

Clinical Characteristics of HER2-Positive Breast Cancer Patients at a Tertiary Referral Hospital in Kenya

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Abstract

Background: HER2-positive breast cancer is an aggressive subtype associated with poor outcomes, particularly in low- and middle-income countries where access to targeted therapy is limited. Despite the growing burden of breast cancer in Kenya, comprehensive data on the clinical characteristics of HER2-positive patients remain scarce. **Objectives:** This study aimed to describe the clinical characteristics of HER2-positive breast cancer patients treated at Moi Teaching and Referral Hospital (MTRH) in Kenya between January 2018 and December 2023. **Methods:** This retrospective cohort study employed a census approach, enrolling 300 histologically confirmed HER2-positive breast cancer patients. Data were extracted from medical records using a standardized abstraction tool. Descriptive statistics were used to summarize demographic characteristics, reproductive history, comorbidities, presenting symptoms, and duration of symptoms before diagnosis. **Results:** The majority of patients (56.0%) were under 50 years, with 32.3% under 40 years. Most patients were married (78.3%) and came from the western region of Kenya, with Uasin Gishu County contributing 18.0% of patients. Housewives (28.0%) and farmers (16.0%) were the predominant occupational groups. Menopausal status was nearly equally distributed between pre-menopausal (45.0%) and post-menopausal (52.7%) patients. A positive family history of breast cancer was reported by only 5.7% of patients. Hypertension (18.7%) and diabetes mellitus (8.3%) were the most common comorbidities. Breast lump was the predominant presenting symptom (97.0%), followed by pain (27.7%), skin changes (18.3%), and nipple discharge (16.7%). The majority of patients (69.3%) presented with symptoms lasting 3 months or longer, with 19.0% having symptoms for more than one year before diagnosis. **Conclusion:** HER2-positive breast cancer at MTRH predominantly affects young women with significant

diagnostic delays. The high prevalence of advanced-stage presentation and comorbidities underscores the need for enhanced early detection strategies, improved breast cancer awareness, and comprehensive multidisciplinary management approaches in Kenya.

Keywords

HER2-Positive Breast Cancer, Clinical Characteristics, Diagnostic Delay, Kenya, Moi Teaching and Referral Hospital

1. Introduction

This template, Breast cancer remains one of the most common malignancies affecting women worldwide, with approximately 2.3 million new cases diagnosed annually [1]. Originating from the epithelial cells lining the milk ducts or lobules of the breast, breast cancer exhibits significant heterogeneity in its clinical presentation, pathological features, and molecular characteristics [2]. While the disease can occur in both sexes, it is far more prevalent in women, with well-established risk factors including advancing age, female gender, familial history of breast cancer, *BRCA1* and *BRCA2* gene mutations, hormonal factors, alcohol consumption, and obesity [3].

Among the various molecular subtypes of breast cancer, HER2-positive breast cancer represents a clinically significant proportion, accounting for approximately 15% - 20% of all breast cancer cases [4]. This subtype is characterized by overexpression of the human epidermal growth factor receptor 2 (HER2) protein, which drives aggressive tumor biology, high-grade histology, rapid progression, and an increased propensity for distant metastasis compared with HER2-negative breast cancers [5].

The advent of HER2-targeted therapies has transformed the treatment landscape and prognosis for patients with this aggressive subtype. Trastuzumab, a monoclonal antibody that specifically targets the HER2 protein, has been shown to significantly improve overall survival and disease-free survival when administered in conjunction with chemotherapy [6] [7]. Subsequent therapeutic advances have introduced additional targeted agents including pertuzumab, ado-trastuzumab emtansine (T-DM1), and lapatinib, further improving treatment outcomes particularly in the metastatic setting [8] [9]. The standard multimodal approach to HER2-positive breast cancer typically encompasses chemotherapy (doxorubicin, cyclophosphamide, paclitaxel, docetaxel), targeted HER2-directed therapies, hormone therapy for hormone receptor-positive cases, surgical intervention (lumpectomy or mastectomy), and radiation therapy [10]-[12]. This comprehensive strategy aims to address the disease at multiple levels and maximize patient outcomes.

Despite the remarkable progress in the treatment of HER2-positive breast cancer in high-income settings, significant disparities persist in low- and middle-in-

come countries (LMICs), including Kenya. The global burden of breast cancer is disproportionately borne by LMICs, where the majority of patients present with advanced-stage disease, and survival rates remain substantially lower than in high-income countries [13] [14]. In sub-Saharan Africa, the estimated five-year survival rate for breast cancer is only 44%, compared with over 90% in high-income countries [15]. This survival gap is attributed to a combination of factors including late presentation, limited access to specialized health care services, inadequate diagnostic infrastructure, and poor availability of targeted therapies [16] [17].

In Kenya, breast cancer is the leading malignancy among women, and HER2-positive breast cancer represents a clinically significant subtype characterized by aggressive tumor biology and poor outcomes [18] [19]. Existing studies have revealed marked discrepancies in reported HER2-positivity rates, ranging from 12.6% in continent-wide scoping reviews to 27.4% in Kenyan multi-centre studies, reflecting a lack of standardized national data [20] [21]. Furthermore, receptor testing (ER/PR/HER2) is available in only three to four centres nationwide, severely limiting population-level molecular characterization and evidence generation [21].

Outcome data for HER2-positive patients in Kenya indicate suboptimal survival. At Kenyatta National Hospital, the four-year survival rate was only 62.5% for curable-stage disease and a mere 5.6% for metastatic disease [19]. At Moi Teaching and Referral Hospital (MTRH)—a major referral centre serving a large and diverse population from western Kenya—only 33.6% of HER2-positive patients completed the full 18-cycle course of trastuzumab, with the high cost of the drug (approximately nine times the average monthly household income in western Kenya) being a major barrier [22]. These poor outcomes likely reflect a combination of late presentation, advanced stage at diagnosis, limited access to HER2-directed therapy, and incomplete treatment courses due to financial constraints.

Despite the disproportionate burden of HER2-positive breast cancer in Kenya, comprehensive data describing the clinical characteristics of these patients remain scarce. At MTRH, no systematic characterization of HER2-positive breast cancer patients has been conducted for the period January 2018 to December 2023. Consequently, clinicians lack locally derived evidence to inform treatment protocols, predict prognosis, or counsel patients accurately. Policymakers are unable to design targeted interventions, allocate resources effectively, or advocate for expanded access to HER2-targeted therapies without reliable baseline data. This study therefore addresses a critical knowledge gap by systematically describing the clinical characteristics of HER2-positive breast cancer patients treated at MTRH, thereby providing essential baseline evidence to guide clinical practice and health policy in Kenya.

2. Materials and Methods

2.1. Study Design

This study employed a retrospective cohort design to describe the clinical charac-

teristics of HER2-positive breast cancer patients treated at Moi Teaching and Referral Hospital (MTRH), a major tertiary referral centre in western Kenya serving a diverse population from both urban and rural areas across the region.

2.2. Study Population

The study included all female patients aged 18 - 80 years with histologically confirmed HER2-positive breast cancer diagnosed at MTRH between January 1, 2018, and December 31, 2023, who met the inclusion criteria. A census approach was used, whereby all eligible medical records were included in the study without sampling, as the total population of HER2-positive breast cancer patients during the study period was estimated to be manageable (approximately 250 - 350 patients).

2.3. Inclusion and Exclusion Criteria

Inclusion criteria were: 1) female patients aged 18 - 80 years; 2) histologically confirmed diagnosis of HER2-positive breast cancer; 3) diagnosis or treatment at MTRH between January 2018 and December 2023; and 4) availability of medical records.

Exclusion criteria were: 1) incomplete medical records (missing more than 50% of key variables); 2) unclear HER2 status (equivocal IHC 2+ without confirmatory FISH testing); and 3) unclear treatment regimens.

2.4. Sampling Technique

Purposive sampling (criterion-based sampling) was employed to select all eligible medical records. All medical records meeting the inclusion criteria were included in the study.

2.5. Data Collection

Data were extracted from medical records using a standardized abstraction tool. The tool captured demographic characteristics (age, county of residence, marital status, education level, occupation), reproductive history (menopausal status), family history of breast cancer, comorbidities, presenting symptoms, and duration of symptoms before diagnosis. Data were entered into a password-protected database and cleaned to ensure accuracy and completeness.

2.6. Statistical Analysis

Statistical analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were computed to summarize demographic characteristics, clinical characteristics, and comorbidities. Categorical variables were presented as frequencies and percentages. Continuous variables were summarized using means, medians, and standard deviations where applicable.

2.7. Ethical Considerations

Ethical approval was obtained from the Moi University/MTRH Institutional Re-

search and Ethics Committee. A waiver of informed consent was granted because of the retrospective nature of the study. Patient confidentiality was maintained throughout the study by using unique study identifiers and storing data in password-protected databases.

3. Results

A total of 300 patients were included in the analysis using a census approach. The results are organized according to the study objectives: demographic characteristics, reproductive and family history, comorbidities, and clinical presentation.

3.1. Demographic Characteristics

The majority of patients (56.0%, $n = 168$) were under 50 years of age, with the largest single age category being < 40 years (32.3%, $n = 97$), followed by 40 - 49 years (23.7%, $n = 71$). Patients aged 50 - 59 years constituted 22.0% ($n = 66$), while those aged 60 - 69 years and ≥ 70 years accounted for 14.3% ($n = 43$) and 7.3% ($n = 22$), respectively.

The majority of patients were married at the time of diagnosis, accounting for 78.3% ($n = 235$) of the study population. Widowed patients constituted 12.7% ($n = 38$), while single patients comprised 5.3% ($n = 16$).

The geographic distribution revealed that the majority came from counties in the western region of Kenya, which is the catchment area of MTRH. Uasin Gishu County, where MTRH is located, contributed the highest proportion of patients at 18.0% ($n = 54$). Kakamega County and Nakuru County were the second most common sources of patients, each accounting for 12.3% ($n = 37$), followed by Nandi County at 10.7% ($n = 32$).

Secondary education was the most common level of education (43.3%, $n = 130$), followed by tertiary education (29.0%, $n = 87$). Primary education was reported by 12.0% ($n = 36$) of patients, while only 1.7% ($n = 5$) had no formal education.

Housewives constituted the largest occupational group (28.0%, $n = 84$), followed by farmers (16.0%, $n = 48$) (**Table 1**).

Table 1. Demographic characteristics of HER2-positive breast cancer patients ($N = 300$).

Characteristic	Category	Frequency (n)	Percentage (%)
Age at Diagnosis (years)	<40 years	97	32.3
	40 - 49 years	71	23.7
	50 - 59 years	66	22.0
	60 - 69 years	43	14.3
	≥ 70 years	22	7.3
County of Residence	Uasin Gishu	54	18.0
	Kakamega	37	12.3
	Nakuru	37	12.3

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	Nandi	32	10.7
	Bungoma	18	6.0
	Siaya	17	5.7
	Kisii	13	4.3
	Not indicated	13	4.3
	Kericho	9	3.0
	Baringo	8	2.7
	Busia	8	2.7
	Trans Nzoia	14	4.7
	Others*	40	13.3
Marital Status	Married	235	78.3
	Widowed	38	12.7
	Single	16	5.3
	Unknown	11	3.7
Highest Education Level	Secondary	130	43.3
	Tertiary	87	29.0
	Primary	36	12.0
	Unknown	42	14.0
	None	5	1.7
Occupation	Housewife	84	28.0
	Farmer	48	16.0
	Not indicated	46	15.3
	Unknown	10	3.3
	Teacher	12	4.0
	Others**	100	33.3

*Others include: Kajiado (n = 3), Kisumu (n = 4), Laikipia (n = 3), Migori (n = 4), Murang'a (n = 2), Narok (n = 2), Nyamira (n = 5), Samburu (n = 2), Turkana (n = 3), Vihiga (n = 6), West Pokot (n = 6). **Others include: business (n = 32), health care worker (n = 8), student (n = 12), office worker (n = 18), driver (n = 10), other professionals (n = 20).

3.2. Reproductive History and Family History

The distribution between pre-menopausal (45.0%, n = 135) and post-menopausal (52.7%, n = 158) patients showed a slight predominance of post-menopausal women, with perimenopausal patients comprising only 0.7% (n = 2).

A positive family history of breast cancer in a first-degree relative was reported by only 5.7% (n = 17) of patients, while 86.0% (n = 258) reported no family history, and 8.3% (n = 25) had unknown status (**Table 2**).

Table 2. Reproductive history and family history of HER2-Positive breast cancer patients (N = 300).

Characteristic	Category	Frequency (n)	Percentage (%)
Menopausal Status	Pre-menopausal	135	45.0
	Post-menopausal	158	52.7
	Perimenopausal	2	0.7
	Unknown	5	1.7
Family History of Breast Cancer (First-degree)	Yes	17	5.7
	No	258	86.0
	Unknown	25	8.3
Total		300	100.0

3.3. Comorbidities

Hypertension was the most common comorbidity, present in 18.7% (n = 56) of patients, followed by diabetes mellitus in 8.3% (n = 25). Other chronic illnesses, including asthma, cardiac disease, epilepsy, thyroid disorders, and others, were present in 8.3% (n = 25) of patients, and HIV infection was documented in 6.7% (n = 20) of patients (Table 3).

Table 3. Comorbidities among HER2-positive breast cancer patients (N = 300).

Comorbidity	Present (n)	Present (%)	Absent/Unknown (n)	Absent/Unknown (%)
Hypertension	56	18.7	244	81.3
Diabetes Mellitus	25	8.3	275	91.7
HIV Positive	20	6.7	280	93.3
Other Chronic Illness*	25	8.3	275	91.7

*Includes asthma (n = 8), cardiac disease (n = 6), epilepsy (n = 4), thyroid disorders (n = 4), and others (n = 3).

3.4. Clinical Presentation

Breast lump was overwhelmingly the most common presenting symptom, reported by 97.0% (n = 291) of patients. Other symptoms were reported as follows: pain in 27.7% (n = 83), skin changes in 18.3% (n = 55), nipple discharge in 16.7% (n = 50), other symptoms in 24.0% (n = 72), and incidental finding in 0.7% (n = 2) (Table 4).

Table 5 presents the duration of symptoms before diagnosis. Among patients with documented symptom duration (n = 247, 82.3% of the total sample), 13.0% (n = 39) presented within 3 months of symptom onset, 29.3% (n = 88) presented between 3 and 6 months, 21.0% (n = 63) presented between 7 and 12 months, and 19.0% (n = 57) presented with symptoms for more than 12 months before diag-

nosis. The majority of patients (69.3% of those with documented duration) presented with symptoms lasting 3 months or longer, indicating significant delays in seeking medical attention. Notably, 19.0% of patients had symptoms for more than one year before receiving a diagnosis, representing a concerning delay that likely contributed to advanced stage at presentation (**Table 5**).

Table 4. Presenting symptoms among HER2-positive breast cancer patients (N = 300).

Symptom	Frequency (n)	Percentage (%)
Breast lump	291	97.0
Pain	83	27.7
Other (incidental, systemic)*	72	24.0
Skin changes (peau d'orange, dimpling)	55	18.3
Nipple discharge	50	16.7
Incidental finding	2	0.7

*Includes weight loss (n = 24), fatigue (n = 18), fever (n = 12), and others (n = 18). Note: Multiple presenting symptoms were allowed, so percentages sum to more than 100%.

Table 5. Duration of symptoms before diagnosis (N = 300).

Duration (months)	Frequency (n)	Percentage (%)
<3 months	39	13.0
3 - 6 months	88	29.3
7 - 12 months	63	21.0
>12 months	57	19.0
Unknown	53	17.7
Total	300	100.0

The majority of patients presented with left-sided breast cancer, accounting for 53.7% (n = 161) of cases, while right-sided breast cancer was observed in 39.0% (n = 117) of patients. Bilateral breast cancer was rare, occurring in only 1.3% (n = 4) of patients, and laterality was undocumented for 6.0% (n = 18) of patients (**Table 6**).

Table 6. Tumor laterality among HER2-positive breast cancer patients (N = 300).

Laterality	Frequency (n)	Percentage (%)
Left	161	53.7
Right	117	39.0
Bilateral	4	1.3
Unknown	18	6.0
Total	300	100.0

4. Discussion

This study provides a comprehensive description of the clinical characteristics of 300 HER2-positive breast cancer patients treated at Moi Teaching and Referral Hospital (MTRH) between January 2018 and December 2023. The findings reveal a population predominantly composed of young women, with 56.0% under 50 years of age and 32.3% under 40 years. This pattern of young-onset disease is consistent with the broader epidemiological profile of breast cancer in sub-Saharan Africa, where the mean age at diagnosis ranges from 45 to 52 years, substantially younger than the typical 62 - 64 years observed in high-income countries [15]. The predominance of HER2-positive disease in younger patients is consistent with findings from Ethiopia and other East African settings, where HER2-enriched tumors are more common in younger age groups [23]. The predominance of young patients has significant clinical implications, including more aggressive tumor biology, higher rates of *BRCA1/BRCA2* mutations, and the need for fertility preservation counseling and psychosocial support tailored to younger patients [24].

The majority of patients were married (78.3%), reflecting the general social structure in the Kenyan context where marriage is the norm for adult women. This finding is consistent with other Kenyan studies, such as Tuwei and Degu [19], who reported that 70% of HER2-positive breast cancer patients at Kenyatta National Hospital were married. The high proportion of married patients may have implications for social support and treatment outcomes, though caregiving responsibilities associated with marriage and childrearing may also compound the burden of cancer treatment [25].

Geographically, the majority of patients came from counties in the western region of Kenya, with Uasin Gishu County contributing the highest proportion (18.0%). This pattern reflects MTRH's role as the primary tertiary referral centre for cancer care in the region. The reliance on a single tertiary centre has important implications for access to care, as patients from distant counties face substantial logistical and financial barriers, including travel costs, accommodation expenses, and lost income during treatment [22].

Secondary education was the most common level of education (43.3%), and housewives (28.0%) and farmers (16.0%) were the predominant occupational groups. The predominance of informal sector employment highlights the economic vulnerability of this population and the potential for financial hardship associated with cancer treatment [26]. This socioeconomic profile underscores the need for financial support mechanisms, including health insurance coverage and social protection programs, to reduce the economic burden of cancer care for patients and their families.

Regarding reproductive history and menopausal status, the study found a near-equal distribution between pre-menopausal (45.0%) and post-menopausal (52.7%) patients. This distribution is consistent with the age profile of the cohort and reflects the distinct epidemiological profile of breast cancer in sub-Saharan Africa compared with high-income countries, where breast cancer predominantly

affects postmenopausal women [4]. The high proportion of pre-menopausal patients (45.0%) has significant clinical implications, including the potential need for ovarian function suppression, fertility preservation considerations, and the more aggressive tumor biology often associated with pre-menopausal status in HER2-positive breast cancer [27].

A positive family history of breast cancer in a first-degree relative was reported by only 5.7% of patients, consistent with the understanding that HER2 amplification is primarily a somatic event rather than a germline mutation [28]. However, the low reported rate may be influenced by incomplete documentation and limited awareness of cancer family history among patients [24].

Hypertension was the most common comorbidity (18.7%), followed by diabetes mellitus (8.3%), other chronic illnesses (8.3%), and HIV infection (6.7%). The prevalence of hypertension and diabetes in this cohort is consistent with the growing burden of non-communicable diseases in Kenya and has important implications for cancer treatment, as these comorbidities can increase the risk of cardiotoxicity from anthracycline-based chemotherapy and trastuzumab, necessitating careful cardiac monitoring during treatment [29]. The presence of HIV in 6.7% of patients has implications for treatment planning, as drug interactions and immune status considerations may influence the choice and timing of cancer therapy [24]. The high prevalence of comorbidities underscores the need for comprehensive multidisciplinary management approaches that address both cancer treatment and the management of underlying chronic conditions.

Breast lump was the predominant presenting symptom (97.0%), consistent with global patterns of breast cancer presentation [24] [30]. However, the high rates of pain (27.7%) and skin changes (18.3%) suggest advanced disease at presentation. Pain is often a symptom of advanced breast cancer and may indicate tumor invasion into surrounding tissues, while skin changes such as peau d'orange and dimpling are signs of dermal lymphatic invasion characteristic of inflammatory breast cancer or locally advanced disease [4].

The prolonged duration of symptoms before diagnosis is a critical finding: among patients with documented symptom duration (82.3% of the sample), the majority (69.3%) presented with symptoms lasting 3 months or longer, with 19.0% having symptoms for more than one year before diagnosis. This pattern of diagnostic delay is consistent with findings from other sub-Saharan African settings [24] [30] and reflects a combination of low breast cancer awareness, limited access to primary health care services, financial barriers, and inadequate referral pathways [31]. The low rate of incidental detection (0.7%) underscores the absence of organized breast cancer screening programs in the region, as most breast cancers are detected symptomatically [1]. The prolonged symptom duration has significant implications for prognosis, as delayed diagnosis allows tumors to progress to more advanced stages, reducing the likelihood of curative treatment and contributing to the poor survival outcomes observed in this population [4].

The majority of patients presented with left-sided breast cancer (53.7%), con-

sistent with global epidemiological patterns that report breast cancer occurs slightly more frequently in the left breast than the right breast [1]. Bilateral breast cancer was rare (1.3%), consistent with the reported incidence of synchronous bilateral breast cancer [32]. The laterality of breast cancer has implications for treatment planning, particularly with respect to radiation therapy, as left-sided breast cancer requires careful cardiac shielding during radiation to minimize the risk of radiation-induced cardiotoxicity [11]. The predominance of left-sided disease in this cohort underscores the importance of appropriate radiation planning and cardiac protection strategies for patients receiving post-mastectomy or breast-conserving radiation therapy.

5. Conclusions

The findings reveal a population that is predominantly young, married, and from the western region of Kenya, with significant socioeconomic vulnerabilities. The near-equal distribution of menopausal status, low prevalence of family history, and high burden of comorbidities reflect the complex clinical profile of this population. The predominance of breast lump as the presenting symptom, high rates of pain and skin changes, and prolonged duration of symptoms before diagnosis underscore the advanced stage at presentation and the urgent need for interventions to promote early detection, enhance breast cancer awareness, and strengthen health systems. These findings are consistent with patterns observed across sub-Saharan Africa and underscore the need for targeted interventions to improve outcomes for HER2-positive breast cancer patients in Kenya.

Recommendations

- 1) There is an urgent need to implement age-appropriate breast cancer care services tailored to young women with HER2-positive breast cancer, including fertility preservation counseling, psychosocial support groups, and interventions addressing the unique challenges faced by mothers with young children, given that 56.0% of patients were under 50 years and 32.3% were under 40 years.
- 2) Interventions to reduce diagnostic delays should be prioritized through community-based breast cancer awareness campaigns targeting both the public and health care providers, establishment of “fast-track” diagnostic pathways at primary and secondary health care facilities, and strengthened referral systems with patient navigation programs to guide patients through the diagnostic process.
- 3) Pre-Treatment evaluation and multidisciplinary management should be strengthened to address the high burden of comorbidities observed in this population, including standardized protocols for cardiac assessment, blood pressure control, glycemic management, and optimization of HIV care before initiating cancer therapy, with multidisciplinary tumor boards ensuring comprehensive treatment planning.
- 4) Health policy interventions should prioritize the decentralization of cancer services through establishment of regional cancer centres to reduce the burden of travel for patients from distant counties, and expansion of health insurance cov-

erage through the Social Health Authority to cover comprehensive cancer care, particularly for vulnerable populations such as housewives and farmers.

5) Health systems strengthening efforts should focus on improving data systems and cancer registration through implementation of comprehensive electronic medical records and strengthening hospital-based and national cancer registries with dedicated staffing, sustainable funding, and mechanisms for data quality assurance to support evidence-based decision-making in cancer care.

Author Contributions

Lordin Alumasa Wanjala: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Writing - original draft. Everisto Opondo: Supervision, Validation, Writing - review & editing. Janai Ondieki: Investigation, Resources, Writing - review & editing. Tracy Irura: Data curation, Formal Analysis, Writing - review & editing.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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