Effect on biopsy technique of the breast imaging reporting and data system (BI-RADS) for nonpalpable mammographic abnormalities

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Objective: To determine if the breast imaging reporting and data system (BI-RADS) defines a group of patients with mammographic abnormalities in whom stereotactic core needle biopsy (SCNB) is appropriate. **Design:** A blinded retrospective validation sample. **Setting:** A university-affiliated hospital. **Patients:** One hundred and nine consecutive patients who underwent fine-wire localization breast biopsy (FWLB) between Jan. 1, 1994, and June 1, 1999, with a known final pathological diagnosis. **Intervention:** Blinded mammographic review and classification using the BI-RADS; review of corresponding pathological findings from FWLBs. **Outcome measures:** Correlation of pathological findings with each BI-RADS category and analysis of the predictive value of clinical and radiologic features. **Results:** BI-RADS findings were as follows: 0 malignant lesions in 10 category 3 cases, 18 malignant lesions (3 in situ, 15 invasive) in 68 category 4 cases and 24 malignant lesions (8 in situ and 16 invasive) in 31 category 5 cases. There was 1 malignant lesion in 22 category 4 cases in women younger than 50 years. **Conclusions:** SCNB should be applied to BI-RADS categories 3 and 4 (< 50 yr of age). FWLB should be reserved for category 4 (> 50 yr of age) and category 5 cases. This algorithm will reduce the morbidity and cost of breast biopsies in patients with nonpalpable mammographic abnormalities.

Objectif : Déterminer si le breast imaging reporting and data system (BI-RADS, ou système de rapports et de données en imagerie du sein) permet de cerner un groupe de patientes présentant une mammographie anormale et chez lesquelles la biopsie à l'aiguille creuse par stéréotaxie est indiquée. **Conception :** Étude rétrospective à l'insu d'un échantillon de validation. **Contexte :** Hôpital universitaire. **Patientes :** Cent neuf patientes consécutives ayant subi une biopsie du sein à l'aiguille fine avec localisation entre le 1er janvier 1994 et le 1er juin 1999, et dont le diagnostic pathologique final est connu. **Intervention :** Examen et classification à l'insu, à l'aide du BI-RADS, des constatations mammographiques; examen des constatations pathologiques correspondantes obtenues à l'aide de la biopsie à l'aiguille fine avec localisation. **Mesures de résultats :** Corrélation entre les constatations pathologiques et chaque catégorie du BI-RADS et analyse de la valeur prédictive des caractéristiques cliniques et radiologiques. **Résultats :** Voici les constatations provenant du BI-RADS : 0 lésion maligne sur 10 cas de catégorie 3, 18 lésions malignes (3 in situ, 15 avec envahissement) sur 68 cas de catégorie 4, et 24 lésions malignes (8 in situ et 16 avec envahissement) sur 31 cas de catégorie 5. Il y a eu une lésion maligne sur 22 cas de catégorie 4 chez des femmes de moins de 50 ans. **Conclusions :** Il faudrait pratiquer une biopsie à l'aiguille creuse par stéréotaxie chez les femmes de moins de 50 ans dont les lésions sont classées dans les catégories 3 ou 4 du BI-RADS. Il faudrait réserver la biopsie à l'aiguille fine avec localisation aux cas de la catégorie 4 (chez des femmes de plus de 50 ans) et aux cas de la catégorie 5. Cet algorithme réduira la morbidité et le coût associés aux biopsies du sein chez les patientes dont la mammographie révèle des anomalies non palpables.

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Presented in part at the annual meeting of the Canadian Society of Surgical Oncology, Toronto, Ont., Apr. 15, 2000.

Accepted for publication Sept. 11, 2001.

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With the understanding that screening mammography reduces breast cancer mortality by as much as 30%,[1,2] enrolment in early detection programs is at an all time high. Unfortunately, as a result of this increased use and mammography's historically low positive predictive value (PPV),[3,4] many women who are found to have benign lesions are subjected to the discomfort, anxiety, morbidity and potential complications of an open surgical biopsy. (The reported frequency of cancer for fine-wire localization biopsy (FWLB) of nonpalpable, mammographically detected abnormalities ranges from 9% to 47%.[5,6] Because of this, alternative diagnostic procedures have developed. Although excisional biopsy remains the "standard," data supporting stereotactic core needle biopsy (SCNB) as an accurate,[7–9] safe, cost-effective[10] and less invasive[11] diagnostic technique is strong.

Although FWLB and SCNB techniques have been independently validated, the appropriate patient population for each procedure is still extensively debated.[9] In this context, the breast imaging reporting and data system (BI-RADS) was developed by the American College of Radiology primarily to improve the communication of mammographic reporting by utilizing a universally accepted complement of descriptive terms.[12] Equally important is the BI-RADS mandate to provide a clear management recommendation for women with nonpalpable breast lesions (Table 1).[12] By offering specific PPVs for given mammographic lesions, the BI-RADS is useful not only in discriminating benign from malignant lesions but in potentially reducing the number of unnecessary open breast biopsies performed.

With the introduction of new biopsy methods there is a danger of incremental costs related to additional procedures with their attendant risks and delays. Because SCNB provides an excellent sample of the tissue in question, it is postulated that the sampling of low-risk lesions with this technique could allow for accurate and timely diagnosis without the need for further surgical confirmation. If the technique is applied to patients with mammographically suspicious lesions, however, a second procedure then becomes necessary to remove the lesion, making SCNB an additional step in diagnosis and management. A recent article from the Division of Clinical Epidemiology, McGill University Health Centre, indicates that the median waiting time for definitive cancer treatment increases with the number of diagnostic procedures from 24 days with 1 procedure to 72 days with 4 procedures.[13] Thus, additional diagnostic procedures that cannot replace existing diagnostic manoeuvres, such as FWLB, merely delay the ultimate management of the breast cancer.

In an attempt to postulate a role for SCNB in our diagnostic armamentarium, we re-evaluated retrospectively the mammograms of 109 women who underwent FWLB over a 4-year period to determine if the BI-RADS could have been used to define a group of patients in whom SCNB alone would have been adequate.

Patients and methods

Mammograms of 109 consecutive women who underwent standard FWLB of suspicious nonpalpable breast lesions between Jan. 1, 1994, and June 1, 1999, at a university teaching hospital, were retrospectively classified using the BI-RADS. The women ranged in age from 37 to 90 years (mean 62 yr).

Mammogram classification was completed by 2 researchers: a radiologist trained in diagnostic mammography and a data clerk with a medical background. Interobserver variability was assessed using 30 unique mammograms and was found to have a mean Cohen κ value[14] of 0.73 and a standard error of 0.02. This limited variability is in the expected range for BI-RADS interpretation[15] and can be considered indicative of "substantial agreement."

Each blinded researcher independently classified all 109 mammograms utilizing craniocaudal, mediolateral–oblique and sometimes magnification or cone-compression views. Limited patient data, including age, relevant family history and location of the area(s) of concern, were offered prior to each reading. Findings were classified by selecting single BI-RADS descriptors for calcification distribution, number and description as well as mass margin, shape and density on a standardized data collection form. Researchers were then asked to assign a final BI-RADS category (i.e., probably benign [category 3], suspicious [category 4] or highly suggestive of malignancy [category 5]). All data were compiled using Excel software (Microsoft, Redmond, Wash.).

Diagnostic impressions from all 109 mammograms were correlated with definitive histopathologic diagnoses (i.e., those available after

Table 1

Breast Imaging Reporting and Data System Categories, Interpretation and Recommended Actions

Category	Interpretation	Recommended action
0	Insufficient study	Obtain additional imaging
1	Negative	Routine follow-up
2	Benign finding	Routine follow-up
3	Probably benign finding	Short-interval follow-up
4	Suspicious finding	Biopsy should be considered
5	Highly suggestive of malignancy	Biopsy necessary

FWLB) to provide distinct PPVs for each BI-RADS final assessment category. In an attempt to refine the predictive value of the final assessment category, various clinical and radiologic features were analyzed. Patients were assigned to subcategories based on lesion calcification and mass subtypes, patient age, medical history, breast quadrant of concern, specimen size and type of mammography views. Associations between BI-RADS lexicon descriptors and each final assessment category were also defined. All tests for statistical significance utilized the χ^2 and Fisher's exact tests from the SPSS statistical program (SPSS, Chicago). Differences were considered significant at a p value of less than 0.05.

Findings

The mean age of the patients overall was 62 years (range from 37–90 yr) with a standard deviation of 9 years. Based on the final pathological diagnosis, 42 (38.5%) of the lesion specimens were malignant and 67 (61.5%) were benign (Table 2). The mean age of patients with malignant lesions was 63 years (range from 40–90 yr) with a standard deviation of 10 years and for those with benign lesions was 58 years (range from 37–88 yr) with a standard deviation of 10 years.

The BI-RADS final assessment categories included 10 (9.2%) category 3 lesions, 68 (62.4%) category 4 lesions and 31 (28.4%) category 5 lesions. Ten women with category 3 lesions underwent FWLB in spite of the benign mammographic appearance because of various patient or surgeon concerns at the time of consultation. As expected, category 1 and category 2 lesions were absent from this preselected FWLB population. With reference to the malignancy rate for each category (Table 3), 0 malignant lesions were classified as category 3; 3 (17%) in-situ and 15 (83%) invasive carcinomas composed category 4, and 8 (33%) in-situ and 16 (67%) invasive cancers made up category 5 lesions.

PPVs for categories 3, 4 and 5 (i.e., before subcategorization) were 0%, 27% and 77% respectively. Furthermore, the frequency of malignancy was greater in category 5 than category 4 for all types of mammographic lesions (i.e., mass and calcification descriptors). The majority of category 5 masses and calcifications represented invasive ductal cancers and ductal carcinoma in situ respectively ($p < 0.05$). Finally, masses of "increased density" typically represented invasive breast disease ($p < 0.05$).

Regarding the clinical and radiologic features used to increase the predictive value of BI-RADS final assessment categories, age was the only significant factor ($p < 0.05$). By separating patients within category 4 by decade of age, distinct PPVs for selected patient groups became evident (Table 4). In women younger than 50 years, only 1 malignant lesion in 22 category 4 cases was noted. As a consequence, the PPV for categories 3 and 5 remained at 0% and 77% respectively, whereas category 4 was divided between those patients under 50 years of age (PPV = 4.5%) and those 50 years of age and over (PPV = 37%).

With reference to specific BI-RADS lexicon descriptors and their influence on final assessment categories, category 3 lesions were typically described as circumscribed, low-density, solitary masses with benign-looking calcifications ($p < 0.05$). Category 4 lesions were not statistically associated with any particular lexicon descriptors. Category 5 lesions were consistent with spiculated, high-density masses, irregular mass shapes and calcifications described as fine branching, segmental or linear in distribution ($p < 0.05$).

Table 2

Histopathological Diagnosis for 109 Fine Wire Localization Biopsies

Diagnosis	Biopsies, no. (and %)
Benign	67 (100)
Fibrocystic disease	39 (58.2)
Fibroadenoma	10 (14.9)
Benign breast tissue	1 (1.5)
Sclerosing adenosis	11 (16.4)
Fat necrosis	1 (1.5)
Papilloma	1 (1.5)
Radial scarring	1 (1.5)
Premalignant	
Atypical ductal hyperplasia	2 (3.0)
Lobular carcinoma in situ	1 (1.5)
Malignant	42 (100)
Ductal carcinoma in situ	12 (28.4)
Comedoductal carcinoma in situ	2 (4.8)
Infiltrating ductal carcinoma	24 (57.1)
Infiltrating lobular carcinoma	1 (2.4)
Colloid carcinoma	3 (7.1)

Table 3

Diagnostic Impression From Mammography Versus Pathological Findings From Surgery

Diagnostic category	Malignant	Benign	Premalignant	Ratio, no. malignant/ total no.	PPV, %
3	0	10	0	0/10	0
4	18	47	3	18/68	26.5
5	24	7	0	24/31	77.4
Total	42	64	3	42/109	38.5

PPV = positive predictive value.

Table 4

Breast Imaging Reporting and Data System Category 4 Age Subcategorization Versus Positive Predictive Value (PPV)

Patient age, yr	Ratio	PPV, %
< 40	0/3	0
40–49	1/19	5.3
50–59	4/16	25
60–69	8/21	38.1
70–79	6/8	75
≥ 80	1/1	100
Total	18/68	26.5

Discussion

As a screening tool, mammography offers a high-sensitivity, low-specificity technique for identifying breast lesions.[16] The BI-RADS was developed to address the lack of standardized terminology for both lesion description and degree of suspicion (i.e., minimally v. slightly v. moderately suspicious) inherent in many nonpathognomic mammograms. By providing distinct PPVs for each final assessment category, the BI-RADS offers a specific probability of carcinoma for given mammographic findings and is advantageous in separating benign from malignant lesions.[17]

In our study, the PPV for category 3 lesions (circumscribed, low-density, solitary masses with benign-appearing calcifications) was 0%, as all lesions were benign. This PPV and set of lesion descriptors is consistent with that in other published series, as malignant lesions typically compose less than 8% of all category 3 biopsy abnormalities.[18,19] Category 4 had a PPV of 27%, although no significant associations between BI-RADS lexicon descriptors and malignant lesions were evident. This PPV is also within the previously described range of 4% to 34%.[17,20] Category 5 lesions had a PPV of 77%, well within the published 54% to 97% limits.[9,20] BI-RADS lexicon features predictive of category 5 designation (spiculated, high-density masses, irregular mass shapes and fine branching, segmental or linear calcification distribution) were also consistent with those reported in the literature.[15,19]

The analysis of stratified PPVs for various BI-RADS categories prompts a discussion of the most appropriate follow-up treatment for these radiologically detected breast lesions. Debate over the precise algorithm for management is extensive. Taking into account auxiliary factors such as patient anxiety, patient preference, risk factors, facility policy and the proportion of second opinion referrals, the BI-RADS and its supporters believe category 3 lesions (probably benign) may be safely managed with a short-interval follow-up of 3 to 6 months.[18,21] Protocols for category 4 and 5 lesions are not as clear, however. Although the BI-RADS recommends that biopsy should be considered for all category 4 (suspicious) lesions and completed for category 5 (highly suggestive of malignancy) lesions, the biopsy modality of choice is still contested. As previously mentioned, SCNB has numerous advantages over traditional FWLB, but because of insufficient long-term follow-up, availability concerns and varying opinions on the need to monitor women with negative SCNBs of suspicious mammographic lesions with FWLBs, SCNB is not currently recommended to completely replace surgical excisional biopsy.[9]

By subdividing category 4 patients based on decade of age, our study further stratifies the predictive probability of a malignant lesion to less than 4.5% for women younger than 50 years. This is a particularly important distinction because it could be argued that these patients, coupled with those from category 3 who may uncommonly necessitate a biopsy, are ideal candidates for SCNB. The confirmation of benignity would lead to significant reduced morbidity and economic savings[9,11,22] and address many of the concerns surrounding low predictive probabilities for category 4 lesions. Furthermore, improvement in the overall FWLB PPV to 54% using this form of BI-RADS subcategorization is substantial. This exceeds the BI-RADS specific PPV range of 19% to 46%[9,20] as well as that for non-BI-RADS mammography FWLBs.[3,5,6] In no circumstance is the physician's threshold for biopsy lowered, but merely biopsy techniques would be tailored to patients on a more individual basis.

Our study has several limitations. First, the inclusion of only those lesions subjected to FWLB may have preselected more "suspicious" and hence malignant lesions, artificially increasing our overall PPV. Second, in spite of including 109 abnormal mammograms, some of the study subgroups were small. Third, because the BI-RADS does not make explicit recommendations regarding lesion assignment into final assessment categories, subjective interpretation is still necessary. This was a potential concern as one of our researchers was not a certified radiologist. The minimal interobserver variability, the PPVs within acceptable limits and the increased frequency of cancer concurrent to increasing BI-RADS categorizations (i.e., more suspicious) provides support that the limitations have been addressed. It is important that this guideline be validated in other settings, however, as varying patient populations may modulate age subcategorization within category 4. We therefore recommend prospective study of this concept on a multi-institutional basis.

With the advent of minimally invasive and relatively low-cost biopsy techniques such as SCNB, it is incumbent upon clinicians to utilize this procedure whenever appropriate. This study has demonstrated that by delineating BI-RADS final assessment categories by decade of age, a patient population benefiting from the use of SCNB becomes evident. As such, it has helped refine the BI-RADS lexicon making it more specific to a patient's own mammogram, increased the information available to patients and improved the ability of the BI-RADS to determine the next diagnostic step. Whereas many radiologists and surgeons have accepted SCNB as a crucial first step in the diagnosis of mammographically detected breast lesions, we feel that its use selectively as a definitive procedure for "likely benign" lesions could avoid the unnecessary delay of a redundant step in definitive diagnosis and management of "likely malignant" abnormalities. By confirming a benign lesion by SCNB we

reduce the anxiety and frequency of follow-up mammography for the patient, and by avoiding the additional step of SCNB in lesions that will require fine wire localization excision we speed the final management of the lesion and reduce unnecessary delays in treatment.

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