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Diagnosis Of Breast Cancer: Clinical-Statistical Analysis And The Role Of The Bi-Rads System In Differentiating Benign And Malignant Lesions

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Abstract

: *Breast cancer is the leading oncological disease among women worldwide, which underscores the critical importance of improving early diagnostic methods. This study presents a retrospective clinical-statistical analysis of mammographic data from 30 patients with breast lesions, assessing the diagnostic value of the BI-RADS classification system. Malignancy was verified in 19 patients (63.3%) and benign lesions in 11 (36.7%). All malignant cases corresponded to BI-RADS categories 4–5, and all benign cases to categories 2–3. The mean age in the malignant group (52.2±7.1 years) was significantly higher than in the benign group (33.3±4.3 years; $t=7.999$; $p<0.0001$). The mean size of malignant lesions was also significantly larger (27.8±7.0 mm vs. 12.0±2.6 mm; $p<0.0001$). The distribution by BI-RADS category differed with high statistical significance between the groups ($\chi^2=30.0$; $df=3$; $p<0.000001$). The findings confirm the high prognostic value of the BI-RADS system in differentiating benign and malignant breast lesions and support its standardized use in routine clinical practice.*

Keywords: *breast cancer; mammography; BI-RADS; differential diagnosis; biostatistics; molecular subtypes; tomosynthesis*

1. INTRODUCTION

Breast cancer (BC) is the most prevalent malignant neoplasm among women worldwide and ranks second among causes of cancer-related mortality in the

female population [1, 2]. According to the Global Cancer Observatory (GLOBOCAN 2020), more than 2.3 million new BC cases are registered annually, accounting for 11.7% of all cancers [3]. Despite significant advances in pharmacological and surgical treatment, the five-year survival rate for stage III–IV BC remains substantially lower compared to early-stage disease, where survival exceeds 90% [4, 5]. This fact underscores the paramount importance of early diagnosis in reducing cancer mortality.

X-ray mammography is recognized as the "gold standard" for BC screening and remains the most widely used breast imaging modality [6, 7]. Large-scale randomized trials have convincingly demonstrated that regular mammographic screening reduces BC mortality by 20–35% in women over 50 years of age [8, 9]. The transition from analog to digital mammography has substantially expanded the diagnostic capabilities of the method, particularly in patients with high mammographic breast density [10].

A key achievement in the standardization of mammographic diagnosis was the development of the Breast Imaging Reporting and Data System (BI-RADS) by the American College of Radiology (ACR). This system provides uniform terminology for describing detected findings, a standardized structure for radiological reports, and a clear patient management algorithm based on the assigned category (from 0 to 6) [11, 12]. The use of BI-RADS minimizes subjective interpretation, identifies indications for morphological verification, and optimizes the patient management pathway [13].

Despite the widespread implementation of BI-RADS in clinical practice, data on its prognostic value for distinguishing benign and malignant lesions within specific clinical settings remain insufficiently studied. Analysis of local clinical data is essential for evaluating the real-world effectiveness of diagnostic algorithms and identifying potential areas for optimization.

Aim of the study: to conduct a clinical-statistical analysis of the diagnostic value of the BI-RADS system in mammographic examination, assessing its role in differentiating benign and malignant breast lesions.

2. MATERIALS AND METHODS

2.1. Study Design and Sample Characteristics

A retrospective analysis was performed on 30 patients (n=30) referred for mammographic examination during the study period at the Republican Oncology and Radiology Center. Inclusion criteria: presence of a detected breast lesion; performance of standard digital mammography; morphological verification of the diagnosis. Exclusion criteria: technically inadequate mammograms; absence of histological confirmation.

Based on the morphologically verified diagnosis, patients were divided into two groups: Group I — malignant lesions (n=19; 63.3%); Group II — benign lesions (n=11; 36.7%).

2.2. Mammographic Examination Methods and BI-RADS Classification

All patients underwent digital mammography in standard projections (craniocaudal and mediolateral oblique views). Based on the examination results, each patient was assigned a BI-RADS category according to the ACR BI-RADS® Atlas (5th edition, 2013). The following lesion characteristics were analyzed: shape (Round / Oval / Irregular), margins (Circumscribed / Indistinct / Spiculated), presence of calcifications (Yes/No), and radiological density (Low/High). Clinical features were also assessed in parallel: presence of pain syndrome, palpable mass, and lymph node changes.

For morphologically verified malignant lesions, additional molecular-biological parameters were recorded: receptor status (ER, PR), HER2 expression, and Ki-67 proliferation index.

2.3. Statistical Analysis

Statistical processing of the data was performed using standard biomedical statistical methods. Quantitative variables are presented as mean (M) and standard deviation (SD): M±SD. Comparison of quantitative parameters between two independent groups was performed using the unpaired Student's t-test. Analysis of associations between categorical variables was performed using Pearson's chi-squared test (χ^2) with calculation of degrees of freedom (df). The critical level of statistical significance was set at $p<0.05$; differences at $p<0.001$ were considered highly significant.

3. RESULTS

3.1. General Sample Characteristics and BI-RADS Distribution

The study included 30 patients. The mean age across the entire sample was 45.3±11.1 years (range 26–63 years). Malignancy was verified in 19 patients (63.3%) and benign lesions in 11 (36.7%). The distribution by BI-RADS category is presented in Table 1.

Table 1 — Distribution of patients by BI-RADS category and morphological diagnosis

BI-RADS Category	n	% of Total	Benign (n)	Malignant (n)	Probability of Malignancy
BI-RADS 2	5	16.7%	5	0	Essentially absent (0%)
BI-RADS 3	6	20.0%	6	0	>0% and <2% (probably benign)
BI-RADS 4	8	26.7%	0	8	2-95% (suspicious)
BI-RADS 5	11	36.7%	0	11	>95% (highly suggestive of malignancy)
Total	30	100%	11 (36.7%)	19 (63.3%)	—

*Note: $\chi^2=30.0$; $df=3$; $p<0.000001$. * — statistically significant differences.*

As shown in Table 1, an absolute distinction between the groups was observed in terms of BI-RADS category assignment: all 11 benign cases belonged to categories 2 (n=5; 45.5%) and 3 (n=6; 54.5%), while all 19 malignant cases fell into categories 4 (n=8; 42.1%) and 5 (n=11; 57.9%). No malignant case was classified below category 4. The distribution by BI-RADS categories differed with high statistical significance between the groups ($\chi^2=30.0$; df=3; $p<0.000001$).

3.2. Comparative Clinical-Morphological Analysis of Groups

The comparative analysis of the main clinical-morphological characteristics in the benign and malignant lesion groups is presented in Table 2.

Table 2 — Comparative clinical-morphological characteristics of patients with benign and malignant breast lesions

Parameter	Benign (n=11)	Malignant (n=19)	Statistics (p-value)
Mean age, years (M±SD)	33.3 ± 4.3	52.2 ± 7.1	t=7.999; p<0.0001*
Mean size, mm (M±SD)	12.0 ± 2.6	27.8 ± 7.0	t=7.139; p<0.0001*
BI-RADS 2, n (%)	5 (45.5%)	0 (0%)	χ^2=30.0; df=3;
BI-RADS 3, n (%)	6 (54.5%)	0 (0%)	p<0.000001*
BI-RADS 4, n (%)	0 (0%)	8 (42.1%)	
BI-RADS 5, n (%)	0 (0%)	11 (57.9%)	
Shape: Irregular, n (%)	0 (0%)	19 (100%)	p<0.0001*
Margins: Spiculated/Indistinct, n (%)	0 (0%)	19 (100%)	p<0.0001*
Calcifications (Yes), n (%)	0 (0%)	13 (68.4%)	p<0.0001*
ER+ (among malignant), n (%)	—	13 (68.4%)	—
HER2+ (among malignant), n (%)	—	9 (47.4%)	—
Ki-67, % (among malignant, M±SD)	—	37.6 ± 10.8	—

*Note: M — mean; SD — standard deviation. * — p<0.0001.*

3.3. Age Characteristics and Lesion Size

The mean age of patients with malignant lesions was 52.2±7.1 years, which significantly exceeded the corresponding value in the benign lesion group — 33.3±4.3 years (t=7.999; p<0.0001). The age gap between the mean values was 18.9 years. The minimum age in the malignant group was 41 years, while in the benign group it was 26 years. This distribution is consistent with the well-established epidemiological patterns of age-related BC risk.

The mean size of malignant lesions (27.8±7.0 mm) was significantly larger than that of benign lesions (12.0±2.6 mm; t=7.139; p<0.0001). The difference in means was 15.8 mm. The maximum size of a malignant lesion reached 40 mm, with a minimum of 18 mm. For benign lesions, the range was 8–16 mm.

3.4. Morphological Features and Molecular Status of Malignant Lesions

Morphological analysis showed that all malignant lesions (100%) were characterized by irregular shape and malignant margins (spiculated or indistinct), while all benign lesions had regular shape (round or oval) and circumscribed margins. Microcalcifications were detected in 13 of 19 patients with malignant lesions (68.4%), while no cases of their presence were recorded in the benign group. High radiological density was observed exclusively in malignant lesions (100%); benign lesions demonstrated low density.

Among malignant lesions, positive estrogen receptor status (ER+) was recorded in 13 cases (68.4%), and HER2 overexpression in 9 (47.4%). The mean Ki-67 proliferation index was 37.6±10.8%, which corresponds to highly proliferative tumors and represents an unfavorable prognostic factor. This distribution indicates a predominance of luminal B subtype in the study sample.

4. DISCUSSION

The results demonstrate the high diagnostic value of the BI-RADS system in distinguishing benign and malignant breast lesions. The absolute concordance between BI-RADS category and morphological diagnosis (BI-RADS 2–3 corresponding exclusively to benign, and BI-RADS 4–5 to malignant lesions) at χ^2=30.0 (p<0.000001) confirms the high prognostic strength of this classification system. Similar patterns have been described in the international literature: according to large multicenter studies, the sensitivity of BI-RADS in detecting

malignant lesions reaches 80–90%, and the specificity at categories 4–5 is 85–95% [24, 25, 26].

The statistically significant difference in mean patient age (52.2±7.1 years in the malignant group vs. 33.3±4.3 years in the benign group; $p<0.0001$) is consistent with known epidemiological data on the pronounced increase in BC incidence in the perimenopausal and postmenopausal periods [3, 16]. The 18.9-year gap in mean age values indicates that young age serves as an additional indirect predictor of a benign nature of a lesion, all other conditions being equal.

The difference in lesion size (27.8 mm for malignant vs. 12.0 mm for benign; $p<0.0001$) confirms the well-known fact that malignant tumors at the time of clinical presentation generally reach larger sizes than benign ones, reflecting their biological aggressiveness. Furthermore, this finding indirectly suggests insufficient coverage by regular screening in the study population, since effective screening is designed to detect tumors less than 10 mm in diameter [27].

The 100% occurrence of irregular shape and malignant margins in BC in our sample is consistent with the literature: spiculated margins and indistinct borders are the most specific mammographic signs of malignancy [28, 29]. The presence of microcalcifications in 68.4% of patients with malignant lesions is also consistent with known data that pleomorphic and segmentally distributed calcifications are closely associated with ductal carcinoma, including in situ [21].

The molecular profile of malignant lesions (ER+ in 68.4%, HER2+ in 47.4%, Ki-67 37.6%) indicates a predominance of biologically aggressive variants with high proliferative activity. The high mean Ki-67 corresponds to luminal B and HER2-enriched subtypes according to the St. Gallen consensus criteria [30], which necessitates the use of multimodal therapeutic approaches.

It should be noted that with a relatively small sample size (n=30), the obtained results are preliminary in nature. Limitations of the study include: retrospective design, single-center nature, and absence of data on breast density according to the ACR classification (a/b/c/d), which precluded assessment of its effect on diagnostic accuracy. Expansion of the sample and inclusion of multicenter data are necessary to generalize the conclusions. Nevertheless, even with this material, the high prognostic value of BI-RADS has been demonstrated, which is consistent with global data.

A promising direction for improving diagnostic accuracy is the use of digital tomosynthesis, particularly in patients with high breast density, and AI-based

systems capable of reducing both false-positive and false-negative results. Integration of BI-RADS with quantitative AI metrics may in the future provide semi-automatic risk stratification, which is of fundamental importance in high-workload radiology settings [31, 32, 33].

5. CONCLUSIONS

Based on the clinical-statistical analysis of data from 30 patients with breast lesions, the following main results were obtained:

1. The BI-RADS system demonstrated absolute discriminatory ability between benign (BI-RADS 2–3) and malignant (BI-RADS 4–5) lesions in the study sample (χ^2=30.0; p<0.000001), confirming its high clinical-diagnostic value.

2. Significant between-group differences were identified in age (52.2±7.1 years vs. 33.3±4.3 years; p<0.0001) and lesion size (27.8±7.0 mm vs. 12.0±2.6 mm; p<0.0001), which may serve as additional clinical predictors of malignancy.

3. Morphological features of malignancy (irregular shape, malignant margins, microcalcifications, high density) were in 100% of cases associated with BI-RADS categories 4–5, confirming the validity of the categorization principles.

4. The molecular profile of malignant lesions, with a predominance of highly proliferative forms (Ki-67 37.6%), indicates the need for timely verification and appropriate comprehensive treatment.

5. Standardized application of the BI-RADS system in routine clinical practice allows optimization of the diagnostic algorithm, timely histological verification, and reduction of false-positive and false-negative conclusions.

The practical significance of the study lies in justifying the mandatory use of the BI-RADS system in all mammographic examinations, the immediate biopsy of BI-RADS 4–5 lesions, and emphasizing the need for active inclusion of women aged 40 and over in regular screening programs.

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REFERENCES

1. Sung H, Ferlay J, Siegel RL, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2021;71(3):209–249.

2. Kaprin AD, Starinskiy VV, Shakhzadova AO. Malignant neoplasms in Russia in 2021 (morbidity and mortality). Moscow: P.A. Herzen Moscow Oncology Research Institute; 2022.
3. World Health Organization. Breast Cancer. Factsheet. 2023. Available at: https://www.who.int/news-room/fact-sheets/detail/breast-cancer
4. Berry DA, Cronin KA, Plevritis SK, et al. Effect of screening and adjuvant therapy on mortality from breast cancer. N Engl J Med. 2005;353(17):1784–1792.
5. Oeffinger KC, Fontham ET, Etzioni R, et al. Breast cancer screening for women at average risk: 2015 guideline update from the American Cancer Society. JAMA. 2015;314(15):1599–1614.
6. Marmot MG, Altman DG, Cameron DA, et al. The benefits and harms of breast cancer screening: an independent review. Br J Cancer. 2013;108(11):2205–2240.
7. Lauby-Secretan B, Scoccianti C, Loomis D, et al. Breast-cancer screening: viewpoint of the IARC Working Group. N Engl J Med. 2015;372(24):2353–2358.
8. Tabár L, Vitak B, Chen TH, et al. Swedish two-county trial: impact of mammographic screening on breast cancer mortality during 3 decades. Radiology. 2011;260(3):658–663.
9. Moss SM, Cuckle H, Evans A, et al. Effect of mammographic screening from age 40 years on breast cancer mortality at 10 years' follow-up: a randomised controlled trial. Lancet. 2006;368(9552):2053–2060.
10. Pisano ED, Gatsonis C, Hendrick E, et al. Diagnostic performance of digital versus film mammography for breast-cancer screening. N Engl J Med. 2005;353(17):1773–1783.
11. American College of Radiology. ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. 5th ed. Reston, VA: ACR; 2013.
12. D'Orsi CJ, Sickles EA, Mendelson EB, Morris EA, et al. ACR BI-RADS® Mammography. In: ACR BI-RADS® Atlas. 5th ed. Reston, VA: ACR; 2013.
13. Magny SJ, Shikhman R, Keppke AL. Breast Imaging Reporting and Data System. In: StatPearls. Treasure Island: StatPearls Publishing; 2022.
14. Kamińska M, Ciszewski T, Łopacka-Szatan K, et al. Breast cancer risk factors. Prz Menopauzalny. 2015;14(3):196–202.
15. Sun YS, Zhao Z, Yang ZN, et al. Risk Factors and Preventions of Breast Cancer. Int J Biol Sci. 2017;13(11):1387–1397.

16. Key TJ, Verkasalo PK, Banks E. Epidemiology of breast cancer. Lancet Oncol. 2001;2(3):133–140.
17. Chlebowski RT, Anderson GL, Aragaki AK, et al. Menopausal Hormone Therapy and Breast Cancer Incidence and Mortality. JAMA. 2020;324(4):369–380.
18. Kuchenbaecker KB, Hopper JL, Barnes DR, et al. Risks of Breast, Ovarian, and Contralateral Breast Cancer for BRCA1 and BRCA2 Mutation Carriers. JAMA. 2017;317(23):2402–2416.
19. Foulkes WD. Inherited Susceptibility to Common Cancers. N Engl J Med. 2008;359(20):2143–2153.
20. Shiovitz S, Korde LA. Genetics of breast cancer: a topic in evolution. Ann Oncol. 2015;26(7):1291–1299.
21. Lakhani SR, Ellis IO, Schnitt SJ, et al. WHO Classification of Tumours of the Breast. 4th ed. Lyon: IARC; 2012.
22. Rakha EA, Reis-Filho JS, Ellis IO. Breast cancer prognostic classification in the molecular era: the role of histological grade. Breast Cancer Res. 2010;12(4):207.
23. Perou CM, Sørlie T, Eisen MB, et al. Molecular portraits of human breast tumours. Nature. 2000;406(6797):747–752.
24. Sickles EA. Periodic mammographic follow-up of probably benign lesions: results in 3,184 consecutive cases. Radiology. 1991;179(2):463–468.
25. Lazarus E, Mainiero MB, Schepps B, et al. BI-RADS lexicon for US and mammography: interobserver variability and positive predictive value. Radiology. 2006;239(2):385–391.
26. Рожкова Н.И., Бурдина И.И., Запирова С.Б. и др. Инновационные технологии в ранней диагностике рака молочной железы // Опухоли женской репродуктивной системы. 2018;14(3):22–29.
27. Myers ER, Moorman P, Gierisch JM, et al. Benefits and harms of breast cancer screening: a systematic review. JAMA. 2015;314(15):1615–1634.
28. Lewin JM, D'Orsi CJ, Hendrick RE, et al. Clinical comparison of full-field digital mammography and screen-film mammography for detection of breast cancer. AJR Am J Roentgenol. 2002;179(3):671–677.
29. Синицын В.Е., Терновой С.К. Применение системы BI-RADS при маммографическом скрининге и диагностике: российский опыт // Вестник рентгенологии и радиологии. 2017;(3):136–142.

30. Goldhirsch A, Winer EP, Coates AS, et al. Personalizing the treatment of women with early breast cancer: highlights of the St Gallen International Expert Consensus 2013. Ann Oncol. 2013;24(9):2206–2223.
31. McKinney SM, Sieniek M, Godbole V, et al. International evaluation of an AI system for breast cancer screening. Nature. 2020;577(7788):89–94.
32. Rodriguez-Ruiz A, Lång K, Gubern-Merida A, et al. Stand-alone artificial intelligence for breast cancer detection in mammography. J Natl Cancer Inst. 2019;111(9):916–922.
33. Freeman K, Dinnes J, Chuchu N, et al. Algorithm based smartphone apps to assess risk of skin cancer in adults. BMJ. 2020;368:m127.