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Association of patient tumour characteristics and 5-Year survival in women with breast cancer in Nigeria: A retrospective cohort study

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Abstract
Objective: The sociodemographic and biological profile of breast cancer differ globally, especially in women of African descent. In Nigeria, limited studies explore the impact of these breast cancer-related factors on survival. This study evaluated the association between patients' tumour characteristics and survival in breast cancer patients in three regional tertiary cancer treatment centres across Nigeria.
Methodology: Data were extracted from patients' case files with a histopathologic diagnosis of breast cancer from January 1, 2005, to January 1, 2019. Patients' sociodemographic and clinical features were presented, and survival probabilities were reported; the Log-rank test was used to determine the association between time to death and categorical variables.
Results: The study included 1020 patients across the three centres. The five-year survival probability was 0.65, and the 95% C.I. was 0.60- 0.69. Most patients were between the ages of 30 and 49, and 49% presented with left-sided breast cancer. Patients aged>70 had significantly better survival. Only 40% had Immunohistochemistry (IHC) done, out of which HR+ breast cancer accounted for 43%, while triple-negative breast cancer was 30%. Patients who received Herceptin and had molecular subtyping (immunohistochemistry) done had a higher survival probability.
Conclusions: Most breast cancer patients in Nigeria present at earlier ages with advanced disease, and the 5-year survival rates are lower than global rates. Only a few patients have access to optimal breast cancer management. There is an urgent need to provide equitable access to cancer treatment by scaling up the implementation of the strategic framework on breast cancer screening and management.

Keywords: Breast cancer, Survival, Nigeria

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Plain English summary
This study investigated breast cancer survival rates and the factors affecting survival in Nigeria. The study analysed data from 1020 breast cancer patients across three regional cancer treatment centres in Nigeria. The study found that, compared to global figures, most patients presented with advanced disease at a younger age (mean age 49.6 years). The 5-year survival probability was 0.65 (65%), significantly lower than global rates. Patients who received targeted treatment (Herceptin) for HER2-positive breast cancer and hormonal therapy for oestrogen receptor-positive breast cancer had better survival outcomes. Limited access to optimal breast cancer management, including molecular subtyping and targeted treatment, contributes to poor survival rates.
The study concluded that there was an urgent need to improve breast cancer care in Nigeria by expanding the implementation of the strategic framework for breast cancer screening and management to increase access to optimal treatment and improve survival rates

Introduction
Breast cancer is the most common female malignancy globally (1, 2). In Nigeria, Breast cancer has overtaken cervical cancer as the leading female malignancy (3). About 100,000 new cancer cases occur annually in Nigeria, with a high case-fatality ratio (4, 5). With 20% of the population of Africa and slightly more than half the population of West Africa, Nigeria contributed 15% to the estimated 681,000 new cases of cancer that occurred in Africa in 2008 (8). In recent years, breast cancer survival rates have increased worldwide. In the United States, the five-year relative survival rates for women with breast cancer have increased from 75% in 1975-77 to about 90% in 2003-09 due to effective breast cancer screening programs which enable early diagnosis and treatment, following this, there has also been a decline in breast cancer mortality (6). In Nigeria, most breast cancer patients present with advanced disease, which often starts with a painless lump that is ignored for a long time (7, 8).

Breast cancer survival depends on factors like stage at diagnosis and axillary lymph node involvement. Breast cancers with different histopathological and biological features exhibit distinct behaviours that lead to varying treatment responses and directly impact survival. As a result, it should be treated with targeted therapeutic strategies. Thus, accurately grouping breast cancers into clinically relevant subtypes is essential for therapeutic decision-making. Classical immunohistochemistry (IHC) markers such as E.R., PR and HER2, together with traditional clinicopathological variables including, e.g., tumour size, tumour grade and nodal involvement, are conventionally used in patient management and to assess prognosis and survival. It is now widely accepted that there are four distinct intrinsic molecular subtypes: luminal A, luminal B, HER2-enriched, and basal-like breast cancer (BLBC) (19, 20, 21). Furthermore, Treatment modalities have evolved from more traditional treatments to targeted therapies based on the molecular subtype of cancer. Treatment modalities include surgery, chemotherapy, radiotherapy, hormonal therapy and targeted therapies.

The National Institute for Cancer Research and Treatment (NICRAT) was established in 2017 by the Federal Government of Nigeria to provide leadership in Cancer Control. The institute guides scientific improvement in cancer prevention, treatment, and care. Nigeria has a national strategic plan for preventing and controlling cancer (12, 13, 14). This comprehensive framework enumerates strategies to improve the country's cancer control program and has a budgetary allocation for implementation. Some state governments and non-governmental organisations also support free coverage, which is minimal. Health insurance coverage in Nigeria is limited, and comprehensive cancer care coverage is not offered. Many cancer patients pay out of pocket for cancer care. In 2020, the Nigerian Cancer Health Fund (CHF) (15) was created to enable standard-of-care cancer treatment to underprivileged populations. It provides access to funding for treatments, chemotherapy, and radiation therapy services for people with breast, cervical, and prostate cancers. It is being piloted in designated centres across the country. The National Health Insurance Scheme and private Insurance companies offer limited coverage for cancer treatment for a select few. Unfortunately, most patients still pay out of pocket for cancer treatment, contributing to poor survival from sub-optimal treatment (16, 17). There is a paucity of published studies exploring the impact of these cancer-related factors on breast cancer survival in Nigerian patients. These studies will serve as advocacy tools to inform health policies on the need to scale various currently available interventions in Nigeria. This descriptive analysis examines the association between patients' tumour characteristics and 5-year survival in breast cancer patients in Nigeria.

Methodology

Study population

This retrospective cohort study included 1020 breast cancer patients diagnosed at three Nigerian tertiary cancer centres, Lagos State University Teaching Hospital, Ikeja, Lagos. (LASUTH), The University of Nigeria Teaching Hospital, Enugu, Enugu State. (UNTH), National Hospital, Abuja (NHA). We included newly diagnosed patients with histopathologic confirmation of breast cancer from ages >18 years, and patients with second malignancies were excluded. We extracted data from patients' case notes from January 1, 2007, to August 2019; these included patients' sociodemographic information, such as age at diagnosis. Clinical data on the stage at diagnosis, IHC results, and treatment therapies received were also extracted. Many patients are often lost to follow-up in Nigerian hospitals. Patient tracking was done using the phone contact numbers of patients or their next of kin to ascertain patients' survival status. Informed consent was obtained over the phone before tracking. Ethical approval was obtained across the three institutions before the commencement of the study.

Statistical analysis

Data was entered into a data extraction Excel spreadsheet and was analysed using Stata version 14 software. Categorical data were presented in frequency and percentages, while numerical data were presented in mean, standard deviation, median, and interquartile range based on normal distribution patterns. The study event is death, and the time to event was measured from the time of histopathologic diagnosis to death, measured in months.

Outcome

The study outcome was to compute 5-year survival rates in breast cancer patients and assess the association between patient characteristics and survival. Overall survival was measured as time from the date of diagnosis to the date of death. This was censored at the last follow-up for surviving patients and those lost to follow-up as of August 30, 2019. Survival probabilities were reported, and restricted means were used if median survival was underestimated due to censored last observations. The Kaplan-Meier method was used to determine survival probability. A log-rank test was used to determine the association between time to death and categorical variables such as immunochemistry status, Herceptin use among patients with HER2-positive, and having IHC done at $p < 0.05$.

Results

Sociodemographic Characteristics

LASUTH contributed to the study's highest number of patients (41.96%) (see Table 1). NHA had the lowest frequency, with 167 patients (16.37%). Their ages ranged from 24 to 92 years; the mean age was 49.6. Regarding gender distribution, male patients comprised 1.3% of the study population. Only 3% of patients had bilateral breast cancer. The stage at diagnosis was unknown in 602 patients (59%). Of those patients with known stages at diagnosis, the majority were diagnosed at stage III (21.18%), followed by stage IV (12.75%) (Table 1)

Table 1: Socio-demographics of study participants (N=1020) from the three centres

Characteristics	Frequencies (n)	Percentages (%)
Age group (years)		
18-29	21	2.06
30-49	529	51.86
50-69	402	39.41
>70	68	6.67
Health Facility		
NHA	167	16.37
UNTH	425	41.67
LASUTH	428	41.96
Gender		
Male	14	1.37
Female	1006	98.63
Stage at diagnosis		
0	2	0.2
I	5	0.49
II	65	6.37

III	216	21.18
IV	130	12.75
Unknown	602	59.02
Side		
Bilateral		
Left	34	3.33
Right	508	49.8
Unknown	462	45.3
	16	1.57

Immunohistochemistry

Only 396 (38.8%) of the patients included in this study had immunohistochemistry done. About a century (103) patients were HER2/neu positive. Of these, 28.4% received targeted treatment with Herceptin (Trastuzumab). Most patients (43.7%) were HR+—and HER2-negative. The minority (10.6%) were triple-positive, and 30.3% were triple-negative (Table 2).

Table 2- Clinical characteristics of study participants N=1020

	Frequencies(N)	Percentages (%)
IHC done		
Yes	396	38.80
No	624	61.20
Immunohistochemistry (N=396)		
HR+- HER2+	61	15.40
HR+- HER2-	173	43.69
Triple-negative	120	30.30
Triple positive	42	10.61
Treatment of Her2 positive N=103		
Herceptin	38	37
Herceptin Naïve	65	63
Status		
Alive	247	24.22
Dead	246	24.12
Lost	527	51.67
Status of Herceptin treatment N: 38		
Completed	15	39.47
Discontinued	8	21.05
On treatment	2	5.26
Unknown	12	31.58
Declined	1	2.63
Chemotherapy		
Neoadjuvant	360	35.29
Adjuvant	373	36.57
Both	154	15.10
None	133	13.04

Neo-adjuvant and Adjuvant Therapy: 35.3% of all patients received neo-adjuvant therapy, 36.5% had adjuvant treatment, 15.1% had neoadjuvant and adjuvant treatment 13% had none. Most patients were lost to follow-up (51.27%). Two hundred forty-seven patients (24.2%) were still alive. With regards to hormonal therapy, less than a quarter of all breast cancer patients included in this study received hormonal therapy, 20.99% of patients had hormonal treatment, and most used Tamoxifen and Letrozole (72.65%); out of the Her2 positive patients (N=103); only 37% (38) received Herceptin. among the Her2 positive patients who received Herceptin, 15 (39.47%) completed treatment, 21%, discontinued and 2% were still on treatment at the time of this analysis (Table 2).

Survival probability after diagnosis: A statistically significant association between time to death and probability of survival was found. Survival rates were higher for patients in the earlier stages after diagnosis (Figure 1).

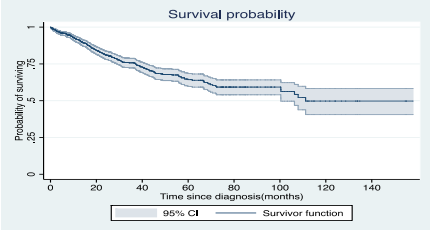


Figure 1. Five-year survival probability for all patients from the three centres

Survival probability based on Age group: A significant association between time to death and the patient's age group was found (p=0.039) (Figure 2).

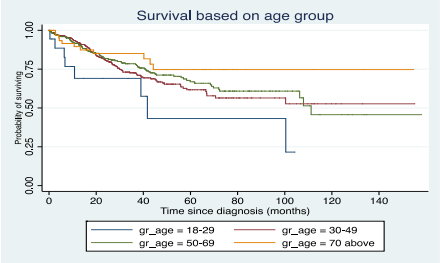


Figure 2a: Survival probability based on age group

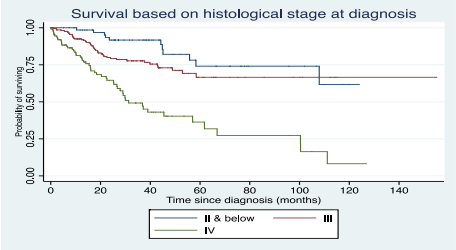


Figure 2b: Survival is based on the stage at diagnosis

Breast cancer patients within the age group 70 and above had a higher survival probability over the past five years than other age groups, 0.75 (95% CI: 0.58- 0.86). Different age groups are as follows: 50-69: 0.71 (95% C.I: 0.65-0.77), 30-49: 0.67 (95% C.I: 0.61-0.72), and 18-29 years: 0.41(95% C.I: 0.12-0.69).

Survival is based on the stage of diagnosis, immunohistochemistry status and molecular subtype.

A statistically significant association between time to death and stage at diagnosis was found (p <0.01) (Figure 3).

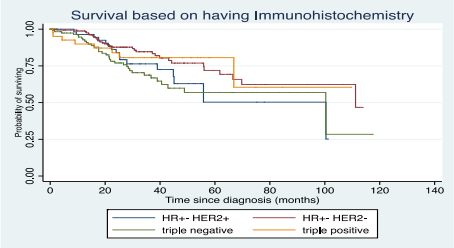


Figure 3a: Survival is based on immunohistochemistry

Among 418 patients with a known stage at diagnosis, breast cancer patients diagnosed at stage II and below had a higher survival probability over the past five years. The probability that a patient survived the past five years with Stage 2 below is 0.77 (95% CI: 0.59- 0.87), Stage 3 is 0.67 (95% CI: 0.56-0.75), and Stage 4 is 0.36 (95% CI: 0.23-0.49). Of the 38.8% who had Immunohistochemistry done, 43.69% were Hormone receptor-positive breast cancer (HR+-

HER2-), followed by triple-negative (30.3%), HER2-positive breast cancer (HR+- HER2+) (15.4%) and triple-positive as the least (10.61%). The survival probability of the past five years for patients with triple-positive: 0.80 (95% C.I: 0.63-0.90) was higher than other immunohistochemistry status, followed by HR+HER2 immunohistochemistry, 0.73; 95% C.I: 0.61- 0.81. Different IHC statuses have the following probabilities of surviving with their corresponding confidence Interval: HR+-HER2+: 0.54 (95% C.I: 0.31-0.72), triple-negative: 0.57 (95% C.I: 0.44-0.69). There was no statistically significant association between time to death and immunohistochemistry status (p=0.14)

Survival probability based on Hormonal treatment in Hormone receptor-positive and triple-positive breast cancer patients

Oestrogen receptor-positive patients who received hormonal therapy had a higher survival probability in the past five years than those who did not. A patient's probability of surviving the past five years after having hormonal therapy is 0.82; 95% C.I.: 0.74- 0.87 compared to those who did not, 0.58; 95% C.I.: 0.52-0.63. A statistically significant association was found between time to death and hormone therapy (p=0.01) (Figure 3b).

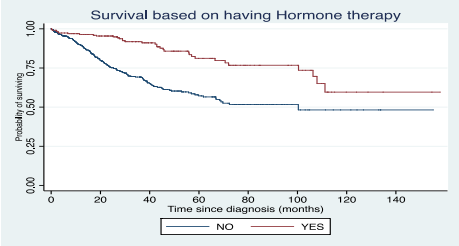


Figure 3b: Survival based on having hormone therapy

Survival based on targeted therapy (Herceptin) use in HER2-positive breast cancer.

Of those who had Immunohistochemistry done, 103 were HER2 positive (HER2+), and 38 received Herceptin treatment. HER-positive patients who reported using at least a dose of Herceptin had a higher survival probability over the past five years than those who never used Herceptin. The likelihood that a patient survived the past five years having used Herceptin among HER-positive patients is 0.70; 95% C.I.: 0.37- 0.88 compared to those who did not use 0.65; 95% C.I.: 0.47- 0.78. No significant association was found between time to death and Herceptin use among patients with HER2-positive status (p=0.55) (Figure 3c).

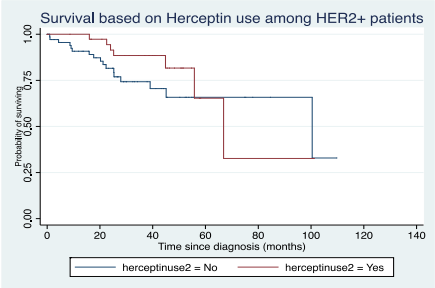


Figure 3c: Survival based on Herceptin use

Discussion

This study shows that breast cancer cases present at earlier ages, and the mean age of participants was 49.6 years, a close range to those from other Nigerian studies (18, 19, 20) but lower when compared to global figures, where countries like China, Japan, Iran, Fiji, and Morocco peaked in females aged 55-60 and, in the USA, Belgium, Australia, and the United Kingdom, were at the age of 70 years (21). The most affected breast was the left breast (49.8%), followed by the right breast (45.3%), as compared to a similar study done in the University College Hospital, Ibadan and in Northern Nigeria (22, 23). Up to half of the patients were lost to follow-up, reflecting the country's poor patient follow-up system. Many of the patients present late, predominantly at stage III, which is similar to findings in other centres in Nigeria (18, 19, 20). Several factors could be responsible for late presentation, such as herbal medicines, lack of

screening programs, late diagnosis and poverty. Therefore, setting up mechanisms for detecting breast cancer in the early stages of the disease is necessary. Most of the patients had no immunohistochemistry done before treatment; this was also observed in South-West Nigeria (19). This is presumed to be hindered by the cost implications of the test, limited access, and poverty, because most patients pay out of pocket for cancer treatment in Nigeria. Among the HER2+ patients, about half used Herceptin (targeted therapy for HER2-positive breast cancer), but not many completed the treatment; this could be a result of the cost implications of this treatment.

The probability that a patient survived the past five years is 0.65; 95% C.I.: 0.60- 0.69. This finding is across the country due to late presentation, leading to poorer survival (8). The molecular subtype is an essential factor in breast cancer management because it guides in selecting the type of chemotherapy given, targeted or hormone therapy. Determining E.R., PR, and HER2/neu receptor status in breast cancer has become common, as patients have a survival advantage (25). However, this study had no statistically significant association between time to death and immunohistochemistry status. This was most probably due to sub-optimal treatment across the different subtypes. As stated above, patients pay out of pocket for this financially toxic cancer treatment, affecting compliance. This study shows that most patients did not receive Herceptin, and for those who received it, most did not complete the treatment. Conversely, Estrogen receptor-positive patients who received hormonal therapy had a higher survival probability in the past five years because these tumours are less aggressive and have better outcomes.

Strengths

This study was conducted across three geopolitical zones in Nigeria, reflecting a national picture of breast cancer survival in Nigeria. Even though most centres still use paper-based record systems, we are confident of the rigorous data extraction process and that our study reflects Nigeria's breast cancer survival landscape.

Limitations

Most patients did not receive optimal cancer treatment for several reasons mentioned in this paper. Most patients were lost to follow-up due to poor patient follow-up and navigation processes in the country. Most public healthcare systems in Nigeria are paper-based and have yet to scale up to electronic medical record-keeping for research.

significantly lower than rates in other parts of the world. In the US & Canada, the 5-year net survival for breast cancer (all stages included) in women is 89% (21, 22). These survival rates for breast cancer reflect continued success in prevention, screening, and treatment in other parts of the world; unfortunately, rates are still low in Nigeria. The 5-year survival probability in stage 1& 2 breast cancer patients was 77% in this study. This shows that despite early presentation, the survival rate is still below global rates of 100%, primarily due to sub-optimal cancer treatment from out-of-pocket payments (21, 24). The most prevalent stage recorded in the study is stage III, a common finding

Most patients didn't have a clinical stage due to the unavailability of the case folders.

Conclusion

This study reflects the current picture of Breast cancer care in Nigeria. It shows that most breast cancer patients in Nigeria present at earlier ages with advanced disease. Regardless of patient tumour characteristics, 5-year survival rates are lower than global rates. The study shows improved treatment outcomes in patients with HER2+ breast cancer who received Herceptin. A limited number of patients have access to optimal breast cancer management in terms of molecular subtyping of breast cancer and targeted treatment. There is an urgent scale-up in the implementation of the strategic framework for breast cancer screening and management in Nigeria to improve Breast cancer survival.

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