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POSITIVE PREDICTIVE VALUE OF NONPALPABLE BREAST LESIONS ACCORDING TO BI-RADS® CLASSIFICATION

Valor preditivo positivo das lesões mamárias não palpáveis utilizando a classificação BI-RADS®

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ABSTRACT

Introduction: Breast cancer is the neoplasm that most affects women in Brazil and the world, and its incidence has increased steadily over the last decade. Due to screening mammography programs, according to age group, the mortality rate of breast cancer has decreased by 31%. With the increase in the number of screening examinations, there has also been increase in the number of suspicious lesions diagnosed and, consequently, increase in the indication and performance of breast biopsies. With the help of the categorizations that the American College of Radiology published, according to the Breast Imaging Reporting and Data System (BI-RADS®), it was possible to standardize the reports and descriptions of breast lesions, both in mammography and ultrasound, facilitating decision-making in regard to suspicious lesions. **Objective:** To evaluate the positive predictive value (PPV) of nonpalpable breast lesions biopsied in the Radiodiagnostic Service of Hospital Naval Marcílio Dias. **Method:** A retrospective and analytical study of 88 patients submitted to stereotaxic guided mammary biopsies from December 2015 to December 2016 with suspected diagnosis of malignant lesions, classified by mammographic BI-RADS in categories 4 and 5 and later correlation with the histopathological reports. **Results:** PPV was high for category 5 lesions, and for category 4 lesions PPV was low and progressively increased with the subcategories. **Conclusion:** BI-RADS categorization is an effective predictor for the risk of malignancy in suspicious mammographic lesions.

KEYWORDS: Breast cancer; mammography; stereotaxic biopsy; histopathological diagnosis; BI-RADS.

RESUMO

Introdução: O câncer de mama é a neoplasia que mais acomete mulheres no Brasil e no mundo e sua incidência vem aumentando progressivamente ao longo dessa última década. Devido aos programas de rastreamento mamográfico, de acordo com a faixa etária, a taxa de mortalidade por câncer de mama diminuiu em 31%. Com o aumento do número de exames de rastreamento houve aumento, também, da quantidade de lesões suspeitas diagnosticadas e, consequentemente, um aumento na indicação e realização de biópsias mamárias. Com o auxílio das categorizações que o American College of Radiology publicou, segundo o Breast Imaging Reporting and Data System (BI-RADS®), foi possível padronizar os laudos e as descrições das lesões mamárias, tanto na mamografia quanto na ultrassonografia, facilitando a tomada de decisão perante a lesões de aspecto suspeito. **Objetivo:** Avaliar o valor preditivo positivo (VPP) das lesões mamárias não palpáveis nas quais foi realizada biópsia no Serviço de Radiodiagnóstico do Hospital Naval Marcílio Dias. **Método:** Estudo retrospectivo e analítico de 88 pacientes submetidas a biópsias mamárias guiadas por estereotaxia no período de dezembro de 2015 a dezembro de 2016 com diagnóstico suspeito de lesões malignas, classificadas no BI-RADS® mamográfico em categorias 4 e 5, com posterior correlação com os laudos histopatológicos. **Resultados:** Foi encontrado alto valor preditivo positivo na categoria cinco e, nas lesões classificadas como categoria quatro, o VPP foi menor, aumentando progressivamente com as subcategorias. **Conclusão:** A categorização BI-RADS® é um preditor eficaz para o risco de malignidade nas lesões suspeitas na mamografia.

PALAVRAS-CHAVE: Câncer de mama; mamografia; biópsia estereotáxica; diagnóstico histopatológico; BI-RADS®.

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INTRODUCTION

Breast cancer is the cancer that most affects women in Brazil[1] and the second most frequent type of neoplasm in the world. According to statistical studies of the National Cancer Institute (INCA) in Brazil, there are reports of approximately 49,000 cases of breast neoplasm, which are responsible for 12,000 deaths per year[2].

In an estimate made for 2014, and for 2015 as well, 57,120 new cases were predicted, representing an estimated risk of 52 cases per 100,000 women per year. According to data from the Globocan 2012, from the International Agency for Research on Cancer (IARC), the risk accumulated during the lifetime of a person having and dying from breast cancer in Brazil is 6.3% (having) and 1.6% (dying)[3]. In low- and middle-income countries, diagnosis tends to be later in the advanced stages of the disease. In high-income countries, because there is organized population screening, the diagnosis is made when the disease is still in localized stages, resulting in important difference in prognosis and morbimortality.

These data show the importance of cancer control strategies with a set of integrated and systematic measures, aimed at reducing morbidity and mortality. Primary prevention is also contemplated, reducing and eliminating risk factors associated with early detection through mammographic screening.

When diagnosed early, the chances of a better prognosis for breast cancer are higher, thus reducing the morbidity associated with treatment. The recommended screening measures include mammography. Breast self-examination, clinical examination, magnetic resonance imaging (MRI), ultrasound (US), thermography, and tomosynthesis may also be helpful in complementing the diagnosis. The early diagnosis actions proposed by the Ministry of Health include strategies for awareness, identification of signs and symptoms, and diagnostic confirmation in a single service[3]. Screening should occur in women aged 50–59 years with an annual mammogram, and up to 69 years, biennially[3].

There are some signs and symptoms that are considered as an urgent reference for the patient to seek a specialized service, such as nodules in women over 50 years old, nodules that persist for more than one menstrual cycle in women over 30, fixed hard nodule that increases in volume, bloody papillary discharge and retraction of the skin on the breast, among others.

Decrease in mortality rate is closely related to early detection of the disease so that the best therapeutic approach can be taken, with the aim of a better prognosis of the disease. Therefore, effective screening is necessary and mandatory.

The INCA recommends, mainly, self-examination of the breasts and mammography starting at 50 years old. Imaging examinations such as MRI and US also enter into the picture as a complement to screening according to INCA. Thus, awareness strategies, early identification of signs and symptoms and diagnostic confirmation are crucial and indispensable in the fight against breast cancer.

The American College of Radiology (ACR) has released an atlas, the Breast Imaging Reporting and Data System (BI-RADS®), which is in its fifth edition, to promote consistency and uniformity in breast imaging reports, reducing any possibility of confusion in the interpretation of images and facilitating recommendations on taking measures or monitoring. This system unifies mammographic, US and MRI data, standardizing specific findings and classifying them into categories according to each method[4,5].

For the early diagnosis of breast cancer, mammography has been the method with more specificity and sensitivity. Since it is performed periodically, sensitivity varies between 71 and 98%, as analyzed by reviews of the literature[6].

The BI-RADS classification for mammography describes category 0 as those cases with inconsistent findings and that need additional evaluation by other methods or comparison with previous examinations, so the patient would need to be recalled. Category 1 is a negative assessment for normal breasts according to the method, with no probability of malignancy. Category 2 includes benign findings such as cutaneous calcifications, metallic foreign bodies, cysts, implants, etc., also essentially without any likelihood of malignancy. Category 3 classifies those changes with up to 2% probability of malignancy, with probably benign findings, requiring follow-up in six months. To reach a conclusion on the lesions of this category, many studies have shown the safety and efficacy of follow-up by periodic mammograms instead of biopsy. The findings that are validated as probably benign include non-calcified circumscribed solid nodules, focal asymmetry and isolated clustering of punctiform calcifications. BI-RADS itself shows that this category often generates unnecessary follow-up or delay in early diagnosis, showing that even with the standardization of reports, we do not always have an exact science when it comes to disease, and therefore, many studies have confronted these findings.

Findings classified as categories 4 and 5 are those suspicious and highly suspicious of malignancy, respectively, that require histopathological studies to rule out malignancy or detect an early neoplasm. Category 6 changes are already malignant proven by biopsy[6].

In the case of category 4, which are suspicious findings, the risk of malignancy varies between 2 and 95%[6]. These findings are subcategorized as: 4A with low suspicion (2 to 10% probability of malignancy), 4B with moderate suspicion (ranging between 10 and 50%), and 4C with high suspicion for malignancy varying between 50 and 95% chance[6]. This category is reserved for those findings that do not have the classic appearance of malignancy, but are suspect enough to justify recommendation for biopsy.

Category 5 is for mammogram findings at a level of suspicion equal to or greater than 95%.

With the development of BI-RADS in 1993, many studies were conducted to correlate imaging findings with histopathological results, and all were heterogeneous regarding patient selection, histopathological method, and palpable or nonpalpable lesions[7].

In a literature review that evaluated 15 studies, the following results were obtained: positive predictive value (PPV) between 4 and 62% for category 4 (median of 20%) and between 54 and 100% for category 5 (median of 89%), regardless of histopathology method or morphological criteria[7]. It was concluded that mammographic screening for breast cancer, obtaining an early diagnosis, is indisputably responsible for a substantial decrease in mortality due to this disease.

However, with many divergences in radiological findings, many biopsies are performed unnecessarily. Among the studies selected for literature review, many used different methods and some did not mention age nor clinical examination data, making it difficult to compare the data and, therefore, also showed significant differences in the detection of cancer. Only three studies of the 15 evaluated achieved a satisfactory PPV when compared to the PPV suggested by the BI-RADS system.

Another study found that the low PPV in category 4 could be related to the fact that the BI-RADS nomenclature is very comprehensive and not specific, and even to the lack of experience of some radiologists[8].

All studies conclude that there is a great variation in PPV, correlated with the heterogeneity of information collected in each of them, limiting the comparison of results. This, once again, shows the difficulty of establishing a medical standardization to be followed by all specialists, proving that we should always be in search of studies aimed at improving the disease diagnosis pattern.

Also illustrating this importance, another study of clinical relevance reached the conclusion that the histopathological studies of 76% of cases were negative for malignancy and only 24% were positive, showing PPV of 7.14, 16.96 and 82.61% for categories 3, 4 and 5, respectively[9].

Based on these findings, the objective of this study was to determine the PPV of nonpalpable breast lesions that were biopsied at the Radiodiagnostic Service of Hospital Naval Marcílio Dias (HNMD), correlating with the findings of the histopathological studies, and to compare the PPV found with those described in the 5th edition of BI-RADS. We also intended to show the importance of the subclassification of BI-RADS category 4 for radiologists in search of better patient care. It is essential that each service seek to improve its performance in favor of patient care through professional qualification, research incentives, availability of research resources and improvement of diagnostic methods.

METHOD

This study was approved by the Research Ethics Committee of HNMD, and the use of an informed consent form was waived. In this retrospective study, we analyzed all mammograms performed at the Radiodiagnostic Service of HNMD from December 2015 to December 2016 and selected those classified as categories 4 and 5 by BI-RADS, in which patients were subjected to a stereotactic breast biopsy, aiming to demonstrate the agreement of PPV for breast cancer between the 5th edition of BI-RADS classification and histopathological results.

All mammograms were analyzed by radiologists with experience in mammographic diagnosis, and the findings were classified according to the BI-RADS system.

Mammograms evaluated in this study were performed on the Mammomat 3000 Nova mammography machine (Siemens Healthcare, Germany), and the images digitized by the CR-85 X (Agfa HealthCare, São Paulo, Brazil), installed in the mammography and stereotaxy section of the HNMD. The examinations were performed in the craniocaudal and mediolateral oblique views, and complementary views occurred when necessary.

The selected data were obtained from the breast biopsy registry of the mammography section and the computer medical records of the institution, from which the mammogram and histopathological reports were also extracted.

We collected data on patient age and family history of breast cancer, as well as the histological type of cancer in the selected cases.

The inclusion criteria were: patients whose mammogram was classified BI-RADS category 4 and its subdivisions and category 5, and also patients who underwent stereotactic breast biopsy at HNMD.

Patients whose biopsy originated from a mammogram classified as other BI-RADS categories and those who were biopsied at other institutions were excluded from the study.

We selected 88 patients whose cases met the inclusion criteria. The data were organized and tabulated in a Microsoft Excel 2010 worksheet, PPV was calculated using a specific formula, and the final results were compared with BI-RADS 5th edition.

RESULTS

Among the 88 selected cases, the mean age of the patients was 58.61 years old (57.81 years for those with benign histopathology and 60.32 years for those diagnosed with cancer), and the minimum age was 37 and the maximum 85.

In the age group 30 to 40 years, only one had a diagnosis of malignancy out of six cases. Between 41 and 50 years, there were five cases. In the 51 to 60 years group, diagnoses of malignancy totaled eight cases. Between 61 and 70 years, six of the 24 selected cases showed malignancy, and, between 71 and 90 years, there were eight cases of cancer for the 17 biopsies (Table 1).

Of the total of 88 cases analyzed, the percentage distribution of mammographic diagnoses among BI-RADS categories was 94.31% (83) for category 4 and 5.68% (five) for category 5, showing predominance of alterations in category 4. Among the BI-RADS 4 subcategories, there were 20 (22.72%) cases of 4A, 19 (21.59%) of 4B and eight (9.09%) of 4C. Among the 88 cases,

36 were category 4 (40.90%), that is, those patients in which the subcategory was not specified. Table 2 shows the total number of patients and percentages distributed by categories, separating the cases as malignant or benign.

The histopathological results showed 60 patients (68.18%) with a benign result and 28 cases (31.81%) diagnosed as malignant. Of the 28 cases of breast cancer, nine had mammograms classified as category 4 without any subdivision, three as category 4A, seven as 4B and four as 4C, and five cases categorized as 5 (Table 3).

Evaluating only category 4, the 83 cases were subdivided, resulting in 24.09% (20) for subcategory A, 22.89% (19) for B and 9.63% (8) for C. Mammograms categorized as 4, without subclassification, accounted for 43.37%, with 36 cases out of 83 (Table 3).

PPV for category 4 was 27.71%, considering only the 36 exams in which the subcategory was not specified. PPV of the subcategories was 15% for category 4A, 36.8% for 4B and 50% for 4C. PPV for category 5 was 100% (Table 4).

Among the histological types found, infiltrating ductal carcinoma predominated with 57.14% of diagnosed cases of cancer (Table 5).

Although it was not the focus of this study, it was observed that there was predominance of negative family history for breast cancer among the selected patients, even in the most suspicious categories. In those classified as categories 4C and 5, only one patient from each category had a positive family history (Table 6).

DISCUSSION

The BI-RADS classification system was the first attempt to standardize mammographic findings in descriptive terms and it is an important instrument to aid in the suspicion of

Table 1. Number of malignant and benign cases according to age group.

Age (years)	Malignant (n)	Benign (n)	Total (n)
30–40	1	5	6
41–50	5	15	20
51–60	8	13	21
61–70	6	18	24
71–90	8	9	17

Table 2. Percent malignant and benign cases according to BI-RADS category.

BI-RADS	Benign - % (n)	Malignant - % (n)	Total - % (n)
4*	30.68 (27)	10.22 (9)	40.90 (36)
4A	19.31 (17)	3.41 (3)	22.72 (20)
4B	13.63 (12)	7.95 (7)	21.59 (19)
4C	4.54 (4)	4.54 (4)	9.09 (8)
5	0 (0)	5.68 (5)	5.68 (5)

*Examinations in which subcategory was not specified.

Table 3. Percent distribution between subdivisions of BI-RADS category 4.

BI-RADS	Benign - % (n)	Malignant - % (n)	Total - % (n)
4*	32.53 (27)	10.84 (9)	43.37 (36)
4A	20.48 (17)	3.61 (3)	24.09 (20)
4B	14.45 (12)	8.43 (7)	22.89 (19)
4C	4.81 (4)	4.81 (4)	9.63 (8)
Total	72.28 (60)	27.71 (23)	100 (83)

*Examinations in which subcategory was not specified.

Table 4. Positive predictive value of selected mammograms.

Categories and Subcategories	Mammograms (n)	Biopsies positive for malignancy (n)	PPV (%)
4*	36	9	25
4A	20	3	15
4B	19	7	36.84
4C	8	4	50.00
5	5	5	100

*Examinations in which subcategory was not specified; PPV: positive predictive value.

Table 5. Distribution of histological types of cancers diagnosed.

Histological type	n	%
Intraductal carcinoma	4	14.28
Infiltrating ductal carcinoma	16	57.14
Infiltrating carcinoma	1	3.64
Invasive carcinoma	7	25

Table 6. Distribution of cases with positive (+) or negative (-) family history.

BI-RADS	(+)	(-)	Total
4*	3	33	36
4ª	4	16	20
4B	4	15	19
4C	1	7	8
5	1	4	5

*Examinations in which subcategory was not specified.

malignancy and in the measures to be taken. Associated with this classification, there was also progressive increase in the number of biopsies.

In the present study, 31.81% of mammograms in which a biopsy was done for histopathological examination showed malignancy, that is, the overall PPV was 31.81%. In the United States, this value varies between 15 and 40%[9-13].

Some studies correlated mammographic and histopathological findings of breast lesions found a PPV for breast cancer between 12.3 and 47.8%[8,14-16]. BI-RADS suggests values above 95% for category 5, and we obtained PPV of 100% in mammograms with this category. The 100% PPV for category 5 is within the range expected from the several cases cited in the literature, in which the values range from 54 to 100%[13-24].

In the literature, mammographic sensitivity is described as greater than 90%, although it has limited specificity, and between 65 and 90% of all biopsied mammary lesions are benign[23,24].

In category 4, the chance of malignancy is between 2 and 95%[5] according to BI-RADS, and PPV is between 2 and 10% in subcategory 4A, between 10 and 50% in 4B, and between 50 and 95% in 4C. In this study, we found PPV of 27.71% for category 4, and in the literature it varies between 4 and 63%. On the other hand, PPV calculated separately for subcategories showed for subcategories 4A, 4B and 4C values of 15, 36.8 and 50%, respectively.

Here, we did not take into account the radiological findings of the selected cases, but, in the experience of this service, microcalcifications are the most commonly biopsied findings using stereotactic guidance.

Malignancy cases in this study predominated in the age ranges of 51 to 60 and 71 to 90, in which the most frequent histological type was infiltrating ductal carcinoma followed by invasive carcinoma, and most cases collected had no positive family history.

With the data found, we observed that the BI-RADS classification allows us to safely predict that there are high suspicion for malignancy in category 5-classified lesions and progressive decrease in suspicion in the lower categories.

In category 4, the percentage variation between the subdivisions is very large, but we can see progressive increase in PPV given to the subclassifications A, B and C, showing that this subdivision contributes, in a more detailed and precise way, to the indication of suspicious lesions, making it necessary to perform systematic biopsies.

This study demonstrated that we should look more and more at the findings of mammographic lesions, always seeking to take into account the BI-RADS category and subcategory, so that we can provide greater assurance for patients and the attending physician.

CONCLUSION

This study showed that the BI-RADS categorization is an effective predictor for the risk of malignancy in suspicious mammographic lesions.

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