

Is the BI-RADS Categorization Valuable for Nonpalpable Breast Lesions in Chinese Women?

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OBJECTIVE To evaluate the feasibility of the Breast Imaging Reporting and Data System (BI-RADS) in the categorization of nonpalpable breast lesions (NPBLs) and to determine its value in aiding decision-making for biopsy in a Chinese population.

METHODS One hundred and seventy-four nonpalpable breast lesions in 155 female patients examined by mammography were retrospectively categorized according to the BI-RAD System, 4th edition, which was established by the American College of Radiology (ACR). All the lesions were diagnosed by a histopathological analysis after mammographically guided wire-localization biopsy.

RESULTS The 174 localizations yielded 125 (71.8%) benign lesions and 49 (28.2%) cancers, including 14 (28.6%) ductal carcinomas in situ and 35 (71.4%) invasive cancers. The overall positive predictive value (PPV) for cancer was 28.2% (49/174). After categorization according to the BI-RAD System, there were 12 category 2, 59 category 3, 83 category 4 and 20 category 5 lesions. The PPV for cancer for each category were 0% (0 of 12 lesions) in category 2, 3.4% (2 of 59 lesions) in category 3, 37.3% (31 of 83 lesions) in category 4 and 80.0% (16 of 20 lesions) in category 5.

CONCLUSION It is concluded that BI-RADS is valuable for the categorization of nonpalpable breast lesions in our Chinese population. This system greatly improved the diagnostic specificity of nonpalpable breast lesions and was feasible in aiding decision-making for biopsy. It is suggested that nonpalpable breast lesions in categories BI-RADS 4 and 5 should receive a biopsy because these lesions have a moderate and high positive predictive value for cancer.

KEYWORDS: nonpalpable breast lesions, mammography, breast neoplasms.

Breast cancer screening programs and the extensive use of imaging techniques for diagnosing breast disease result in the detection of a considerable number of nonpalpable breast lesions (NPBLs).^[1] But only a small portion prove to be malignant by biopsy, contributing to increased health care costs and patient morbidity. The Breast Imaging Reporting and Data System (BI-RADS),^[2] which was created by the American College of Radiology (ACR) to standardize terminology and features in mammographic reporting, is widely used in Western countries to estimate risk of malignancy, and to help in selecting patients for biopsy. However, it has been suggested that in Chinese populations, the sensitivity of mammograms is significantly lowered due to smaller breast volume and denser breast images.^[3-5] In this context, the question is whether BI-RADS categorization is as useful for our Chinese women as it is for our Western counterparts?

The aim of our study was to determine the incidence of cancer following wire-localization biopsy in a series of Chinese patients with

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mammographically detected NPBLs and, hence, determine the positive predictive value of BI-RADS in these patients. The feasibility of BI-RADS categorization in the selection of appropriate patients with NPBLs for surgical biopsy is also discussed.

MATERIALS AND METHODS

Patients

We retrospectively reviewed all patients with nonpalpable breast lesions (NPBLs) who were examined by mammography and followed by wire-localization biopsy over a 7-year period from March 1998 through May 2005. All patients were managed in the Department of Abdominal Surgery, The Diagnosis and Treatment Center of Breast Diseases, Cancer Hospital, Chinese Academy of Medical Science, China.

There were 178 female patients with 199 NPBLs who underwent mammographically guided wire-localization biopsy over this period of time. All 198 NPBLs received definite pathological diagnosis after surgery. Mammography was available for 174 localizations in the 155 patients who were studied. The mean age of the study cohort was 47 years with a range of 28 to 73 years.

The mammographic findings are summarized as follows. Microcalcifications alone (149/174, 85.6%) were

the most common lesions reported. The remaining lesions included a mass (14/174, 8.1%) and architectural distortion or a mass with associated microcalcifications (11/174, 6.3%).

Wire-localization biopsy of nonpalpable breast lesions⁶⁻⁹

Wire placement prior to open surgical biopsy was performed under mammographic surveillance (Mammo DIAGNOST 3000, PHILIPS CO.) in the Department of Imaging. Then surgeons removed the lesions under the guidance of the wire in the operating room. Following surgical biopsy, the resected breast tissue was X-rayed to confirm complete excision of the lesion. All specimens were routinely processed and subjected for histological evaluation. Histological reports were retrieved from the case notes.

The mammograms preceding the needle localizations were interpreted prior to routine use of the BI-RADS assessment categories. The decision for wire-localization biopsy was made mainly by surgeons based on mammographic findings, risk factors and the consent of the patient.

Categorization of nonpalpable breast lesions according to the BI-RAD System, 4th edition¹²

Mammographic findings for each nonpalpable breast

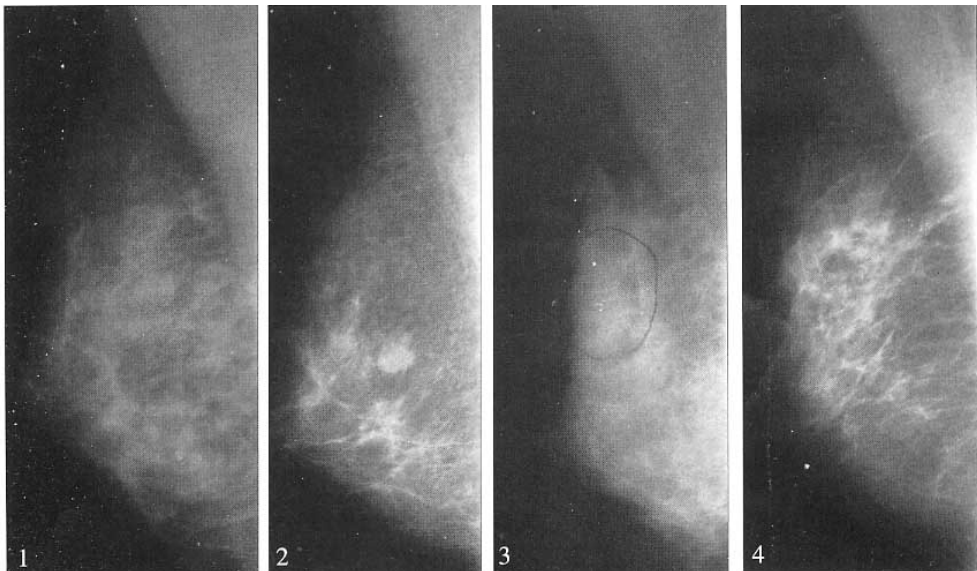


Fig.1. Nonpalpable breast lesions of each BI-RADS category. ① BI-RADS category 2 lesion: eggshell calcifications, biopsy yielded fat necrosis. ② BI-RADS category 3 lesion: circumscribed mass, biopsy showed fibrotic adenoma. ③ BI-RADS category 4 lesion: a cluster of pleomorphic calcifications, biopsy yielded ductal carcinoma in situ with microinvasion. ④ BI-RADS category 5 lesion: pleomorphic calcifications with linear distribution, biopsy yielded ductal carcinoma in situ with microinvasion.

lesion were categorized into BI-RADS 2 to 5 based on guidelines from the American College of Radiology (Fig.1) by an independent radiologist who was unaware of the final pathological diagnosis until the assignment was completed.

The BI-RADS category was assigned as follows: BI-RADS category 0 for lesions with additional imaging evaluation recommended because of inadequate radiographic materials; BI-RADS category 1 for negative findings (without any radiographic abnormalities); BI-RADS category 2 for lesions classified as benign; BI-RADS category 3 for lesions classified as probably benign; BI-RADS category 4 for lesions classified as suspicious or indeterminate; BI-RADS category 5 for lesions classified as highly suggestive or diagnostic of carcinoma and BI-RADS category 6 for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.

The options of BI-RADS category 0, 1 and 6 did not exist in our series. The 174 nonpalpable breast lesion were all mammography detected abnormalities (non BI-RADS category 1), all had integrated radiographic films (non BI-RADS category 0) and were evaluated by an independent radiologist who was unaware of the final pathological diagnosis (non BI-RADS category 6).

Statistical analysis

The positive predictive value (PPV) for cancer was calculated for the overall NPBLs and lesions of each BI-RADS category. The PPV was defined as the number of malignant results divided by the total number of biopsies.

RESULTS

The overall PPV for cancer of nonpalpable breast lesions

Of the 174 open biopsies, 125 (71.8%) NPBLs showed benign histology, which included fibrocyst, fibroadenoma, duct papilloma, duct ectasia, benign cyst, atypical ductal hyperplasia/atypical lobular hyperplasia, fat necrosis, abscess and inflammation. The histopathologic results demonstrated malignancy in 49 (28.2%) lesions, including 35 (71.4%) invasive cancers and 14 (28.6%) ductal carcinoma in situ (DCIS). So the overall PPV for cancer was 28.2% (49/174).

The BI-RADS category distribution of nonpalpable breast lesions

The distribution of BI-RADS categorization of NPBLs was as follows: most lesions were categorized as probably benign (BI-RADS 3) and suspicious or indeterminate (BI-RADS 4), which were 59 (33.9%) and 83 (47.7%) lesions, respectively. Of all the lesions, 20 (11.5%) were categorized as highly suspicious of malignancy (BI-RADS 5) and 12 (6.9%) were categorized as benign findings (BI-RADS 2).

The positive predictive value for cancer of each BI-RADS category

The PPV for cancer was 0% (0 of 12 biopsies) for category 2 lesions, 3.4% (2 of 59 biopsies) for category 3 lesions, 37.3% (31 of 83 biopsies) for category 4 lesions, 80.0% (16 of 20 biopsies) for category 5 lesions, respectively, as shown in Fig.2.

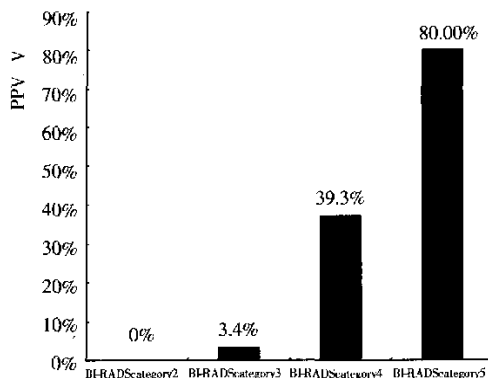


Fig.2. The positive predictive value (PPV) for cancer of nonpalpable breast lesions after categorization according to the BI-RADS.

The PPV for cancer of BI-RADS categories 4 and 5 combined was 45.6% (47 of 103 biopsies) compared with the PPV for categories 2 and 3 combined of 2.8% (2 of 71 biopsies; $P < 0.001$).

DISCUSSION

Breast cancer screening programs and the extensive use of breast imaging techniques result in the detection of a considerable number of nonpalpable breast lesions (NPBLs). It is estimated that approximately 500,000 of these lesions are detected annually in the United States.^[6,7] Biopsies of NPBLs greatly improved the early diagnosis of breast cancer because most of the nonpalpable breast cancers were stage 0 and stage I carcinomas, which had good prognosis with appropriate treatment.^[1,10] Most mammographically detected suspi-

cious lesions for which biopsy is recommended will prove to be benign. In the United States, the positive predictive value (PPV) for biopsies performed because of mammographic findings, or the number of cancers detected divided by the total number of biopsies performed, is reported to be in the range of 15%~40%.^[10,11] The large number of biopsies of benign lesions lead to increased health care costs and patient morbidity. So, the overlap in the mammographic appearance between benign and malignant nonpalpable breast lesions remains one of the limitations of mammographic diagnosis. This problem may cause a dilemma as to how to manage these patients properly.

The American College of Radiology (ACR) has developed the Breast Imaging Reporting and Data System (BI-RADS),^[12] which is intended to standardize the terminology in mammographic reports, the assessment of the findings, and the recommendation of the action to be taken. On the basis of the mammographic findings and the level of suspicion, mammographically detected lesions in our series were assigned into one of four BI-RADS categories: category 2 for benign lesions, category 3 for probably benign lesions, category 4 for suspicious lesions, and category 5 for highly suspicious lesions.

BI-RADS category 2 (benign finding) and category 3 (probably benign finding) lesions were classified as negative, while nonpalpable breast lesions with BI-RADS category 4 (suspicious) and category 5 (highly suggestive of malignancy) were classified as positive. They should be managed with different protocols according to their BI-RADS assessment categories since each category has its own positive predictive value (PPV) for cancer. Lesions that were classified as benign (BI-RADS category 2) require no further evaluation. For lesions that were classified as probably benign (BI-RADS category 3), short-term follow-up mammography was suggested and biopsy could be avoided. Placing a lesion into BI-RADS category 3 was highly predictive of a benign lesion and the PPV for cancer was generally less than 2%. A short-term follow-up mammographic protocol to document stability includes imaging the ipsilateral breast 6 months after the initial mammogram, and then both breasts 12, 24 and 36 months after the initial mammogram. The short-term follow-up protocol could allow us to detect carcinoma at an early stage while minimizing the number of benign biopsies.

There are several prospective clinical studies demonstrating the safety and efficacy of short-term follow-up for these findings. Varas et al.^[12] and Vizcaino

et al.^[13] studies indicated that 97~99% of BI-RADS 3 category lesions remained stable during a short-term mammographic follow-up. In the biopsies prompted due to interval lesion progressions, only 14.3~28.6% were found to be malignant, which were 0.3~0.4% of the whole study population. In lesions categorized as suspicious (BI-RADS category 4) and highly suggestive of malignancy (BI-RADS category 5), where the cancer incidence is moderate and high, localization biopsy should be considered.^[11,14,15]

BI-RADS categorization has been accepted gradually in Western countries to estimate risk of malignancy and thereby help to select patients for biopsy. However, it has been suggested that in Asian populations, such as Chinese women, where smaller breast volumes result in relatively dense breast images on mammograms, the sensitivity of mammograms is correspondingly lowered.^[3-5] In this context, it was questionable whether BI-RADS categorization remains as useful for us as for our Western counterparts?

In our series, the mammograms preceding the wire localizations were interpreted prior to the introduction of the BI-RADS lexicon and assessment categories. The decision for wire-localization biopsy was made mainly by surgeons based on mammographic findings, risk factors and the consent of the patient. There was no accepted criterion for the management of various nonpalpable breast lesions. The overall PPV of all wire localization biopsies for cancer was 28.2% (49 of 174 localizations) in our series, which consistent with other studies.^[11,14]

With the introduction of the BI-RADS lexicon, lesions in which a wire localization biopsy was performed can now be assigned into one of the assessment categories, and the PPV for cancer can be determined for each category. We found that 40.8% (71 of 174 localizations) of the wire localizations were performed when the mammographic report indicated benignity (12 lesions in BI-RADS category 2) or probable benignity (59 lesions in BI-RADS category 3), and the PPVs were 0% (0 of 12 localizations) for BI-RADS category 2 and 3.4% (2 of 59 localizations) for BI-RADS category 3. In contrast, 59.2% ($n=103$) of the 174 needle localizations were performed when the mammographic finding was positive (83 lesions in BI-RADS category 4 and 20 lesions in BI-RADS category 5). The PPVs were 37.3% (31 of 83 localizations) for category 4 and 80.0% (16 of 20 localizations) for category 5. That means if we select BI-RADS 4 and 5 as the indication for biopsy, 40.8% of the patients with BI-RADS category 2 and 3 lesions would be spared from surgery and

the PPV for cancer of the breast biopsy will increase from the overall 28.2% (49 of 174 lesions) to 45.6% (47 of 103 lesions). Only 2 malignant lesions categorized as BI-RADS 3 would subsequently miss the surgical biopsy. But both lesions were stage I breast cancers, with the diagnosis of a DCIS with micronivasion and an invasive ductal carcinoma. We think that the short-term follow-up protocol could allow us to guarantee the safety and efficacy in the management of BI-RADS category 3 lesions.^[12,13]

To our knowledge, this is the first report on the feasibility of BI-RADS categorization for nonpalpable breast lesions in Chinese patients. Our results are in keeping with the studies from Western countries,^[11, 14] and demonstrate that BI-RADS categorization remains a useful tool to estimate risk of malignancy for nonpalpable breast lesions in a population with increased breast density such as Chinese women. As mammography becomes more commonplace in our country, an increasing number of nonpalpable breast lesions are being found. With the breast cancer screening program in the near future in China, an enormous number of nonpalpable breast lesions are expected to be mammographically detected. We think that BI-RADS categorization may be valuable in helping us to treat patients with different lesions properly, for example, to select biopsy indications for nonpalpable breast lesions.

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