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# ACR BI-RADS classification in the diagnostic management of suspicious breast lesions: A multicentre study (2014–2025), Democratic Republic of the Congo

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**ABSTRACT**

**Introduction**
Breast cancer remains a major global health burden, particularly in low- and middle-income countries. The American College of Radiology Breast Imaging Reporting and Data System (ACR BI-RADS) standardises breast imaging interpretation and guides clinical decision-making. However, evidence on its diagnostic performance in the Democratic Republic of the Congo (DRC) is limited.

**Purpose**
To assess the diagnostic and clinical contribution of BI-RADS in the management of suspicious breast lesions in the DRC using radiological–histopathological correlation.

**Methods**
A retrospective multicentre diagnostic accuracy study was conducted across five hospitals in the DRC (2014–2025). Patients with BI-RADS-classified breast imaging and histopathological confirmation were included. BI-RADS 4–5 were considered positive for malignancy, while BI-RADS 2–3 were negative or low suspicion. Histopathology served as the reference standard. Diagnostic performance was evaluated using sensitivity, specificity, predictive values, Youden's index, and AUC. Multivariable logistic regression identified factors associated with malignancy.

**Results**
Of 3,447 patients, 3,046 BI-RADS 1 cases were excluded due to lack of histological indication, leaving 401 patients for analysis. Malignancy was confirmed in 66.6% (267/401). Mean age was 49.5 ± 13.9 years, and 96.5% presented with a palpable mass. Mammography showed a sensitivity of 93.3%, specificity of 70.9%, and AUC of 0.857. Ultrasound showed a sensitivity of 88.0%, specificity of 75.4%, and AUC of 0.840. Age ≥70 years, multiparity, and advanced clinical stage were independently associated with malignancy, while physical activity was protective.

**Conclusion**
BI-RADS demonstrates good diagnostic performance for suspicious breast lesions in the DRC. Mammography is more sensitive, while ultrasound is more specific, supporting their complementary use. Strengthening radiologist training, standardised reporting, and access to biopsy and pathology services is essential for optimising BI-RADS effectiveness in low-resource settings.

## INTRODUCTION

Breast tumours constitute a major public health concern because of their high incidence and substantial contribution to morbidity and mortality, particularly among women. Breast cancer is the most frequently diagnosed cancer globally and remains the leading cause of cancer-related death among women. According to recent global estimates, approximately 2.3 million new cases and 670,000 deaths were recorded in 2022, underscoring its considerable public health burden (Bray et al., 2024; Siegel et al., 2023; Sung et al., 2021). Although breast cancer is uncommon in men, it remains an important clinical entity requiring timely diagnosis and appropriate management (Elbachiri et al., 2017; Sah et al., 2025).

The burden of breast cancer is increasing rapidly in low- and middle-income countries, particularly in sub-Saharan Africa, where rising incidence is accompanied by persistently high mortality rates. These outcomes are largely attributable to delayed presentation, limited awareness, inadequate screening programmes, shortages of specialised healthcare personnel, and restricted access to diagnostic and treatment services (Anyigba et al., 2021; Jedy-Agba et al., 2020; Pace & Shulman, 2015). In the Democratic Republic of the Congo (DRC), these challenges are compounded by inadequate health infrastructure, limited availability of breast imaging services, shortages of pathology facilities, financial barriers to care, and the absence of organised population-based screening programmes. Consequently, many patients present with advanced-stage disease, thereby reducing opportunities for curative treatment and adversely affecting survival (Luyeye et al., 2019).

Early detection of breast cancer depends on a coordinated diagnostic pathway that integrates community awareness, clinical breast examination, imaging evaluation, tissue sampling, and histopathological confirmation. Mammography remains the reference imaging modality for breast cancer screening because of its proven effectiveness in detecting early-stage disease and microcalcifications before they become clinically apparent. Breast ultrasonography serves as an important complementary modality, particularly in younger women, patients with dense breast tissue, and those presenting with palpable abnormalities requiring targeted evaluation (Berg et al., 2004; Kolb et al., 2002). More advanced imaging techniques, including digital breast tomosynthesis, magnetic resonance imaging (MRI), and contrast-enhanced mammography, have further improved lesion detection and characterisation. However, their availability remains limited in many low-resource settings because of financial, technical, and human resource constraints (Dromain et al., 2019; Haute Autorité de Santé, 2019).

To improve the consistency and quality of breast imaging interpretation, the American College of Radiology developed the Breast Imaging Reporting and Data System (BI-RADS), an internationally recognised reporting framework that standardises the description of imaging findings across mammography, ultrasonography, and breast MRI. BI-RADS provides a uniform lexicon, estimates the probability of malignancy, and recommends appropriate clinical management, thereby facilitating communication among radiologists, surgeons, oncologists, pathologists, and other members of the multidisciplinary breast care team (American College of Radiology, 2025; D'Orsi et al., 2013). The widespread adoption of BI-RADS has improved reporting consistency, reduced interpretive variability, and supported quality assurance in breast imaging practice.

Nevertheless, the diagnostic performance of BI-RADS is influenced by several factors, including image quality, radiologist expertise, patient characteristics, availability of image-guided biopsy, access to histopathological services, and adherence to recommended follow-up protocols. In particular, BI-RADS category 4 encompasses a heterogeneous group of lesions with varying probabilities of malignancy and is therefore recommended to be subdivided into categories 4A, 4B, and 4C to improve risk stratification and clinical decision-making (Sardanelli et al., 2017). Consequently, radiological assessment alone cannot establish a definitive diagnosis, making histopathological confirmation the reference standard for suspicious lesions.

Although the use of breast imaging has gradually expanded within the DRC, evidence regarding the diagnostic performance and clinical utility of BI-RADS in routine practice remains scarce. Published studies from

the country have largely focused on the epidemiological profile of breast cancer rather than the accuracy of imaging-based risk stratification. To the best of our knowledge, no multicentre study spanning more than a decade has evaluated the diagnostic performance of BI-RADS using histopathological confirmation as the reference standard across multiple healthcare institutions in the DRC. This represents an important evidence gap, particularly in a healthcare system where diagnostic resources are limited and efficient use of available services is essential.

Conceptually, BI-RADS forms part of an integrated diagnostic pathway linking imaging findings with estimation of malignancy risk, decisions regarding surveillance or biopsy, histopathological confirmation, and subsequent therapeutic management. In low-resource settings, the effectiveness of this pathway depends not only on the diagnostic accuracy of the BI-RADS classification itself but also on the availability of trained personnel, standardised reporting practices, timely pathology services, multidisciplinary collaboration, and mechanisms for patient follow-up (World Health Organization, 2023). Evaluating the performance of BI-RADS within this broader clinical context is therefore essential for strengthening breast cancer diagnosis and improving patient outcomes in resource-constrained environments.

The present study aimed to evaluate the contribution of the BI-RADS classification to the diagnosis and clinical management of suspicious breast lesions in the Democratic Republic of the Congo through radiological–histopathological correlation. Specifically, the study sought to determine the frequency of malignant lesions among patients with BI-RADS-classified breast abnormalities, describe their sociodemographic, clinical, and radiological characteristics, evaluate the diagnostic performance of mammography and ultrasonography using histopathology as the reference standard, and identify factors associated with malignant breast lesions. The findings are expected to provide evidence to support the optimisation of breast imaging practices and strengthen diagnostic pathways for breast cancer in the DRC and similar low-resource settings.

## METHODS

### *Study Design and Setting*

This retrospective multicentre diagnostic accuracy study with radiological–histopathological correlation was conducted between January 2014 and January 2025 in five referral hospitals in the Democratic Republic of the Congo (DRC). The participating institutions included the University Clinics of Kinshasa, Camp Kokolo Military Hospital, HJ Hospital, and two referral hospitals located in Kongo Central Province. These hospitals were purposively selected because they routinely provide breast imaging services and have access to histopathological diagnostic facilities, thereby enabling radiological–pathological correlation.

The study evaluated the diagnostic performance of the American College of Radiology Breast Imaging Reporting and Data System (ACR BI-RADS) in the assessment of suspicious breast lesions by comparing imaging findings with histopathological diagnoses, which served as the reference standard.

### *Study Population*

The source population comprised all patients who underwent breast imaging during the study period. Eligible participants were patients who presented with a breast lesion or swelling, underwent at least one BI-RADS-classified breast imaging examination (mammography and/or ultrasonography), and subsequently had histopathological confirmation of the lesion.

Patients whose imaging examinations were classified as BI-RADS category 1 (negative examination) were excluded from the diagnostic accuracy analysis because histopathological confirmation was not clinically indicated in the absence of suspicious imaging findings. Consequently, only patients with BI-RADS categories 2–5 who had complete histopathological diagnoses were included in the final analysis.

Of the 3,447 patients who underwent breast imaging during the study period, 3,046 (88.4%) were classified as BI-RADS 1 and were excluded. The remaining 401 patients, classified as BI-RADS categories 2–5 with complete histopathological confirmation, constituted the final study population.

### *Sampling Technique*

No formal sample size calculation was performed because the study employed exhaustive sampling. All eligible patients meeting the inclusion criteria during the study period were included to maximise statistical power and minimise selection bias inherent in retrospective hospital-based studies.

### *Study Variables*

The primary outcome variable was the histopathological diagnosis of the breast lesion, categorised as benign or malignant.

Independent variables included:

- **Sociodemographic characteristics:** age, province of residence, occupation, educational attainment, and marital status.
- **Reproductive and medical history:** age at menarche, gravidity, parity, number of children, menopausal status, history of abortion, family history of cancer, alcohol consumption, tobacco use, medication history, and physical activity.
- **Clinical characteristics:** presenting complaint, breast symptoms, side of involvement, presence of a palpable mass, nutritional status, body mass index (BMI), and clinical stage according to the Tumour–Node–Metastasis (TNM) classification.
- **Radiological variables:** imaging modality, breast density, presence of calcifications, and BI-RADS category assigned on mammography and ultrasonography.
- **Treatment and outcome variables:** surgery, chemotherapy, radiotherapy, survival status, mortality, and loss to follow-up.

### *Breast Imaging Evaluation*

Breast imaging examinations included mammography and ultrasonography performed as part of routine clinical care. Imaging findings were interpreted by qualified radiologists and classified according to the American College of Radiology BI-RADS lexicon applicable at the time of reporting.

For diagnostic accuracy analysis, BI-RADS categories were dichotomised as follows:

- **Positive imaging result:** BI-RADS categories 4 and 5.
- **Negative or low-suspicion imaging result:** BI-RADS categories 2 and 3.

Because BI-RADS category 1 examinations did not undergo histopathological verification, they were excluded from the diagnostic performance analysis to avoid inappropriate comparison with the reference standard.

Although BI-RADS category 4 is conventionally subdivided into categories 4A, 4B, and 4C, these subcategories were not consistently documented across participating centres throughout the study period and therefore could not be analysed separately.

### *Histopathological Assessment*

Histopathological examination of tissue specimens obtained through biopsy or surgical excision served as the reference standard for diagnosis. Final histopathological diagnoses were extracted from pathology reports contained in hospital records and were categorised as benign or malignant.

Radiological findings were subsequently compared with histopathological diagnoses to evaluate the diagnostic performance of BI-RADS classification.

### *Data Collection Procedures*

Data were retrieved retrospectively from physical medical records, electronic hospital databases, radiology registers, pathology reports, and surgical records using a standardised data extraction form developed for the study. The extracted information included patient demographics, clinical presentation, imaging findings, BI-RADS classification, histopathological diagnosis, treatment received, and patient outcomes. Data completeness and consistency were verified before entry into the study database to minimise transcription errors.

### *Statistical Analysis*

Data were entered into Microsoft Excel and analysed using Stata version 18 (StataCorp LLC, College Station, TX, USA).

Continuous variables were summarised using means and standard deviations for normally distributed data or

medians and interquartile ranges where appropriate. Categorical variables were presented as frequencies and percentages.

Comparisons between benign and malignant lesions were performed using the Pearson chi-square test or Fisher's exact test for categorical variables, as appropriate. Continuous variables were compared using Student's *t*-test or the Mann–Whitney *U* test, depending on data distribution.

Variables considered clinically relevant or demonstrating statistical significance in univariable analyses were entered into a multivariable logistic regression model to identify factors independently associated with malignant breast lesions. Adjusted odds ratios (aORs), 95% confidence intervals (CIs), and corresponding *p*-values were reported. Statistical significance was established at $p < .05$.

### *Diagnostic Accuracy Analysis*

Histopathological diagnosis was considered the reference standard against which the diagnostic performance of mammography and ultrasonography was evaluated.
Diagnostic accuracy measures included:

- Sensitivity
- Specificity
- Positive predictive value (PPV)
- Negative predictive value (NPV)
- Youden's index
- Area under the receiver operating characteristic (ROC) curve (AUC)

Receiver operating characteristic curves were generated separately for mammography and ultrasonography to assess their overall ability to discriminate between benign and malignant lesions. AUC values were interpreted according to established diagnostic performance criteria, with higher values indicating better discriminatory ability.

### *Bias and Quality Considerations*

Several measures were undertaken to enhance methodological rigour. Exhaustive inclusion of all eligible patients during the study period reduced sampling bias. Histopathological diagnosis served as the reference standard for all included cases, thereby permitting direct radiological–pathological correlation.

Nevertheless, because histopathological confirmation was not routinely indicated for BI-RADS category 1 examinations, diagnostic accuracy estimates were restricted to patients with BI-RADS categories 2–5 who underwent tissue diagnosis. This may have introduced partial verification bias, a recognised limitation of retrospective diagnostic accuracy studies.

Furthermore, imaging examinations were performed over an 11-year period across multiple institutions. Although BI-RADS reporting followed American College of Radiology recommendations throughout the study period, variations in imaging equipment, reporting practices, and radiologist experience between centres could not be entirely excluded. In addition, BI-RADS category 4 subcategories (4A, 4B, and 4C) were not consistently documented, and interobserver agreement among radiologists was not assessed.

### *Ethical Considerations*

Ethical approval for the study was obtained from the Ethics Committee of the School of Public Health of the University of Kinshasa, acting as the National Ethics Committee (Approval No. ESP/CE/B45/2024).

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and its subsequent amendments. Because of the retrospective nature of the study, only routinely collected clinical data were analysed. Patient anonymity was preserved by removing all personal identifiers before analysis, and strict confidentiality of patient information was maintained throughout the study.

## RESULTS

### *Study Population*

During the study period, 3,447 patients underwent breast imaging across the participating centres. Of these, 3,046 patients (88.4%) were classified as BI-RADS 1 and were excluded from the diagnostic accuracy analysis because histopathological confirmation was not clinically indicated. The remaining 401 patients with BI-RADS categories 2–5 and available histopathological diagnoses constituted the final study population for all subsequent analyses.

### *Sociodemographic Characteristics*

The mean age of the study population was 49.5 ± 13.9 years. Patients aged 41–69 years constituted the largest age group, accounting for 60.1% (n = 241) of the study population, followed by those aged <40 years (27.9%; n = 112) and those aged ≥70 years (12.0%; n = 48).

More than half of the participants were married (51.6%; n = 207), whereas 31.4% (n = 126) were single, 15.0% (n = 60) were widowed, and 1.9% (n = 8) were divorced.

With respect to occupation, the majority of participants were employed in the formal sector (55.1%; n = 221), while 34.7% (n = 139) were housewives and 10.2% (n = 41) worked in the informal sector.

Regarding educational attainment, secondary education was the most frequently reported level (56.6%; n = 227), followed by higher or university education (32.2%; n = 129) and primary education (11.2%; n = 45) **(Table 1)**.

**Table 1:**
Sociodemographic characteristics of the study population (N = 401)

| Variable | n | % |
|---|---|---|
| **Age (years), mean ± SD** | **49.5 ± 13.9** | – |
| <40 | 112 | 27.9 |
| 41–69 | 241 | 60.1 |
| ≥70 | 48 | 12.0 |
| **Marital status** | | |
| Married | 207 | 51.6 |
| Single | 126 | 31.4 |
| Widowed | 60 | 15.0 |
| Divorced | 8 | 2.0* |
| **Occupation** | | |
| Housewife | 139 | 34.7 |
| Formal sector | 221 | 55.1 |
| Informal sector | 41 | 10.2 |
| **Educational level** | | |
| Primary | 45 | 11.2 |
| Secondary | 227 | 56.6 |
| Higher/University | 129 | 32.2 |

*Percentages may not total exactly 100% because of rounding.

### *Clinical Characteristics*

Overall, 45.9% of participants were either overweight or obese, comprising 32.9% (n = 132) who were overweight and 13.0% (n = 52) who were obese, whereas 54.1% (n = 217) had a normal nutritional status.

Regarding reproductive history, 60.6% (n = 243) of participants had experienced two or more pregnancies, and 61.8% (n = 248) had two or more children. Menopause was reported by 25.9% (n = 104) of participants.

The most common presenting complaint was a painful breast mass, reported by 58.1% (n = 233) of patients, followed by a painless breast mass (37.7%; n = 151). Less frequent reasons for consultation included breast pain without a palpable mass (2.0%), ulceration (1.0%), isolated axillary lymphadenopathy (0.7%), and family history prompting consultation (0.5%).

A palpable breast mass was identified on clinical examination in 96.5% (n = 387) of patients. The left breast was affected more frequently than the right (69.6% vs. 30.4%).

Lifestyle characteristics showed that 26.4% (n = 106) of participants reported alcohol consumption, whereas tobacco use was uncommon (1.2%; n = 5). Only 9.2% (n = 37) reported regular physical activity. Approximately one-third of participants (34.9%; n = 140) reported practising breast self-palpation, and the same proportion indicated that they had previously received information about breast cancer.

Clinical staging demonstrated that Stage II disease was the most common presentation (37.2%; n = 149), followed by Stage I (32.2%; n = 129) and Stage III (28.9%; n = 116). Only 1.7% (n = 7) of patients presented with Stage IV disease **(Table 2)**.

**Table 2:**
Clinical characteristics of the study population (N = 401)

| Variable | n | % |
|---|---|---|
| **Nutritional status** | | |
| Normal | 217 | 54.1 |
| Overweight | 132 | 32.9 |
| Obese | 52 | 13.0 |
| **Menopause** | 104 | 25.9 |
| **Number of pregnancies** | | |
| 0 | 97 | 24.2 |
| 1 | 61 | 15.2 |
| ≥2 | 243 | 60.6 |
| **Number of children** | | |
| 0 | 102 | 25.4 |
| 1 | 51 | 12.7 |

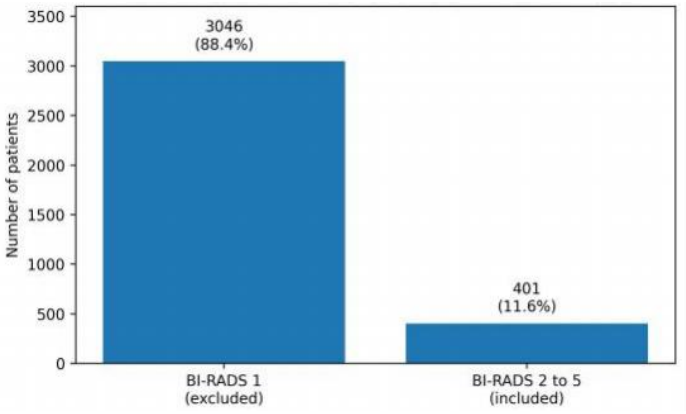
| Variable | n | % |
|---|---|---|
| ≥2 | 248 | 61.8 |
| **Family history of cancer** | 7 | 1.7 |
| **Reason for consultation** | | |
| Painful breast mass | 233 | 58.1 |
| Painless breast mass | 151 | 37.7 |
| Breast pain without mass | 8 | 2.0 |
| Axillary lymphadenopathy | 3 | 0.7 |
| Family history | 2 | 0.5 |
| Ulceration | 4 | 1.0 |
| **Tobacco use** | 5 | 1.2 |
| **Alcohol use** | 106 | 26.4 |
| **Medication use** | 37 | 9.2 |
| **Regular physical activity** | 37 | 9.2 |
| **Breast self-palpation** | 140 | 34.9 |
| **Previous breast cancer information** | 140 | 34.9 |
| **Affected breast** | | |
| Left | 279 | 69.6 |
| Right | 122 | 30.4 |
| **Palpable breast mass** | 387 | 96.5 |
| **Clinical stage** | | |
| Stage I | 129 | 32.2 |
| Stage II | 149 | 37.2 |
| Stage III | 116 | 28.9 |
| Stage IV | 7 | 1.7 |

## *Radiological Characteristics*

### *Breast Imaging and BI-RADS Distribution*

A total of 3,447 breast imaging examinations were performed during the study period, including both mammography and ultrasonography **(Figure 1)**.

**Figure 1:**
Distribution of patients according to initial BI-RADS classification




On ultrasonography, BI-RADS 1 was the most frequent classification, accounting for 3,046 cases (88.4%), followed by BI-RADS 4 in 214 cases (6.2%), BI-RADS 3 in 124 cases (3.6%), BI-RADS 5 in 54 cases (1.6%), and BI-RADS 2 in 9 cases (0.3%).

A similar distribution was observed on mammography, where BI-RADS 1 also predominated (88.4%; n = 3,046). BI-RADS 4 accounted for 213 cases (6.2%), BI-RADS 3 for 103 cases (3.0%), BI-RADS 5 for 75 cases (2.2%), and BI-RADS 2 for 10 cases (0.3%).

### *Breast Density and Imaging Features*

Breast density assessment showed that ACR B density predominated, representing 62.9% on ultrasound and 63.2% on mammography. This was followed by ACR A density (26.4% on both modalities). Less dense patterns were less frequent, with ACR C accounting for approximately 9% and ACR D for 1.7–2.0%, depending on modality.

Calcifications were relatively uncommon but slightly more frequently detected on mammography (2.2%; n = 76) compared with ultrasonography (1.6%; n = 54) **(Table 3)**.

**Table 3:**
Radiological characteristics according to imaging modality (N = 3,447)

| Variable | Ultrasound n (%) | Mammography n (%) |
|---|---|---|
| **BI-RADS classification** | | |
| BI-RADS 1 | 3046 (88.4) | 3046 (88.4) |
| BI-RADS 2 | 9 (0.3) | 10 (0.3) |
| BI-RADS 3 | 124 (3.6) | 103 (3.0) |
| BI-RADS 4 | 214 (6.2) | 213 (6.2) |
| BI-RADS 5 | 54 (1.6) | 75 (2.2) |
| **Breast density (ACR)** | | |
| A | 910 (26.4) | 910 (26.4) |
| B | 2168 (62.9) | 2178 (63.2) |
| C | 309 (8.9) | 310 (9.0) |
| D | 70 (2.0) | 59 (1.7) |
| **Calcifications** | | |
| No | 3393 (98.4) | 3371 (97.8) |
| Yes | 54 (1.6) | 76 (2.2) |

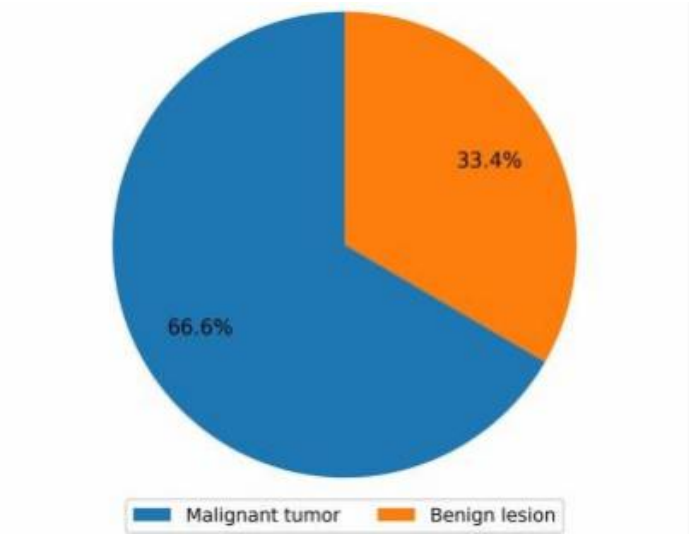
## *Histopathological Findings*

### *Overall Histological Profile*

Among the 401 patients included in the final analysis, histopathological examination confirmed that 267 cases (66.6%) were malignant, while 134 cases (33.4%) were

benign, corresponding to an approximate 2:1 ratio in favour of malignancy (Figure 2).

**Figure 2:**
Distribution of tumors according to histopathological profile




*Types of Benign and Malignant Lesions*

Among benign lesions (n = 134), the most frequently identified diagnoses were apocrine cysts (20.9%), epithelial hyperplasia (18.7%), and chronic inflammatory lesions (17.2%). Fibroadenoma accounted for 11.9%, while less common benign entities included abscesses, duct ectasia, sclerosis, and granulomatous mastitis.

Among malignant lesions (n = 267), invasive ductal carcinoma was the predominant histological subtype, representing 61.4% of cases. This was followed by invasive carcinoma (15.0%) and adenocarcinoma (13.5%). Less frequent malignancies included micropapillary carcinoma, mucosecretory adenocarcinoma, lobular carcinoma, and rare tumour types such as malignant phyllodes tumour (Table 4).

**Table 4:**
Histopathological classification of breast lesions (N = 401)

| Lesion type | n | % |
|---|---|---|
| **Benign lesions (n = 134)** | | |
| Apocrine cysts | 28 | 20.9 |
| Hyperplasia | 25 | 18.7 |
| Chronic inflammation | 23 | 17.2 |
| Fibroadenoma | 16 | 11.9 |
| Acute inflammation | 8 | 6.0 |
| Tuberculous granulomatous mastitis | 8 | 6.0 |
| Sclerosis | 8 | 6.0 |
| Abscess | 6 | 4.4 |
| Duct ectasia | 4 | 3.0 |
| Granular cell tumour | 4 | 3.0 |
| Fibrosis | 3 | 2.2 |
| Lipomatosis | 1 | 0.7 |
| **Malignant lesions (n = 267)** | | |
| Ductal carcinoma | 164 | 61.4 |
| Invasive carcinoma | 40 | 15.0 |
| Adenocarcinoma | 36 | 13.5 |
| Micropapillary carcinoma | 8 | 3.0 |
| Mucosecretory adenocarcinoma | 7 | 2.6 |
| Lobular carcinoma | 6 | 2.2 |
| Nodal carcinoma | 2 | 0.7 |
| Carcinoma (NOS) | 1 | 0.4 |
| Granular cell tumour (malignant) | 1 | 0.4 |
| Malignant phyllodes tumour | 1 | 0.4 |
| Phyllodes tumour | 1 | 0.4 |

## *Factors Associated with Breast Cancer*

*Sociodemographic Characteristics According to Histological Diagnosis*

Patients with malignant lesions were significantly older than those with benign lesions (mean age: 52.2 ± 12.8 years vs. 44.0 ± 14.5 years; $p < 0.001$).

The proportion of patients aged 41–69 years was higher in the malignant group (65.9%) compared with the benign group (48.5%), while a higher proportion of benign lesions occurred in patients aged <40 years.

Multiparity (≥2 pregnancies) was significantly more frequent among patients with malignant lesions (66.3% vs. 49.3%; $p < 0.001$). Similar patterns were observed for number of children, with 67.4% of malignant cases having ≥2 children compared with 50.7% of benign cases.

Marital status, occupation, and educational level did not show statistically significant associations with histological outcome (Table 5).

**Table 5:**
Sociodemographic characteristics according to histological diagnosis (N = 401)

| Variable | Malignant (n = 267) | Benign (n = 134) | p-value |
|---|---|---|---|
| **Age (years), mean ± SD** | 52.2 ± 12.8 | 44.0 ± 14.5 | <0.001 |
| **Age group** | | | |
| <40 years | 52 (19.5) | 60 (44.8) | |
| 41–69 years | 176 (65.9) | 65 (48.5) | |
| ≥70 years | 39 (14.6) | 9 (6.7) | |



https://doi.org/10.4314/orapj.v7i5.46

| Variable | Malignant (n = 267) | Benign (n = 134) | p-value |
|---|---|---|---|
| Marital status | | | 0.096 |
| Married | 154 (57.7) | 53 (39.6) | |
| Single | 60 (22.5) | 66 (49.3) | |
| Widowed | 48 (18.0) | 12 (9.0) | |
| Divorced | 5 (1.9) | 3 (2.2) | |
| Occupation | | | 0.335 |
| Housewife | 97 (36.3) | 42 (31.3) | |
| Formal sector | 160 (59.9) | 61 (45.5) | |
| Informal sector | 10 (3.7) | 31 (23.1) | |
| Education level | | | 0.285 |
| Primary | 32 (12.0) | 13 (9.7) | |
| Secondary | 156 (58.4) | 71 (53.0) | |
| Tertiary | 79 (29.6) | 50 (37.3) | |
| Number of pregnancies | | | <0.001 |
| 0 | 44 (16.5) | 53 (39.6) | |
| 1 | 46 (17.2) | 15 (11.2) | |
| ≥2 | 177 (66.3) | 66 (49.3) | |
| Number of children | | | <0.001 |
| 0 | 47 (17.6) | 55 (41.0) | |
| 1 | 40 (15.0) | 11 (8.2) | |
| ≥2 | 180 (67.4) | 68 (50.7) | |

*Clinical Characteristics According to Histological Diagnosis*

Menopausal status was significantly associated with malignancy, with a higher proportion of postmenopausal women in the malignant group (28.8% vs. 20.1%; p = 0.039).

Patients with malignant lesions more frequently presented with a painful breast mass (62.5%) compared with those with benign lesions (49.3%; p = 0.001). Conversely, painless masses were relatively more common in benign disease.

Advanced clinical stage was strongly associated with malignancy. Stages II and III accounted for 40.8% and 41.2% of malignant cases, respectively, compared with 29.9% and 4.5% in benign cases (p < 0.001).

Physical activity was less frequent among patients with malignancy (6.0% vs. 15.7%; p = 0.002), suggesting a potential protective association.

No statistically significant differences were observed for tobacco use, alcohol consumption, or BMI categories (Table 6).

**Table 6:**
Clinical characteristics according to histological diagnosis (N = 401)

| Variable | Malignant (n = 267) | Benign (n = 134) | p-value |
|---|---|---|---|
| Weight (kg), mean ± SD | 69.2 ± 12.3 | 70.1 ± 12.3 | 0.488 |
| Height (cm), mean ± SD | 164.8 ± 5.1 | 164.9 ± 9.5 | 0.870 |
| BMI (kg/m²), mean ± SD | 25.5 ± 4.2 | 26.4 ± 10.7 | 0.201 |
| Nutritional status | | | 0.689 |
| Normal | 147 (55.1) | 70 (52.2) | |
| Overweight | 88 (33.0) | 44 (32.8) | |
| Obese | 32 (12.0) | 20 (14.9) | |
| Menopause | 77 (28.8) | 27 (20.1) | 0.039 |
| Family history of breast cancer | 7 (2.6) | 0 (0.0) | 0.056 |
| Painful mass | 167 (62.5) | 66 (49.3) | 0.001 |
| Painless mass | 92 (34.5) | 59 (44.0) | |
| Pain without mass | 1 (0.4) | 7 (5.2) | |
| Axillary lymph node | 3 (1.1) | 0 (0.0) | |
| Ulceration | 2 (0.7) | 2 (1.5) | |
| Tobacco use | 4 (1.5) | 1 (0.7) | 0.758 |
| Alcohol use | 64 (24.0) | 42 (31.3) | 0.073 |
| Drug use | 26 (9.7) | 11 (8.2) | 0.382 |
| Physical activity | 16 (6.0) | 21 (15.7) | 0.002 |
| Self-palpation | 91 (34.1) | 49 (36.6) | 0.350 |
| Breast cancer information | 92 (34.5) | 48 (35.8) | 0.435 |
| Clinical stage | | | <0.001 |
| Stage I | 41 (15.4) | 88 (65.7) | |
| Stage II | 109 (40.8) | 40 (29.9) | |
| Stage III | 110 (41.2) | 6 (4.5) | |
| Stage IV | 7 (2.6) | 0 (0.0) | |

*Factors Independently Associated with Malignancy (Logistic Regression)*

In multivariate logistic regression analysis, age ≥70 years was independently associated with increased odds of malignancy (adjusted OR = 3.17; 95% CI: 1.88–8.22; p = 0.001).

Multiparity (≥2 pregnancies) was also independently associated with malignancy (adjusted OR = 1.93; 95% CI: 1.01–3.68; p = 0.047).

Advanced clinical stage showed the strongest association with malignancy. Patients with stage II disease had higher odds of malignancy (adjusted OR = 3.17), while those with stage III–IV disease had substantially higher odds (adjusted OR = 5.73; 95% CI: 3.07–9.46; p < 0.001).

Physical activity was independently associated with reduced odds of malignancy (adjusted OR = 0.39; 95% CI: 0.29–0.62; p = 0.039) (Table 7).



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**Table 7:**
Logistic regression analysis of factors associated with breast malignancy (N = 401)

| Variable | Univariate OR (95% CI) | p | Adjusted OR (95% CI) | p |
|---|---|---|---|---|
| Age ≤40 | 1 (reference) | – | 1 (reference) | – |
| 41–69 | 1.60 (0.74–3.49) | 0.237 | 1.91 (0.79–4.64) | 0.151 |
| ≥70 | 5.00 (2.22–11.29) | <0.001 | 3.17 (1.88–8.22) | 0.001 |
| Menopause (yes) | 1.61 (1.10–2.64) | 0.038 | 0.65 (0.33–1.28) | 0.212 |
| ≥2 pregnancies | 3.23 (1.98–5.27) | <0.001 | 1.93 (1.01–3.68) | 0.047 |
| Physical activity (yes) | 0.34 (0.17–0.68) | 0.002 | 0.39 (0.29–0.62) | 0.039 |
| Stage I | 1 (reference) | – | 1 (reference) | – |
| Stage II | 4.85 (2.01–7.98) | <0.001 | 3.17 (1.97–6.87) | <0.001 |
| Stage III–IV | 7.16 (2.92–10.55) | <0.001 | 5.73 (3.07–9.46) | <0.001 |

**Figure 3:**
Characterization of ultrasound and mammography BI-RADS risk

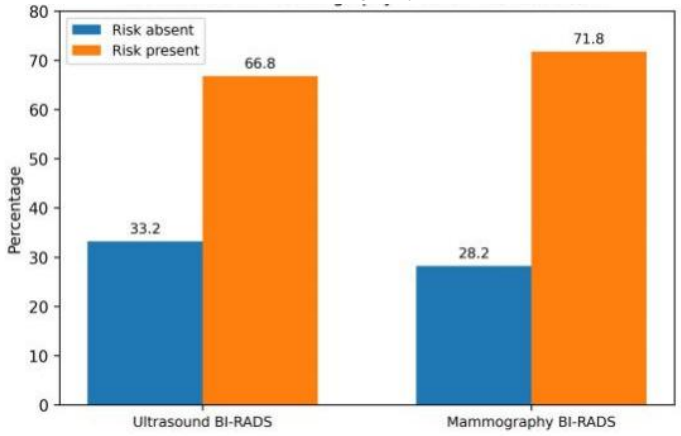



**Figure 4:**
ROC curve of the diagnostic performance of ultrasound BI-RADS for breast cancer

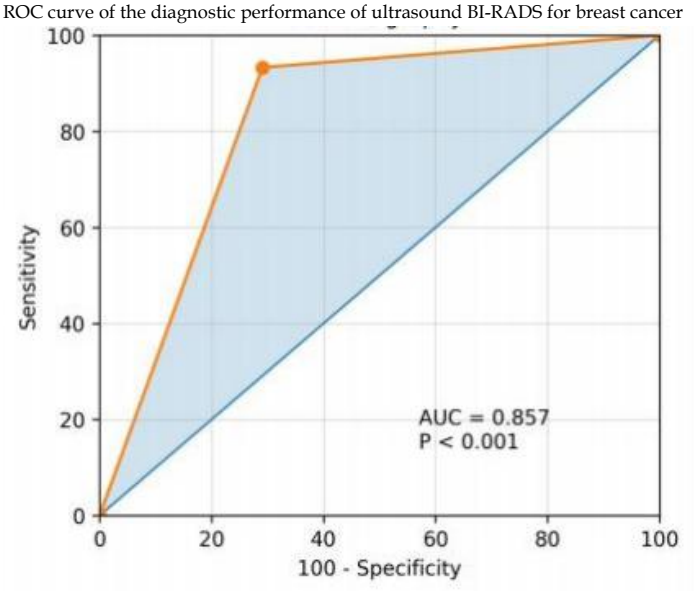
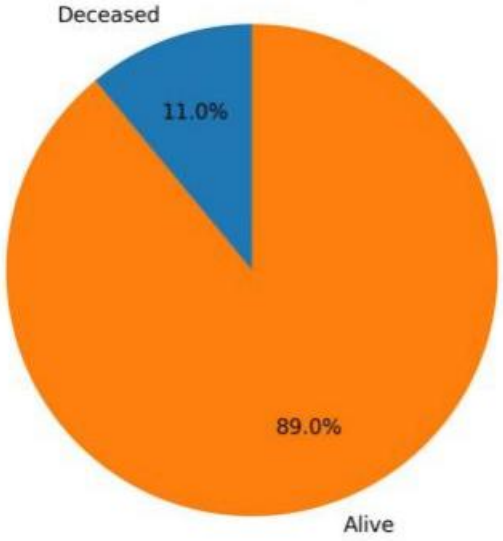



**Table 8:**
Ultrasound and mammography performance for breast cancer diagnosis

| Variable | Ultrasound *BI- RADS value* | 95% CI | Mammography *BI-RADS value* | 95% CI |
|---|---|---|---|---|
| Sensitivity (%) | 88.0 | 83.5–91.7 | 93.3 | 89.6–96.0 |
| Specificity (%) | 75.4 | 67.2–82.4 | 70.9 | 62.4–78.4 |
| PPV (%) | 87.7 | 83.2–91.1 | 86.5 | 83.0–89.3 |
| NPV (%) | 75.9 | 69.2–81.6 | 84.1 | 76.9–89.3 |
| Youden's index | 0.634 | 0.548–0.715 | 0.642 | 0.548–0.718 |
| AUC | 0.840 | 0.801–0.875 | 0.857 | 0.819–0.890 |

Most patients were alive at the time of assessment (89.0%), while a smaller proportion had died (11.0%) **(Figure 6)**.

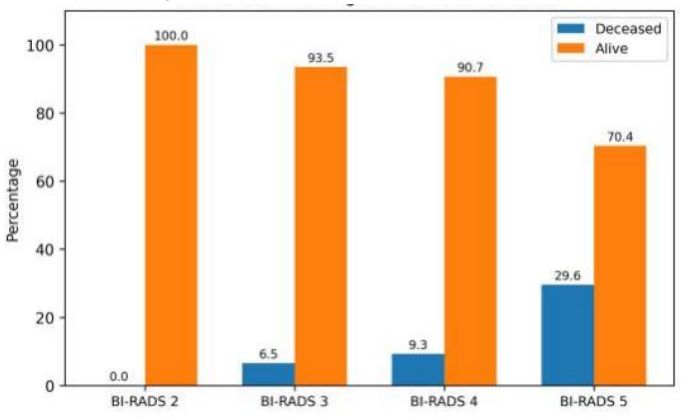
**Figure 6:**
Distribution of patients according to vital status




### *Vital status according to BI-RADS classification*

The proportion of deaths increased with higher BI-RADS categories, reaching 29.6% among patients classified as BI-RADS 5 **(Figure 7)**.

**Figure 7:**
Vital status according to BI-RADS classification



## DISCUSSION

This multicentre study evaluated the contribution of the BI-RADS classification to the diagnostic management of suspicious breast lesions in the Democratic Republic of the Congo (DRC), with histopathological correlation across five hospitals over an 11-year period. The findings demonstrate a high proportion of malignant lesions among patients undergoing diagnostic work-up, a predominance of late-stage presentation, and good overall diagnostic performance of both mammography and ultrasonography when interpreted using the BI-RADS system.

### *Burden of malignancy and clinical presentation*

In this study, malignancy was confirmed in 66.6% of cases, a proportion higher than that reported in several sub-Saharan African hospital-based series, including Nigeria and Ethiopia, where reported malignancy proportions range between approximately 48% and 54% (Jedy-Agba et al., 2020; Kantelhardt et al., 2014). This difference is most likely explained by selection bias inherent to hospital-based diagnostic cohorts, in which patients are referred primarily for imaging due to symptoms or clinical suspicion rather than population screening.

The high frequency of palpable breast masses (96.5%) and the predominance of stage II and III disease further confirm that most patients presented with clinically evident disease. These findings are consistent with earlier reports from Kinshasa and other sub-Saharan African settings, where delayed presentation is common due to limited screening infrastructure, low awareness, and barriers to accessing diagnostic services (Luyeye et al., 2019; Pace & Shulman, 2015).

### *Age distribution and epidemiological pattern*

The mean age of patients with malignant lesions (52.2 years) aligns with the typical age distribution reported in sub-Saharan Africa, where breast cancer is frequently diagnosed in women aged 40–55 years (Sung et al., 2021; Bray et al., 2024). This is notably younger than in high-income countries, where diagnosis tends to occur in older populations. The observed difference likely reflects a combination of demographic structure, reproductive patterns, genetic susceptibility, and health system constraints that delay early detection.

### *Reproductive and lifestyle factors*

Multiparity was significantly associated with malignancy in both univariate and multivariate analyses. While this finding appears counterintuitive when compared with established evidence suggesting a protective effect of parity, it should be interpreted cautiously. The association observed in this study is likely confounded by age and menopausal status, as multiparous women in this cohort were generally older and therefore more likely to develop breast cancer independent of reproductive history.

Similarly, physical activity appeared to be inversely associated with malignancy, consistent with global evidence indicating a protective role of regular physical activity in breast cancer risk reduction (Friedenreich et al., 2016; World Cancer Research Fund, 2018). However, given the retrospective design, physical activity was self-reported and not quantitatively measured, limiting causal inference.

Other variables such as alcohol use, tobacco use, and BMI did not show statistically significant associations with malignancy, which may reflect limited statistical power for lifestyle risk stratification in this hospital-based cohort.

### *Diagnostic performance of BI-RADS and imaging modalities*

The study demonstrated good diagnostic performance of BI-RADS-based interpretation for both mammography and ultrasonography. Mammography showed higher sensitivity (93.3%) compared with ultrasonography (88.0%), while ultrasonography demonstrated slightly higher specificity (75.4% vs. 70.9%). Both modalities achieved acceptable discriminative performance, with AUC values of 0.857 for mammography and 0.840 for ultrasound, indicating good overall diagnostic accuracy.

These findings are consistent with previous studies demonstrating that mammography is generally more sensitive for detecting microcalcifications and non-palpable lesions, whereas ultrasonography is more specific in differentiating cystic from solid lesions, particularly in dense breasts and younger women (Berg et al., 2004; Kolb et al., 2002; Lehman et al., 2015).

Importantly, the results reinforce the complementary nature of mammography and ultrasound, rather than a hierarchical superiority of one modality. In resource-

limited settings such as the DRC, ultrasonography often plays a central role due to its lower cost, portability, and wider availability, while mammography remains essential for structured diagnostic evaluation and early lesion detection when available.

### *BI-RADS as a standardisation tool*

The findings support the value of BI-RADS as a standardised communication and decision-making framework in breast imaging. The system enables stratification of malignancy risk, facilitates biopsy decisions, and improves consistency in reporting across institutions.

However, the study also highlights an important limitation of BI-RADS implementation in low-resource settings: the heterogeneity of BI-RADS category 4, which could not be systematically subdivided into 4A, 4B, and 4C in this dataset. This limitation reduces risk stratification precision and may influence biopsy referral patterns. Internationally, such subcategorisation is recommended to improve diagnostic accuracy and reduce unnecessary biopsies (Sardanelli et al., 2017; D'Orsi et al., 2013).

### *Predictors of malignancy*

Multivariate analysis identified advanced age (≥70 years), multiparity, and advanced clinical stage as factors associated with malignancy, while physical activity was associated with reduced odds of malignancy. Among these, clinical stage showed the strongest association, reflecting disease severity at presentation rather than causal risk.

The association between multiparity and malignancy should not be interpreted as a causal relationship, but rather as a likely reflection of confounding by age, hormonal status, and reproductive timing, none of which were fully adjusted for in the present analysis.

Similarly, advanced clinical stage should be interpreted as an indicator of delayed diagnosis and healthcare access barriers, rather than a biological risk factor for cancer development.

### *Public health and system-level implications*

The study underscores the importance of strengthening early detection pathways for breast cancer in the DRC. The predominance of late-stage disease highlights ongoing gaps in awareness, screening access, and diagnostic delay.

From a health systems perspective, BI-RADS implementation offers a practical framework for improving diagnostic consistency and guiding clinical decisions. However, its effectiveness depends on several enabling conditions, including:

- Continuous training of radiologists and sonographers
- Standardised imaging protocols
- Reliable access to biopsy services
- Strengthened histopathology infrastructure
- Effective referral and follow-up systems

Without these components, BI-RADS alone cannot significantly improve outcomes in breast cancer care.

## *Study limitations*

This study has several limitations that should be acknowledged. First, its retrospective design introduces risks of missing data and variability in clinical documentation across centres. Second, the hospital-based nature of the sample introduces selection bias, as most patients were symptomatic or had clinically suspicious lesions.

Third, diagnostic accuracy was assessed only among patients with histopathological confirmation, excluding BI-RADS 1 cases, which introduces verification bias and may inflate performance estimates. Fourth, the absence of systematic subdivision of BI-RADS category 4 limited more granular risk analysis.

Finally, the study lacked external image re-evaluation and inter-observer agreement assessment, which limits conclusions regarding reproducibility of BI-RADS interpretation across radiologists.

## *Future research directions*

Future studies should adopt prospective, multicentre designs with population-based sampling to reduce selection bias and improve generalisability. Standardised application of BI-RADS subcategories (4A–4C) is essential to refine diagnostic precision.

Additionally, inter-observer variability studies and external validation of imaging interpretation should be prioritised. The integration of digital tools and artificial intelligence-assisted imaging analysis may also improve diagnostic consistency, particularly in low-resource settings, provided such tools are locally validated and used as adjuncts rather than replacements for clinical expertise.

**Authors' Contributions:** *Study conception and design:* NMN, DMI, and GML; *Data acquisition:* DMI and NMN; *Data analysis and interpretation:* NMN, RKN, and GML; *Manuscript drafting:* NMN, AAM, and GML. *Critical revision and final approval of the manuscript:* All authors.

**Data Availability Statement:** The anonymized datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request. Data sharing is subject to qualified researchers and must align with participant consent and institutional ethical requirements.

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**Ethical Approval:** This study was approved by the Ethics Committee of the School of Public Health at the University of Kinshasa (Approval No. ESP/CE/B45/2024). The research was conducted in accordance with the Declaration of Helsinki, ensuring patient confidentiality and strict data protection throughout.

**Informed Consent:** Nil required.

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