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Financial, geographic, laboratory and sociocultural barriers to histopathological confirmation of breast cancer in Niger: a multicenter retrospective study

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Research Article

Keywords: Breast cancer, Histopathology, Fine-needle aspiration cytology, Pathology services, Immunohistochemistry, Diagnostic pathway, Health systems, Sub-Saharan Africa, Niger

Posted Date: September 14th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10589617/v1

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Additional Declarations: No competing interests reported.

Financial, geographic, laboratory and sociocultural barriers to histopathological confirmation of breast cancer in Niger: a multicenter retrospective study

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ABSTRACT

Background
Histopathological confirmation is the cornerstone of breast cancer diagnosis and is essential for tumour classification, biomarker assessment and evidence-based treatment planning. However, access to pathology services remains limited in many low-resource settings. This study aimed to determine the rate of histopathological confirmation among women with cytologically diagnosed breast cancer and to identify factors associated with failure to obtain histopathological confirmation in Niger.

Methods
We conducted a retrospective multicenter study in the two national referral hospitals providing specialized breast cancer care in Niger between January 2020 and December 2024. Women with malignant fine-needle aspiration cytology (FNAC) were included. Sociodemographic, clinical, diagnostic and treatment data were extracted from medical records. Patients were classified according to the availability of histopathological confirmation. Factors associated with failure to obtain histopathological confirmation were evaluated using multivariable logistic regression. Adjusted odds ratios (aORs) with 95% confidence intervals (95% CIs) were calculated.

Results
A total of 674 women with cytologically diagnosed breast cancer were included. Only 172 (25.5%) subsequently underwent histopathological confirmation, whereas 502 (74.5%) were managed without histological confirmation. Multivariable analysis identified : Age <50 years (AOR 3.24; P<0.001), rural residence (aOR 3.40; P<0.001), absence of formal education (aOR 2.36; P=0.003), consultation delay >6 months (aOR 1.80; P<0.001), advanced breast cancer stage (III-IV) at diagnosis (aOR 2.76; P<0.001), axillary lymph node involvement (aOR 2.78; P<0.0001), and primary management in a periphery hospital (aOR 4.5 ; P<0.001) as independent predictors of failure to obtain histopathological confirmation. During the study period, pathology services in Niger were characterized by limited laboratory capacity, prolonged turnaround times, absence of immunohistochemistry and hormone receptor testing, and highly centralized diagnostic facilities.
Conclusions
Histopathological confirmation remains insufficient among women with cytologically diagnosed breast cancer in Niger, representing a major gap in the breast cancer diagnostic pathway. Strengthening pathology services, expanding laboratory capacity, improving access to diagnostic investigations and introducing routine immunohistochemistry should be prioritized to improve diagnostic completion and facilitate guideline-concordant breast cancer care. These findings provide evidence to support implementation of the World Health Organization Global Breast Cancer Initiative in low-resource settings.

Keywords: Breast cancer; Histopathology; Fine-needle aspiration cytology; Pathology services; Immunohistochemistry; Diagnostic pathway; Health systems; Sub-Saharan Africa; Niger.

1. BACKGROUND

Breast cancer is the most frequently diagnosed cancer and the leading cause of cancer-related death among women worldwide. According to the latest GLOBOCAN estimates, approximately 2.3 million new cases and more than 660,000 deaths occurred in 2022, with an increasing proportion of the disease burden occurring in low- and middle-income countries, where access to timely diagnosis and effective treatment remains limited [1]. Despite substantial improvements in survival in high-income countries, marked disparities persist across regions because of differences in health system capacity, socioeconomic conditions, and access to quality cancer care [2].

Recognizing these inequities, the World Health Organization (WHO) launched the Global Breast Cancer Initiative (GBCI), which aims to reduce breast cancer mortality by 2.5% annually through three complementary pillars: early detection, timely diagnosis, and comprehensive treatment [2]. A central objective of the GBCI is that all women with suspected breast cancer should undergo prompt tissue diagnosis, including pathology assessment, to enable accurate staging and evidence-based therapeutic decisions [2]. Histopathological confirmation remains the diagnostic gold standard and is essential not only for confirming malignancy but also for

determining tumor subtype, grade, and biomarker status, including estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2), which guide modern systemic therapies [3-5].

Unfortunately, implementation of these recommendations remains challenging in many sub-Saharan African countries. Previous studies have consistently reported late-stage presentation, prolonged diagnostic delays, inadequate pathology services, limited access to immunohistochemistry, and frequent treatment abandonment, all of which contribute to poor survival outcomes [6-9]. The African Breast Cancer-Disparities in Outcomes (ABC-DO) study further demonstrated that deficiencies in diagnostic and treatment pathways represent major determinants of excess breast cancer mortality across the region [7, 8].

Niger faces particularly important structural constraints. During the study period, only four pathology laboratories were operating nationwide, two public laboratories located in Niamey and Zinder and two private laboratories located in Niamey. Histopathology, core needle biopsy and fine-needle aspiration cytology were financed almost entirely through out-of-pocket payments. Women living outside these cities often had to transport biopsy specimens over distances exceeding 1,500 km using informal transport networks because no organized medical specimen transportation system existed. In addition, pathology turnaround times frequently ranged from one to six months, and immunohistochemistry as well as hormone receptor testing were unavailable nationwide. These structural barriers were compounded by widespread poverty, insecurity related to armed conflict in several regions, and sociocultural beliefs that discourage submission of surgical specimens for pathological examination because excised tissues are considered an integral and sacred part of the individual that should be buried according to traditional rites.

Although these contextual barriers are widely recognized by clinicians working in Niger, little empirical evidence has been published describing their consequences on histopathological confirmation of breast cancer. Most African studies have focused on stage at diagnosis, treatment patterns, or survival, whereas the specific determinants of inadequate pathological confirmation remain poorly documented [6-9]. Excluding women without histological confirmation creates an important selection bias in African breast cancer research.

Therefore, this multicenter retrospective study aimed to determine the proportion of women with cytologically diagnosed breast cancer who subsequently underwent histopathological confirmation and to identify the demographic, clinical, and health-system factors associated with failure to obtain histopathological confirmation in two national referral hospitals in Niger. By documenting these barriers, our findings may help inform national cancer control policies and support implementation of the WHO Global Breast Cancer Initiative in resource-limited settings.

2. METHODS

2.1 Study design and setting

We conducted a multicenter, retrospective observational study of women with breast cancer managed between 1 January 2020 and 31 December 2024 in the two principal national referral

hospitals for breast cancer care in Niamey, Niger: Issaka Gazobi Maternity Hospital (MIG) and the National Cancer Control Center (CNLC).

MIG is the country's largest tertiary referral maternity hospital and serves as a referral center for surgery and hospitalization for breast and gynecological cancers from all eight administrative regions of Niger. Surgical management of breast diseases is performed within its Department of Obstetrics and Gynecology.

The CNLC is the national referral institution responsible for cancer diagnosis and treatment.

In Niger, women with suspected breast cancer are initially evaluated at peripheral health facilities or referral hospitals. Following cytological or histopathological diagnosis, patients requiring oncological management are systematically referred to the National Cancer Control Center (Centre National de Lutte Contre le Cancer, CNLC), which coordinates systemic treatment and provides government-funded cancer care. Each patient receives a unique CNLC identification number that is retained throughout treatment, irrespective of the hospital where the diagnosis or initial surgery was performed. This centralized referral system enables reliable linkage of medical records across participating institutions and facilitates longitudinal follow-up.

2.2 Health system context

During the study period, breast cancer diagnosis and treatment in Niger were delivered within a severely resource-constrained health system. While chemotherapy, surgery, radiotherapy and staging investigations were largely subsidized by the government (Decree N° 2007-261/PRN/MSP (July 19, 2007)[10], diagnostic pathology services including fine-needle aspiration cytology (FNAC), core needle biopsy and histopathological examination were financed almost entirely through out-of-pocket payments by patients. Nationwide, only four pathology laboratories were operational: two public laboratories located in Niamey and Zinder and two private laboratories located in Niamey. No laboratory performed immunohistochemistry or hormone receptor testing during the study period.

Women living outside these cities frequently had to transport biopsy specimens over distances exceeding 1,500 km through informal transportation networks because no organized medical specimen transport system existed. Histopathology turnaround times generally ranged from one to six months.

2.3 Study population

Eligible participants were women with a diagnosis of breast cancer established by fine-needle aspiration cytology (FNAC), with or without subsequent histopathological confirmation, between 1 January 2020 and 31 December 2024, who subsequently received oncological management at either participating institution.

2.4 Inclusion criteria

Patients were eligible if they:

were female; had cytological confirmation of breast malignancy by FNAC; received all or part of their management at MIG or CNLC between January 2020 and December 2024; had available medical records containing the minimum required clinical and diagnostic information.

2.5 Exclusion criteria

Patients were excluded if:

the diagnosis of breast cancer was not confirmed by malignant cytology; the medical record was unavailable or contained insufficient information for analysis.

2.6 Sample size

As this was a retrospective multicenter study, no formal sample size calculation was performed before study initiation. Instead, all consecutive women meeting the predefined eligibility criteria and managed at the two national referral hospitals between 1 January 2020 and 31 December 2024 were included. This exhaustive sampling strategy was chosen to maximize statistical precision and minimize selection bias.

2.7 Identification of participants and duplicate management

Potentially eligible patients were identified from pathology laboratory registers, surgical registers, oncology records, and CNLC treatment databases.

Because many women underwent diagnosis, biopsy, or surgery at one institution before referral to the CNLC for oncological treatment, duplicate records could occur across hospitals. Duplicate entries were identified and removed using the unique national CNLC identification number, which is assigned to every patient receiving cancer treatment in Niger. When duplicate records were identified, information from all available sources was merged into a single study record to maximize completeness while ensuring that each woman contributed only once to the cohort.

2.8 Study procedures and diagnostic pathway

In Niger, women presenting with suspected breast cancer generally undergo clinical breast examination followed by FNAC as the first-line diagnostic investigation because of its affordability and availability. Histopathological confirmation is recommended whenever a core needle biopsy or surgical specimen is available. However, performance of histopathological examination depends on the patient's ability to pay laboratory fees, transport biological specimens to one of the limited pathology laboratories, and overcome logistical and sociocultural barriers. Immunohistochemistry and hormone receptor assessment (ER, PR and HER2) were unavailable throughout the country during the study period.

2.9 Data collection

Data were extracted from standardized medical records using a predefined collection form by trained investigators.

Whenever possible, information was cross-checked using surgical registers, chemotherapy records, pathology reports, imaging reports, hospitalization records, and outpatient oncology files to improve data completeness and accuracy.

2. 10 Variables

The primary outcome variable was histopathological confirmation.
Patients were categorized into:
Histopathological confirmation = 0
No histopathological confirmation = 1
The following explanatory variables were extracted:
Age; place of residence; educational level; reproductive history; consultation delay; clinical presentation; tumor laterality; tumor size; axillary lymph node involvement;
AJCC clinical TNM stage; cytological diagnosis; histopathological confirmation; immunohistochemistry; surgical procedures; systemic treatment; radiotherapy; endocrine therapy; treatment completion; recurrence; vital status; and dates of diagnosis, treatment, follow-up, and death when available.
Clinical staging was assigned according to the 8th edition of the American Joint Committee on Cancer (AJCC) TNM classification using clinical examination and available imaging performed before initiation of treatment.

2.11 Definition of study variables

Histopathological confirmation was defined as documentation of histological examination of either a core needle biopsy or surgical specimen.
Overall survival was defined as the interval between the date of cytological diagnosis (FNAC) and death from any cause.
Advanced-stage disease was defined as American Joint Committee on Cancer (AJCC) stage III or IV, whereas stages I and II were classified as early-stage disease.
Consultation delay corresponded to the interval between the patient's first recognition of breast symptoms and her first consultation with a qualified healthcare professional.

2.12 Statistical analysis

Analyses were performed using SPSS Statistics version 27.0.2. Continuous variables were summarized as means with standard deviations (SD) or medians with interquartile ranges (IQR), depending on their distribution. Categorical variables were presented as frequencies and percentages.
Comparisons between patients with and without histopathological confirmation were performed using the Chi-square test or Fisher's exact test for categorical variables and the Student's t-test or Mann-Whitney U test for continuous variables, as appropriate.
Variables associated with failure to obtain histopathological confirmation at $P < 0.20$ in univariable analyses, together with clinically relevant covariates identified a priori, were entered

into a multivariable logistic regression model using the enter method. Adjusted odds ratios (aORs) and their 95% confidence intervals (95% CIs) were estimated.
Model assumptions were assessed before interpretation. Multicollinearity among independent variables was evaluated using the variance inflation factor (VIF). Model calibration was assessed using the Hosmer-Lemeshow goodness-of-fit test. Model discrimination was evaluated by calculating the area under the receiver operating characteristic (ROC) curve (AUC), and the explanatory performance of the model was summarized using the Nagelkerke pseudo-R^2. The ratio of outcome events to the number of predictor variables included in the final model (events per variable, EPV) was also assessed to minimize the risk of model overfitting.

Before statistical analysis, data completeness was assessed for all eligible medical records. According to the predefined exclusion criteria, patients with unavailable medical records or insufficient clinical or diagnostic information were excluded before study inclusion. Consequently, the final analytical dataset contained complete information for all variables included in the descriptive and multivariable analyses, and no additional methods for handling missing data or multiple imputation were required.

2.13 Ethical considerations

The study was approved by the Institutional Review Board of the Faculty of Health Sciences, Abdou Moumouni University, Niamey, Niger (Approval No. 000978/2AUA/FSS/SS).

Because of the retrospective design and the exclusive use of anonymized, routinely collected medical records, the Institutional Review Board waived the requirement for informed consent. All data were anonymized before analysis, and the study was conducted in accordance with the principles of the Declaration of Helsinki.

3. RESULTS

3.1 Study population

During the five-year study period (January 2020 to December 2024), 1,155 women were managed for malignant diseases at the two participating national referral hospitals. Of these, 674 women were diagnosed with breast cancer, representing 58.4% of all female cancer cases managed during the study period. Following the application of the predefined eligibility criteria, all 674 women with cytologically diagnosed breast cancer were included in the final analysis (Figure 1). Among these, 172 had histopathological confirmation representing a rate of 25.5%.
The annual number of women managed for breast cancer increased steadily throughout the study period, rising from 69 cases in 2020 to 209 cases in 2024, corresponding to an approximately threefold increase.

All included patients had complete data for the variables required for the planned analyses, following the exclusion of records with insufficient information according to the predefined eligibility criteria.

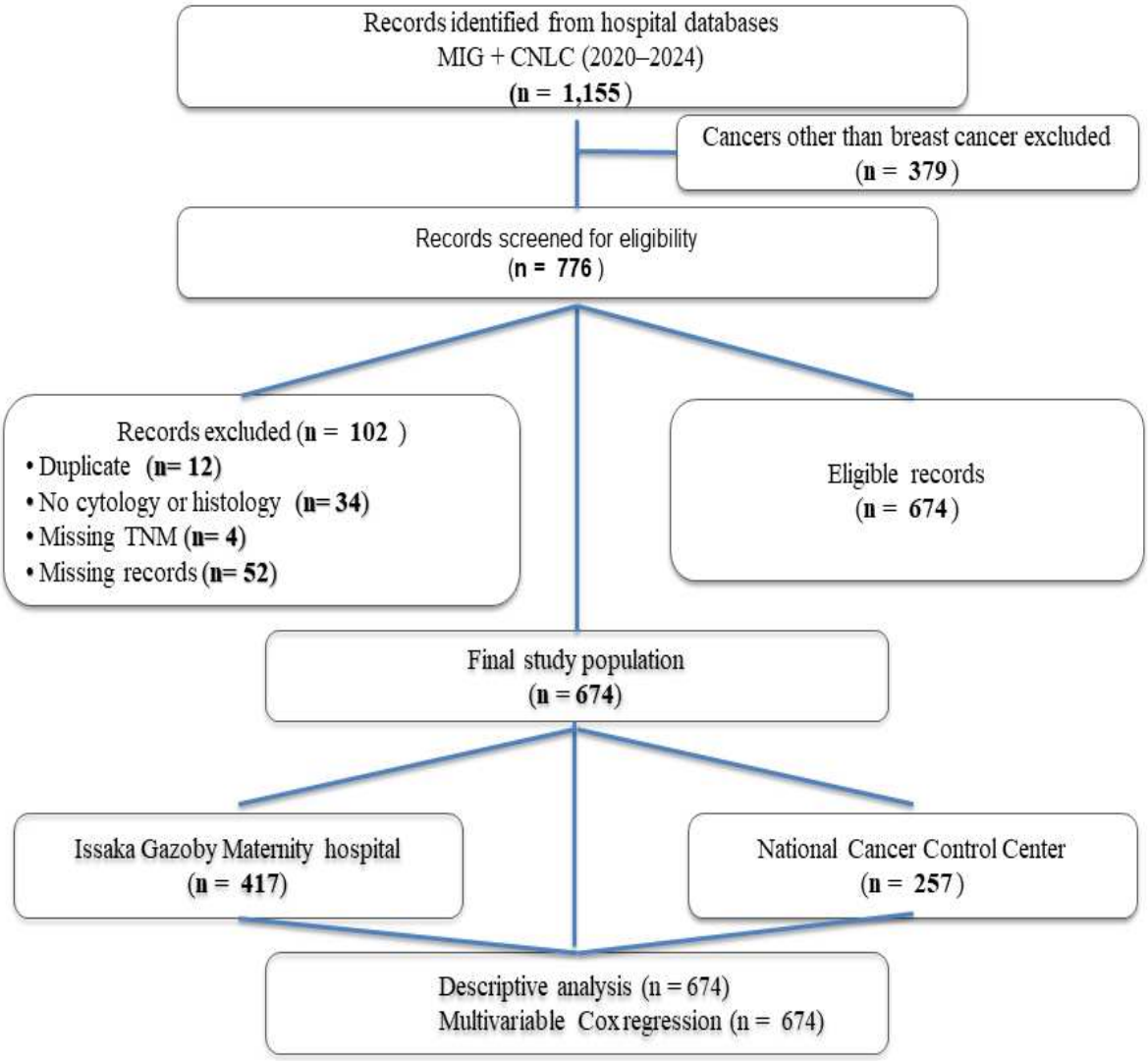


Figure 1. STROBE flow diagram of participant selection

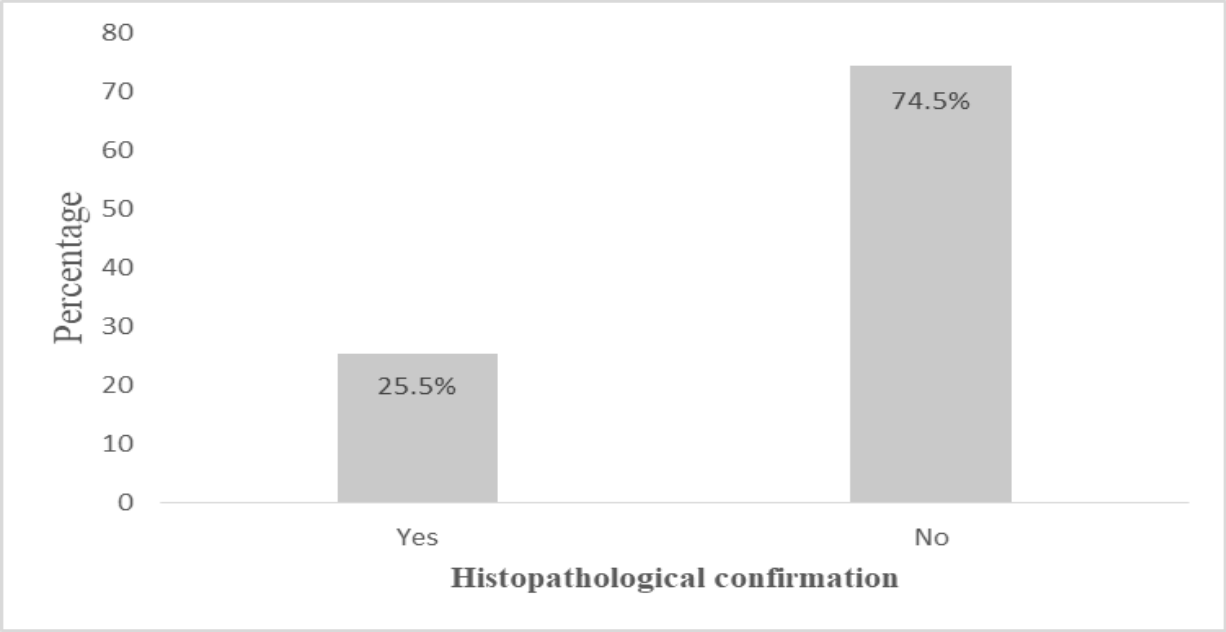


Figure 2. Proportion of patients with and without histopathological confirmation

3.2 Sociodemographic characteristics according to histopathological confirmation

The mean age was 47.0±05.1 years in the histopathological confirmation group, compared with 46.0±8.6 years in the control group.

The rate of a family history of breast cancer was significantly higher among the histopathological confirmation cases (48.3% vs. 6.4%, P <0.001).

Regarding the patients' place of residence, 76.7% of patients with histopathologically confirmed breast cancer came from urban areas, while most patients without histopathological confirmation (74.7%) came from rural areas. Regarding the patients' educational level most patients with breast cancer without histopathological confirmation had no formal education (75.7% vs 32.5% P<0.001). Unemployed women were more represented in breast cancer without histopathological confirmation group (84.9% vs 65.7%). The rate of histopathological confirmation was higher in patients managed primarily at CNLC than those managed at MIG (31.1% vs 22.0% P= 0.002). Furthermore, the rate of histopathological confirmation was higher in patients diagnosed in the year 2024 than those diagnosed in 2020 (31.1% vs 13.0% P<0.001). Table 1 present the sociodemographic characteristics of patients according to histopathological confirmation.

Table 1. Sociodemographic characteristics of women with cytologically diagnosed breast cancer according to histopathological confirmation in two national referral hospitals in Niger.

Variable	Overall (N=674)	Histopathological confirmation(n=172)	No histopathological confirmation(n=502)	P-value
Age (years)				0.023
Mean ± SD	46.5±12.6	47.0±05.1	46.0±8.6	

<40	209 (31.0%)	36 (17.2%)	173 (82.8%)	
40-49	203 (30.1%)	33 (16.3%)	170 (83.7%)	
50-69	219 (32.5%)	96 (43.8%)	123 (56.2%)	
≥70	43 (6.4%)	7 (16.3%)	36 (83.7%).	
Marital status				0.340
Single	16 (2.4%)	5 (31.5%)	11 (68.8%)	
Married	516 (76.5%)	105 (20.3%)	411 (79.7%)	
Divorced/Separated	36 (5.3%)	16 (44.4%)	20 (55.6%)	
Widowed	106 (15.7%)	46 (43.4%)	60 (56.6%)	
Educational level				<0.001
No formal education	436(64.7%)	56 (12.8%)	380 (87.2%)	
Schooling	238 (35.3%)	116 (48.7%)	122 (51.3%)	
Occupation				<0.001
Unemployed	539 (80.0%)	113 (21.0%)	426 (79.0%)	
Civil servant	40 (5.9%)	13 (32.5%)	27 (67.5%)	
Self-employed	32 (4.8%)	19 (59.4%)	13 (40.6%)	
Other	63 (9.3%)	27 (42.9%)	36 (57.1%)	
Place of residence				<0.001
Urban	259 (38.5%)	132 (51.0%)	127 (49.0%)	
Rural	415 (61.2%)	40 (9.6%)	375 (90.4%)	
Menopausal status				0.003
Premenopausal	329 (48.8%)	78 (23.7%)	251(76.3%)	
Postmenopausal	345 (51.2%)	94(27.2%)	251 (72.8%)	
Parity				0.515
Mean ± SD	3.6 ± 2.5			
Nulliparous	10 (1.5%)	9 (90%)	1 (10%)	
1–3	325 (48.2%)	66(20.3%)	259 (79.7%)	
≥4	339 (50.3%)	97 (28.6%	242 (71.4%)	
Family history of breast cancer				<0.001
Yes	115 (17.0%)	83 (72.2%)	32(27.8%)	
No	559 (83.0%)	89 (15.9%)	470 (84.1%)	
Hormonal contraceptive use				0.062
No	621(92.1%)	157 (25.3%)	464 (74.7%)	
Yes	53 (7.9%)	15 (28.3%)	38 (71.7%)	
Breastfeeding history				0.122
Yes	663 (98.4%)	170(25.6%)	493 (74.4%)	
No	11 (1.6%)	2 (18.2%)	9 (81.8%)	
Hospital of primary treatment				0.002
Referral hospital	319 (47.3%)	92 (28.8%)	227 (71.2%)	

Periphery hospital	355 (52.7%)	80 (22.5%)	275 (77.5%)	
Year of diagnosis				<0.001
2020	69 (10.2%)	9 (13.0%)	60 (87.0%)	
2021	107 (15.9%)	21 (19.6%)	86 (80.4%)	
2022	135 (20.0%)	32 (23.7%)	103 (76.3%)	
2023	154 (22.9%)	45 (29.2%)	109 (70.8%)	
2024	209 (31.0%)	65 (31.1%)	144 (68.9%)	

Abbreviations: SD: standard deviation; IQR: interquartile range.

3.3 Clinical characteristics and diagnostic pathway

The clinical characteristics and diagnostic pathway of the study population are summarized in Table 2. The median consultation delay was 5 months (IQR: 3-9) in patients with histopathologically confirmed breast cancer compared with 8 months (IQR: 5-12) in patients without histopathological confirmation. Most patients in the two groups presented with tumor size >2cm (85.5% vs 89.4%; P=0.021).

Advanced stage breast cancer (stage III-IV) was most frequent in patients without histopathological confirmation compared with the histopathologically confirmed group (75.5% vs 54.1%; P=0.004). Axillary lymphadenopathy involvement was more frequent in histopathologically confirmed group (83.1% vs 68.3%; P=<0.001).

Breast cancer mostly involved the right breast in patients with histopathological confirmation (47.1%), and was bilateral in 9.3%. However, left breast was most frequently involved in patients without histopathological confirmation (51.6%) with 3.2% of bilateral breast cancer (P=0.074).

Core needle biopsy was performed in 7.0% of patients with histopathologically confirmed breast cancer compared with 0.2% in the control group.

Surgical treatment was performed in all patients in the histopathological confirmation group (100%) compared with 339 patients (67.5%) in the group without histopathological confirmation. Surgical specimen and/or core biopsy were submitted for pathology in all patients with histopathological confirmation (100%) compared with only 13/340 cases (3.8%) in the control group.

3.4 Rate of histopathological confirmation

A total of 185(27.4%) surgical specimen and/or core biopsy were submitted for pathology including 172 surgical specimens and 13 core biopsies. Of whom, 172 histopathological reports were available representing an overall confirmation rate of 93%. Histopathological confirmation was performed with surgical specimen in 160/172 cases (93%), while it was performed with core biopsy in 12/172 cases (7%). Overall, 13/185 (7.0%) histopathological reports were not received.

Among patients with histopathological confirmation, invasive ductal carcinoma was the predominant histological subtype (81.4%), and Grade II tumors represented the most frequent histological grade (61.0%). No patients underwent immunohistochemical characterization during

the study period (Table 2). The distribution of patients according to Histopathological confirmation of breast cancer is illustrated in Figure 2.

Table 2 Clinical characteristics, diagnostic pathway and treatment according to histopathological confirmation.

Variable	**Overall (N=674)**	**Histopathological confirmation(n=172)**	**No histopathological confirmation(n=502)**	**P-value**
Consultation delay (months)				0.002
Median (IQR)	7 (4-12)	5 (3-9)	8 (5-12)	
<6	266 (39.5%)	110 (41.4%)	156 (58.6%)	
≥6	408 (60.5%)	62 (15.2%)	346 (84.8%)	
Reason for consultation				0.082
Breast lump	469 (69.6%)	98 (20.9%)	371 (79.1%)	
Breast pain	51(7.6%)	24 (47.1%)	27 (52.9%)	
Ulceration	40(5.9%)	19 (47.5%)	21 (52.5%)	
Nipple discharge	37(5.5%)	17 (45.9%)	20 (54.1%)	
Other	77(11.4%)	14 (18.2%)	63 (81.8%)	
Tumor laterality				0.074
Right	308 (45.7%)	81 (26.3%)	227 (73.7%)	
Left	334 (49.5%)	75 (22.5%)	259 (77.5%)	
Bilateral	32 (4.7%)	16 (50%)	16 (50%)	
Breast quadrant (N=706)* ***32 bilateral cases**		**n=188**	**(n=518)**	0.060
Upper outer	384 (54.4%)	99 (25.8%)	285 (74.2%)	
Upper inner	180 (25.5%)	43 (23.9%)	137 (76.1%)	
Lower outer	46 (6.5%)	16 (34.8%)	30 (65.2%)	
Lower inner	49 (7.0%)	14 (28.6%)	35 (71.4%)	
Central	47 (6.6%)	16 (34.0%)	31 (66.0%)	
Clinical tumor size				0.021
≤2 cm	78 (11.6%)	25 (32.0%)	53 (68.0%)	
>2-5 cm	512 (76.0%)	134 (26.2%)	378 (73.8%)	
>5 cm	84 (12.5%)	13 (15.5%)	71 (84.5%)	
Axillary lymphadenopathy				<0.001
Present	486 (72.1%)	143 (29.4%)	343 (70.6%)	
Absent	188 (27.9%)	29 (15.4%)	159 (84.6%)	
Clinical stage (AJCC)				0.004
Stage I	82 (12.2%)	28 (34.1%)	54 (65.9%)	
Stage II	120 (17.8%)	50 (41.7%)	70 (58.3%)	
Stage III	430 (63.8%)	84 (19.5%)	346 (80.5%)	
Stage IV	42 (6.2%)	9(21.4%)	33 (78.6%)	
Diagnostic pathway				0.01
FNAC performed	674 (100%)	172 (100%)	502 (100%)	
Core needle biopsy performed	13 (1.9%)	12 (92.3%)	1 (7.7%)	
Surgical specimen and/or core	185 (27.4%)	172 (93.0%)	13 (7.0%)	0.08

biopsy submitted for pathology *				
Immunohistochemistry performed	0 (0%)	0 (0%)	0(0%)	NA
Histological findings (n=172)				NA
Invasive ductal carcinoma	140 (81.4%)	140 (100%)	NA	
Invasive papillary carcinoma	14 (8.2%)	14 (100%)	NA	
Invasive lobular carcinoma	9 (5.2%)	9 (100%)	NA	
Other	9 (5.2%)	9 (100%)	NA	
Histological grade (n=172)				NA
Grade I	24 (14.0%)	24 (100%)	NA	
Grade II	105 (61.0%)	105 (100%)	NA	
Grade III	43 (25.0%)	43 (100%)	NA	

Abbreviations: **FNAC**: fine-needle aspiration cytology; **AJCC**: American Joint Committee on Cancer; **SD**: standard deviation; **IQR**: interquartile range; **NA**: Not applicable; * for 13 women biopsy and surgical specimen were submitted for pathology.

3.5 Factors associated with histopathological confirmation

The factors associated with failure to obtain histopathological confirmation among patients are summarized in Table 3. After adjustment, failure to obtain histopathological confirmation was independently associated with: age <50 years (AOR 3.24; 95% CI : 1.58-5.08; P<0.001), rural residence (AOR 3.40; 95% CI : 2.18-4.62; P<0.001), absence of formal education (AOR 2.36; 95% CI : 1.24-4.13; P=0.003), consultation delay >6 months (AOR 1.80; 95% CI : 1.17-3.97; P<0.001), and advanced breast cancer stage (III-IV) at diagnosis (AOR 2.76; 95% CI : 1.32-4.70; P<0.001). The analysis also revealed that Axillary lymph node involvement (AOR 2.78; 95% CI : 1.23-5.06; P<0.0001), and primary management in a periphery hospital (AOR 4.51; 95% CI : 2.09-6.93; P<0.001) were all associated with an increased rate of failure to obtain histopathological confirmation. Furthermore, the year of diagnosis (AOR 3.40; 95% CI : 2.10-5.0; P<0.001), was significant factors associated with failure to obtain histopathological confirmation. The histopathological confirmation rate increased from 10.2% in patients diagnosed with breast cancer in 2020, to 20.0% in 2022, and 31.0% in 2024.

The final multivariable logistic regression model demonstrated good calibration (Hosmer-Lemeshow goodness-of-fit test, χ^2 =8.07; P = 0.63). The model showed acceptable discrimination with an AUC of 0.87 (95% CI 0.83-0.91). The Nagelkerke pseudo-R^2 was 0.32, indicating that approximately 32% of the variability in histopathological confirmation was explained by the included predictors. The final model included eight independent variables, corresponding to an events-per-variable ratio of 21.5, suggesting a low risk of model overfitting.

No evidence of problematic multicollinearity was observed among the independent variables included in the final multivariable model (all variance inflation factors < 2.0).

Table 3. Independent predictors of failure to obtain histopathological confirmation among women with cytologically diagnosed breast cancer (N=674).

Variables	cOR	95% CI	aOR	95% CI	P
Age <50 years	3.70	[1.62-5.78]	3.24	[1.58-5.08]	<0.001
Rural residence	4.74	[2.90-6.61]	3.40	[2.18-4.62]	<0.001
No formal education	3.95	[2.15-5.75]	2.36	[1.24-4.13]	0.003
Consultation delay >6 months	2.27	[1.48-4.39]	1.80	[1.17-3.97]	<0.001
Advanced stage (III-IV) at diagnosis	2.97	[1.88-4.16]	2.76	[1.32-4.70]	<0.001
Axillary lymph node involvement	2.90	[1.28–4.52]	2.78	[1.23-5.06]	<0.001
Primary management in periphery hospital	4.63	[2.76-6.59]	4.51	[2.09-6.93]	<0.001
Year of diagnosis					
2020	3.45	[2.01-5.02]	3.40	[2.10-5.0]	<0.001
2021	2.80	[1.16-4.47]	2.50	[1.38-3.82]	0.002
2022	2.31	[1.20-3.62]	1.80	[1.11-3.49]	0.03
2023	2.97	[1.12-5.18]	1.20	[0.76-2.10]	0.31
2024	1.0	reference	1.0	Reference	-

Footnote: Variable with P<0.20 in univariable analyses and clinically relevant covariates were entered into the multivariable logistic regression model. **cOR** : Crude odds ratio; **aOR** : Adjusted odds ratio; **CI** : Confidence intervals, **P** : p-value of adjusted model.

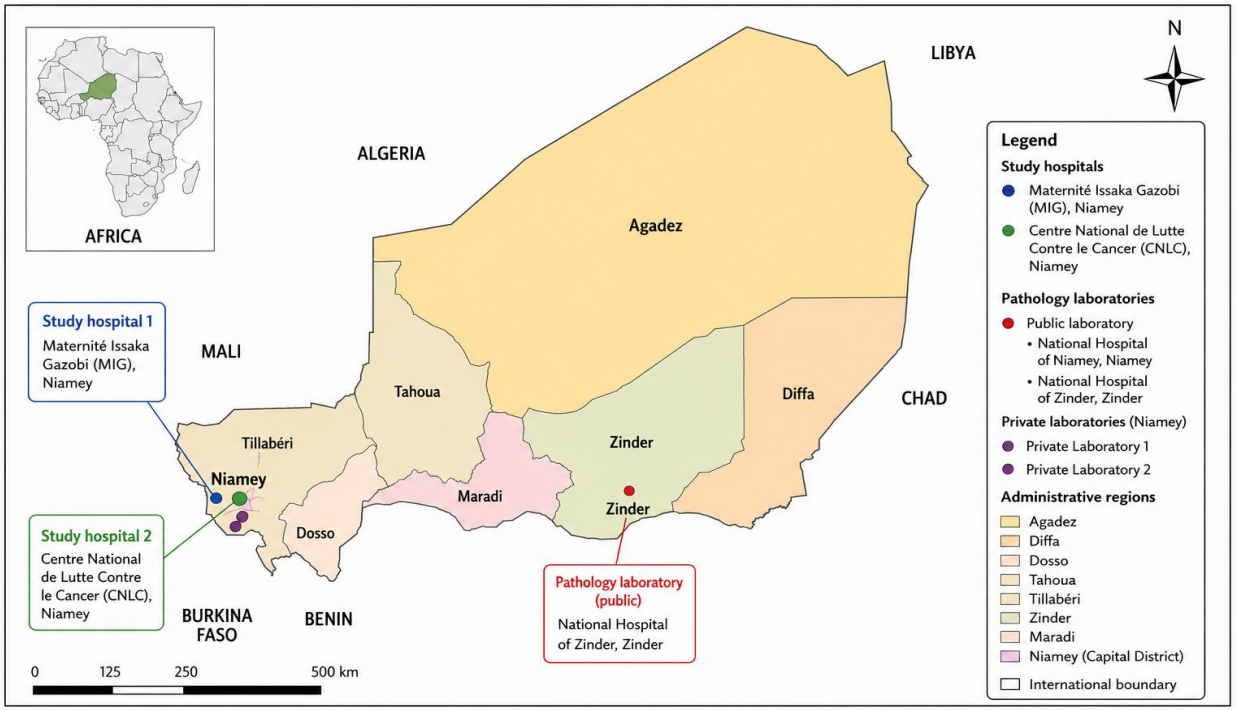
3.6 Health-system barriers to pathological diagnosis

During the study period, only four pathology laboratories providing histopathological diagnostic services were available in Niger, distributed across two of the country's eight regions (Figure 3). Three laboratories were located in Niamey (the country's capital), including one public laboratory within the grounds of the Niamey National Hospital, and two private laboratories. The fourth laboratory was located in Zinder, also within the grounds of the Zinder National Hospital.
These four laboratories performed the analysis of fine-needle aspiration cytology, core biopsy, and surgical specimens. However, none of the laboratories had the necessary equipment to perform immunohistochemistry or hormone receptor assays.
Table 4 presents the origin of the patients as well as the distance traveled to access a pathology laboratory.

Table 4. Origin of patients and distance travelled to access the pathology laboratory.

Region of origin of the patient	Number of cases	Distance from the initial hospital to the Zinder laboratory	Distance from the initial hospital to the Niamey laboratories
Niamey	251(37.2%)	852- 900 km	10- 33km
Tillabéry	105 (15.6%)	967-1028 km	115- 291 km
Dosso	98 (14.5%)	753- 778km	139 - 197km
Tahoua	78 (11.6%)	580 -746 km	455-567km
Agadez	56 (8.3%)	440-678 km	864-1102 km
Zinder	68 (10.1%)	4.4 -15km	852km
Maradi	9 (1.3%)	235- 402km	622-789 km
Diffa	4 (0.6%)	475-596 km	1313 - 1444km
Neighboring countries (Benin, Nigeria)*	8 (1.2%)	-	-

* Patients from countries bordering Niger are first treated in hospitals in the regions of Niger before being referred to the National Cancer Center in Niamey.



MIG: Maternité Issaka Gazobi; CNLC: Centre National de Lutte Contre le Cancer; Labs: Laboratories.

Note: pathology laboratories (n=4).
Figure 3. Geographical distribution of pathology laboratories and referral pathways in Niger.

4. DISCUSSION

Principal findings

To our knowledge, this multicenter retrospective study is the first to comprehensively investigate histopathological confirmation among women with cytologically diagnosed breast cancer in Niger. Although all 674 included women had malignant fine-needle aspiration cytology (FNAC), only a minority subsequently underwent histopathological confirmation, and none had access to immunohistochemistry or hormone receptor testing. Multivariable analysis further identified independent predictors of failure to obtain histopathological confirmation, highlighting important patient and health system-related determinants of incomplete diagnostic evaluation. These findings demonstrate that the principal challenge in Niger extends beyond delayed presentation to include failure to complete the diagnostic pathway required for evidence-based breast cancer management. Histopathological confirmation is considered the cornerstone of modern breast cancer care and is recommended by the World Health Organization (WHO), the European Society for Medical Oncology (ESMO), and the National Comprehensive Cancer Network (NCCN). [2,7,11, 12].

Our findings extend previous evidence from sub-Saharan Africa by specifically quantifying the proportion of women who failed to complete pathological confirmation after a malignant cytological diagnosis. While most African studies have focused on late-stage presentation, treatment delays or survival, few have evaluated this critical step in the diagnostic pathway. Consequently, our study addresses an important evidence gap by showing that many women never reach the stage at which histology and biomarker assessment can guide individualized treatment [7, 8,13,14].

The clinical implications are substantial. Histopathology is required not only to confirm malignancy but also to determine histological subtype, tumour grade, lymphovascular invasion, surgical margin status and eligibility for biomarker testing, including estrogen receptor (ER), progesterone receptor (PR) and HER2 assessment. Without these data, treatment decisions rely largely on cytological findings and clinical staging, increasing the risk of suboptimal therapy and limiting implementation of international treatment guidelines [7].

These findings are directly relevant to the WHO Global Breast Cancer Initiative (GBCI), which identifies timely diagnosis and pathology services as essential components of effective breast cancer control. They suggest that strengthening pathology capacity including histopathological confirmation, biomarker testing and diagnostic infrastructure should become a national priority to improve guideline-concordant care and reduce breast cancer mortality in Niger and other low-resource settings [2, 7, 8].

Comparison with international and African studies

The present study confirms that limited access to histopathological confirmation remains a major barrier to breast cancer care in low-resource settings. While histopathological examination is considered the international standard for confirming breast cancer and guiding treatment decisions, most women in our cohort failed to complete this essential diagnostic step despite having malignant FNAC. This finding contrasts with current WHO Global Breast Cancer Initiative (GBCI), ESMO and NCCN recommendations, which advocate tissue diagnosis before definitive treatment whenever feasible. Failure to obtain histopathological confirmation compromises accurate tumour classification, biomarker assessment and evidence-based treatment planning [2, 7,11, 12, 14].

Our findings are consistent with reports from sub-Saharan Africa identifying pathology services as one of the weakest components of the breast cancer care continuum. However, unlike most previous African studies, which enrolled only women with histologically confirmed breast cancer, our study specifically quantified the proportion of patients who failed to obtain histopathological confirmation after a malignant cytological diagnosis. Consequently, it captures an often-overlooked population that is generally excluded from conventional hospital-based breast cancer cohorts [7, 14].

The recently published ABC-DO Ghana study provides a useful comparison. Although approximately one-fifth of women did not undergo biopsy, pathology reports were available for all biopsy specimens, with a median turnaround time of only 14 days. In contrast, histopathological confirmation remained markedly lower in our study, reflecting substantial differences in pathology infrastructure, laboratory organization and specimen referral systems between the two countries. Similar observations have been reported by the multicountry ABC-DO consortium, which demonstrated that diagnostic delays, limited pathology capacity and incomplete treatment contribute substantially to poor breast cancer outcomes across sub-Saharan Africa. [7, 14].

Evidence from Nigeria further supports the importance of strengthening pathology services. Although Nigerian studies have primarily focused on the quality and completeness of pathology reports rather than access to pathology itself, they similarly highlight deficiencies in pathology systems that may compromise breast cancer management. Together, these findings suggest that improving pathology capacity should become a priority throughout the region [15].

Another important distinction concerns pathology turnaround time. Whereas pathology reports in Ghana are generally available within two weeks, women in Niger frequently waited one to six months before receiving histopathological results. Such delays may postpone definitive treatment and increase the likelihood of disease progression before therapy. Moreover, the complete absence of immunohistochemistry during the study period prevented molecular classification of breast cancer and individualized treatment according to current WHO, ESMO and NCCN recommendations. These findings indicate that the principal challenge in Niger extends beyond delayed presentation to include profound limitations in pathology infrastructure and diagnostic capacity, emphasizing the need for sustained investment in pathology services as a cornerstone of comprehensive breast cancer control [2,11, 12, 14].

Financial barriers to histopathological confirmation

Financial constraints appear to be one of the major barriers to completion of the breast cancer diagnostic pathway in Niger. During the study period, although surgery, chemotherapy, radiotherapy and staging investigations were largely subsidized by the government, patients were required to pay out-of-pocket for essential diagnostic procedures, including FNAC, core needle biopsy and histopathological examination. In a country where most households live below the poverty line and health insurance coverage remains extremely limited, these costs are likely to represent a substantial obstacle to obtaining a definitive pathological diagnosis [2, 16-18].

Our findings are consistent with evidence from sub-Saharan Africa identifying financial hardship as one of the principal barriers to breast cancer care. A systematic review reported that financial constraints were the most frequently cited obstacle to accessing diagnostic and treatment services across the continent. Similarly, studies from Nigeria demonstrated that out-of-pocket expenditure and the lack of health insurance significantly reduce access to breast cancer diagnosis and treatment, with many women experiencing catastrophic health expenditure during their cancer journey [16-18, 19].

The financial burden observed in Niger may be particularly important because pathology investigations represent an additional expense before treatment can be initiated. Besides the direct costs of FNAC, biopsy and histopathological examination, many patients also incur transportation expenses for specimen referral, repeated hospital visits and temporary accommodation. Although our study did not directly measure household income or patient-reported reasons for declining histopathological examination, the remarkably low confirmation rate observed is consistent with the financial barriers documented in other African settings. Therefore, these findings should be interpreted as reflecting the broader health-system context rather than establishing direct causal relationships at the individual patient level [20, 21].

The consequences of these financial barriers extend beyond delayed diagnosis. Failure to obtain histopathological confirmation precludes accurate tumour characterization and prevents biomarker testing, including ER, PR and HER2 assessment, thereby limiting personalized treatment. The WHO Global Breast Cancer Initiative recognizes financial protection as a fundamental component of equitable cancer care and recommends reducing out-of-pocket expenditure for essential diagnostic services. Our findings therefore support the integration of pathology investigations, including histopathology and basic immunohistochemistry, into publicly financed cancer care packages in Niger [2, 18, 21].

Overall, our results suggest that strengthening pathology infrastructure alone will be insufficient unless accompanied by policies that improve financial access to diagnostic services. Expanding health insurance coverage, subsidizing pathology investigations and reducing patient-borne diagnostic costs are likely to improve completion of the diagnostic pathway and contribute to more equitable breast cancer care, in line with the objectives of the WHO Global Breast Cancer Initiative [2, 16, 21].

Geographical and laboratory barriers to histopathological confirmation

Beyond financial constraints, our findings suggest that geographical disparities and limited pathology infrastructure constitute major barriers to histopathological confirmation in Niger. During the study period, pathology services were restricted to only four laboratories nationwide two public laboratories in Niamey and Zinder and two private laboratories in Niamey requiring many patients to travel long distances or arrange specimen referral over hundreds of kilometers. Although these barriers were not individually measured in our study, they provide important contextual information for interpreting the low rate of histopathological confirmation observed in our cohort.

These findings are consistent with reports from sub-Saharan Africa showing that pathology services remain one of the weakest components of cancer care. Regional surveys have documented severe shortages of pathologists, inadequate laboratory infrastructure, limited equipment, reagent shortages and major geographical inequalities in access to diagnostic services, all of which compromise the quality and timeliness of breast cancer diagnosis [21].

In Niger, these structural limitations are compounded by the absence of an organized medical specimen transportation system. Tissue samples obtained through biopsy or surgery frequently rely on informal transport over distances exceeding 1,500 km, increasing transportation costs, delaying diagnosis and exposing specimens to suboptimal pre-analytical conditions. Such delays may adversely affect tissue preservation and reduce the quality of histopathological interpretation and immunohistochemical analyses. These challenges have also been reported in other sub-Saharan African countries, where weaknesses in specimen referral systems contribute to delayed and incomplete cancer diagnosis [21].

Another major finding is the prolonged turnaround time for pathology reports, which ranged from one to six months during the study period. These delays greatly exceed those reported in several African referral centers and may postpone surgery, systemic therapy and radiotherapy, thereby increasing the risk of disease progression before treatment initiation. Timely pathology reporting is recognized by the WHO Global Breast Cancer Initiative as a key indicator of effective breast cancer care because it directly influences treatment initiation and patient outcomes [2, 21, 22].

Equally concerning is the complete absence of immunohistochemistry (IHC) throughout the study period. Without assessment of ER, PR and HER2 status, molecular classification and personalized treatment according to current ESMO and NCCN recommendations were impossible. Similar deficiencies have been described across sub-Saharan Africa, where many laboratories still lack the equipment, reagents and trained personnel required for routine biomarker testing. Recent pathology capacity-building initiatives have emphasized that expanding access to high-quality immunohistochemistry should be a priority for improving breast cancer diagnosis and treatment in low-resource settings [11, 12, 21, 22].

These findings suggest that improving breast cancer outcomes in Niger will require more than increasing the number of pathology laboratories. Establishing an organized national specimen referral system, decentralizing pathology services, strengthening laboratory quality assurance, expanding the pathology workforce and introducing routine immunohistochemistry should be

considered essential priorities. Such investments would improve diagnostic completion, facilitate evidence-based treatment and support implementation of the WHO Global Breast Cancer Initiative in Niger and other resource-limited settings. [23, 24].

Clinical implications of the absence of histopathological confirmation and immunohistochemistry

The present study demonstrates that the absence of histopathological confirmation has consequences extending far beyond diagnostic uncertainty. Although all women in our cohort had malignant FNAC findings, most were treated without histopathological confirmation, and none had access to immunohistochemistry (IHC) or hormone receptor testing. Consequently, therapeutic decisions frequently relied on cytological findings and clinical staging alone, without the pathological information required for contemporary evidence-based breast cancer management. This practice differs substantially from current international recommendations, which advocate histological confirmation and biomarker assessment before definitive treatment whenever feasible [2, 11, 12].

According to current ESMO and NCCN guidelines, pathological evaluation should include histological subtype, tumour grade and routine assessment of estrogen receptor (ER), progesterone receptor (PR) and HER2 status, preferably from a core needle biopsy. These parameters are essential for molecular classification and guide decisions regarding endocrine therapy, HER2-targeted therapy and chemotherapy. Without this information, clinicians cannot reliably individualize treatment, increasing the risk of both under-treatment and over-treatment [11, 12].

The complete absence of immunohistochemistry in our study has particularly important therapeutic implications. Patients who might benefit from endocrine therapy or HER2-targeted treatment cannot be identified, and newer therapeutic strategies based on HER2-low expression remain inaccessible. Consequently, advances in precision oncology cannot be translated into routine clinical practice despite their growing importance in international breast cancer guidelines [11, 25].

Histopathological assessment also plays a central role in surgical and multidisciplinary management. Examination of surgical specimens provides information on tumour size, histological grade, lymphovascular invasion, margin status and nodal involvement, all of which influence postoperative treatment decisions. In our cohort, many women underwent surgery without pathological examination of the surgical specimen, limiting accurate staging and multidisciplinary treatment planning. [11, 25, 26].

Beyond patient management, limited pathology capacity also compromises cancer surveillance and research. Histopathological confirmation is essential for the accuracy of cancer registries, epidemiological monitoring and evaluation of national cancer control programmes. The WHO Global Breast Cancer Initiative therefore recognizes pathology services as a fundamental component of effective breast cancer control. Expanding access to histopathology and basic immunohistochemistry would improve diagnostic accuracy, facilitate personalized treatment,

strengthen multidisciplinary care and enhance the quality of cancer surveillance in Niger and other resource-limited settings [2, 11, 26].

Implications for health policy and the WHO Global Breast Cancer Initiative

Our findings have important implications for breast cancer control policies in Niger and other low-resource settings. They suggest that improving breast cancer outcomes requires strengthening the entire diagnostic pathway rather than focusing exclusively on treatment availability. Although surgery, chemotherapy and radiotherapy are increasingly supported through public funding in Niger, these investments cannot achieve their full impact if women are unable to access timely histopathological confirmation and biomarker assessment. Pathology services should therefore be considered an essential component of comprehensive cancer care rather than an optional diagnostic procedure, in line with the WHO Global Breast Cancer Initiative [2, 27].

The WHO GBCI identifies early detection, timely diagnosis and comprehensive treatment as the three pillars required to reduce breast cancer mortality. Our study highlights weaknesses affecting both timely diagnosis and comprehensive management, including limited pathology infrastructure, prolonged diagnostic delays and the complete absence of immunohistochemistry. These deficiencies compromise implementation of guideline-concordant care and underscore the need to strengthen pathology services as a national priority [2, 27].

Reducing financial barriers should represent another key policy objective. In many low-income countries, cancer treatment is increasingly subsidized, whereas diagnostic investigations remain largely financed through out-of-pocket payments. This fragmented financing model limits completion of the diagnostic pathway and delays evidence-based treatment. Integrating FNAC, core needle biopsy, histopathology and basic immunohistochemistry into publicly funded cancer care packages could substantially improve equitable access to diagnosis and support implementation of universal health coverage [2, 27].

Strengthening pathology capacity will also require organizational reforms beyond infrastructure expansion. Establishing a national specimen referral network, decentralizing pathology services, standardizing pathology reporting, strengthening quality assurance systems and expanding the pathology workforce should be prioritized. In addition, introducing routine immunohistochemistry for ER, PR and HER2 assessment would enable molecular classification and facilitate evidence-based treatment according to international recommendations. Similar priorities have been identified by recent regional pathology capacity-building initiatives across sub-Saharan Africa [2, 28].

Finally, our study provides baseline evidence to guide future national cancer planning. Monitoring pathology capacity, turnaround times, access to biomarker testing and diagnostic completion should become integral components of cancer programme evaluation. Prospective studies evaluating socioeconomic barriers, pathology financing and the impact of health-system interventions will be essential for supporting implementation of the WHO Global Breast Cancer

Initiative and improving equitable breast cancer care in Niger and other resource-limited settings. [2].

Study strengths and limitations

This study has several important strengths. To our knowledge, it is the first multicenter study from Niger to specifically investigate histopathological confirmation among women with cytologically diagnosed breast cancer. Unlike most previous African studies restricted to histologically confirmed cases, our study evaluated the diagnostic pathway following malignant fine-needle aspiration cytology (FNAC), thereby identifying women who failed to complete pathological confirmation. This approach provides a more comprehensive assessment of diagnostic completion and addresses an important but underexplored gap in breast cancer care within low-resource settings.

The study also included a relatively large cohort of 674 consecutive women managed in the two national referral hospitals for breast cancer over a five-year period. As these institutions receive patients from all regions of Niger, our findings provide valuable insight into routine breast cancer management at the national referral level. Furthermore, multivariable logistic regression with assessment of model calibration and discrimination strengthened the robustness of the statistical analysis and the identification of independent predictors of failure to obtain histopathological confirmation.

Several limitations should nevertheless be acknowledged. First, the retrospective design is inherently subject to missing data and information bias. Second, because the study was conducted in two national referral hospitals, the findings may not be generalizable to women who never reached tertiary care, introducing the possibility of referral bias. Third, although our study demonstrated a remarkably low rate of histopathological confirmation, the individual reasons for not performing histopathological examination were not systematically documented in the medical records. Consequently, financial, geographical, laboratory and sociocultural barriers should be interpreted as contextual characteristics of the national health system rather than patient-level variables directly measured in this study. Fourth, although patients with incomplete medical records were excluded to ensure data quality, this approach may have introduced a small risk of selection bias if excluded patients differed systematically from those included.

Another important limitation is the complete absence of immunohistochemistry during the study period, which prevented analysis of molecular breast cancer subtypes and their potential influence on treatment patterns and outcomes. Finally, as with all observational studies, causal relationships cannot be established, and residual confounding by unmeasured socioeconomic or health-system factors cannot be excluded. Prospective multicenter studies incorporating patient-level economic, geographical and cultural determinants are needed to better understand barriers to histopathological confirmation and evaluate interventions aimed at improving access to pathology services.

Despite these limitations, our study provides robust evidence on one of the least investigated aspects of breast cancer care in sub-Saharan Africa. By documenting the magnitude of incomplete histopathological confirmation and highlighting its implications for diagnosis and treatment, our findings provide an important evidence base to inform future clinical practice, health policy and implementation of the WHO Global Breast Cancer Initiative in Niger and similar resource-limited settings.

5. CONCLUSION

This multicenter study demonstrates that histopathological confirmation remains a major unmet need in the management of breast cancer in Niger. Although all women had malignant fine-needle aspiration cytology, only a minority subsequently underwent histopathological confirmation, and no patient had access to immunohistochemistry. These findings highlight substantial deficiencies in the diagnostic pathway that may compromise accurate tumour characterization and guideline-concordant treatment.

Improving breast cancer outcomes will require strengthening pathology services through expansion of laboratory capacity, implementation of organized specimen referral systems, reduction of financial barriers to diagnostic investigations, and introduction of routine immunohistochemistry. Integrating these essential pathology services into national cancer control programmes and universal health coverage should be considered a priority to improve equitable access to high-quality breast cancer care.

Future prospective studies should evaluate patient-level determinants of incomplete histopathological confirmation and assess the impact of interventions designed to improve access to pathology services. Such evidence will support implementation of the WHO Global Breast Cancer Initiative and contribute to reducing disparities in breast cancer outcomes across resource-limited settings.

Author contributions

M.O., H.S.D., A.O.S., I.I.D., and M.N: Study's conception and design, data collection, manuscript drafting, draft review, and manuscript finalization.

A.A., Z.S.L., A.A.I., and R.S: Data collection, formal analysis, interpretation and review.

All authors read and approved the final manuscript.

Acknowledgments

Not applicable

Funding

No funding was received for this study.

Conflict of interest statement

The authors declare no competing interests.

Consent for publication

Not applicable.

Ethics approval

Ethical approval for this study was obtained from the Institutional Review Board (IRB) of the Faculty of Health Sciences of Abdou Moumouni University, Niamey, Niger (Approval No. 000978/2AUA/FSS/SS).

Consent to participate

Given the retrospective design of the study and the use of routinely collected, fully anonymized hospital data, the need for consent to participate was waived by the Institutional Review Board (IRB) of the Faculty of Health Sciences of Abdou Moumouni University (Approval No. 000978/2AUA/FSS/SS).

Data availability statement

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

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