub-Saharan Africa, while special carcinomas are predominantly HER2-negative.^{13,19} However, these authors emphasize the inter-study variability related to small sample sizes of rare subtypes, differences in immunohistochemical practices, and limited access to molecular confirmation techniques. However, the very small number of special histological subtypes in this study does not allow meaningful statistical comparison between histological types, and this observation should therefore be interpreted with caution.

Nevertheless, it should be emphasized that in the present study. The small number of special-type carcinomas limits the strength of conclusions regarding the absence of HER2 overexpression in these subgroups. This observation should therefore be interpreted with caution and does not formally exclude HER2 expression in certain rare subtypes, as has been occasionally reported in other series using combined IHC–ISH approaches.²⁰

HER2 Tumor Size and Histological Grade

No statistically significant association was found between HER2 overexpression and tumor size or histological grade. The absence of statistically significant associations observed in this study may be related to the relatively small sample size and limited statistical power. Therefore, the absence of statistical significance should be interpreted with caution and may reflect insufficient statistical power rather than the absence of a true biological relationship. The presence of HER2-positive tumors among both small and larger tumors, as well as across different histological grades, suggests that HER2 overexpression is not strictly linked to conventional morphological criteria of tumor aggressiveness. Recent analyses conducted in sub-Saharan Africa have similarly shown that classical morphological characteristics do not always reflect the molecular status of breast tumors, particularly in resource-limited settings.^{13,19}

HER2 and Hormone Receptors

In this study, a higher proportion of HER2-positive tumors was observed among estrogen receptor–negative tumors, without reaching statistical significance. Recent reviews available on PMC indicate that the relationship between HER2 status and hormone receptor expression is variable and depends on the overall biological context and the evaluation methods used (Popli et al 2021,¹⁴ Onyia et al 2023¹³). The observed results thus suggest the coexistence of diverse biological profiles within the breast carcinomas studied, without an exclusive relationship between HER2 overexpression and hormone receptor status.

Diagnostic Implications in the Local Context

The presence of equivocal HER2 cases (score 2+) highlights the limitations of immunohistochemistry alone for accurate HER2 status classification. Recent reviews on breast cancer in sub-Saharan Africa emphasize that the lack of molecular confirmation techniques represents a major obstacle to optimal classification of breast tumors.^{13,19} These diagnostic constraints should be considered when interpreting results and underscore the need to strengthen molecular diagnostic capacities in resource-limited settings.

Study Limitations

This study has several limitations, including its retrospective design, the limited sample size, and the absence of molecular confirmation by in situ hybridization for equivocal HER2 cases. In addition, some biological data were incomplete, and the study was conducted in a limited number of centers. The relatively small sample size may have reduced the statistical power of the study and may explain the absence of statistically significant associations between HER2 expression and clinicopathological variables. These factors may also limit the generalizability of the results. The absence of confirmatory testing by in situ hybridization for equivocal HER2 cases may have led to possible misclassification of HER2 status. This limitation may have influenced the estimated frequency of HER2 overexpression and may also have affected the analysis of clinicopathological correlations. Multivariate logistic regression analysis was not performed due to the limited sample size, which may limit the identification of independent predictors of HER2 overexpression. Furthermore, although the study period dates from 2014–2016, HER2 expression patterns are not expected to change significantly over time in this context.

Conclusion

This study shows that HER2 oncoprotein overexpression affects approximately one quarter of invasive breast carcinomas diagnosed in the Democratic Republic of the Congo. No statistically significant association was observed between HER2 status and the clinicopathological characteristics analyzed, including age, tumor size, histological grade, histological type, and estrogen receptor status.

In this series, HER2 overexpression was observed independently of the clinicopathological parameters studied, without any statistically significant association. These findings underscore the importance of systematic assessment of HER2 status in all patients with invasive breast carcinoma, regardless of clinicopathological profile.

Finally, the absence of molecular confirmation for equivocal HER2 cases highlights the need to strengthen local molecular diagnostic capacities in order to improve tumor classification accuracy and optimize the therapeutic management of breast cancer in the Democratic Republic of the Congo.

Disclosure

The authors report no conflicts of interest in this work.

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