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Inter-Observer Agreement in BI-RADS Classification of Breast Masses Among Ultrasonography Performers at a Tertiary Hospital in Uganda

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Breast Ultrasonography; BI-RADS Classification; Inter-observer Agreement; Breast Cancer Diagnosis

1. Abstract

1.1. Background: Breast ultrasound is a critical diagnostic tool in breast imaging, used for detecting and characterizing breast masses. Applying the Breast Imaging Reporting and Data System (BI-RADS) lexicon is essential for accurate lesion differentiation, demanding high inter-observer agreement a notable challenge in clinical radiological practice. This study assessed the inter-observer agreement in BI-RADS classification of breast masses among ultrasonography performers at a tertiary hospital in Uganda.

1.2. Methodology: A cross-sectional study was conducted from January to March 2019, involving three radiologists, three radiographers, and three radiology residents who independently described 124 breast images. Each image was displayed on a large screen, with two minutes allotted for each participant to describe the lesion using BI-RADS terminology and assign a final BI-RADS category. Inter-observer agreement was measured using Fleiss kappa statistics, interpreted according to Landis and Koch guidelines.

1.3. Results: Inter-observer agreement varied; radiologists demonstrated fair to good agreement across most descriptors and final categorization—echopattern ($\kappa=0.38$), shape and posterior acoustic features ($\kappa=0.57$ and $\kappa=0.51$, respectively), and orientation and margin ($\kappa=0.68$ and $\kappa=0.62$, respectively). Radiographers showed similar levels of agreement, whereas residents varied from poor to good, with particularly low agreement in echopattern ($\kappa=0.19$). Grouping the final assessments into negative, imaging follow-up, and positive categories improved the reproducibility of the final assessment, with moderate agreement among radiologists and radiographers, and fair among residents.

1.4. Conclusions: Radiologists and radiographers achieved fair to good consensus on BI-RADS terminology descriptors and final categorization, yet resident agreement was inconsistent. The study underlines the difficulty in classifying subgroups of non-circumscribed margins and advocates for the adoption of a condensed ultrasound BI-RADS lexicon and rigorous review of residents' preliminary reports by attending radiologists to enhance diagnostic accuracy.

2. Introduction

Breast cancer continues to be a major global health issue, significantly addressed through advancements in diagnostics that enhance early detection and management. Breast ultrasonography reporting, pivotal in diagnosing cancer in dense breast tissues where mammography may be less effective, has been standardized by the American College of Radiology - Breast Imaging Reporting and Data System (BI-RADS) since 2003. This system enhances communication and diagnostic accuracy among healthcare professionals, including comprehensive descriptors for breast mass characteristics to distinguish between benign and malignant lesions. Yet, its effectiveness hinges on the consistent application by ultrasound practitioners [1–5].

At a tertiary hospital in Uganda, the variability in BI-RADS categorization among different practitioners has led to inconsistent patient management outcomes, thereby questioning the reliability of breast ultrasound as a diagnostic tool. Our study focuses on the inter-observer agreement among radiologists, radiographers, and residents at the hospital, a critical assessment given the growing dependence on ultrasonography in breast cancer diagnosis and the increasing role of non-physician operators in resource-constrained environments [6–9].

There is a notable lack of comprehensive studies analyzing inter-observer agreement across different types of practitioners within Uganda. Our research aims to bridge this gap by providing empirical data on agreement levels, informing targeted educational interventions and efforts to standardize ultrasonographic practices at the tertiary hospital and comparable institutions. Aligning local practices with internationally recognized standards is expected to improve diagnostic accuracy and enhance clinical outcomes for patients at risk of breast cancer [10–13].

3. Material and Methods

3.1. Study Design and Period

This cross-sectional study was conducted from January to March 2019 to assess the level of agreement among radiologists, radiographers, and radiology residents in describing breast ultrasound images using BI-RADS terminology.

3.2. Study Setting

The study was carried out at the Radiology Department of a tertiary hospital in Uganda. The Radiology Department operates from Monday to Friday and accepts referrals from the in-house breast clinic as well as external private hospitals. The department includes a team of 11 radiologists, 33 radiographers, 26 radiology residents, and additional auxiliary staff, and handles an average of 15 patients presenting with breast pathologies each week.

3.3. Participants

Participants were recruited from the radiologists, radiographers, and radiology residents working in the radiology department who regularly perform breast ultrasound examinations. The inclusion criteria were registration with the Uganda Medical and Dental Practitioners' Council for radiologists, the Allied Health Professional's Council for radiographers, and enrollment at Makerere University for radiology residents. Exclusion criteria included those not performing breast ultrasound and those absent during the data collection period due to leave or travel.

3.4. Sample Size

The sample size calculation was based on achieving 80% power at a 95% confidence level, with a kappa statistic indicative of agreement ($\kappa = 0.612$) from prior studies. The calculated minimum sample size was 36. However, to enhance the reliability of the findings, the study used 124 B-mode ultrasound images based on recommendations by Allan Donner and Michael A. Rotondi (2010) for agreement studies using three raters.

3.5. Data Collection Methods

Data were collected using a structured form by the principal investigator. Breast ultrasound examinations were performed using a SIUI 5300 model 2015 ultrasound machine with a high-resolution linear array transducer (5–12 MHz). Each image was assessed by the study participants in a controlled setting on a large screen, with each image being displayed for two minutes. Participants described the lesions using BI-RADS terminology without prior specific training for the study but based on their existing knowledge and experience.

3.6. Study Variables

Independent variables included the age, sex, educational level, and years of experience in ultrasound scanning of the participants, as well as their recent involvement in continuous medical education related to BI-RADS. The dependent variable was the level of agreement on the ultrasound descriptors and BI-RADS categorization, quantified using Fleiss' kappa statistic.

3.7. Data Management and Analysis

Data were checked for completeness, entered into a computer, and analyzed using STATA version 14. Descriptive statistics summarized the characteristics of the study participants. Agreement levels among the raters were assessed using Fleiss' kappa to evaluate the consistency of BI-RADS categorization and sonographic descriptions of breast masses.

4. Results

4.1. Participant Enrolment and Demographics

A total of 125 women were enrolled in this study, yielding 144 images relevant for analysis, as detailed in Figure 1 which illustrates the flow of participants through the study.

4.2. Description of study participants

Nine ultrasonography performers who met the inclusion criteria were included in the study. These were comprised of three radiologists, three radiographers, and three residents, selected randomly from eligible candidates. The average age of these participants was 37.7 years (SD = 11.45), predominantly male [n = 7, (77.8%)], with the majority (88.8%) having attended at least one continuous medical education (CME) session on US BI-RADS in the past 12 months. They averaged nine years (SD = 7.48) in performing ultrasound scans. The pie charts in Figures 2 and 3 display the distribution of the study participants by level of education and their participation in recent CME sessions, respectively.

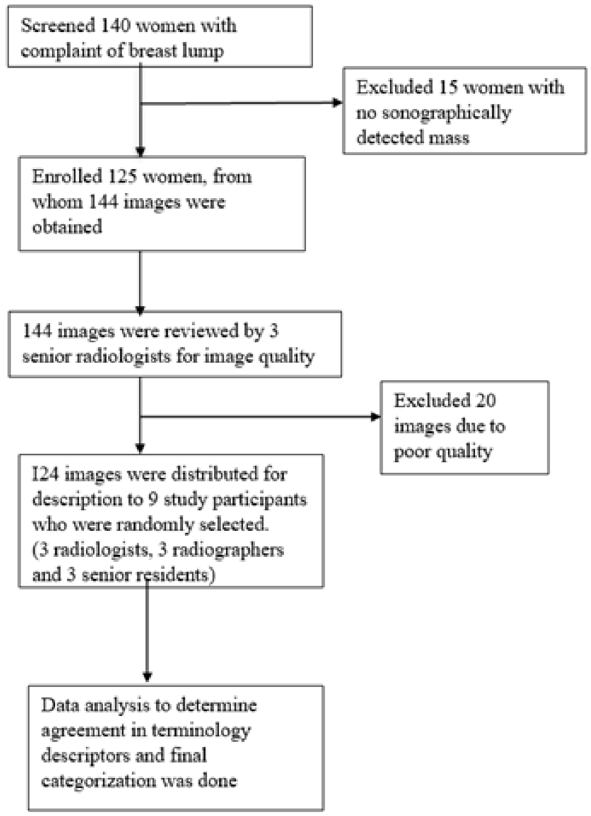

Figure 1: participants profile.

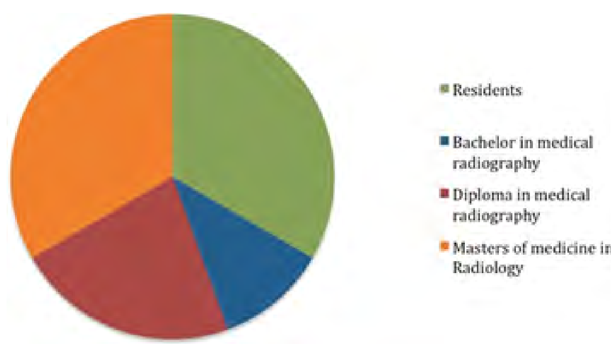

Figure 2: A pie-chart: Distribution of the study participants by level of education

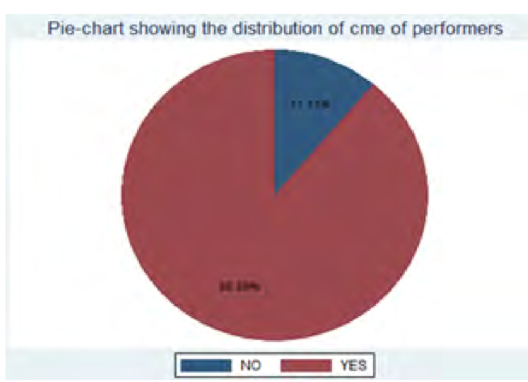

Figure 3: A pie chart: Distribution of study participants according to whether they had at least one CME session in US BI-RADS in the past 12months.

The patients involved ranged from 15 to 68 years of age (mean, 43.7 years), encompassing 124 breast masses described in this study.

4.3. Inter-observer agreement in terminology descriptors among radiologists, radiographers and residents

Radiologists demonstrated agreement ranging from fair to good across all descriptors, with kappa values from 0.38 (fair) for echo pattern to 0.68 (good) for orientation. Radiographers exhibited a similar pattern of agreement, with kappa values from 0.38 (fair) for echo pattern to 0.73 (good) for orientation. Residents showed the most variability, with kappa values from 0.19 (poor) for echo pattern to 0.64 (good) for margin. Detailed kappa values for each group across different BI-RADS (Table 1).

4.4. Inter-observer agreement in terminology descriptors between the different groups of ultrasonography performers.

The comparison between different groups of ultrasonography performers revealed agreement levels ranging from moderate to good. Notably, the highest kappa value, 0.8, was observed for shape between radiologists and radiographers. The agreement between radiologists and residents varied from fair to good, although it was significantly lower for the echo pattern descriptor (kappa = 0.31). Detailed inter-group kappa values are provided in Table 2.

Table 1: Inter-observer agreement in terminology descriptors among radiologists, radiographers and residents

	k-value*		
BI-RADS Descriptors	**Radiologist**	**Radiographers**	**Residents**
Shape	0.57	0.64	0.58
Orientation	0.68	0.73	0.5
Margin	0.62	0.65	0.64
Echo-pattern	0.38	0.38	0.19
Posterior acoustic features	0.51	0.42	0.45

* k=0.00-0.20 (Poor agreement), k=0.21-0.40 (Fair agreement), k=0.41-0.60 (Moderate agreement), k=0.61-0.80 (Substantial agreement), k=0.81-1.00(Excellent agreement)

Table 2: Inter-observer agreement in terminology descriptors between the different groups of ultrasonography performers

	k-value*			
Descriptors/ Cadre	Radiologists Vs. Radiographers	Radiologists Vs. Residents	Radiographers Vs. Residents	Overall Agreement
Shape	0.8	0.72	0.72	0.75
Orientation	0.74	0.63	0.62	0.66
Margin	0.6	0.75	0.65	0.67
Echopattern	0.57	0.31	0.42	0.43
Posterioracoustic features	0.41	0.41	0.52	0.45

Vs. – Versus

* k=0.00-0.20 (Poor agreement), k=0.21-0.40 (Fair agreement), k=0.41-0.60 (Moderate agreement), k=0.61-0.80 (Substantial agreement), k=0.81-1.00(Excellent agreement)

4.5. Inter-observer agreement for margins using subgroups of non-circumscribed margins within ultrasonography performers

Agreement levels were fair when describing non-circumscribed margins using the four subgroups (indistinct, angular, micro-lobulated, and speculated), with kappa values of 0.35, 0.25, and 0.31 for radiologists, radiographers, and residents, respectively.

4.6. Inter-observer agreement in final BI-RADS category

The reproducibility of the final assessment when assigning lesions as BI-RADS category 2,3,4 or 5 was fair among radiologists (k-0.35), moderate among radiographers (k-0.43) and poor among residents (k-0.18). After grouping the final BI-RADS categories into negative (BI-RADS 0,2), imaging follow up (BI-RADS 3) and positive (BI-RADS 4,5) the level of agreement was improved and went higher for each ultrasonography performers group. The level of agreement was moderate for radiologists and radiographers (k-0.45 and 0.49 respectively), and for residents the level of agreement was fair (k-0.36) Table 3.

4.7. Recommendations based on same BI-RADS categorization

Of all the masses which the radiologists, radiographers and residents categorized as BI-RADS 4/ 5, they all recommended to do biopsy for tissue diagnosis of the masses. For the BI-RADS 3 masses, the radiologists recommended a follow up plan in 83% of the masses. The radiographers recommended a follow up in 26% of the masses. Of the masses, which the radiographers categorized as BI-RADS 2, they recommended a routine clinical screening in 71% of the masses while residents recommended the same in 30% of the masses (Table 4).

4.8. Breast ultrasound images

Figures 4 through 6 depict breast ultrasound images showing variations in mass descriptions and the consequential recommendations made by the observers. These images highlight the challenges and nuances in interpreting and categorizing breast ultrasound findings.

Table 3: Inter-observer agreement in final BI-RADS categorization

Ungrouped (k*-statistic)				Grouped (k*-statistic)		
BI-RADS Classification	Radiologists	Radiographers	Residents	Radiologists	Radiographers	Residents
BI-RADS	0.35	0.43	0.18	0.45	0.49	0.36
Recommendation	N/A	N/A	N/A	0.43	0.3	0.33

* k=0.00-0.20 (Poor agreement), k=0.21-0.40 (Fair agreement), k=0.41-0.60 (Moderateagreement), k=0.61-0.80 (Substantial agreement), k=0.81-1.00(Excellent agreement)

Table 4: Recommendations based on same final categorization

Grouped BI-RADS	Radiologists	Radiographers	Residents
Negative (2)	-	71%	30%
Follow up (3)	83%	26%	0
Positive (4/5)	100%	100%	100%

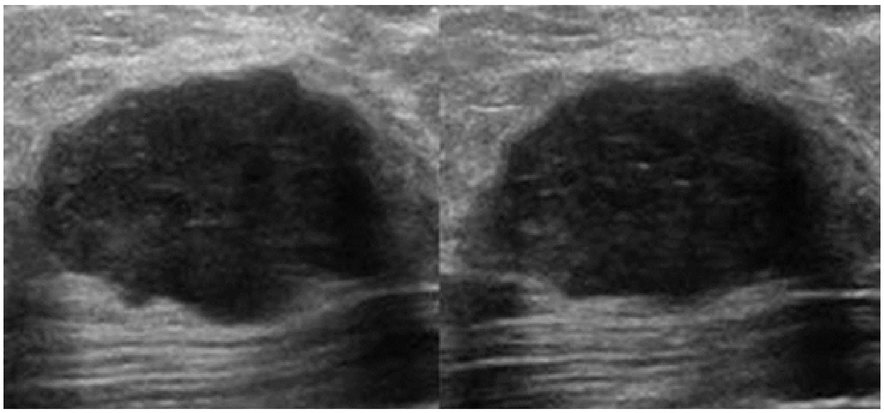

Figure 4: Breast US image showing a mass with more than 3 gentle lobulations in which some observers described it as having an irregular shape and some described it as having oval shape.

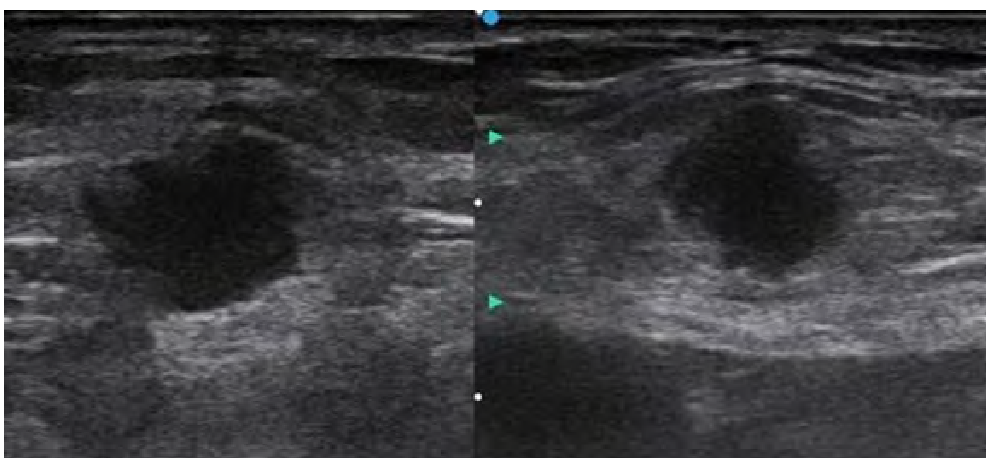

Figure 5: Breast US image showing a mass with more than one type of margin, some described it to have indistinct margin, some angular margin and some micro lobulated margin.

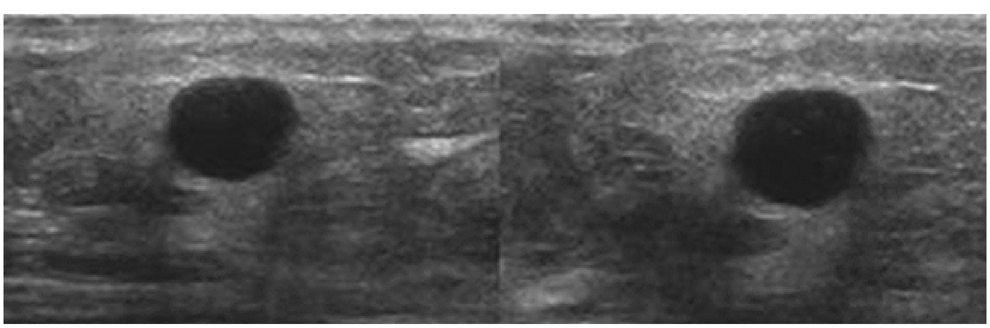

Figure 6: Breast US image in which observers had same description of the mass but disagreed on final assessment and recommendation. Some assigned it to category 2 and recommended clinical routine follow up, some category 3 and recommended short interval follow up and some category 4 and recommended a biopsy.

5. Discussion

This study conducted at a tertiary Hospital aimed to ascertain the level of inter-observer agreement in BI-RADS terminology descriptors and final categorization of breast masses among different ultrasonography performers, along with describing their socio-demographic characteristics. The American College of Radiology (ACR) emphasizes the importance of consensus among both experienced and novice groups in the application of BI-RADS, a standard that aims to reduce variability in breast imaging interpretations [35]. However, variability persists as evidenced by studies showing differences in the assessment of breast masses [8,12,15,36]. Such discrepancies are pivotal as they affect the description, final categorization and management of breast lesions, which could ultimately influence patient outcomes [4,5,6].

In this study, the professional backgrounds of the radiologists, radiographers, and residents varied, which might have influenced their interpretative agreement. The radiologists and radiographers showed similar agreement levels, likely due to their comparable experience and shared educational sessions on the US BI-RADS lexicon [12]. Conversely, the residents demonstrated a wider range of agreement, likely due to their ongoing training and lesser experience [12]. Notably, for descriptors such as the shape of breast masses, challenges arose when classifying masses with multiple lobulations, which could significantly impact the categorization of a mass as benign or suspicious [12].

The study revealed a trend where more straightforward descriptors like orientation showed higher agreement levels among experienced practitioners compared to residents. This disparity underscores the influence of experience and familiarity with the BI-RADS lexicon in achieving consistency in ultrasound interpretations. The agreement on margins was uniformly good across all groups, aligning with other studies like that by Berg et al. However, when details within the non-circumscribed margins were considered, agreement dropped, illustrating the complexity of categorizing more nuanced features [8,9,34].

Echo pattern and posterior acoustic features presented the lowest agreement levels, reflecting the intrinsic challenge of interpreting these features from static images, which lacks the dynamic perspective provided by real-time ultrasound [8,34]. This finding points to the necessity of real-time evaluation in clinical practice to enhance diagnostic accuracy and agreement among ultra sonographers.

The variability in final BI-RADS categorization, with only moderate to fair reproducibility, suggests a need for improved standardization and training, particularly for less experienced clinicians. Grouping categories improved agreement, indicating that broader classifications might reduce observer variability. This could be further enhanced by integrating clinical histories and correlating sonographic findings with other imaging modalities, as demonstrated in studies where combined imaging approaches improved diagnostic agreement [10].

6. Conclusions

This study conducted at a tertiary Hospital revealed that the use of the sonographic BI-RADS lexicon resulted in a fair to good level of agreement among radiologists and radiographers for most terminology descriptors and final assessments. However, the residents exhibited a broader range of agreement, from poor to good, highlighting the impact of experience on diagnostic consistency. Notably, the agreement on echo-pattern and final BI-RADS categorization was consistently low across all groups, with a particular decline in agreement observed within the subgroups of non-circumscribed margins. Given the challenges in reproducibility for subgroups of non-circumscribed margins, we advocate for the adoption of a condensed Ultrasound BI-RADS lexicon to reduce variability. Continued medical education tailored to BI-RADS ultrasound is crucial for both radiologists and radiographers, and there is a specific need for specialized BI-RADS training for residents. Furthermore, it is essential that attending radiologists review and verify the residents' preliminary interpretations to ensure accuracy and consistency.

This investigation serves as foundational research, shedding light on the current state of inter-observer agreement within ultrasonography at a tertiary hospital setting. It underscores the potential benefits of educational interventions in this field. We strongly recommend conducting further studies to assess inter and intra-observer agreement post-educational sessions, coupled with histopathological correlations, to evaluate whether continuous medical education can significantly enhance the reliability of BI-RADS lexicon application in clinical practice.

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