

Prevalence and Predictors of Triple-Negative Breast Cancer Among Sudanese Women: A Retrospective Analysis of Newly Diagnosed Cases

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Purpose: Triple-negative breast cancer (TNBC) is an aggressive subtype with limited treatment options and a poor prognosis. Data on TNBC in Sudan are scarce. This study assessed the prevalence and predictors of TNBC and other molecular subtypes (Luminal A, Luminal B, and HER2-enriched) in relation to histopathological patterns, age at diagnosis, and sociodemographic risk factors.

Methods: A retrospective, single-center study was conducted of 1480 women diagnosed with breast cancer between 2016 and 2021. Histological subtypes included carcinoma in situ (CIS), invasive ductal carcinoma (IDC), invasive lobular carcinoma (ILC), or medullary carcinoma (MC). Estrogen receptor (ER), progesterone receptor (PR), and HER2 status were determined by immunohistochemistry. Multivariate logistic regression identified predictors of TNBC.

Results: TNBC accounted for 21% (n=307; mean age, 49 years) of all cases. Luminal A tumors represented 49% (n=722; mean age, 55), Luminal B 16% (n=237; mean age, 51), and HER2-enriched 14% (n=214; mean age, 50). TNBC was particularly frequent in MC (77%) compared to IDC (21%), CIS (20%), and ILC (15%). In multivariate analysis, younger age was a significant predictor of TNBC; each additional year of age reduced the odds by approximately 3% (Adjusted Odds Ratio [AOR]=0.97; 95% CI: 0.96–0.99; p<0.001). Histological subtype was also a significant determinant, with MC showing the strongest association with TNBC compared to other diagnoses.

Conclusion: TNBC is highly prevalent among Sudanese women, especially those younger than 50 years and those with MC. These findings underscore the importance of early diagnosis and wider access to molecular profiling to guide treatment in low-resource settings.

Keywords: triple-negative breast cancer, Sudanese women, histological subtypes, immunohistochemistry, medullary carcinoma, breast cancer epidemiology

Introduction

Breast cancer (BC) is the most frequently diagnosed cancer in women and remains a significant health challenge worldwide.^{1,2} It affects women's lives, regardless of race, income, and geography, but outcomes vary significantly; not all women have the same chance of survival.^{3,4} In low-resource settings, limited access to screening, early diagnosis, and treatment means that women are often diagnosed at later stages, and survival rates are significantly lower.^{5–9} This disparity is even more evident in sub-Saharan Africa, which has experienced a rapid rise in BC cases in recent years.^{10–13}



In Sudan, many women are diagnosed when the disease has already progressed to an advanced stage, including distant metastasis, which is one of the main contributors to the country's high mortality rate.^{14,15} The underlying reasons are complex yet painfully familiar, including insufficient healthcare infrastructure, widespread poverty, and deep-rooted inequalities in how care is delivered.¹⁵ Furthermore, preventive screening is uncommon, and limited public awareness leaves many women either unaware of their risk or unable to obtain timely diagnostic services.^{16,17} Additionally, cultural beliefs, cancer-related stigma, and reliance on traditional or spiritual healing practices may further delay care-seeking.¹⁵ The situation has worsened further since April 2023, when conflict and political instability escalated, and many hospitals were affected, making it even more difficult for women to receive the care they desperately need.¹⁸

Breast cancer is a highly heterogeneous disease comprising multiple molecular and histological subtypes, each of which exhibits distinct variations in biological behavior, aggressiveness, and clinical outcomes.^{19–21} These subtypes reflect underlying variations in gene expression profiles and are often linked to high tumor grade, necrosis, rapid mitotic activity, and a storm of immune cell infiltration.¹⁹ Molecular subtypes are classified based on the expression of estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2), including receptor-positive subtypes (luminal A, luminal B, and HER2-enriched) and the receptor-negative subtype, triple-negative breast cancer (TNBC).^{19,21,22} TNBC is a particularly aggressive subtype characterized by a lack of ER, PR, and HER2 expression, which are key targets in conventional BC treatment.^{19,23,24} As comprehensive gene profiling of tumors is often expensive and not always feasible, particularly in low-resource settings, immunohistochemistry (IHC) is frequently used as a practical stand-in to identify TNBC subtypes, serving as a surrogate for basal-like tumors.¹⁹ Unfortunately, patients with TNBC often experience relatively higher mortality and poorer survival rates than those with the other subtypes.^{19,23,24} Unlike receptor-positive breast cancers, which respond to hormonal therapies and HER2 inhibitors, TNBC is a therapeutic challenge, underscoring the need for a deeper understanding of its epidemiology and molecular features.^{25,26}

Beyond molecular differences, BC is also categorized by histopathological features, including how the tumor appears under the microscope, its anatomical origin, and the growth pattern within the breast.^{27–29} These subtypes include carcinoma in situ (CIS), invasive ductal carcinoma (IDC), invasive lobular carcinoma (ILC), medullary carcinoma (MC), and other mixed carcinomas.^{27–30} CIS represents the earliest non-invasive subtype, which is typically detected by screening mammography and confirmed by biopsy.^{31,32} When caught early, it can often be cured through surgery and, in some cases, hormone therapy.^{33–36} Although CIS generally has a favorable prognosis, triple-negative (TN) variants of CIS may still be linked to poor outcomes even when detected early.³⁷ Invasive ductal carcinoma is the most common subtype of BC, accounting for 70–80% of all cases, followed by ILC.^{30,38} MC, on the other hand, is a rare but aggressive subtype. It tends to affect young women, particularly those with inherited BRCA1 gene mutations.³⁹ Compared to IDC, medullary breast cancers are more likely to be TN, highlighting the need for early diagnosis and customized treatment plans.^{40,41}

This study integrates epidemiological and histopathological perspectives to provide a more comprehensive understanding of BC subtypes in Sudan. It aims to assess the frequency and distribution of the TNBC and other subtypes (Luminal A, Luminal B, and HER2-enriched), as well as histological classifications such as CIS, IDC, ILC, MC, and others. Additionally, we examined how these subtypes vary in terms of sociodemographic characteristics, age at diagnosis, and potential predictors.

Materials and Methods

Study Design and Setting

This retrospective study was conducted using medical chart data from the Khartoum Breast Care Center (KBCC), which included women diagnosed with BC between 2016 and 2021. KBCC is a nonprofit, specialized, interdisciplinary BC center in Sudan equipped with digital mammography and offering triple assessment (clinical examination, imaging, and core needle biopsy). The study was approved by the Institutional Review Board (IRB) of the KBCC (reference number KBCC/IRB 06–2021), and all patient data were de-identified prior to analysis in accordance with the Declaration of Helsinki.

All imaging, histopathological diagnoses, and hormone receptor evaluations were performed and confirmed at the KBCC. Histological and immunohistochemical reports were independently reviewed and verified by two board-certified pathologists to ensure diagnostic accuracy and quality control. Cases with incomplete information were excluded, and a total of 1,480 patients with fully documented ER, PR, and HER2 status were included in the final analysis.

Tissue Processing and Histopathology

Core needle biopsies were performed under ultrasound guidance by a board-certified radiologist. The specimens were fixed in 10% neutral buffered formalin and processed in the KBCC histopathology laboratory using a Leica TP1020 tissue processor (RRID: SCR_024535). Samples were embedded in paraffin using a Leica EG1150 (RRID: SCR_020227), sectioned at a thickness of 4–5 μm using a Leica RM2125 rotary microtome (RRID: SCR_018040), mounted on glass slides, dried, and stained with hematoxylin and eosin (H&E). Histological classification was performed by board-certified pathologists according to the guidelines of the Royal College of Pathologists (RCPath) and the NHS Breast Screening Program dataset for breast pathology reporting and breast core biopsy interpretation (B-coding system).⁴² Evaluation included assessment of tumor grade, mitotic index, nuclear pleomorphism, and necrosis.

Diagnoses were classified as follows:

Carcinoma in situ (CIS): non-invasive lesions confined to ducts or lobules (B5a), including ductal carcinoma in situ (DCIS) and lobular carcinoma in situ (LCIS), both characterized by marked nuclear pleomorphism.

Invasive ductal carcinoma (IDC): malignant invasion, where cells invade the surrounding stroma (B5b).

Invasive lobular carcinoma (ILC): malignant cells invading in a single-file growth pattern (B5b).

Medullary carcinoma (MC): a rare, aggressive subtype with syncytial growth and prominent lymphoplasmacytic infiltrate (B5b).

Other subtypes: include inflammatory, intracystic papillary, invasive cribriform, invasive histiocytoid, invasive papillary, invasive tubular, metaplastic, mixed, mucinous (colloid), and scirrhous carcinomas.

Hormonal Receptor Assessment

Hormone receptor status was determined using IHC to evaluate nuclear staining for ER and PR, and membrane staining for HER2. IHC was performed according to Dako's protocol using the EnVision FLEX high pH mini kit (#GV82311-5, Dako Omnis/Agilent Technologies, CA, USA), which includes hematoxylin, secondary antibodies, and DAB+ chromogen for visualization. The following primary antibodies were used: monoclonal rabbit anti-human estrogen receptor α clone EP1 (#GA08461-5, RRID: AB_2617140; Dako Omnis/Agilent), monoclonal mouse anti-human progesterone receptor clone PgR 1294 (#GA09061-5; RRID: AB_2252608, Dako Omnis/Agilent), and polyclonal rabbit anti-human c-erbB-2/c-neu (#A048529-1, RRID: AB_2335701, Dako Omnis/Agilent).

ER and PR expression were evaluated using the Allred scoring system, which combines the proportion and intensity of tumor cell staining for a total score (range 0–8); scores of 0–2 were classified as negative, and scores of 3–8 as positive. HER2 status was assessed based on the membrane staining intensity and scored as 0/1+ (negative), 2+ (equivocal), or 3+ (positive) following ASCO/CAP guidelines.

Fluorescence in situ hybridization (FISH) was recommended for HER2 equivocal (2+) cases; however, this test was not routinely available at KBCC, and patients were referred to external laboratories when possible. Some patients could not afford FISH confirmation due to financial constraints. Only HER2-negative, HER2 3+ positive, or HER2 2+ cases with FISH-confirmed amplification were included in this study.

Molecular subtypes were defined as:

Luminal A: ER and/or PR positive, HER2 negative

Luminal B: ER and/or PR positive, HER2 positive

HER2-enriched: ER and PR negative, HER2 positive

Triple-negative breast cancer (TNBC): ER, PR, and HER2 negative

Sociodemographic Data

Sociodemographic variables included age at diagnosis, employment status, marital status, and geographical origin. The geographic locations were categorized into five regions: Khartoum, River Nile and Red Sea States, Darfur, Nuba Mountains, and international (outside Sudan). The ages of patients at diagnosis ranged from 18 to 90 years, with the mean and standard deviation (SD) reported in the results section.

Statistical Analyses

Descriptive statistics summarize the study variables. Categorical variables (eg, histological subtype, molecular profile, marital status, occupation, and place of residence) were reported as frequencies and percentages, while continuous variables (eg, age) were presented as means with SD.

Associations between molecular subtypes and categorical variables were tested using chi-square or Fisher's exact tests. One-way analysis of variance (ANOVA) was used to compare age differences across the molecular subtypes (Luminal A, Luminal B, HER2-enriched, and TNBC), followed by Tukey's test for post hoc multiple comparisons. Assumptions of normality and homogeneity of variance were verified.

A multivariate logistic regression model was used to analyze the prevalence of TNBC. Five risk factors were considered, including age (years), marital status (divorced, married, single, or widowed), occupation (employed or homemaker), histological subtype, and place of residence. Statistical significance was set at $p < 0.05$, and 95% confidence intervals (CIs) of the adjusted odds ratios (AORs) were reported. No collinearity was observed between covariates.

Missing data were handled using the multiple imputation method with the R package mice, and the final regression results were pooled based on 10 imputation runs. Because this was a retrospective study, no a priori power calculation was performed. Instead, we assessed model adequacy post hoc using the events-per-variable (EPV) approach, which indicated sufficient model stability given the number of TNBC cases relative to included predictors. Since this was a descriptive retrospective observational study, randomization was not applicable. Pathologists evaluating receptor status were blinded to patients' demographics.

Analyses were performed using SAS software (version 9.4 M7; SAS Institute Inc., Cary, NC, USA, RRID: SCR_008567) and R software (version 4.5.1; R Core Team; RRID: SCR_001905). Data cleaning, visualization plots (package: ggplot2), and the multivariate logistic regression (package: stats) with the multiple imputation (package: mice) were conducted in R.

Results

Demographic Characteristics

A total of 1,480 women with newly diagnosed breast cancer (BC) were included in this study. The mean age at diagnosis was 53 years (95% CI: 51.9–53.3). Most patients were married (70%; 95% CI: 67.7–72.3) and homemakers (72%; 95% CI: 69.8–74.3). Geographically, more than half of the cohort (55%; 95% CI: 52.8–57.9) originated from the River Nile and Red Sea regions, followed by Khartoum (36%; 95% CI: 33.3–38.2). The prevalence of TNBC across demographic categories ranged from 16% to 27%; however, chi-square analysis revealed no statistically significant associations with marital status, occupation, or place of residence ([Table S1](#)).

Histological and Molecular Subtypes of Breast Cancer

Invasive ductal carcinoma (IDC) was the most predominant histological subtype, accounting for 76% of all cases (95% CI: 73.8–78.2). ILC and CIS each represented 9% (95% CI: 7.3–10.2), while MC was identified in 0.9% of cases (95% CI: 0.04–1.4). Among molecular subtypes, Luminal A tumors were the most prevalent, comprising 49% ($n = 722$; 95% CI: 46.2–51.3). Luminal B tumors occurred in 16% ($n = 237$; 95% CI: 14.1–17.9), while TNBC was found in 21% of patients ($n = 307$; 95% CI: 18.7–22.8). HER2-enriched tumors accounted for 14% ($n = 214$; 95% CI: 12.7–16.3) ([Table 1](#)). TNBC distribution varied notably by histological subtype ([Figure 1](#)): TNBC was present in 77% of MC cases, compared with 21% of IDC cases, 20% of CIS cases, 15% of ILC cases, and 15% of other rare subtypes.

Table 1 Distribution of Breast Cancer Cases by Histological and Molecular Subtypes Among 1,480 Sudanese Women Diagnosed Between 2016 and 2021

Histological Subtype	Total	Molecular Subtype			
		TNBC	Luminal A	Luminal B	HER2-Enriched
CIS					
n	129	26	71	11	21
%	8.7	20.2	55.0	8.5	16.3
95% CI	7.3–10.2	13.2–27.1	46.4–63.6	3.7–13.4	9.9–22.7
IDC					
n	1,125	239	495	218	173
%	76	21.2	44.0	19.4	15.4
95% CI	73.8–78.2	18.9–23.6	41.1–46.9	17.1–21.7	13.3–17.5
ILC					
n	139	21	102	4	12
%	9.4	15.1	73.4	2.9	8.6
95% CI	7.9–10.9	9.1–21.1	66.0–80.7	0.1–5.7	4.0–13.3
MC					
n	13	10	2	0	1
%	0.9	76.9	15.4	0	7.7
95% CI	0.4–1.4	54.0–99.9	0-35.0	—	0-22.2
Other*					
n	74	11	52	4	7
%	5	14.9	70.3	5.4	9.5
95% CI	3.9–6.1	6.8–23.0	59.8–80.7	0.2–10.6	2.8–16.1
Total of all cases					
n	1,480	307	722	237	214
%	100	20.7	48.8	16.0	14.5
95% CI	—	18.7–22.8	46.2–51.3	14.1–17.9	12.7–16.3

Notes: *Other includes the following diagnoses: inflammatory carcinoma, intracystic papillary carcinoma, invasive cribriform carcinoma, invasive histiocytoid carcinoma, invasive papillary carcinoma, invasive tubular carcinoma, metaplastic carcinoma, mixed carcinoma, mucinous (colloid) carcinoma, and scirrhous carcinoma.

Abbreviations: IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; CIS, carcinoma in situ; MC, medullary carcinoma; TNBC, triple-negative breast cancer; CI, confidence interval.

Age Distribution

The age at diagnosis differed significantly across both histological and molecular subtypes (ANOVA, $p < 0.05$). Women with ILC were generally older than those with CIS or IDC. Across receptor groups, TNBC patients had the youngest mean age at diagnosis (49 years; 95% CI: 47.7–50.7), followed by HER2-enriched tumors (50 years; 95% CI: 48.2–51.4), Luminal B tumors (51 years; 95% CI: 49.5–52.8), and Luminal A tumors (55 years; 95% CI: 54.4–56.3). Post hoc analysis showed that TNBC patients were significantly younger than those with Luminal A tumors (Tukey's test, $p <$

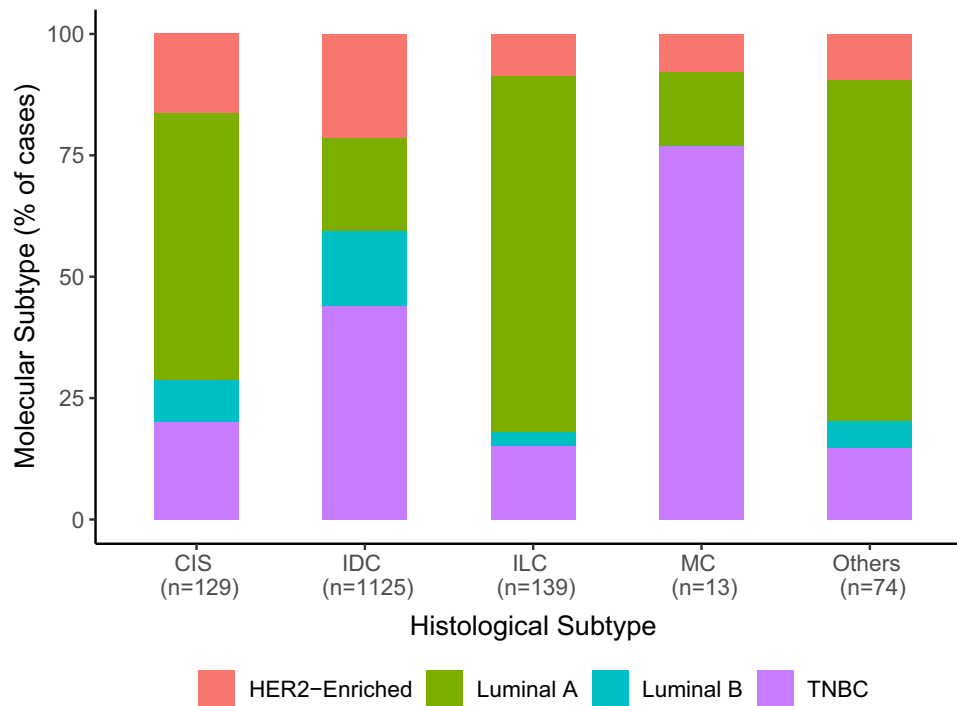


Figure 1 Distribution of breast cancer cases by histological and molecular subtypes among 1,480 Sudanese women diagnosed between 2016 and 2021. The stacked bar charts show the percentages of molecular subtypes—Luminal A, Luminal B, HER2-enriched, and TNBC—within each histological category: carcinoma in situ (CIS); invasive ductal carcinoma (IDC); invasive lobular carcinoma (ILC); medullary carcinoma (MC); and others.

0.01) (Table 2). As shown in Figure 2, the age distribution of TNBC cases was skewed toward younger women, with a substantial proportion diagnosed before age 55.

Within the TNBC group, additional age differences were observed by sociodemographic factors. Employed women were diagnosed at a younger mean age (49 years; 95% CI: 48.1–50.2) compared with unemployed/homemakers (54

Table 2 Mean Age at Diagnosis Across Histological and Molecular Subtypes Among 1,480 Sudanese Women Diagnosed with Breast Cancer Between 2016 and 2021

Histological Subtype	Age	Total	Molecular Subtype			
			TNBC	Luminal A	Luminal B	HER2-Enriched
Total	Mean	52.6	49.2	55.4	51.2	49.8
	95% CI	51.9–53.3	47.7–50.7	54.4–56.3	49.5–52.8	48.2–51.4
CIS	Mean	51.7	52.0	53.2	45.4	49.9
	95% CI	49.7–53.8	46.1–57.9	50.6–55.8	39.4–51.3	45.7–54.2
IDC	Mean	52.2	49.1	54.7	51.3	50.3
	95% CI	51.4–53.0	47.4–50.8	53.6–55.9	49.6–53.1	48.5–52.2
ILC	Mean	53.8	46.7	56.5	54.3	42.7
	95% CI	51.6–56.0	41.5–51.9	54.0–59.0	26.3–82.2	37.6–47.8
MC	Mean	51.0	51.8	55.0	—	35.0
	95% CI	41.0–61.0	40.2–63.4	—	—	—

(Continued)

Table 2 (Continued).

Histological Subtype	Age	Total	Molecular Subtype			
			TNBC	Luminal A	Luminal B	HER2-Enriched
Other*	Mean	58.1	45.7	61.9	56.3	50.4
	95% CI	54.6–61.6	40.1–51.4	58.0–65.8	27.4–85.1	33.8–67.0

Notes: *Other includes the following diagnoses: inflammatory carcinoma, intracystic papillary carcinoma, invasive cribriform carcinoma, invasive histiocytoid carcinoma, invasive papillary carcinoma, invasive tubular carcinoma, metaplastic carcinoma, mixed carcinoma, mucinous (colloid) carcinoma, and scirrhous carcinoma.

Abbreviations: IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; CIS, carcinoma in situ; MC, medullary carcinoma; TNBC, triple-negative breast cancer; CI, confidence interval.

years; 95% CI: 53.1–54.7). Marital status revealed the same trends: single women diagnosed with TNBC had the youngest age at presentation (43 years; 95% CI: 36.3–49.7), whereas widowed patients were older (62 years; 95% CI: 58.1–65.8) ([Table S2](#)).

Predictors of TNBC

In the multivariate logistic regression model ([Table 3](#) and [Figure 3](#)), younger age was a significant predictor of TNBC; each additional year of age decreased the odds of TNBC by approximately 3% (AOR = 0.97; 95% CI: 0.96–0.99, $p < 0.001$).

Histological subtype was also strongly associated with TNBC. Using MC as a reference group, all other subtypes showed significantly lower odds of being triple-negative, including CIS (AOR = 0.08; 95% CI: 0.02–0.36), IDC (AOR = 0.08; 95% CI: 0.02–0.31), ILC (AOR = 0.06; 95% CI: 0.01–0.24), and other subtypes (AOR = 0.07; 95% CI: 0.01–0.32) (all $p < 0.001$). No significant associations were found between TNBC and the other variables, including marital status, occupation, or place of residence, in the adjusted model ($p > 0.05$).

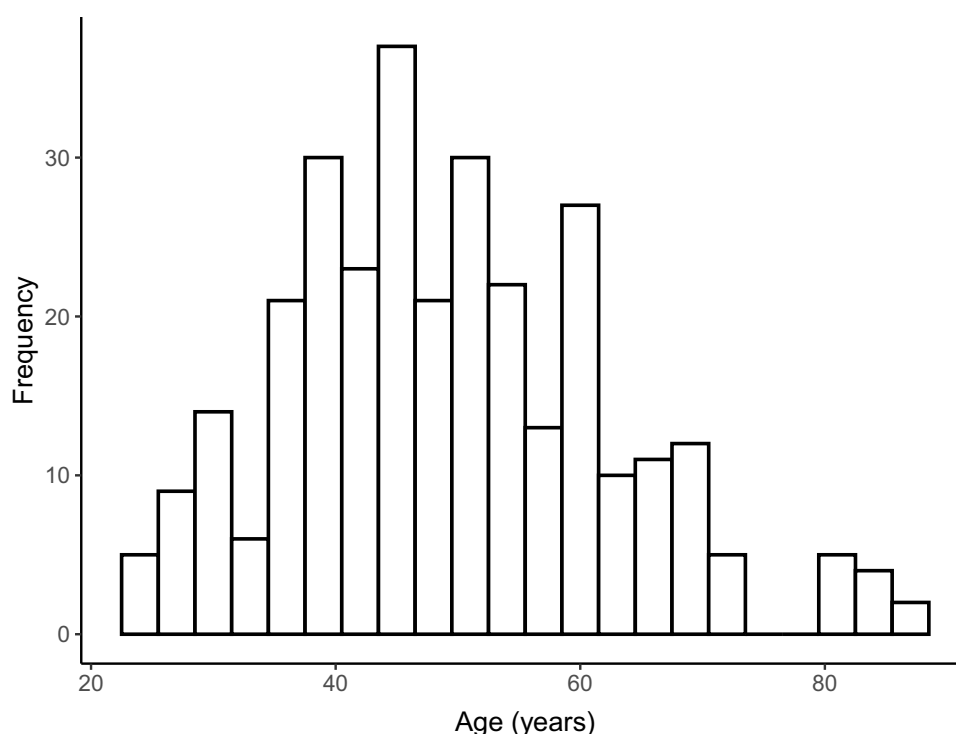


Figure 2 Histogram showing the frequency distribution of triple negative breast cancer (TNBC) by age (years) among Sudanese women diagnosed between 2016 and 2021.

Table 3 Multivariate Logistic Regression Analysis of Factors Associated with Triple-Negative Breast Cancer (TNBC) Among 1,480 Sudanese Women Diagnosed Between 2016 and 2021

	Adjusted Odds Ratio*	p-value
Intercept	—	—
Age	0.97 (0.96, 0.99)	<0.001
Marital Status		
Divorced	—	—
Married	0.98 (0.60, 1.60)	0.94
Single	0.85 (0.46, 1.56)	0.59
Widowed	0.97 (0.54, 1.73)	0.91
Occupation		
Employed	—	—
Homemaker	0.92 (0.69, 1.23)	0.58
Histopathological Subtype		
Medullary Carcinoma	—	—
In Situ	0.08 (0.02, 0.36)	<0.001
Invasive Ductal Carcinoma	0.08 (0.02, 0.31)	<0.001
Invasive Lobular Carcinoma	0.06 (0.01, 0.24)	<0.001
Other	0.07 (0.01, 0.32)	<0.001
Place of Residence		
Darfur	—	—
Khartoum	0.88 (0.51, 1.51)	0.64
Nuba Mountains	0.81 (0.28, 2.35)	0.70
River Nile and Red Sea States	0.85 (0.49, 1.46)	0.55
Outside	1.19 (0.36, 3.87)	0.78

Notes: *The interval following each adjusted odds ratio represents the corresponding 95% confidence interval. The model adjusted for age, marital status, occupation, histological subtype, and place of residence.

Carcinoma in situ

Among the 129 CIS cases, ductal carcinoma in situ (DCIS) was the most prevalent subtype ($n = 115$), followed by lobular carcinoma in situ (LCIS) ($n = 12$), and mixed DCIS/LCIS ($n = 2$). Within the CIS group, TNBC was identified in 20% of cases, including 19% of patients with DCIS showing a TN profile (Table 4).

The mean age at diagnosis varied by molecular subtype among CIS cases, although the differences were not statistically significant (ANOVA, $p > 0.05$). The youngest age was observed in Luminal B (45 years), followed by TNBC patients (52 years), Luminal A (53 years), and HER2-enriched tumors (50 years) (Table 5).

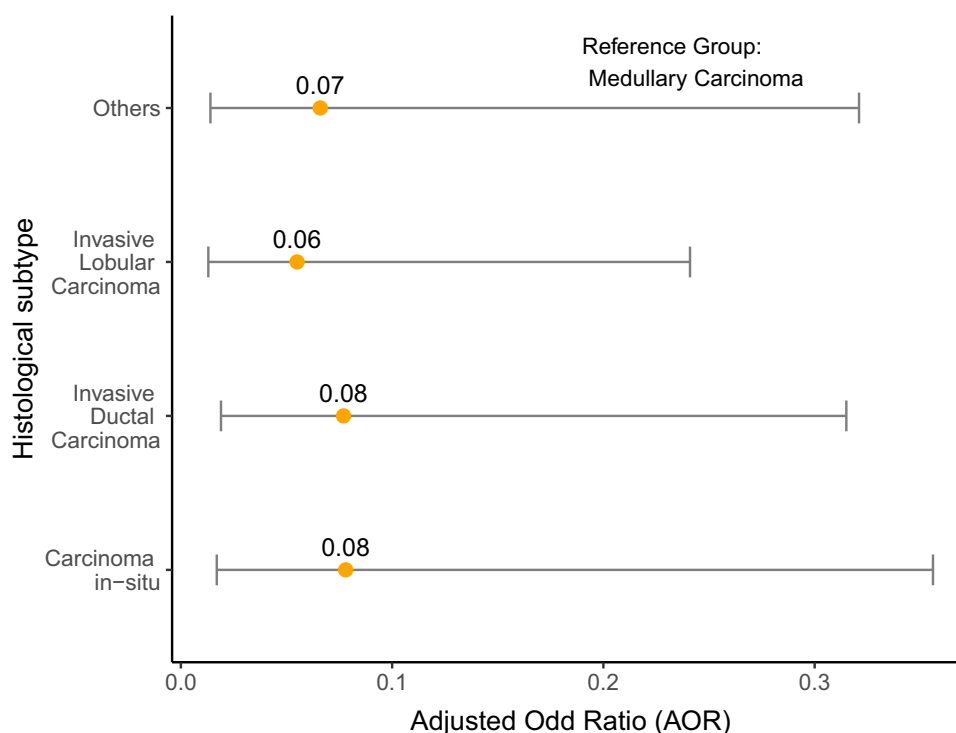


Figure 3 Forest plot displaying adjusted odds ratios (AORs) with 95% confidence intervals (CI) for predictors of triple negative breast cancer (TNBC) among Sudanese women diagnosed between 2016 and 2021. Each point represents the AOR derived from the multivariate logistic regression model, and the horizontal lines denote the corresponding 95% CI. The model was adjusted for age, marital status, occupation, and place of residence. Medullary carcinoma (MC) served as the reference category for histological subtypes.

Abbreviations: AOR, adjusted odds ratio; CI, confidence interval; TNBC, triple-negative breast cancer; MC, medullary carcinoma.

Discussion

This study establishes TNBC prevalence and clinicopathological characteristics of triple-negative breast cancer (TNBC) in Sudan and provides baseline data that can guide national cancer control strategies—particularly in screening, diagnostic testing, and treatment allocation. The findings also enable comparative epidemiology with other African

Table 4 Molecular Subtype Distribution Among Carcinoma in situ (CIS) Cases, 2016–2021

		Total	Molecular Subtype			
			TNBC	Luminal A	Luminal B	HER2-Enriched
Total CIS	n	129	26	71	11	21
	%	100	20.2	55.0	8.5	16.3
	95% CI	—	13.1–27.2	46.3–63.7	3.6–13.4	9.8–22.7
DCIS	n	115	22	62	11	20
	%	89.1	19.1	53.9	9.6	17.4
	95% CI	83.7–94.6	11.8–26.4	44.7–63.1	4.1–15.0	10.4–24.4
LCIS	n	12	3	8	0	1
	%	9.3	25.0	66.7	0	8.3
	95% CI	4.2–14.4	0.2–49.8	39.6–93.7	—	0.0–24.2

(Continued)

Table 4 (Continued).

		Total	Molecular Subtype			
			TNBC	Luminal A	Luminal B	HER2-Enriched
Mixed CIS (DCIS + LCIS)	n	2	1	1	0	0
	%	1.6	0.5	0.5	0	0
	95% CI	0-3.7	0.0–100.0	0.0–100.0	—	—

Abbreviations: DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ; TNBC, triple-negative breast cancer; CI, confidence interval.

Table 5 Mean Age at Diagnosis of Carcinoma in situ (CIS) Cases by Molecular Subtype, 2016–2021

		Total	Molecular Subtype			
			TNBC	Luminal A	Luminal B	HER2-Enriched
Age						
Total CIS	Mean	51.7	52.0	53.2	45.4	49.9
	95% CI	49.7–53.8	46.1–57.9	50.6–55.8	39.4–51.3	45.7–54.2
	Median	52.0	49.5	55.0	40.0	45.0
DCIS	Mean	52.2	53.2	53.7	45.4	50.2
	95% CI	50.1–54.3	46.9–59.6	51.0–56.5	39.4–51.3	45.8–54.6
	Median	52.0	51.5	55.5	40.0	47.5
LCIS	Mean	49.3	50.0	49.8	—	44.0
	95% CI	41.5–57.2	11.0–89.0	39.0–60.5	—	—
	Median	46.5	43.0	50.5	—	44.0
Mixed (DCIS + LCIS)	Mean	39.0	31.0	47.0	—	—
	95% CI	—	—	—	—	—
	Median	39.0	31.0	47.0	—	—

Abbreviations: DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ; TNBC, triple-negative breast cancer; CI, confidence interval.

and global cohorts, contributing to discussions on genetic and ethnic variation in TNBC burden. In our cohort, TNBC accounted for 21% of all cases, which is substantially higher than the 10–15% range reported in the United States (US) across all racial groups.^{43,44} This elevated prevalence aligns with the pattern observed in women of African descent, who face a disproportionately higher burden of TNBC, regardless of whether they live in sub-Saharan Africa or in Western countries.^{45,46}

In the US, numerous studies have provided valuable insights into the burden of TNBC among African American women.^{19,47–52} For instance, Swede et al reported that TNBC was more prevalent among black patients than white patients and was associated with poorer clinical outcomes and higher mortality rates. Furthermore, the study highlighted a two-fold higher frequency of ER-/PR- phenotypes among Black patients.¹⁹ However, only a few studies have explored the epidemiology of TNBC in Africa.^{11,50,53,54} A meta-analysis by Hercules et al estimated the pooled frequency of TNBC across Africa to be 27%, with regional variation being highest in West Africa (45.7%) and lowest in Central Africa (14.9%).⁵⁴

Mohammed and Harford noted that discrepancies in positive and negative hormone receptor results reported across African studies may, in part, be due to technical limitations in receptor testing. In particular, the use of archived tissue samples can lead to false-negative results, potentially inflating estimates of TNBC prevalence.⁵³ In contrast, all testing reported in our study was performed under an established diagnostic workflow with strict quality control, thereby minimizing this bias. At the center, ultrasound-guided core biopsies are processed promptly and stained within the same facility, ensuring consistency and improving the reliability of receptor assessment. Pathologists also routinely report other histopathological features associated with TNBC, such as high tumor grade or high mitotic activity, which could serve as additional surrogate markers for the aggressive basal-like phenotype beyond ER/PR/HER2 immunohistochemistry.

In this study, invasive ductal carcinoma (IDC) was the most common histological subtype, accounting for 76% of all diagnoses. This percentage is slightly lower than the 82% previously reported in Sudan but aligns with a 2020 study that recorded an IDC prevalence of 70%.^{55,56} Among patients with IDC, 21% exhibited a TN receptor profile, compared to 15% in ILC cases; however, in our regression analysis, neither IDC nor ILC showed a statistically significant difference in the odds of being TNBC. In contrast, previous studies have consistently shown that patients with lobular carcinoma are less likely to have TNBC than those with ductal tumors.^{19,57} A comparative study between German and Sudanese women focusing on IDC further reported TNBC as a frequent subtype associated with aggressive clinicopathologic features and unfavorable prognostic biomarkers.⁵⁸

Carcinoma in situ (CIS) is an early form of BC with a good prognosis when detected early. However, its asymptomatic nature makes its detection challenging, and it is often identified by chance through routine mammographic screening,⁵⁹ which is not widely accessible or used in many parts of Sudan.¹⁵ In our cohort, CIS accounted for approximately 9% of all diagnoses, with DCIS being the predominant subtype (8%; 115 of 1,480). This rate is notably higher than earlier estimates from Sudan, where DCIS prevalence was reported to be as low as 0.5%;⁵⁶ yet still considerably lower than the 20–25% reported in high-income countries such as the US.⁵⁹ The relatively high detection rate observed in this study likely reflects the gradual improvements in screening capacity at the center level. Nonetheless, early detection nationwide remains low due to persistent barriers, such as cultural and social beliefs, financial constraints, and hesitancy to seek medical care.⁶⁰

Despite its rarity, medullary carcinoma (MC) showed a strong association with the TNBC phenotype in our cohort. Histopathological correlations with TNBC, especially in MC cases, remain underreported in the African literature. This adds novelty to our findings, as most prior studies have emphasized IDC, while MC is rarely highlighted. This study is the first to assess the prevalence of TNBC in the MC subtype among Sudanese women. Although MC has often been described as a triple-negative subtype with a comparatively favorable prognosis,^{39–41} recent genomic studies suggest that MC remains within the aggressive TNBC spectrum, characterized by basal-like molecular features and immune-related pathway activation.⁶¹ Budzik et al reported that 92% of MC exhibit a TN phenotype,⁴¹ while a previous study from Sudan estimated the MC rate at 7%, although hormone receptor status was not evaluated for these cases.⁵⁶

In this study, the mean age at diagnosis among all BC cases was 53 years, nearly a decade younger than the reported average of 62–63 years among patients with BC in the US.^{47,62} Previous studies have also highlighted the tendency of Sudanese women to develop BC at a younger age than that of Western women.^{56,63} Moreover, we found an inverse relationship between age and TNBC, with each additional year of age associated with a 3% reduction in odds of developing TNBC. This finding aligns with established biological patterns and, when confirmed in a Sudanese cohort, provides valuable insight into global TNBC epidemiology. A similar pattern has been observed among African American women in the US, who are also diagnosed at a younger age.^{62,64} Recent evidence has shown that TNBC in African American women (aged 50 years and younger) exhibits distinct DNA methylation profiles, suggesting a biologically and epigenetically unique subgroup that may contribute to poorer outcomes in this population.⁶⁴ Furthermore, a large US population-based study by Scott et al identified younger age, advanced stage at diagnosis, and race, particularly among non-Hispanic Black women, as significant predictors of TNBC.⁴⁷ Other studies have also explored social determinants of health, such as employment status, marital status, and geographical location, as potential predictors.⁸ However, in our multivariate analysis, age remained a significant factor, while other sociodemographic variables were not, suggesting that biological rather than social determinants may play a more dominant role in TNBC risk among Sudanese women.

Despite the promising findings of this study, several limitations should be acknowledged. First, this was a retrospective, single-center analysis that may not represent the broader Sudanese population. As the center is a specialized referral facility located in the capital, its patients may differ socioeconomically and demographically from the general Sudanese population, potentially introducing selection bias. Excluding cases lacking complete HER2 data further limits the sample size. In addition, the absence of a national cancer registry in Sudan constrains the ability to determine how representative this cohort is of the broader Sudanese population.

Resource and infrastructure constraints have prevented the use of advanced molecular techniques beyond immunohistochemistry, limiting insight into TNBC's genetic heterogeneity. Although BC stage, follow-up, and management data are routinely collected and available at the center, these data were not accessible for this analysis. Consequently, it was not possible to determine whether the higher TNBC prevalence and younger age at diagnosis were associated with more advanced disease at presentation. Future studies should integrate staging and clinical outcome data to provide deeper insight into disease aggressiveness and prognosis among Sudanese women.

Conclusions

By examining receptor-defined molecular profiles alongside histological categories, this study provides valuable insights into molecular and pathological characteristics of BC in Sudanese women, thereby bridging an important knowledge gap in TNBC research within Sub-Saharan Africa.

We observed a younger average age at diagnosis, a higher rate of TNBC cases, and a strong association between MC cases and the TN phenotype. Sociodemographic variables were not significant predictors of TNBC, suggesting that biological rather than social factors may be more closely linked to TNBC risk in Sudanese women.

Given Sudan's ongoing political conflict and health system collapse, along with the prevalence of poverty, limited public awareness, and deep-rooted inequalities in care delivery, these findings highlight the urgent need to improve early detection and diagnostic capabilities. Breast cancer patients in Sudan would benefit from more comprehensive laboratory testing, including genomic profiling, to improve prognosis. Further research should focus on identifying molecular and clinical risk factors associated with aggressive TNBC subtypes.

Abbreviations

AOR, adjusted odds ratio; BC, breast cancer; CI, confidence interval; CIS, carcinoma in situ; DCIS, ductal carcinoma in situ; ER, estrogen receptor; FISH, fluorescence in situ hybridization; HER2, human epidermal growth factor receptor 2; IDC, invasive ductal carcinoma; IHC, immunohistochemistry; ILC, invasive lobular carcinoma; IRB, Institutional Review Board; KBCC, Khartoum Breast Care Center; LCIS, lobular carcinoma in situ; MC, medullary carcinoma; OR, odds ratio; PR, progesterone receptor; SD, standard deviation; TNBC, triple-negative breast cancer.

Data Sharing Statement

All data used or analyzed in this article are available from the corresponding authors upon reasonable request and with permission from KBCC.

Ethics Approval and Informed Consent

This retrospective chart review complied with the Declaration of Helsinki and was approved by the Khartoum Breast Care Center (KBCC) Institutional Review Board (KBCC/IRB 06-2021). Because only de-identified records were used, the IRB waived the requirement for individual informed consent.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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The authors declare that they have no conflict of interest.

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