PREDICTIVE VALUES OF BI-RADS CATEGORIES 3, 4 AND 5 IN NON-PALPABLE BREAST MASSES EVALUATED BY MAMMOGRAPHY, ULTRASOUND AND MAGNETIC RESONANCE IMAGING*

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Abstract **OBJECTIVE: To evaluate the predictive value of BI-RADS™ categories 3, 4 and 5 in non-palpable breast masses assessed by mammography, ultrasound and magnetic resonance imaging. MATERIALS AND METHODS: Twenty-nine patients with BI-RADS categories 3, 4 and 5 non-palpable breast masses identified by mammograms were submitted to complementary ultrasound and magnetic resonance imaging studies, besides excisional biopsy. In total, 30 biopsies were performed. The lesions as well as their respective BI-RADS classification into 3, 4 and 5 were correlated with the histopathological results. The predictive values calculation was made by means of specific mathematical equations. RESULTS: Negative predictive values for category 3 were: mammography, 69.23%; ultrasound, 70.58%; and magnetic resonance imaging, 100%. Positive predictive values for category 4 were: mammography, 63.63%; ultrasound, 50%; and magnetic resonance imaging, 30.76%. For category 5, positive predictive values were: mammography and ultrasound, 100%; and magnetic resonance imaging, 92.85%. CONCLUSION: For category 3, the negative predictive value of magnetic resonance imaging was high, and for categories 4 and 5, the positive predictive values of the three modalities were moderate.**

Keywords: BI-RADS; Breast cancer; Mammography; Predictive value.

Resumo *Valores preditivos das categorias 3, 4 e 5 do sistema BI-RADS em lesões mamárias nodulares não-palpáveis avaliadas por mamografia, ultra-sonografia e ressonância magnética.*

OBJETIVO: Avaliar os valores preditivos positivo e negativo das categorias 3, 4 e 5 do sistema BI-RADS™ em lesões mamárias nodulares não-palpáveis avaliadas por mamografia, ultra-sonografia e ressonância magnética. MATERIAIS E MÉTODOS: Vinte e nove pacientes com achados mamográficos de lesões mamárias nodulares não-palpáveis, das classes 3, 4 e 5 do BI-RADS, que realizaram exames complementares de ultra-sonografia e ressonância magnética, além de biópsia excisional. Realizaram-se 30 biópsias e correlacionaram-se as lesões e suas respectivas classificações de 3 a 5 do BI-RADS com os resultados histopatológicos. O cálculo dos valores preditivos foi feito utilizando-se equações matemáticas específicas. RESULTADOS: O valor preditivo negativo da categoria 3 pela análise mamográfica foi de 69,23%, pela análise ultra-sonográfica foi de 70,58% e pela análise por ressonância magnética foi de 100%. O valor preditivo positivo da categoria 4 pela análise mamográfica foi de 63,63%, pela análise ultra-sonográfica foi de 50% e pela análise por ressonância magnética foi de 30,76%. O valor preditivo positivo da categoria 5 foi de 100% pelas análises mamográfica e ultra-sonográfica e de 92,85% pela análise por ressonância magnética. CONCLUSÃO: O valor preditivo negativo da categoria 3 foi elevado na análise pela ressonância magnética e os valores preditivos positivos foram moderados na categoria 4 e elevados na categoria 5 pelos três métodos.

Unitermos: BI-RADS; Câncer mamário; Mamografia; Valor preditivo.

INTRODUCTION

It is unquestionable that the programs of mammographic breast cancer screening have caused a significant decrease in the mortality by this disease thanks to the early diagnosis in a considerable number of cases, as evidenced by several clinical investigations[1–6].

However, the mammographic screening started being complemented by a great number of unnecessary biopsies, since a considerable part of lesions considered as suspect of malignancy have been found to be benign. Of 1,000,000 women submitted to breast biopsy in the USA as a result of abnormal mammographic findings in breast cancer screening programs, 700,000 to 850,000 presented negative results[7].

Aiming at improving the effectiveness of breast cancer screening programs, with

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an increase in quality of reports issued by radiologists; and recognizing the necessity of providing meaningful and unambiguous reports to allow a reliable data acquisition, the American College of Radiology, in a collaborative effort with the American Cancer Institute and American College of Surgeons, in 1992 developed a system for not only classifying mammographic images, but also for structuring reports by means of lesions description and standardization of conclusions, and suggesting a course of action to be adopted depending on the final findings classification.

The result of such collaborative effort is the Breast Imaging Reporting and Data System (BI-RADS™), contemplating not only a classification of outcomes, but also the recommendation of a specific course of actions which, if adopted, will allow a higher efficacy of programs for early breast cancer detection. The system includes an introduction, a breast imaging lexicon and a reporting standardization and diseases coding system, besides a reliable methodology for outcomes monitoring and follow-up[8].

Based on a descriptive lexicon of radiological lesions, the system classifies the findings into seven categories, aiming at facilitating the decision making on a specific course of action by physicians in face of abnormal image findings. On its fourth and latest issue released in December 2003, the BI-RADS Atlas, formerly restricted to the area of mammography, extends the standardization to the areas of ultrasonography and magnetic resonance imaging[8].

The BI-RADS introduction raised the radiologists and breast specialists concern about the predictive values of categories 3, 4 and 5, aiming at improving the management of abnormal, non-palpable findings.

BI-RADS classification

Category 3 – A finding in this category presents a high probability of benignity. However, considering a very low possibility of malignancy, a short interval follow-up is recommended for evaluation of the lesion stability (Figure 1).

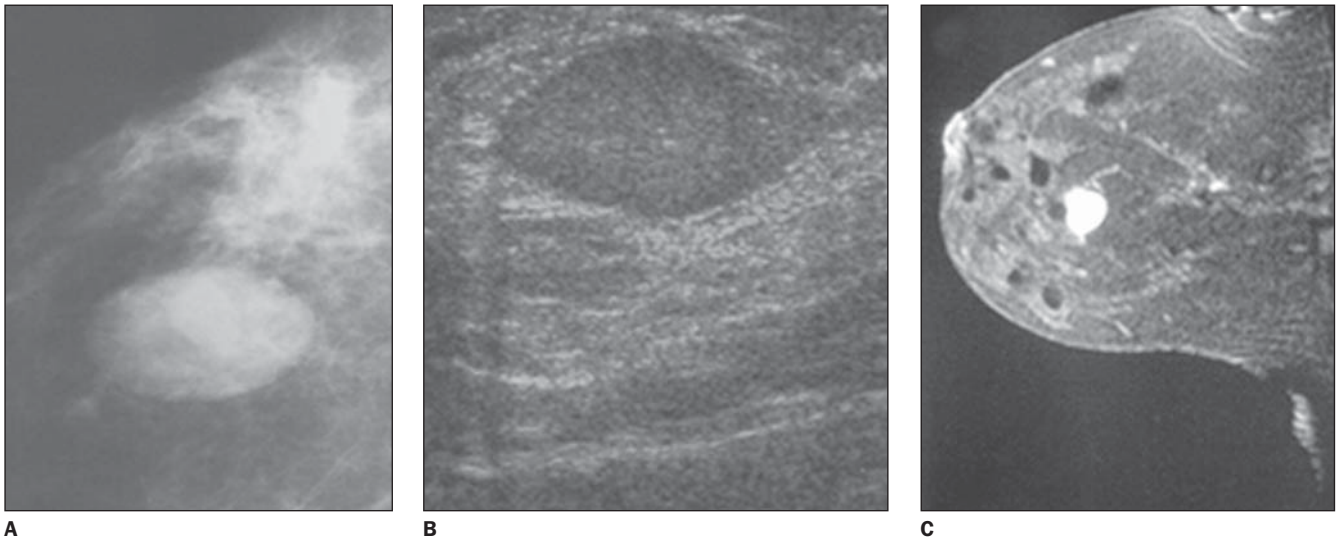
Category 4 – The lesions do not present any morphological characteristics typical of cancer, although with high probability of malignancy. The images raise sufficient concern to suggest a biopsy (Figure 2).

Category 5 – Lesions with morphological characteristics highly suggestive of malignancy (Figure 3).

A review of the literature regarding the predictive values of BI-RADS categories 3, 4 and 5 has demonstrated the inexistence of studies on mammography exclusively related to non-palpable breast masses.

As regards breast ultrasound, Hong et al.[9] have studied 403 solid breast lesions, aiming at determining the positive predictive value (PPV) and negative predictive value (NPV) of these findings, according to echographic characteristics and respective histological diagnoses described in the new BI-RADS lexicon. They have found 141 (35%) positive cases with characteristics described by BI-RADS as malignant demonstrating high PPV. Solid lesions with spiculated margins presented 86% PPV (19 of 22); irregular lesions, 62% PPV (102 of 164); lesions with a non-parallel orientation in relation to the costal grid, 69% PPV (75 of 109). As regards NPV, high values also have been observed for findings described by BI-RADS, such as circumscribed margins in 90% (160 of 178), parallel orientation in relation to the costal grid in 78% (228 of 294), and oval shape in 84% (200 of 237). These results show that the characteristics described in the new BI-RADS sonographic lexicon may be useful for differentiating between malignant and benign solid lesions.

Gokalp and Topal[10] have developed a study aiming at analyzing magnetic resonance imaging as method for evaluating supposedly benign lesions classified as BI-RADS category 3. They have studied 56 lesions present in 43 female patients, comparing the studies with the respective histological results, and calculating sensitivity, specificity and predictive values. The values found for lesions classified as probably benign were: 100% for sensitivity, 94.6% for specificity, 33.3% for PPV, and



A B C

Figure 1. Examples of nodules classified as BI-RADS category 3. **A:** Mammographic image of an isodense, well-circumscribed ovoid nodule. **B:** Sonographic image of hypoechoic, well-circumscribed ovoid nodule, presenting parallel orientation and without posterior acoustic shadowing. **C:** Magnetic resonance image showing homogeneously contrast-enhanced round, well-circumscribed nodule.

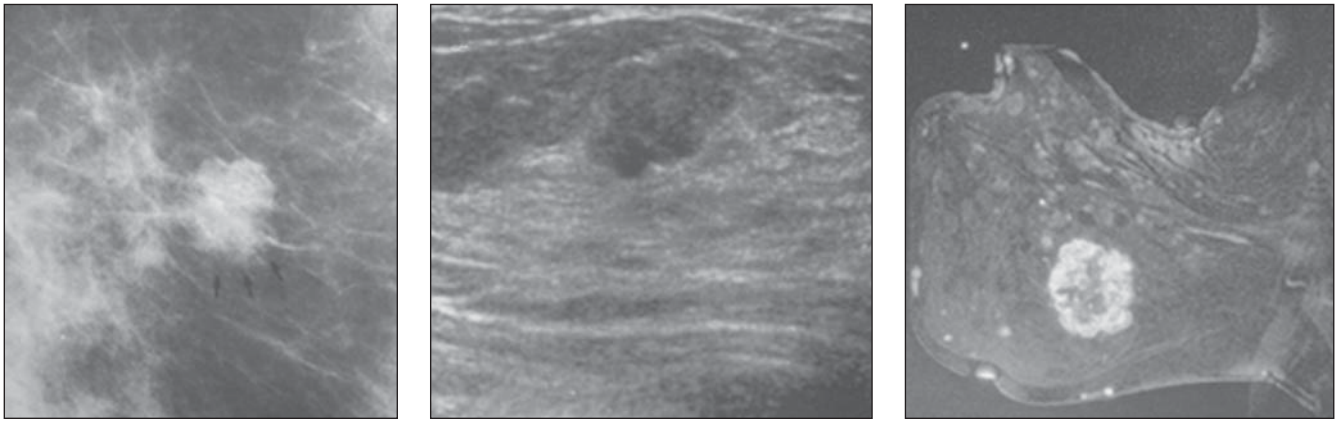


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Figure 2. Examples of nodules classified as BI-RADS category 4. **A:** Mammographic image showing an isodense, irregular nodule with microlobulated margins. **B:** Sonographic image showing hypoechoic, ovoid nodule with microlobulated margins and presenting non-parallel orientation. **C:** Contrast enhanced magnetic resonance image showing circumscribed, lobulated nodule, with a ring-like enhancement.

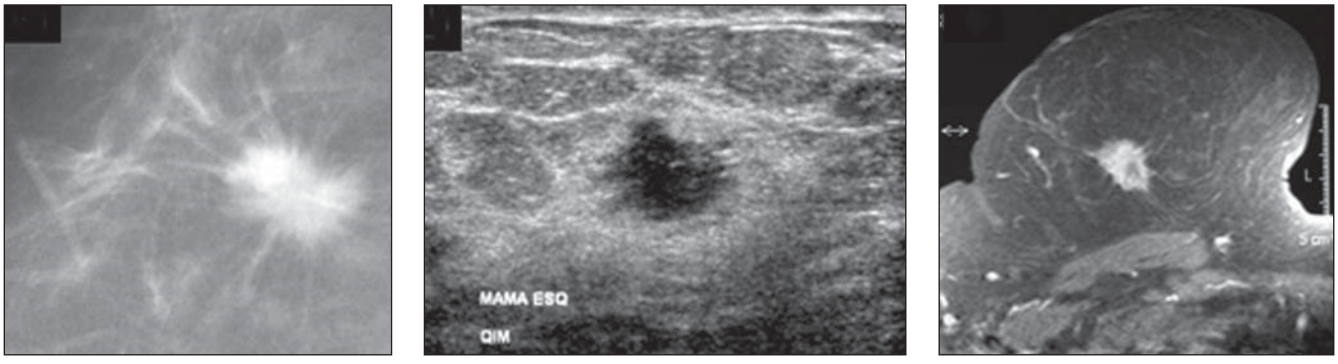

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Figure 3. Examples of nodules classified as BI-RADS category 5. **A:** Mammographic image showing a hyperdense, irregular nodule, with spiculated margins **B:** Sonographic image showing hypoechoic, irregular nodule with spiculated margins, non-parallel orientation and without posterior acoustic shadowing. **C:** Contrast enhanced magnetic resonance image showing an ovoid nodule with irregular margins and ring-like enhancement.

100% for NPV, allowing us to conclude that the system may be useful in a conservative management of alterations classified as BI-RADS category 3.

A similar study developed by Sadowski and Kelcz[11] aimed at determining the chance of malignancy for breast lesions classified as probably benign, has retrospectively evaluated 473 patients submitted to magnetic resonance imaging in the period between March 1994 and March 2002, and observed that 17% (79 of 473) were classified as probably benign. Of this group, 68 patients were followed-up during a minimum two-year period, and 6% (4 of 68) presented breast cancer in 14 to 18 months subsequent to the initial assessment. This study has led us to the conclusion that patients evaluated by means of magnetic resonance imaging and classified as BI-RADS category 3 are at higher risk for breast cancer than those evaluated by mammography in the same category.

The present study was aimed at evaluating the PPV and NPV of BI-RADS categories 3, 4 and 5 in non-palpable breast masses evaluated by mammography, ultrasound and magnetic resonance imaging.

MATERIALS AND METHODS

Twenty-nine dossiers of patients with mammographic findings of nodular lesions in BI-RADS categories 3, 4 and 5 were evaluated. One of the patients presented with findings in both breasts, so the number of lesions increased to 30. The patients also had their lesions evaluated by ultrasound and magnetic resonance imaging.

The following exclusion criteria were taken into consideration for the casuistic selection: 1) abnormal mammographic findings visualized on a single view; 2) abnormal findings with superficial or retroareolar localization; 3) patients with findings classified as BI-RADS categories 0, 1, 2 and 6 on complementary ultrasound and magnetic resonance imaging; 4) patients previously submitted to radiotherapy, chemotherapy or hormone therapy.

The mammographic examinations were performed in a Philips M 3000 model equipment, with 0.1 and 0.3 mm microfocus, molybdenum anode, rhodium filter and automatic exposure meter.

All the patients were submitted to bilateral examination on craniocaudal and mediolateral oblique, 25° angle views; additional views with spot-compression and image magnification were made as necessary.

The images were analyzed in a dark room by means of a 4-compartment negato-

scope with the aid of a magnifying glass, and reports were elaborated by one of the authors of the present study, who is radiologist and specialist in breast imaging, and by another radiologist also experienced in breast imaging.

All the images were rated according to characteristics of the findings of non-palpable masses, based on the definitions of BI-RADS categories 3, 4 and 5.

Ultrasound studies were performed in a digital model 1500 HDI equipment, with a 7.5–10.0 MHz linear transducer.

All the patients underwent bilateral examination, with radial, anti-radial and transverse scanning technique, and the documentation was elaborated in digital file. The same radiologists responsible for the mammographic reports elaboration performed the examinations.

All the sonographic images were classified according to characteristics of the findings of non-palpable masses, based on the definitions of BI-RADS categories 3, 4 and 5.

The magnetic resonance imaging studies were performed in a 1.0 tesla Philips, T10 NT model equipment, with a breast coil. The same radiologists responsible for the mammographic reports elaboration performed the examinations.

Initially, sagittal, T2-weighted sequences were performed; and after, axial and sagittal, T1-wieghted sequences at a 5 mm interval, before and after intravenous paramagnetic contrast injection.

The contrast agent utilized was gadolinium-diethylenetriamine pentaacetic acid (Gd-DTPA), administered in 10 ml bolus.

The images were analyzed by the same radiologists and classified according to characteristics of the findings of non-palpable masses, based on the definitions of BI-RADS categories 3, 4 and 5.

All of the non-palpable lesions were submitted to wire-guided surgical biopsy[12]. After the radiological control, the specimens were sent for histopathological study, in plastic recipients containing formol at 10%, positioning the guide wire the nearest possible of the lesion for an easier identification.

The biopsy slides reading was performed in an ordinary optical microscope. The reports with results were issued in compliance with the World Health Organization standards.

PPV and NPV were calculated according to the methodology included in the BI-RADS chapter 5 – "Results Monitoring". In this methodology, the classification of images and respective anatomopathological results are taken into consideration (Table 1).

PPV calculation – PPV is defined as the percentage of all the biopsies performed because of abnormal mammographic findings which have resulted in a diagnosis of cancer. The PPV calculation in the different BI-RADS categories was made by means of the following equation:

True-positive (TP) / true-positive (TP) + + false-positive (FP)

NPV calculation – The NPV is defined as the percentage of all the biopsies performed because of abnormal mammographic findings which have not resulted in a diagnosis of cancer. The NPV calculation in the three BI-RADS categories was made by means of the following equation:

True-negative (TN) / true-negative (TN) + + false-negative (FN)

Statistical analysis – The statistical analysis was performed after the descriptive analysis tabulation of data included in explanatory tables and graphs. For testing the groups' homogeneity as regards (positive and negative) predictive values, the Fisher's exact test was employed for expected frequencies of < 5. The null hypothesis rejection level was set at 5% ($p < 0.05$). The kappa concordance index was utilized for evaluating the concordance of the classification of mammographic, sonographic and magnetic resonance imaging findings with the histopathological results[13].

RESULTS

The data indicate a predominance of benign results in patients with BI-RADS category 3 findings in mammographic (69.23%), sonographic (70.58%) and magnetic resonance imaging (100%) evaluations.

Among patients with BI-RADS category 4 findings, the cases of histopathological malignancy increased progressively on mammographic, sonographic and magnetic resonance imaging evaluations, representing respectively 63.63%, 50% and 30.76%. On the other hand, cases of histopathological benignity in BI-RADS category 4, constituted respectively 30.76%, 50% and 69.23%.

A similar phenomenon was observed in the evaluation of patients with results in the BI-RADS category 5. A progressive increase is observed on mammographic, sonographic and magnetic resonance imaging evaluations, representing 100% in the first two modalities, and 92.85% in the latest. On the other hand, the cases of histopathological benignity decreased to 0% in category 5 for mammographic and sonographic evaluations, and 7.15% for magnetic resonance imaging.

For the mammographic analysis of 13 cases of supposedly benign findings included in category 3, 10 cases presented histopathological negative results for malignancy, showing 69.23% NPV. For the sonographic analysis of 17 cases of supposedly benign findings included in category 3, 12 presented histopathological negative results for malignancy, showing 70.58% NPV. For the analysis by magnetic resonance imaging of three cases of supposedly benign findings included in category 3, all the cases presented histopathological negative results for malignancy, showing 100% NPV.

For the mammographic analysis of 11 cases of supposedly malignant findings included in category 4, seven cases presented histopathological positive results for malignancy, showing 63.63% PPV. For the sonographic analysis of two cases of supposedly malignant findings included in

Table 1 Parameters for determination of true- and false-positive, and true- and false-negative results.

	Biopsy positive for malignancy	Biopsy negative for malignancy
Positive mammogram BI-RADS 4 and 5	True-positive (TP)	False-positivo (FP)
Negative mammogram BI-RADS 3	False-negative (FN)	True-negative (TN)

category 4, one case presented histopathological positive results for malignancy, showing 50% PPV. For the analysis by magnetic resonance imaging of 13 cases of supposedly malignant findings included in category 4, four cases presented histopathological positive results for malignancy, showing 30.76% PPV.

For the mammographic analysis of six cases of supposedly malignant findings included in category 5, all the cases presented histopathological positive results for malignancy, showing 100% PPV. For the sonographic analysis of 11 cases of supposedly malignant findings included in category 5, all the cases presented histopathological positive results for malignancy, showing 100% PPV. For the analysis by magnetic resonance imaging of 14 cases of supposedly malignant findings included in category 5, four cases presented histopathological positive results for malignancy, showing 92.85% PPV (Tables 2 to 4).

In a comparison between the different imaging modalities and the BI-RADS categories, one may observe high PPV in the three modalities for the category 5 (100% doe mammography, and 92.85% for magnetic resonance imaging). Magnetic resonance imaging presents a high NPV for category 3 (100%), while mammography and ultrasound present similar, intermediate PPV (respectively 69.23% and 70.58%). Additionally, the results demonstrate that the three imaging modalities presented intermediate PPV for category 4: mammography, 63,63%; ultrasound, 50%; and magnetic resonance imaging, 65.96% (Tables 2 to 4).

DISCUSSION

As previously mentioned, BI-RADS category 3 includes lesions with high probability of benignity. Notwithstanding the BI-RADS itself recommends not performing biopsy in patients with lesions in category 3, this procedure is performed in a great number of cases. The main factors influencing the biopsy practice are: patient's anxiety, physician's insecurity, and presence of risk factor for breast cancer.

The definition of BI-RADS categories 4 and 5 PPV, and category 3 NPV would be a contribution to aid breast specialists in the decision making about submitting patients to biopsies.

Studies in the literature evaluating the predictive values of these BI-RADS categories for mammography cover all types of non-palpable breast lesions[14–16]. In these studies, the NPV of category 3 ranged between 97% and 100%, while the PPV ranged between 23% and 34% for category 4, and between 81% and 97% for category 5.

Comparing the above mentioned results with those found by the present study exclusively about non-palpable breast masses, clear differences in predictive values are observed. Such differences are particularly remarkable when BI-RADS category 3 is considered; in this category we have found a lower NPV. This difference is explained by the fact that, because of their etiological and morphological diversity, the greatest part of calcifications are classified as probably benign.

Also, in the present study, with respect to category 4, we have observed a higher PPV compared with those found by other authors. Considerable differences have not been found in PPV for category 5, considering that lesions in this category present typical features of malignancy in both groups, reducing the variability in the images interpretation.

Table 2 Distribution of mammographic cases according to BI-RADS classification and histological diagnosis of benignity or malignancy.

	Histopathological diagnosis					
	Benign		Malignant		Total	
BI-RADS	N	%	N	%	N	%
3	9	69.23	4	30.76	13	31.58
4	4	36.36	7	63.63	11	47.36
5	–	–	6	100	6	21.06
Total	13	43.33	17	56.66	30	100

BI-RADS 3: NPV = 69.23%; BI-RADS 4: PPV = 63.63%; BI-RADS 5: PPV = 100%.

Table 3 Distribution of sonographic cases according to BI-RADS classification and histopathological diagnosis of benignity or malignancy.

	Histopathological diagnosis					
	Benign		Malignant		Total	
BI-RADS	N	%	N	%	N	%
3	12	70.58	5	29.41	17	56.66
4	1	50	1	50	2	11.76
5	–	–	11	100	11	36.66
Total	13	31.57	17	68.42	30	100

BI-RADS 3: NPV = 70.58%; BI-RADS 4: PPV = 50%; BI-RADS 5: PPV = 100%.

Table 4 Distribution of cases of magnetic resonance imaging, according to BI-RADS classification and histopathological diagnosis of benignity or malignancy.

	Histopathological diagnosis					
	Benign		Malignant		Total	
BI-RADS	N	%	N	%	N	%
3	3	100	–	–	3	10
4	9	69.23	4	30.76	13	43.33
5	1	7.14	13	92.85	14	46.66
Total	13	31.57	17	68.42	30	100

BI-RADS 3: NPV = 100%; BI-RADS 4: PPV = 30.76%; BI-RADS 5: PPV = 92.85%.

Analyzing the sonographic findings in BI-RADS categories 3, 4 and 5 as to their predictive value in relation to the malignant or benign nature of detected non-palpable breast masses, we have observed that the NPV of category 3 presented moderate levels; category 4, moderate PPV; and category 5, high PPV. Our results are similar to those presented by Hong et al.[9], emphasizing the capacity of predicting malignancy in cases of non-palpable breast lesions evaluated by ultrasound, if the BI-RADS is utilized, especially in the category 5.

In our sampling, magnetic resonance imaging findings classified as BI-RADS categories 3, 4 and 5 were analyzed for a global evaluation of positive and negative predictive values. Correlating these findings with histopathological results from biopsy specimens, we have concluded that PPV have shown to be moderate for categories 4 and 5 as whole, while category 3 NPV and category 5 PPV have shown to be high. Our results were similar to those from the study developed by Gokalp and Topal[10] and Sadowski and Kelcz[11].

The present study, as well as other investigations developed employing mammography, ultrasound and magnetic resonance imaging, is aimed at improving the prediction of malignancy or benignity of non-palpable breast lesions for a better management of the disease and improvement of the biopsies practice.

As regards category 4, the present study corroborates the systematic necessity of biopsy for non-palpable breast masses, since the PPV observed for mammography, ultrasound and magnetic resonance imaging was higher than those reported by the international literature covering all the types of abnormal mammographic findings[14–16].

It is our opinion that the greatest contribution of the present study is related to non-palpable breast masses detected by mammography, ultrasound and magnetic resonance imaging and classified as BI-RADS category 3. Magnetic resonance imaging, because of the high NPV in this group of patients, should be considered as an important imaging method in the conservative management of lesions classified as category 3, to avoid unnecessary biopsies, according to the results found both by the present study and Gokalp and Topal[10].

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