

Concordance between imaging and pathology in breast lesions: multicenter analysis in institutions specialized in gynecology

Concordancia entre imagen y patología en lesiones mamarias: análisis multicéntrico en instituciones especializadas en ginecología

Gloria A. Castañeda-García¹, María E. Castelán-Casados¹, Cintia M. Sepúlveda-Rivera², José M. Reyes-Garita³, Isabel Sollozo-Dupont⁴, Guillermo Moreno-Flores⁵, and David F. Cantú-de León^{5*}

¹Department of Gynecology and Obstetrics, Hospital Regional de Alta Especialidad de la Mujer, Villahermosa, Tabasco; ²Head of Gynecologic Surgery, Instituto Nacional de Perinatología Isidro Espinosa de los Reyes, Mexico City; ³Department of Gynecology and Obstetrics, Hospital de Especialidades en la Mujer y Neonatología, Mexico City; ⁴Deputy Directorate of Organizational Development, Instituto Nacional de Perinatología Isidro Espinosa de los Reyes, Mexico City; ⁵Deputy Directorate of Clinical Research, Instituto Nacional de Cancerología, Mexico City. Mexico

Abstract

Objective: To assess the concordance between imaging findings and pathology results from biopsied breast lesions. **Method:** A retrospective, comparative study was conducted at three women's health centers (A, B, and C). The study included patients with suspicious imaging findings who underwent breast biopsy between January 2019 and July 2024. Descriptive and inferential statistics were applied, and Cohen's kappa coefficient was used to evaluate imaging-pathology concordance. **Results:** A total of 434 patients were included (248 from A, 85 from B, and 101 from C). Overall concordance between imaging and pathology was 43%, with institutional variations: 39% at A, 62% at B, and 19% at C. The mean patient age was 34 years. Center B had the highest use of hormone therapy (22%; $p = 0.001$). Center A reported the lowest educational level (4% illiteracy), while A had the highest rate of poverty among its patients (88%). Excisional biopsy was the predominant technique at center C (73%). **Conclusions:** The low imaging-pathology concordance observed reflects significant institutional disparities. These findings highlight the need for improved medical training to enhance the appropriate indication and interpretation of breast biopsies.

Keywords: Breast lesions. BI-RADS. Concordance. Image. Pathology.

Resumen

Objetivo: Conocer la concordancia entre imagen y patología de biopsias realizadas a lesiones mamarias. **Método:** Estudio retrospectivo y comparativo en tres centros especializados en salud femenina (A, B y C). Se incluyeron pacientes con estudios de imagen sospechosos sometidos a biopsia entre enero de 2019 y julio de 2024. Se utilizó estadística descriptiva e inferencial, aplicando el coeficiente kappa de Cohen para evaluar la concordancia entre imagen y patología. **Resultados:** Se incluyeron 434 pacientes (248 en A, 85 en B y 101 en C). La concordancia global fue del 43%, con variaciones por institución: A 39%, B 62% y C 19%. La edad media fue de 34 años. El centro B destacó por uso de hormonoterapia (22%; $p = 0.001$). El centro C reportó menor escolaridad (4% analfabetismo) y el A mayor pobreza (88%). La biopsia escisional prevaleció en el centro C (73%). **Conclusiones:** La baja concordancia entre imagen y patología refleja disparidades institucionales. Se requiere mayor entrenamiento médico para optimizar la indicación y el análisis de biopsias mamarias.

Palabras clave: Lesiones mamarias. BI-RADS. Concordancia. Imagen. Patología.

*Correspondence:

David F. Cantú-de León
E-mail: dcantude@gmail.com

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Introduction

Breast lesions represent a broad spectrum of alterations ranging from benign nonproliferative lesions to invasive malignant neoplasms with metastatic potential. In gynecologic oncology practice, the diagnostic approach to these conditions constitutes a constant challenge due to their clinical, radiologic, and histopathologic variability¹⁻⁴.

Breast cancer is currently the most common malignant neoplasm among women worldwide and the leading cause of cancer-related death in several countries, including Mexico. According to data from the Global Cancer Observatory (GLOBOCAN), in 2022 there were 2,296,840 new cases worldwide, with 666,103 attributable deaths. In Mexico, in the same year, 31,043 new cases of breast cancer and 8195 deaths were reported, representing an incidence of 39.9 and a mortality of 10.3 per 100,000 women⁵. This increasing trend has been attributed to numerous factors, including changes in reproductive patterns, greater exposure to endogenous and exogenous estrogens, sedentary lifestyle, obesity, and family history of cancer, among others⁶⁻⁹.

In this context, early detection represents one of the fundamental pillars for reducing mortality from this disease. Mammography is recognized as the method of choice for population screening due to its ability to identify lesions before they become palpable¹⁰⁻¹². The BI-RADS (Breast Imaging Reporting and Data System) classification system, developed by the American College of Radiology in 1993, has standardized the interpretation of mammographic findings, categorizing lesions according to their probability of malignancy and thereby guiding clinical decisions¹³⁻¹⁶.

Diagnostic mammography reported according to BI-RADS allows identification of suspicious lesions (categories 4 and 5)^{17,18}. These include findings such as microcalcifications, nodules, asymmetries, or architectural distortion¹⁸⁻²³. BI-RADS categories 4 and 5 correspond to suspicious lesions and must be studied by biopsy to confirm or rule out malignant neoplasm^{13,24}. Core needle biopsy is the ideal method indicated for solid lesions. Fine-needle aspiration biopsy has markedly decreased in use, with overall sensitivity ranging from 25% to 86.4%; currently, it is reserved for special situations such as evacuation of palpable cysts or biopsy of axillary lymph nodes^{19,25-28}. In the study by Aziz et al.²⁹ invasive ductal carcinoma and ductal carcinoma in situ were reported as the

most frequent neoplasms, whereas fibroadenoma and intraductal papilloma were the most common benign lesions.

Recent studies have documented considerable variability in the interpretation of imaging findings between institutions and even among healthcare professionals, which may directly impact the indication of invasive procedures such as breast biopsy²⁷⁻³⁰. Imaging-pathology correlation, that is, the degree of concordance between the radiologic finding (BI-RADS) and the definitive histopathologic diagnosis, has emerged as a crucial tool for evaluating the quality of the diagnostic process in breast disease. Adequate concordance not only validates the appropriateness of biopsy indication but also improves clinical efficiency, reduces costs, and avoids unnecessary interventions^{30,31}.

Despite efforts to standardize the diagnostic management of suspicious breast lesions, inequalities persist in Mexico regarding access to imaging services, physician training, and availability of technological resources³². This heterogeneity may translate into significant differences in diagnostic quality and patient outcomes, particularly in public health institutions or those not directly specialized in breast oncology. Multicenter evaluation of imaging-pathology concordance offers a unique opportunity to identify these disparities and generate evidence to optimize clinical practice nationwide.

The present study arises from the need to evaluate this concordance in three Mexican institutions providing specialized gynecologic care but not serving as referral centers for malignant neoplasms.

Method

We conducted a retrospective, observational, analytical, and comparative study in patients with abnormal mammographic findings who underwent breast biopsy between January 2019 and July 2024 in three institutions (A, B, and C). Records lacking complete information for study purposes were excluded. Clinical variables, BI-RADS stratification, and disease results were identified.

Statistical analysis

Measures of central tendency were calculated using medians and ranges for continuous variables, and absolute and relative frequencies for qualitative variables. Comparative analysis between groups was performed using the Mann-Whitney U test, Wilcoxon

rank-sum test, χ^2 test, or Fisher's exact test, depending on variable type. Cohen's kappa was used to determine concordance between imaging findings and pathology results. A significant difference was defined as $p < 0.05$. Statistical analysis was performed using IBM SPSS Statistics Version 24. The study was approved by the Research and Ethics Committee of center A (reference A, -0021-2024).

Results

A total of 434 patients were identified and included (248 in A, 85 in B, and 101 in C) who met inclusion and exclusion criteria. The mean age was 34 years (range: 13-87). When comparing institutions, statistically significant differences were observed: patients in A were significantly younger (34.6 years) than those in B (42.6 years) and C (48.6 years) ($p = 0.001$), with age differences of up to 14 years; however, no significant difference was observed between C and B ($p = 0.858$).

Center B reported lower educational level (4% illiteracy), and center C reported higher poverty rates (88%). Smoking as a risk factor was identified in 19% of patients in center A. Regarding body mass index (according to World Health Organization classification), 39% ($n = 96$) in A were overweight, 48% ($n = 41$) in B, and 43% ($n = 43$) in C. Center B stood out for higher use of hormone replacement therapy (22%) compared with the other two centers ($p = 0.001$) (Table 1).

Regarding BI-RADS imaging reports, BI-RADS 2 lesions were reported in 2% ($n = 5$) in A, 11% ($n = 9$) in B, and 6% ($n = 6$) in C. BI-RADS 3 reports accounted for 71% ($n = 175$) in A, 48% ($n = 41$) in B, and 6% ($n = 6$) in C. BI-RADS 4A reports corresponded to 22% in A, 18% ($n = 15$) in B, and 29% ($n = 29$) in C. BI-RADS 4B reports were 3% ($n = 8$) in A, 14% ($n = 12$) in B, and 36% ($n = 36$) in C. No BI-RADS 4C reports were recorded in A, whereas they accounted for 2% ($n = 2$) in B and 15% ($n = 9$) in C. BI-RADS 5 reports were 2% ($n = 4$) in A, 7% ($n = 6$) in B, and 9% ($n = 9$) in C (Table 2).

The most frequently used biopsy type was fine-needle aspiration biopsy in A (39%, $n = 97$) and core needle biopsy in B (40%, $n = 34$); notably, excisional biopsy was the most frequently performed procedure in C (73%, $n = 74$) ($p = 0.0001$).

Final pathology reports (Table 3) showed:

- Fibroadenoma: 69% ($n = 170$) in A, 44% ($n = 37$) in B, and 35% ($n = 35$) in C.

- Fibrocystic mastopathy: 2% ($n = 6$) in A, 7% ($n = 6$) in B, and 0% in C.
- Carcinoma in situ: 1% ($n = 2$) in A, 4% ($n = 3$) in B, and 9% ($n = 9$) in C.
- Invasive carcinoma: 6% ($n = 14$) in A, 14% ($n = 12$) in B, and 19% ($n = 19$) in C.

Other benign results were reported in 19% ($n = 47$) in A, 29% ($n = 25$) in B, and 27% ($n = 27$) in C. Other malignant results were reported in 3% ($n = 7$) in A, 1% ($n = 1$) in B, and 7% ($n = 7$) in C.

Overall imaging-pathology concordance was only 43%. By institution, concordance was 39% in A, 62% in B, and 19% in C.

Discussion

Breast lesions encompass a broad spectrum of alterations, from benign nonproliferative changes to advanced breast cancer. Imaging-pathology correlation is an essential tool in clinical decision-making; however, it may vary significantly between institutions, particularly those that are not referral centers for breast cancer diagnosis and treatment^{33,34}.

Recent studies have demonstrated the usefulness of the BI-RADS system for stratifying malignancy risk, particularly in subcategories 4A, 4B, and 4C, which show progressively increasing malignancy rates^{33,34}. In this study, concordance between BI-RADS categories and histopathological findings was evaluated in patients with abnormal mammography or ultrasound studies who underwent biopsy at three specialized gynecology institutions that are not oncologic referral centers.

A total of 434 patients were included, most of whom were treated at Center A (57.1%, $n = 248$), followed by Center C (23.3%, $n = 101$) and Center B (19.6%, $n = 85$). This distribution may be explained by the nature of Center A as a regional referral hospital serving a large population in the southeastern region of the country. In contrast, Centers B and C have more specific admission criteria.

During the analysis, significant differences were observed both in the distribution of BI-RADS categories and in the concordance between imaging and disease, suggesting variability in diagnostic practice among institutions. At Center A, for example, patients were significantly younger, which may be related to its role as a high-volume regional hospital, resulting in biopsies being performed in younger women than reported in other studies, such as that of Arruel Caraveo et al.³⁵ which reported a mean age of 53 years,

Table 1. Demographic characteristics of the subjects

Characteristics	A (n = 248)	B (n = 85)	C (n = 105)	p
Age, years (range)	34 (13-67)	42 (18-76)	48 (21-81)	
Body mass index				0.128
18-24.99	85 (34%)	28 (33%)	24 (24%)	
25-29.99	96 (39%)	41 (48%)	43 (43%)	
30-34.99	51 (21%)	10 (12%)	28 (28%)	
35-39.99	13 (5%)	3 (3%)	5 (5%)	
≥ 40	3 (1%)	3 (3%)	1 (1%)	
Smoking				0.016
Yes	48 (19%)	10 (12%)	8 (8%)	
No	200 (81%)	75 (88%)	93 (92%)	
Alcohol use				0.754
Yes	43 (17%)	17 (20%)	16 (16%)	
No	205 (82%)	68 (80%)	85 (84%)	
Physical activity				0.107
Yes	44 (18%)	12 (15%)	9 (9%)	
No	204 (82%)	73 (85%)	92 (91%)	
Family history of breast cancer				0.002
Yes	37 (15%)	23 (27%)	9 (9%)	
No	211 (85%)	62 (73%)	92 (91%)	
Hormone replacement therapy				0.001
Yes	10 (4%)	19 (22%)	6 (6%)	
No	238 (96%)	66 (78%)	95 (94%)	
Education level				0.0002
None	1 (1%)	0 (0%)	4 (4%)	
Primary	49 (20%)	7 (8%)	19 (19%)	
Secondary	115 (46%)	37 (43%)	48 (48%)	
High school	58 (23%)	34 (40%)	19 (19%)	
Bachelor's degree	25 (10%)	7 (9%)	11 (10%)	
Socioeconomic level				0.0001
Low	219 (88%)	61 (72%)	63 (62%)	
Middle	13 (5%)	21 (25%)	13 (13%)	
Lower-middle	16 (6%)	3 (3%)	25 (25%)	
Type of biopsy				0.0001
Fine-needle aspiration	97 (39%)	18 (21%)	3 (3%)	
Core needle	63 (25%)	34 (40%)	21 (21%)	
Ultrasound-guided	8 (4%)	1 (1%)	1 (1%)	
Stereotactic	5 (2%)	0 (0%)	2 (2%)	
Excisional	75 (30%)	32 (38%)	74 (73%)	

consistent with the peak incidence of breast cancer in Mexico.

Although age alone is not directly associated with a higher or lower risk of malignancy, it may influence the sensitivity of imaging studies, since dense breasts in younger women make radiological interpretation more difficult. Moreover, breast cancer in younger women tends to be more aggressive and associated with a poorer prognosis³⁶. This may lead to more interventional clinical decisions in cases of doubtful lesions.

Regarding the distribution of BI-RADS categories, BI-RADS 3 predominated at Center A (40.3%), whereas at Center C high-suspicion BI-RADS categories were mainly observed (approximately 90%). Center B showed an intermediate profile, with predominance of BI-RADS 4A and 4B and also a high proportion of BI-RADS 3 (48%).

In contrast to the study by Arruel Caraveo et al.³⁵ in which most biopsies corresponded to BI-RADS 4A (55.9%) and only 17% to BI-RADS 3, in our study biopsies were performed on a greater number of

Table 2. Cases referred for biopsy

	A	B	C
BI-RADS 2	5 (2%)	9 (11%)	6 (6%)
BI-RADS 3	175 (70%)	41 (48%)	6 (6%)
BI-RADS 4A	55 (22%)	15 (18%)	29 (29%)
BI-RADS 4B	8 (3%)	12 (14%)	36 (35%)
BI-RADS 4C	1 (1%)	2 (2%)	15 (15%)
BI-RADS 5	4 (2%)	6 (7%)	9 (9%)
Total	248 (100%)	85 (100%)	101 (100%)

Table 3. Histopathologic report

Diagnosis	A	B	C
Fibroadenoma	170 (68%)	37 (44%)	35 (35%)
Fibrocystic mastopathy	6 (2%)	6 (7%)	0 (0%)
Papilloma	2 (1%)	1 (1%)	4 (4%)
Carcinoma in situ	2 (1%)	3 (4%)	9 (9%)
Invasive carcinoma	14 (6%)	12 (14%)	19 (19%)
Others (benign)	47 (19%)	25 (29%)	27 (26%)
Others (malignant)	7 (3%)	1 (1%)	7 (7%)
Total	248 (100%)	85 (100%)	101 (100%)

lesions classified as BI-RADS 3. This difference may be explained by institutional and sociocultural factors, as well as by the absence of strong referral and counter-referral mechanisms within the health system. At Center A, in particular, many biopsies were requested directly by patients, motivated by fear of breast cancer and the perception of limited access to medical follow-up. This situation compromises adherence to criteria established by the American College of Radiology.

When histopathological results were analyzed, 91.7% of lesions classified as BI-RADS 2, 3, 4A, and 4B were benign, whereas in categories 4C and 5, 48.4% were malignant. Although this result is consistent with the progressive risk trend, the proportion of malignancy in category 5 was lower than expected (> 95%)³⁵. This could reflect overdiagnosis and lack of timely follow-up, leading to biopsies being performed even in cases of minimal suspicion.

Compared with the study by Arruel Caraveo et al.³⁵ which reported 95% benignity in low- to moderate-suspicion categories and 60.4% malignancy in

BI-RADS 4C and 5, our results are slightly lower. However, that study reported a sensitivity of 0.99 and a specificity of 0.91, indicating high diagnostic performance of the BI-RADS system when used appropriately.

In our study, overall concordance between BI-RADS and histopathology (benign vs. malignant) was moderate, with a kappa coefficient of 0.43 ($p < 0.001$), demonstrating both limitations of the system and possible deficiencies in radiologic interpretation. This situation may be exacerbated by delays in performing biopsies, delivering pathology results, and initiating treatment, ultimately negatively impacting quality of care.

Regarding concordance by center, at Center A, of 235 BI-RADS lesions of low to moderate suspicion, 93.1% were benign and 6.9% malignant. In the high-suspicion group, 61.5% were malignant. A kappa value of 0.391 ($p < 0.001$) was obtained, indicating weak to moderate concordance. It is concerning that 16 malignant lesions were found in the low-suspicion group, compromising the specificity of the BI-RADS lexicon, while five benign lesions underwent unnecessary biopsy in the high-suspicion group, which is less concerning than the opposite scenario.

At Center B, moderate to good concordance was observed, with a kappa value of 0.62 ($p < 0.001$). In the low- to moderate-suspicion group, 93.8% were benign and 6.2% malignant. In the high-suspicion group, 65% were malignant. Although the results are more consistent, unnecessary biopsies were still observed in BI-RADS 3, which is expected since BI-RADS 3 is not an indication for biopsy.

Finally, Center C showed the lowest concordance, with a kappa value of 0.18 ($p = 0.030$). In the low- to moderate-suspicion group, 19.5% of biopsies were malignant, whereas in the high-suspicion group only 40% were malignant. This indicates overestimation of risk in many lesions, highlighting the need to improve radiologic evaluation quality.

A study conducted at the Instituto Mexicano del Seguro Social in 2020 found even lower concordance (overall index: 0.2), with very low values in BI-RADS 4A and 4B and moderate values in 4C, reinforcing evidence of suboptimal image interpretation at different levels of the health system³⁷. These findings have not only clinical implications but also profound social repercussions.

Fragmentation of the health system, lack of standardized protocols, insufficient continuous training of medical personnel, and limited technological infrastructure result in unequal access to accurate and

timely diagnoses, especially for women in more vulnerable sectors.

When diagnostic decisions are influenced more by lack of follow-up, fear of cancer, or social pressure than by well-founded clinical criteria, a chain of unnecessary interventions is generated, increasing the emotional, economic, and physical burden on patients. Conversely, underestimation of malignant lesions in institutions with lower concordance may translate into diagnostic delays, late treatment, and increased mortality.

This dual aspect of the problem-overdiagnosis on one hand and underdiagnosis on the other – reflects a structural crisis in which women, particularly those with limited access to information or resources, are most affected.

In this context, improving diagnostic accuracy should not be understood solely as a technical or academic challenge but as an imperative of health equity. Decision-makers must recognize that ensuring proper interpretation of breast imaging studies is also a matter of social justice, as it reduces diagnostic uncertainty, improves system efficiency, and above all protects the health and dignity of thousands of women facing the fear of breast cancer in a system still marked by inequalities³⁸.

Conclusions

Our study demonstrates a positive trend between increasing BI-RADS category and probability of malignancy in histopathological reports; however, the presence of malignant results in categories traditionally considered low risk (such as BI-RADS 2) underscores limitations in interpretation and the need for a comprehensive diagnostic approach.

Interinstitutional variability and discrepancies in diagnostic quality highlight the importance of implementing continuous educational strategies and advanced technologies to improve diagnostic accuracy. In addition, the high proportion of biopsies in young women raises critical questions regarding biopsy indications at early ages and their cost–benefit relationship.

Interobserver variability represents an important limitation that could be assessed in future research, potentially supported by systems incorporating artificial intelligence and machine learning, which are currently emerging as tools to strengthen diagnostic standardization and optimize clinical decision-making,

minimizing unnecessary procedures and ensuring that high-risk patients receive timely interventions.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of humans and animals. Not applicable (research without experimentation).

Confidentiality, informed consent, and ethical approval. Ethics Committee approval was obtained for analysis of routinely collected and anonymized clinical data. Due to the nature of the study, individual informed consent was not required. Relevant ethical recommendations were followed.

Declaration on the use of artificial intelligence (AI). The authors declare that no generative artificial intelligence was used in the drafting or content creation of this manuscript.

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