# **ORIGINAL ARTICLE**

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Original contribution and importance: Quality indicators for clinical, imaging and histopathologic correlation were identified to improve standards in our mastology clinics.

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# Clinical, radiological and histopathological correlation in breast lesions: 10 years of experience

# Correlación clínica, radiológica e histopatológica en lesiones de mama: experiencia a 10 años

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ABSTRACT Introduction: Breast cancer remains a global public health problem. It is estimated that its incidence will increase in the coming years. It is important to evaluate screening studies in breast clinics through indicators in order to obtain an adequate clinical, imaging and histopathological correlation. Objectives: To evaluate the correlation between clinical, radiological and histopathological studies in women who underwent breast cancer screening tests over a 10-year period. Methods: A cross-sectional, descriptive, retrospective cohort study was conducted using the records of a referral center from June 2013 to June 2023, of women who underwent breast cancer screening. In those who underwent biopsy, the samples were analyzed at our institution. Results: The records of 6 754 women who met the inclusion criteria were analyzed, where the average age of the study population was 50.7 years. It was recorded that 73.2% of the studies were categorized BI-RADS 2 and the majority of the participants were asymptomatic. Of those 551 women who received a BI-RADS >4 mammogram, 226 (41%) had a malignant result. Conclusions: Mammography has been shown to be the only imaging tool that has managed to have an impact on mortality. There are modalities, such as tomosynthesis, that have increased the performance of this test. It is valid to use new technologies to maintain quality standards in the studies.

Key words: Mammography, Early detection of cancer, Breast cancer, Breast density, Diagnostic imaging, Ultrasonography, mammary

#### RESUMEN

Introducción. El cáncer de mama continúa siendo un problema de salud pública a nivel global. Se estima que su incidencia incrementará en los próximos años. Es importante evaluar a través de indicadores los estudios de escrutinio de las clínicas de mastología con el fin de obtener una adecuada correlación clínica, imagenológica e histopatológica. Objetivos. Evaluar la correlación que existe entre la clínica, los estudios radiológicos e histopatológicos en mujeres que acudieron a exámenes de escrutinio para cáncer de mama en un periodo de 10 años. Métodos. Se realizó un estudio transversal, descriptivo de cohorte retrospectiva efectuado de los registros de un centro de referencia en el periodo de junio del 2013 a junio 2023, de mujeres quienes acudieron a tamizaje para cáncer de mama. En aquellas que se les realizó toma de biopsia, las muestras fueron analizadas en nuestra institución. Resultados. Se analizaron los registros de 6754 mujeres que cumplieron los criterios de inclusión, en donde la edad promedio de la población de estudio fue de 50,7 años. Se registró que 73,2% de los estudios se categorizaron BI-RADS 2 y la mayoría de las participantes cursaba asintomática. De aquellas 551 mujeres que recibieron una mamografía BI-RADS >4, 226 (41%) obtuvieron un resultado de malignidad. Conclusiones. La mamografía ha demostrado ser la única herramienta de imagen que logrado tener un impacto sobre la mortalidad. Existen modalidades, como la tomosíntesis, que han incrementado el rendimiento de esta prueba. Es válido auxiliarse de nuevas tecnologías para mantener estándares de calidad en los estudios.

Palabras clave. Mamografía, Detección temprana de cáncer, Cáncer de mama, Densidad mamaria, Diagnóstico por imagen, Ultrasonografía mamaria

#### INTRODUCTION

Breast cancer represents a global public health problem<sup>(1)</sup>. At the beginning of the last decade, this entity was responsible for 16% of cancer deaths in women. It is estimated that the overall 5-year survival rate in developed countries is 90%, in contrast to 66% in developing countries, which represents an area of opportunity to improve breast cancer screening indicators in our Latin American countries<sup>(2,3)</sup>.



In the latest report by the Global Cancer Observatory (GLOBOCAN), it was documented that breast cancer is the cancer with the highest incidence and mortality in Mexico. Annually, 31 043 new cases are reported, which corresponds to 15-20% of all malignant neoplasms in the country<sup>(4,5)</sup>.

Early detection through screening has made it possible to diagnose a greater number of cases in the early stages, which allows us to offer curative and less invasive treatments. The American College of Radiology (ACR) recommends starting screening at 40 years of age and annual follow-up to maximize the benefits of screening<sup>(6)</sup>. Mammography, considered the gold standard as a screening method, has been shown to reduce mortality by 26-41% in the average risk population<sup>(7)</sup>.

Tomosynthesis mammography is a useful resource, with limited availability, which has shown greater sensitivity for the detection of lesions, asymmetries and distortions in the architecture compared to digital mammography, with a difference that ranges between 5 and 7%<sup>(8)</sup>. However, this modality is not exempt from false positive results, which can lead to overdiagnosis and increase the rate of second calls<sup>(9,10)</sup>. This means that some lesions that do not pose a risk to the patient's life or that will not progress to a malignant process have a potential for overtreatment through repeat biopsies, surgery, radiotherapy or other adjuvant therapies<sup>(11,12)</sup>. International standards dictate that the false positive rate should not exceed 10% of all screening mammograms in order to reduce the rate of second callbacks<sup>(13)</sup>.

Breast cancer is an entity with a widely heterogeneous clinical picture, which can present with or without specific symptoms<sup>(14)</sup>. Nowadays, the focus is on precision medicine, where it is imperative to establish an adequate radiological-pathological correlation in order to obtain biological information on tumors through biopsies and provide targeted therapy<sup>(15)</sup>.

There are infrequent findings in screening mammograms such as focal, global and developing asymmetries, which do not exceed 5%<sup>(16)</sup>. Other findings, such as inflammatory processes, which represent a challenge for the clinician, make it necessary to rule out a malignant process. Typically, these findings will be related to benign processes. However, it is valid to request complementary studies, such as ultrasound, in order to obtain greater accuracy in the radiological-pathological correlation and avoid invasive procedures<sup>(17,18)</sup>.

Recently, the introduction of artificial intelligence in mastology has proved to be a promising auxiliary tool. This will allow suspicious images to be identified through programmed algorithms in order to improve said correlation and perform selective biopsies in those findings highly suggestive of malignancy<sup>(19)</sup>.

The objective of the present study was to evaluate the correlation between clinical, radiological and histopathological studies in women who attended screening examinations for breast cancer over a 10-year period.

### **METHODS**

A cross-sectional, descriptive, retrospective cohort study was conducted at Hospital Angeles Lomas, in Huixquilucan, Mexico in the period between June 2013 and June 2023. The clinical, imaging and histopathological records of women who attended screening studies for breast cancer were analyzed. All women underwent tomosynthesis mammography and in selected cases the study was complemented with breast ultrasound.

The inclusion criteria for the study were women who underwent screening mammography by tomosynthesis, age over 40 years, histopathological study analyzed in the pathological anatomy service of our institution in those women who underwent cutting needle biopsy.

The exclusion criteria were male patients, diagnostic and follow-up mammograms, confirmed diagnosis of breast cancer, history of any type of oncologic process and its treatment in the last 10 years, and follow-up in another institution.

Women whose records were incomplete or duplicated and those who did not authorize the use of personal data were eliminated.

The present study obtained the approval of the Ethics and Research Committee of the same institution with folio HAL-23-017. All participants gave authorization for the use of their personal data for research purposes, safeguarding the privacy of their identity.

The following variables were collected: 1) clinical variables: age, thyroid alterations, history of hormone therapy, family history of breast cancer, BRCA1 and 2 gene mutation, symptomatology at the time of the study; 2) imaging characteristics: all mammograms were categorized according to the Breast Imaging Reporting and Data System (BI-RADS) 5th edition, breast density, distortion of the architecture, presence of calcifications and nodes, associated benign lesions; 3) histopathological findings: histological lineage of breast cancer.

For statistical analysis, a 95% confidence interval was established, with statistical significance a value <0.05. The statistical software used was JASP version 0.18. All categorical variables are expressed in frequency and percentages and the chi-square test was used as a statistical test for proportional differences between groups.

## RESULTS

From June 2013 to June 2023, 6 754 women attended the mastology clinic, of which 259 studies were excluded because they did not meet the inclusion criteria of the protocol: 7 male patients, 112 women under 39 years of age, 89 records were incomplete, 4 women only attended for surgical marking, 11 women were in follow-up and 36 women had a pending or inconclusive histopathological result.

The 6 495 women who met all the inclusion criteria were evaluated and grouped into three age groups: 1) 40-49 years, 2) 50-69 years and 3) older than 70 years, in order to obtain a better analysis in accordance with the recommendations of the different international societies in breast cancer screening (Table 1).

The average age of the study population was 50.7 years, with an age range between 40 and 91 years. The age group with the largest volume of women was 40-49 years (55.8%), while the group of women over 70 years of age only represented 5.9%. The most prevalent thyroid disorder in the population was hypothyroidism (6.7%), 12.3% of women reported hormonal use, the majority of participants, 5 148 (79.2%) had no family history of breast cancer, known mutations in the BRCA1 and 2 genes, as documented by 6 416 (98.7%)

women. The majority of participants, 5,296 (81.5%) reported being asymptomatic at the time of screening. Most of the screening studies were categorized within the BI-RADS 2 category. The most predominant density was type B density, i.e. those mammary glands with dispersed fibroglandular tissue. Among the mammographic findings, the most common were suspicious amorphous calcifications, which were found in 4.2% of the mammograms. Lymph nodes were less frequent findings, being more common those intramammary compared to axillary nodes. A benign condition was found in 55.8% of the mammograms, the most frequent being fibrocystic mastopathy (43.8%) followed by fibroadenomas (19.8%), especially in the 40-49 age group (Table 1).

On the other hand, there were 226 women who were diagnosed with malignancy, whose average age was 56.5 years. Most of them had no hereditary family history of breast cancer, that is, their presentation was de novo (81.4%). A genetic study was obtained from all women with malignant pathology, where 15.5% presented mutation in the BRCA1 or BRCA2 genes. The majority of women, 115 (50.8%) reported being asymptomatic at the time of the study. The BI-RADS category most associated with breast cancer was BI-RADS 5, occurring in 31% (Figure 1). The most prevalent histological strain was invasive ductal carcinoma (59.6%), followed by ductal carcinoma in situ (25.3%). Likewise, less prevalent strains were documented in the literature, such as Paget's disease and non-Hodgkin's lymphoma (Table 2). Type B breast density was the most reported in women with a confirmed diagnosis of malignancy (Figure 2).

In the present study, screening mammography using tomosynthesis, in those women with studies categorized within BI-RADS 4 and 5, obtained a sensitivity of 90.9%, a specificity of 41%, a positive predictive value of 96.4% and a negative predictive value of 90%, figures that may vary depending on the age group, secondary to breast density (Table 3).

### DISCUSSION

Breast cancer in Mexico has shown an increase in incidence over the decades, similar to what has been reported internationally. This may be due to various circumstances such as population aging, higher life expectancy, lifestyle and the great-



TABLE 1. DEMOGRAPHIC CHARACTERISTICS, MAMMOGRAPHIC AND HISTOLOGIC FINDINGS BY AGE GROUP. ALL RESULTS ARE REPORTED IN FREQUENCIES (PERCENTAGES).

|                                 | Total (n=6 495)                              | 40-49 years n=3 627<br>(55.8%) | 50-69 years n=2 480<br>(38.1%) | ≥70 years n=388 (5.9%) | p value |  |  |
|---------------------------------|--|--------------------------------|--------------------------------|------------------------|---------|--|--|
|                                 |  | Clinical history               |                                |                        |         |  |  |
| Average age (Range)             | 50.7 (40 -91)                                | 43.5 (40-49)                   | 57.6 (50-69)                   | 74.6 (70-91)           | <0.05   |  |  |
| Thyroid disorder                |  |                                |                                |                        |         |  |  |
| Hypothyroidism                  | 435 (6.7)                                    | 259 (7.1)                      | 147 (5.9)                      | 29 (7.5)               | 0.01    |  |  |
| Thyroid cancer                  | 2 (0.03)                                     | 1 (0.02)                       | 1 (0.4)                        |                        | 0.01    |  |  |
| Hormone use                     | 796 (12.3)                                   | 471 (12.9)                     | 279 (11)                       | 46 (12)                |         |  |  |
| Family history of breast cancer |  |                                |                                |                        |         |  |  |
| Yes                             | 1347 (20.7) 781 (21.5) 441 (17.7) 125 (32.2) |                                | 125 (32.2)                     | 0.07                   |         |  |  |
| No                              | 5148 (79.2)                                  | 2846 (78.4)                    | 2039 (82.2)                    | 263 (67.7)             | 0.07    |  |  |
| Mutation in BRCA1 y 2           |  |                                |                                |                        |         |  |  |
| Yes                             | 79 (1.2)                                     | 52 (1.4)                       | 23 (0.9)                       | 4 (1)                  | 0.001   |  |  |
| No                              | 6416 (98.7)                                  | 3575 (98.5)                    | 2457 (99)                      | 384 (98.9)             |         |  |  |
| Symptoms referred to screening  |  |                                |                                |                        |         |  |  |
| Palpable nodule                 | 993 (15.2)                                   | 646 (17.8)                     | 283 (11.4)                     | 64 (16.4)              |         |  |  |
| Changes in color                | 57 (0.8)                                     | 14 (0.3)                       | 36 (1.4)                       | 7 (1.8)                | 0.006   |  |  |
| Mastalgia                       | 125 (1.9)                                    | 49 (1.3)                       | 43 (1.7)                       | 33 (8.5)               |         |  |  |
| Telorrhea                       | 24 (0.3)                                     | 14 (0.3)                       | 8 (0.3)                        | 2 (0.5)                |         |  |  |
| Asymptomatic                    | 5296 (81.5)                                  | 2904 (80)                      | 2110 (85)                      | 282 (72.6)             |         |  |  |
|                                 | Imag   | ing studies Mammographic       | findings                       |                        |         |  |  |
| <b>BI-RADS</b> category         |  |                                |                                |                        |         |  |  |
| BI-RADS O                       | 370 (5.6)                                    | 254 (7)                        | 100 (4)                        | 16 (4.1)               |         |  |  |
| BI-RADS 1                       | 264 (4)                                      | 222 (6.1)                      | 40 (1.6)                       | 2 (0.5)                |         |  |  |
| BI-RADS 2                       | 4, 752 (73.1)                                | 2538 (69.9)                    | 1916 (77.2)                    | 298 (76.8)             |         |  |  |
| BI-RADS 3                       | 538 (8.2)                                    | 353 (9.7)                      | 170 (6.8)                      | 15 (3.8)               | 0.02    |  |  |
| BI-RADS 4A                      | 147 (2.2)                                    | 86 (2.3)                       | 86 (2.3) 55 (2.2) 6 (1.5)      |                        | 0.02    |  |  |
| BI-RADS 4B                      | 277 (4.2)                                    | 126 (3.4)                      | 125 (5)                        | 26 (6.7)               |         |  |  |
| BI-RADS 4C                      | 55 (0.8)                                     | 21 (0.5)                       |                                |                        |         |  |  |
| BI-RADS 5                       | 92 (1.4)                                     | 17 (O.4)                       | 39 (1.5)                       | 16 (4.1)               |         |  |  |
| Breast density                  |  |                                |                                |                        |         |  |  |
| A                               | 783 (12)                                     | 243 (6.6)                      | 443 (17.8)                     | 97 (25)                |         |  |  |
| В                               | 3021 (46.5)                                  | 1637 (45.1)                    | 1198 (48.3)                    | 186 (47.9)             | 0.05    |  |  |
| С                               | 2645 (40.7)                                  | 1714 (47.2)                    | 826 (33.3)                     | 105 (27)               | 0.05    |  |  |
| D                               | 46 (0.7)                                     | 33 (0.9)                       | 13 (0.5)                       |                        |         |  |  |
| Distortion of architecture      | 475 (7)                                      | 210 (5.8)                      | 229 (9)                        | 36 (9.3)               |         |  |  |
| Calcifications                  |  |                                |                                |                        |         |  |  |
| Amorphous                       | 270 (4.2)                                    | 101 (2.8)                      | 152 (6)                        | 17 (4.4)               | 0.049   |  |  |
| Thin, linear and branched       | 7 (0.1)                                      | 5 (0.1)                        |                                | 2 (0.5)                | 0.049   |  |  |
| Lymph nodes                     |  |                                |                                |                        |         |  |  |
| Axillary                        | 263 (4)                                      | 138 (3.8)                      | 116 (5)                        | 9 (2.3)                | 0.01    |  |  |
| Intramammary                    | 867 (13.3)                                   | 397 (10.9)                     | 390 (16)                       | 80 (20.6)              | 0.01    |  |  |
|                                 | Pa   | thological findings: Benign l  | esions                         |                        |         |  |  |
| Benign pathology                | 3,264 (55.8)                                 | 2,065 (56.9)                   | 1,364 (55)                     | 195 (50.3)             |         |  |  |
| Type of breast lesion           |  |                                |                                |                        |         |  |  |
| Fibrocystic mastopathy          | 1.586 (43.8)                                 | 1.012 (49.1)                   | 518 (38.1)                     | 56 (28.7)              | 0.04    |  |  |
| Fibroadenoma                    | 715 (19.8)                                   | 420 (20.4)                     | 261 (19.2)                     | 34 (17.4)              |         |  |  |
| Calcifications                  | 329 (9.1)                                    | 148 (7.2)                      | 155 (11.4)                     | 26 (13.3)              |         |  |  |
| Lymph nodes                     | 230 (6.4)                                    | 118 (5.7)                      | 96 (7.1) 16 (8.2)              |                        |         |  |  |
| Asymmetries                     | 353 (9.8)                                    | 185 (9)                        | 141 (10.4)                     | 27 (13.8)              |         |  |  |
| Other                           | 404 (11.1)                                   | 179 (8.6)                      | 189 (13.8)                     | 36 (18.6)              |         |  |  |

TABLE 2. CLINICAL CHARACTERISTICS, RADIOLOGICAL AND HISTOPATHOLOGICAL FINDINGS IN WOMEN WITH A DIAGNOSIS OF MALIGNANCY. ALL RESULTS ARE REPORTED IN FREQUENCIES (PERCENTAGES).

|                                | Total (n=226)       | Ac               | e groups n=226 (100 |                | <i>p</i> value     |  |
|--------------------------------|---------------------|------------------|---------------------|----------------|--------------------|--|
|                                |                     | 40-49 years n=79 | 50-69 years n=118   | >70 years n=29 |                    |  |
|                                | Clinical h          | istory           |                     |                |                    |  |
| Average age (Range)            | 56.5 (37-90)        | 44.6 (40-49)     | 58.8 (50-69)        | 77.5 (71-90)   | 0.005              |  |
| Thyroid disorder               |                     |                  |                     |                |                    |  |
| Hypothyroidism                 | 26 (11.5)           | 12 (15.1)        | 9 (7.6)             | 5 (17.2)       | 0.02               |  |
| Thyroid cancer                 | 1 (0.4)             |                  | 1 (0.8)             |                |                    |  |
| Hormonal use                   | 91 (40.2)           | 51 (64.5)        | 28 (23.7)           | 12 (41.3)      |                    |  |
| amily history of breast cancer |                     |                  |                     |                |                    |  |
| Yes                            | 42 (18.6)           | 14 (17.7)        | 18 (15.2)           | 10 (34.4)      | 0.01               |  |
| No                             | 184 (81.4)          | 65 (82.3)        | 100 (84.7)          | 19 (65.1)      | 0.01               |  |
| BRCA1/2 mutation               |                     |                  |                     |                |                    |  |
| Yes                            | 35 (15.5)           | 13 (16.4)        | 18 (15.2)           | 4 (13.7)       |                    |  |
| No                             | 191 (84.5)          | 66 (83.5)        | 100 (84.7)          | 25 (86.3)      | 0.13               |  |
| Symptoms                       |                     |                  |                     |                |                    |  |
| Palpable nodule                | 41 (18.1)           | 12 (15.1)        | 24 (20.3)           | 5 (17.2)       |                    |  |
| Changes in color               | 29 (12.8)           | 6 (7.5)          | 20 (16.9)           | 3 (10.3)       |                    |  |
| Mastalgia                      | 31 (13.7)           | 11 (13.9)        | 17 (14.4)           | 3 (10.3)       | 0.45               |  |
| Telorrhea                      | 10 (4.4)            | 3 (3.7)          | 5 (4.2)             | 2 (6.8)        |                    |  |
| Asymptomatic                   | 115 (50.8)          | 47 (59.4)        | 52 (44)             | 16 (55.1)      |                    |  |
|                                | naging studies Mamr |                  |                     | 10 (55.1)      |                    |  |
|                                | BI-RADS Co          |                  |                     |                | _                  |  |
| BI-RADS O                      | 3 (1.3)             | 1 (1.2)          | 2 (1.69)            |                |                    |  |
| BI-RADS 1                      |                     |                  |                     |                | 0.001              |  |
| BI-RADS 2                      |                     |                  |                     |                |                    |  |
|                                |                     |                  |                     |                |                    |  |
| BI-RADS 3                      | 2 (0.9)             | 2 (2.5)          |                     |                |                    |  |
| BI-RADS 4A                     | 21 (9.3)            | 8 (10.1)         | 12 (10.1)           | 1 (3.4)        |                    |  |
| BI-RADS 4B                     | 67 (29.6)           | 28 (35.4)        | 34 (28.8)           | 5 (17.2)       |                    |  |
| BI-RADS 4C                     | 43 (19)             | 14 (17.7)        | 24 (20.3)           | 5 (17.2)       |                    |  |
| BI-RADS 5                      | 90 (31)             | 26 (20.2)        | 46 (32.2)           | 18 (55.17)     |                    |  |
| Breast density                 |                     |                  |                     |                |                    |  |
| А                              | 16 (7.0)            | 2 (2.5)          | 8 (6.7)             | 6 (20.6)       |                    |  |
| В                              | 119 (52.6)          | 61 (26.9)        | 47 (39.8)           | 11 (37.9)      | 0.02               |  |
| С                              | 90 (39.8)           | 15 (18.9)        | 63 (53.3)           | 12 (41.3)      | 0.02               |  |
| D                              | 1 (0.4)             | 1 (1.2)          |                     |                |                    |  |
| Distortion of architecture     | 75 (33.1)           | 13 (16.4)        | 56 (47,4)           | 6 (20.6)       |                    |  |
| Calcifications                 | VV                  |                  |                     |                |                    |  |
| Amorphous                      | 35 (15.4)           | 8 (10.1)         | 23 (19.4)           | 4 (13.7)       | 0.10               |  |
| Thin, linear and branched      |                     |                  |                     |                | 0.10               |  |
| Lymph nodes                    |                     |                  |                     |                |                    |  |
| Axillary                       | 33 (14.6)           | 10 (12.6)        | 15 (12.7)           | 8 (27.5)       | 0.01               |  |
| Intramammary                   | 16 (7)              | 6 (7.5)          | 8 (6.7)             | 2 (6.8)        | 0.01               |  |
|                                | Histopathologi      | cal findings     |                     |                |                    |  |
| Invasive ductal carcinoma      | 134 (59.6)          | 47 (59.4)        | 69 (58.4)           | 18 (62)        | <0.001             |  |
| Ductal carcinoma in situ       | 57 (25.3)           | 23 (29.1)        | 28 (23.7)           | 6 (20.6)       |                    |  |
| Invasive lobular carcinoma     | 9 (4)               | 1 (1.2)          | 7 (5.9)             | 1(3.4)         |                    |  |
| Lobulillar carcinoma in situ   | 6 (2.7)             | 3 (3.7)          | 3 (2.5)             |                |                    |  |
| Inflammatory carcinoma         | 5 (2.2)             | 1 (1.2)          | 4 (3.3)             |                |                    |  |
| Malignant phyllodes tumor      | 5 (2.2)             | 3 (3.7)          |                     | 2 (6.8)        | 0.00               |  |
| Mucinous carcinoma             |                     |                  |                     |                | 1 (3.4)<br>1 (3.4) |  |
|                                | 3 (1.3)             |                  | 2 (1.6)             |                |                    |  |
| Non-Hodgkin lymphoma           | 3 (1.3)             |                  | 2 (1.6)             |                |                    |  |
| Others                         | 3 (1.2)             |                  | 3 (2.5)             |                |                    |  |



FIGURE 1. HEAT GRAPH: DISTRIBUTION OF BREAST CANCER ACCORDING TO BI-RADS CATEGORIES.

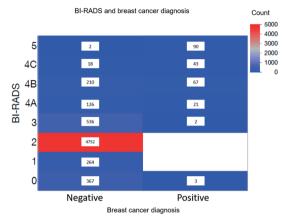


FIGURE 2. HEAT PLOT: DISTRIBUTION OF BREAST CANCER ACCORDING TO BREAST DENSITY.

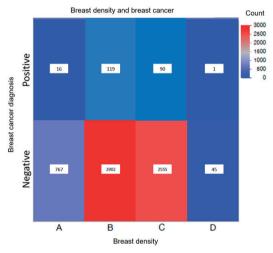


TABLE 3. DIAGNOSTIC TEST VALUES OF THE WOMEN STUDIED IN BI-RADS 4 and 5.

|                           | Values | CI 95%     |  |
|---------------------------|--------|------------|--|
| Sensitivity               | 90.9%  | 83.7-98.1% |  |
| Specificity               | 41.0%  | 29.8-52.2% |  |
| Positive predictive value | 93.4%  | 86.2-94.1% |  |
| Negative predictive value | 90.0%  | 85.6-94.4% |  |

CI=confidence intervals

er number of cases diagnosed due to a greater number of screening studies. It has been estimated that by the year 2040, the number of new cases per year will be around 3 million and there will be approximately 1 million secondary deaths from this cause worldwide<sup>(20,21)</sup>.

These data justify the need to make society aware of a culture of screening, with the aim of diagnos-

ing diseases in early stages, always adhering to the recommendations issued by the American College of Radiology according to the BI-RADS system. This was designed so that the multidisciplinary teams use the same terminology, there is a systematization in the mammography report, the lesions are categorized according to the degree of suspicion, and recommendations are issued according to the category of the lesion, in order to obtain a quality control in the indicators of each mastology clinic. This system integrates other imaging tools such as ultrasound or nuclear magnetic resonance<sup>(22)</sup>.

The clinic is important as a first approach, since most lesions, regardless of their benign or malignant nature, will manifest as a palpable nodule. Mastalgia is not related to malignant processes. Once the lesion has been identified, it is pertinent to request auxiliary imaging studies<sup>(23)</sup>.

Mammography has been the only imaging tool that has had an impact on reducing mortality. Despite being the most important pillar of screening, it is not exempt from reporting false positives and negatives. It is therefore important to carry out quality control through indicators that evaluate the clinical, imaging and histopathological correlation<sup>(24)</sup>.

There are intrinsic conditions of the mammary gland that reduce the sensitivity of this test, which can lead to both false-positive and false-negative results, which in turn lead to overtreatment or to overlooking lesions that merit protocolization (24). It has been reported that high breast density is closely related to reducing the sensitivity of this test, in addition to itself conferring an increased risk for breast cancer. Because of these two situations, in women with high breast density, complementary studies to mammography should be considered<sup>(25)</sup>. In the present study, women with breast cancer presented mainly B and C breast densities, which surely established an independent risk for their condition and made diagnosis difficult. Because of this, most of them were asked for additional studies in order to make a correct categorization.

In order to reduce the false positive rate, other mammographic methods have been validated, such as tomosynthesis, which was used in all the participants of the present study. The aim of the use of new technologies is the early detection of breast cancer in asymptomatic women. Thao-Ouyen and colleagues compared digital mammography with tomosynthesis, where the number of false positives was lower with the latter modality and, in turn, a higher detection rate was obtained. This is due to the reduction of the confounding effect of the superpositioning of breast tissue. Another advantage of using tomosynthesis mammography is the diagnostic accuracy of non-calcified lesions, since it reduces the need to obtain other projections due to the third dimension it uses<sup>(26)</sup>. The sensitivity obtained by tomosynthesis mammography in the present study was 90.9%, similar to what has been reported in the literature.

BI-RADS categories 3 and 4 have always been a dilemma in their categorization. In the study published by Offit and his group, where they compared digital mammography with tomosynthesis, a limit of 2% was set for the accepted malignancy rate, that is, the maximum percentage of studies reported as false negatives, where tomosynthesis showed a better performance, registering 1.8% compared to 5% with digital mammography. However, one of the disadvantages of tomosynthesis mammography has been the higher rate of false positives, especially in those lesions categorized as BI-RADS 4<sup>(27)</sup>.

Once the anatomopathologic result was obtained, it was observed that the most frequent type of cancer recorded in the present study was invasive ductal carcinoma, similar to that published in the medical literature.

In this study a relationship was found between mammography and final histopathological results, where more positive results for malignancy were obtained according to a higher BI-RADS category, as shown in Figure 1. The positive predictive value obtained for these categories was 93.4%. However, it was not free of false positives.

It is important to mention that innovative tools such as artificial intelligence (AI) are currently available. This has turned out to be an ally for the interpretation of mammograms through deep learning algorithms. Its acceptance has made it possible to reduce the radiologist's tunnel vision, which causes him to overlook some suspicious images, by reducing the workload without affecting the sensitivity of the study. The support generated by these tools does not replace the work of the radiologist, who will always have the criterion to make a diagnosis<sup>(28)</sup>. Dembrower et al. compared the performance of radiologists against AI, concluding that their assessment is superior to AI. However, this tool has proven to be useful as a complement in practice<sup>(29)</sup>.

It is essential to emphasize that clinical and imaging findings do not provide a definitive determination on their own, which is why it is imperative to obtain a histopathological result, which is known as triple test. Likewise, this must be performed in a context of discordance between the clinical and imaging findings. It has been shown that, if clinicians adhere to the practice of the triple test, the correlation between clinical, imaging and histopathology improves its performance, decreasing the rate of false positives and negatives<sup>(30)</sup>.

The present study had some limitations. First, its retrospective design, since it was limited to clinical records and studies of past years, which could represent a bias. The main strength of the present study was the number of cases analyzed, which allows us to reflect on the quality indicators in our mastology clinic, in order to obtain better results that correlate clinical, imaging studies and histopathologic findings. We currently have new technologies such as AI, which in the future will allow us to further improve these quality standards.

In conclusion, mammography has been the only imaging tool that has had a positive impact on reducing breast cancer mortality. The tomosynthesis mammography modality has increased the yield of this test by detecting subclinical lesions. However, caution should be exercised in the categorization of BI-RADS 3 and 4 lesions, as they represent the highest number of false positives and negatives. With the advent of new technologies, a better correlation between clinical, imaging and histopathology is expected.

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