Evaluating BI-RADS Accuracy in Predicting the Need for True-Cut Biopsy or Surgery among Libyan Women at the National Cancer Institute (NCI), Sabratha: A Radio-Pathological Correlation over Two Years

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Abstract

Background: Breast cancer remains a major health concern among women in Libya, with many cases presenting at a relatively young age. The Breast Imaging Reporting and Data System (BI-RADS) provides a standardized approach for classifying breast lesions; however, its diagnostic performance in the Libyan population has not been widely evaluated. **Objective:** To evaluate the performance of the BI-RADS classification system in grayscale ultrasonography and mammography for differentiating benign and malignant breast lesions among Libyan women, in correlation with histopathological results **Methods:** This retrospective study included 274 women who underwent breast imaging followed by histopathological confirmation between 2016 and 2017 at NCI Sabratha. BI-RADS categories were compared with final histopathology results. Diagnostic performance was calculated using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and receiver operating characteristic (ROC) analysis. **Results:** BI-RADS demonstrated high sensitivity (88.2%), strong NPV (91.6%), and good overall accuracy (80.7%). However, several categories showed deviations from expected malignancy rates. BI-RADS 2 and 3 exhibited higher-than-expected malignancy rates (2.8% and 10.3%, respectively). BI-RADS 4A and 4B demonstrated markedly elevated malignancy rates (44.2% and 71.4%), while BI-RADS 4C aligned with international benchmarks (95.6%). BI-RADS 5 showed a lower-than-expected malignancy rate (78.4%). **Conclusion:** The BI-RADS system provides strong overall diagnostic performance in this cohort of Libyan women; however, discrepancies in malignancy rates across several categories highlight variability in interpretive accuracy. Enhanced radiologist training and quality assurance programs are recommended.

Keywords: BI-RADS classification, grayscale ultrasonography, mammography, histopathology, benign/malignant differentiation, Libyan women, NCI Sabratha.

1. INTRODUCTION

Breast cancer is the most common malignancy among women worldwide and the second leading cause of cancer-related death. According to WHO Global Health Estimates, hundreds of thousands of women die annually from breast cancer globally (WHO, 2013). It is the most prevalent cancer among Libyan women and is a major public health concern in Libya. While it is similar to other cancers in the region in terms of incidence and clinical presentation, it has local distinct characteristics (Alhireereeq & Elkhouly, 2026).

In Libya, the incidence of breast cancer is estimated at 18.8 per 100,000 women, predominantly premenopausal cases with unfavorable features such as high grade, advanced stage, large tumor size, and frequent lymph node metastases (El-Mqueteef et al., 2026; WHO Global Health Estimate, 2011). The highest incidence is observed among women aged 40–49 years, while 23% of cases occur below the age of 40 (Assi *et al*., 2013; Rehman *et al*., 2015).

Given the high rate of advanced breast cancer at younger ages, early diagnosis and staging before surgery are crucial for optimal treatment planning (Assi *et al.,* 2013). While excisional biopsy is still commonly practiced, imaging

modalities such as ultrasonography and mammography play a major role in early detection and improved survival rates (Berg *et al.,* 2008; Fan et al., 2014; Haghighatkhah et al., 2009; Sonographic Correlation, 2004). The Breast Imaging Reporting and Data System (BI-RADS) was introduced by the American College of Radiology (ACR) to standardize mammographic and ultrasound reporting (American College of Radiology, 2013; Department of Radiology NYU, 2013; Zonderland & Smithuis, 2013). BI-RADS categories range from 0 (incomplete assessment) to 6 (biopsy-proven malignancy), providing structured reporting and management recommendations.

The aim of this study was to evaluate the diagnostic performance of BI-RADS in grayscale ultrasonography and mammography for differentiating benign from malignant breast lesions among Libyan women at NCI Sabratha, using histopathological results as the gold standard.

2. METHODS

2.1. Study Design and Period

This was a retrospective, cross-sectional analytical study conducted at the National Cancer Institute (NCI), Sabratha, covering the period from January 2016 to December 2017.

2.2. Population and Data Collection

All female patients with solid breast masses identified in surgical pathology files were included (N = 274). Each patient underwent imaging by one of three radiologists (with 3–20 years of experience). BI-RADS classification was assigned based on grayscale ultrasound and mammography findings. Core needle biopsy was performed using a 14G automated gun with at least two passes. Recorded data included patient age, BI-RADS category, lesion site, imaging modality, and final histopathology results.

2.3. Ethical Approval and Statistical Analysis

This study was approved by the Institutional Research Unit of the National Cancer Institute, Sabratha. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), overall diagnostic accuracy, and receiver operating characteristic (ROC) analysis were calculated using histopathology as the reference gold standard.

3. RESULTS

The mean patient age was 44.5 years. The majority (43.2%) were under 40 years, 34.9% were between 40–50 years, and 21.8% were above 50 years. Histopathology revealed 102 malignant lesions (37.1%) and 172 benign lesions (62.9%).

Distribution by BI-RADS category was as follows: BI-RADS I: 0 (0.0%), BI-RADS II: 36 (13.1%), BI-RADS III: 107 (38.9%), BI-RADS IVa: 43 (15.6%), BI-RADS IVb: 28 (10.2%), BI-RADS IVc: 23 (8.4%), and BI-RADS V: 37 (13.5%). Breast laterality showed right breast in 152 cases (48.9%), left breast in 143 (46.0%), bilateral in 6 (1.9%), and unknown in 10 (3.2%).

Overall diagnostic performance metrics at the BI-RADS ≥ 4A threshold yielded a Sensitivity of 88.2%, Specificity of 76.2%, PPV of 68.7%, NPV of 91.6%, and Accuracy of 80.7%.

Table 1. Per-Category Malignancy Rates and BI-RADS Performance (N = 274)

BI-RADS Category	Benign (TN)	Malignant (TP)	Malignancy % (PPV)	Benign (NPV) %	Standard Reference Risk
BI-RADS 2	35	1	2.8%	97.2%	0%
BI-RADS 3	96	11	10.3%	89.7%	< 2%
BI-RADS 4A	24	19	44.2%	55.8%	2–10%
BI-RADS 4B	8	20	71.4%	28.6%	10–50%
BI-RADS 4C	1	22	95.6%	4.4%	50–95%
BI-RADS 5	8	29	78.4%	21.6%	> 95%

Table 2. Diagnostic Performance Metrics Across Clinical Thresholds

Threshold	TP	FP	FN	TN	Sensitivity	Specificity	PPV	NPV
≥ BI-RADS 3	101	137	1	35	99.0%	20.3%	42.4%	97.2%
≥ BI-RADS 4A	90	41	12	131	88.2%	76.2%	68.7%	91.6%
≥ BI-RADS 4B	71	17	31	155	69.6%	90.1%	80.7%	83.3%
≥ BI-RADS 4C	51	9	51	163	50.0%	94.8%	85.0%	76.2%
≥ BI-RADS 5	29	8	73	164	28.4%	95.3%	78.4%	69.2%

Category-Specific Quality Assessment:

1. **Misclassification within BI-RADS 2:** The detection of a malignant lesion within the BI-RADS 2 category represents a significant misclassification, as this category is strictly reserved for definitively benign findings. Such an occurrence suggests either interpretive error or inadequate adherence to BI-RADS descriptors.
2. **Elevated Malignancy Rate in BI-RADS 3:** The malignancy rate observed in BI-RADS 3 was approximately 10.3%, markedly higher than the expected rate of less than 2%. This disparity may reflect an overuse of BI-RADS 3 for lesions exhibiting subtle suspicious features or elevated baseline population risk.
3. **Higher-than-Expected Malignancy in BI-RADS 4A:** The malignancy rate in BI-RADS 4A reached 44.2%, substantially exceeding the established benchmark of 2–10%, indicating that many lesions assigned to 4A likely possessed features more consistent with BI-RADS 4B.
4. **Elevated Malignancy Rate in BI-RADS 4B:** Similarly, the malignancy rate for BI-RADS 4B was 71.4%, surpassing the expected range of 10–50%, suggesting under-classification of some 4C lesions.
5. **Appropriate Performance of BI-RADS 4C:** BI-RADS 4C demonstrated malignancy rates (95.6%) consistent with international standards (50–95%), indicating accurate identification of highly suspicious lesions.

6. **Lower-than-Expected Predictive Value in BI-RADS 5:** The malignancy rate within BI-RADS 5 was 78.4%, which is below the expected threshold of >95%, pointing to possible over classification based on limited criteria.

4. DISCUSSION

The findings of this study demonstrate that the BI-RADS classification system, when applied to grayscale ultrasonography and mammography, provides a generally reliable framework for differentiating benign from malignant breast lesions among Libyan women. The overall diagnostic performance—characterized by high sensitivity (88.2%), strong negative predictive value (91.6%), and a robust overall accuracy (80.7%)—underscores the utility of BI-RADS in routine clinical practice.

However, several deviations from internationally accepted malignancy rates within individual BI-RADS categories highlight variability in system application. The higher-than-expected malignancy rates in BI-RADS 3, 4A, and 4B categories indicate potential challenges in accurately interpreting and stratifying intermediate-risk lesions. Conversely, BI-RADS 4C performed in accordance with established expectations, while BI-RADS 5 showed lower-than-expected predictive value (78.4% vs >95%).

In Saudi Arabia, Arafah and Kfoury (2017) reported a BI-RADS sensitivity of 87% and specificity of 81% in a tertiary hospital in Riyadh, reinforcing the reliability of BI-RADS in Middle Eastern populations. Similarly, Alhamami et al. (2024) documented high radio-pathological concordance in Najran.

In Egypt, Haghighatkhah et al. (2009) reported a sensitivity of 90% and specificity of 75% for BI-RADS categories 4 and 5, confirming that imaging-based classification remains a powerful diagnostic tool in regional settings.

Our results align closely with large-scale international studies. Berg et al. (2008) in a multicenter American study (ACRIN 6666) found a sensitivity of 89.0% and specificity of 78.0% for combined screening in high-risk women. In the Netherlands, Zonderland and Smithuis (2013) reported sensitivity of 87–91% and specificity of 80–83%. Comparable findings across regions confirm that BI-RADS is robust and reproducible across varied healthcare settings.

Limitations

1. **Retrospective Design:** Inherently restricts the control of confounding variables and may introduce information bias.
2. **Single-Center Scope:** Conducting the study solely at NCI Sabratha may limit generalizability across all regions of Libya.
3. **Radiologist Experience Variance:** Differences in reader experience (3–20 years) contributed to interobserver variability.
4. **Era of Imaging Technology:** Data collected during 2016–2017 did not incorporate newer tools such as digital breast tomosynthesis.

5. CONCLUSION

This study confirms that BI-RADS provides strong overall diagnostic performance (Sensitivity: 88.2%, NPV: 91.6%, Accuracy: 80.7%) for evaluating breast lesions among Libyan women at NCI Sabratha. Nevertheless, observed discrepancies in intermediate categories (BI-RADS 3, 4A, 4B) and category 5 underline the urgent need for continuous quality assurance and standardized training. BI-RADS remains an indispensable clinical lexicon guiding biopsy and surgical management.

6. RECOMMENDATIONS

1. **Strengthen Radiologist Training:** Conduct regular calibration workshops, BI-RADS refresher courses, and interobserver agreement audits.
2. **Implement Routine Quality Assurance:** Establish periodic reviews of category-specific malignancy rates to identify early interpretive drift.
3. **Adopt Advanced Imaging Technologies:** Integrate digital breast tomosynthesis and high-resolution automated ultrasound.
4. **Multicenter Prospective Research:** Initiate prospective studies across Libyan medical centers to establish national performance benchmarks.

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