Published in final edited form as:

Clin Imaging. 2016 ; 40(2): 200–204. doi:10.1016/j.clinimag.2015.10.011.

A history of breast cancer and older age allow risk stratification of mammographic BI-RADS 3 ratings in the diagnostic setting

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Abstract

Objectives—To investigate whether risk stratification of mammographic BI-RADS3 can be accomplished in the diagnostic setting.

Methods—We analyzed 4,941 BI-RADS3 rated patients (23 malignant outcomes) and built logistic-regression models with age, personal and family history of breast cancer, fibroglandular density and additional mammographic findings as predictive variables.

Results—A personal history of breast cancer (odds ratio: 5.53) and older age (odds ratio: 12.44/10.93 for age 50–64/>64) are independent risk factors. Patients with both risk factors have a risk >2%.

Conclusion—Biopsy may be warranted in older patients with a history of breast cancer who would be otherwise assigned BI-RADS3.

Keywords

BI-RADS; mammography; probably benign; risk stratification; breast cancer

Introduction

The breast imaging: reporting and data system (BI-RADS) requires the interpreting radiologist to assign a final assessment category to a described mammographic lesion (1). The BI-RADS 3 assessment category was developed based on evidence that short term follow-up, rather than biopsy, is safe and appropriate for certain mammographic findings. These specific findings have a probability of malignancy <2% based on large observational

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Conflict of interest: none

studies (2, 3) and are formally defined in the BI-RADS lexicon (1). The recommended management is an initial follow-up examination after six months, followed by additional examinations to establish long-term stability (2 to 3 years) of the lesion (1). In practice, a considerable proportion of diagnostic mammography examinations are assessed as BI-RADS 3; estimates range between 15% and 22% (4, 5). Since the vast majority of BI-RADS 3 lesions will be ultimately proven benign, anxiety experienced during the short interval follow-up regime (6) is unnecessary in most cases. For these reasons, ensuring that only appropriate women are rated BI-RADS 3, the optimal use of this assessment category is an important objective.

Optimal use of BI-RADS 3 can be accomplished in two ways: by labeling fewer high risk lesions as BI-RADS 3 (converting to BI-RADS category 4—i.e. recommend immediate biopsy) or by labeling fewer benign lesions as BI-RADS 3 (converting them to BI-RADS 2). The American College of Radiology (ACR) has a strict definition of BI-RADS 3 lesions in terms of mammographic lesion descriptors: noncalcified circumscribed solid mass lesions, focal asymmetries and solitary groups of punctate calcifications (1, 2, 3). In clinical routine, however, the literature shows that this definition is sometimes loosely applied, and malignant lesions that exhibit suspicious features (not appropriate for a BI-RADS 3 assessment) can be identified as such retrospectively (7). Various lesion descriptors allow the radiologist to assign a BI-RADS 4 or 5: e.g. a spiculated mass margin (8) or fine linear calcifications (9). Despite available risk stratification on the descriptor level, no recommendations direct how certain patient characteristics should influence the assignment of BI-RADS category 3.

We therefore aim to identify patient characteristics that are associated with inappropriate assignment of BI-RADS 3 according to agreed-upon risk thresholds in order to advance the evidence-base and to improve risk stratification inherent in this assessment category.

Materials and Methods

Institutional ethical review board approval was obtained for this retrospective, single-center investigation. We analyze all patients in whom diagnostic mammography was performed between April 1999 and February 2004 (n=10,989). Our study population is a subpopulation of a larger radiological-epidemiological research database on which research has been published before (10). No dedicated analysis of the BI-RADS 3 cases has been performed yet. All mammography examinations were read by radiologists certified by the 1992 United States Mammography Quality Standards Act.

We select patients in whom at least one BI-RADS 3 rated lesion is present (n=4,941). Patients with two or more mammography exams rated BI-RADS 3 in our database are only included once to guarantee statistical independence of each observation. We use our institutional cancer center tumor registry as our reference standard to determine the outcome, benign versus malignant, for each BI-RADS 3 lesion; details of the matching-procedure are provided in (10). The tumor registry provides detailed information about laterality and clockface location of the reported lesions. The same information is mandatorily documented in our structured radiology reports. A report of in-situ or invasive

cancer within 365 days after the mammography examination is considered malignant. All other patients with benign biopsy results or without a cancer registry match within 365 days after the mammography are considered to have a benign outcome. Reporting of all cancers by hospitals and physicians to the cancer registry is mandatory by state law (Wisconsin).

We collect the following information for each patient: age, status of personal history of breast cancer (positive or negative), status of family history of breast cancer (none, minor: one or more non first-degree family members affected, major: one or more first-degree family members affected) and density of the breast parenchyma according to the ACR (1). Patient age is stratified into groups that are commonly used in the literature (11): younger than 50 years, 50 to 64 years, older than 64 years. We also record whether additional mammographic findings are present at the selected mammography examination: we distinguish between the presence of clearly benign findings (BI-RADS category 2) and the presence of more suspicious findings (BI-RADS category 4 or 5). For further characterization of our study population we search our database for indicated clinical signs or symptoms that prompted diagnostic mammography.

We analyze our data with main effect logistic regression models (12). We first build univariate models for each predictive variable, and then build a multivariate model taking into account all of the predictive variables. Logistic regression models estimate the odds ratio of predictive variables for the disease under consideration. Odds ratios measure the strength of the association of the predictive variable and a binary outcome variable, in our case benign versus malignant. We provide 95% confidence intervals for the estimated odds ratios. We test odds ratios for statistical significance with the Wald test and consider a P-value <0.05 to denote statistical significance. We refer to predictive variables with odds ratios significantly >1 as risk factors. All analyses are performed with R 2.15.3 (13).

Results

The mean (standard deviation) patient age in our patient population is 54.3 (12.7) years. Out of the 4,941 total BI-RADS 3 lesions, 23 are malignant (prevalence: 0.47%) These malignant lesions are comprised of: seven in-situ (one grade 1, one grade 2, one grade 3, four of unknown grade) and 16 invasive (seven grade 1, seven grade 2 and two grade 3) carcinomas. The BI-RADS descriptors of the malignant lesions (Table 1) include suspicious descriptors – e.g. spiculated margin, linear calcification shape, and architectural distortion – not included in the definition of BI-RADS 3. The expected patient demographics in terms of age range and breast density distribution (Table 2) are similar to prior BI-RADS 3 populations (2, 3, 7). The distribution of indicated clinical problems is as follows: 137 skin thickening, 122 skin retraction, 3 nipple retraction, 1 skin lesion, 490 palpable abnormality, 411 difficult physical examination, 72 pain, 360 malignant neoplasm elsewhere, 28 enlarged axillary lymph nodes; for the remaining cases no clinical reason was found in our database.

Our univariate logistic regression models (Table 3) and our multivariate logistic regression model (Table 4) demonstrate that a personal history of breast cancer is a risk factor for malignancy, with an odds ratio of 5.53 in the multivariate model ($P<0.001$). Two age ranges also confer risk for a malignant outcome in the univariate and multivariate analysis. The

multivariate model determines that women between 50 and 64 have an odds ratio of 12.44 ($P<0.05$) and women older than 64 have an odds ratio of 10.93 ($P<0.05$).

Our results demonstrate effective risk stratification as when we partition the study population by age and personal history (Figure 1). Notably, in older patients with a personal history of breast cancer the percentage of malignant outcomes is more than 2%. In patients younger than 50, independent from a possible personal history of breast cancer, the percentage of a malignant outcome is 0.05% (1/2006). The single malignant lesion in this subpopulation is a DCIS of unknown grade.

Discussion

We demonstrate that a personal history of breast cancer and older age are independent risk factors of malignancy that should be taken into account when final BI-RADS assessment categories are assigned and BI-RADS category 3 is considered. Given the presence of both risk factors, the prevalence of malignancy in our study population is more than 2% (Figure 1), as compared to the 0.47% among the entire population. Our second main finding pertains to young patients: for women younger than 50 we find a prevalence of 0.05% in our study population (Figure 1). In the BI-RADS lexicon, assessment category 3 has been refined over the years (1, 14, 15), with a trend of moving to more personalized care. Evidence-based integration of patient characteristics like age and a history of breast cancer into the diagnostic process therefore appears intuitive.

Generally, a risk of 2% of malignancy is considered the threshold at which to recommend immediate biopsy of a mammographic lesion (1, 16). Based on our results we reason that an upgrade of BI-RADS category 3 ratings into BI-RADS category 4 for older patients with a history of breast cancer should be considered. On the other hand, while there is no stated lower-bound-risk of malignancy for BI-RADS 3, we find a very low likelihood of cancer in women younger than 50. In fact, this group has only one cancer diagnosed, a case of DCIS and the remaining 2005 findings are benign in this subpopulation. Our results indicate that further research is required to determine if these patients could appropriately be assigned BI-RADS 2 or whether a prolonged initial follow-up interval could be more appropriate for these patients.

Older age has been proven to be one of the strongest identified risk factors for breast cancer (17). According to the most recent SEER (Surveillance, Epidemiology, and End Results Program, National Cancer Institute, USA) data, breast cancer incidence is 42.84/100,000 per year in women younger than 50, and 338.55/100,000 per year in women older than 50. For comparison, women between 25 and 29 have an incidence rate of 8.6/100,000 per year (17). Our findings, with high odds ratios for women 50 years or older, are in accordance with these statistics. Varas and colleagues reported in 1992 an, albeit statistically non-significant, association between age and frequency of cancer in BI-RADS 3 cases (3). Two malignancies were found in 256 women <50 years, 7 malignancies were found in 279 women >50 years (3).

More caution is necessary for the interpretation of our second identified risk factor: a personal history of breast cancer. In the two large studies upon which the definition of BI-RADS 3 is based, patients with a prior history of breast cancer were not candidates for short-term interval follow-up and thus were not included in these studies (2, 3). Because the BI-RADS 5th edition, the de-facto standard for mammography interpretation, does not exclude women with a personal history of breast cancer as candidates for a BI-RADS 3 assessment, we consider our patient population to be representative of current clinical practice. This is further supported by the BI-RADS 3 malignancy rate of our study, which agrees with prior literature (18, 19, 20, 21, 22). Importantly, our results appear to support the initial decision by Sickles (2) and Varas and colleagues (3) to exclude patients with a history of malignant breast disease from their study populations.

We emphasize that a personal history of breast cancer is identified as an independent risk factor of malignancy (12, 23). However, older patients are more likely to have a personal history of breast cancer (17), raising the possibility that the effect of personal history is confounded by age. Multivariate logistic regression (Table 4) reports odds ratios adjusted for the other predictive variables (12, 23). In other words, age and personal history both independently confer risk in the setting of a BI-RADS 3 assessment.

Our logistic regression models did not identify breast density as a significant risk factor in our study population. Generally, higher fibroglandular densities have been found to be associated with an increased risk of a malignant outcome in the screening setting (24). Our study of BI-RADS 3 in the diagnostic setting analyzed fewer individuals and thus may not have the power to detect this effect. However further investigation may be warranted.

Limitations of our study are primarily related to the data set used for analysis. Due to the date range (1999–2004) of our cases, our mammograms necessarily included a mix of analog and digital studies. Though the definition of the BI-RADS 3 assessment category “probably benign” had been established and disseminated in practice since initial publication in 1991/1992 (2, 3), the definition continued to evolve from BI-RADS 3rd Edition (14) to 4th Edition (15), the latter being published in 2003 - during the timeframe of our study. We therefore cannot exclude the possibility that reading standards of the radiologists have changed in the data acquisition period. However, morphological descriptors that warrant a BI-RADS 3 rating have been established since 1991 and have undergone only moderate changes until the most recent, 5th edition of the BI-RADS lexicon (1). Second, our analysis is retrospective in nature. Therefore, analysis of additional features collected in the diagnostic work-up (e.g. ultrasound features that might have been collected to complete the diagnostic imaging) cannot be analyzed to determine whether they might also provide improved risk stratification.

Our study of over 4,900 patients with BI-RADS 3 assessment is one of the largest retrospective collections of cases to date. However, we encourage further validation of our findings in more recent populations. Validation of a clinical prediction rule in populations that are independent from the population the prediction rule was developed with is regarded mandatory (25, 26). This validation is required to guarantee stable performance of the prediction rule before actual application in clinical practice. Because cancers are rare in the

BI-RADS 3 population, large numbers are required to draw statistically sound inferences. Even in our population, confidence intervals (Tables 3 and 4) are large for the identified risk factors due to the relatively small number of malignant outcomes. As noted, some of the malignant lesions were described with suspicious descriptors not appropriate for the BI-RADS 3 assessment category, a phenomenon that has been previously published (7). In the future, validation of our findings, as well as investigation of the impact of deviation from strict BI-RADS 3 definitions on magnitude of risk stratification (i.e. odds ratios) will further contribute to this work.

In conclusion, we demonstrate that patient age and a personal history of breast cancer are important to further risk stratify diagnostic mammography findings assessed as BI-RADS 3 in order to comply with the agreed upon malignancy risk threshold of 2%. Biopsy for patients with both of these risk factors, whose risk of malignancy is >2% in our population, may be warranted. On the other hand, the very low cancer yield in young women without a history of breast cancer assessed as BI-RADS 3 on mammography may indicate that further study of optimal management is warranted. As individualized risk estimates are increasingly available in routine clinical care, studies like ours, when replicated, will likely help to develop optimized management recommendations based on unique patient characteristics.

Acknowledgments

This work was made possible by DFG (German Research Foundation) grant BE5474/1-1, NIH grant R01LM010921 and NIH grant R01CA165229.

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Figure 1.

Partition of our study population according to the identified risk factors. The two subpopulations with potential of prolonged follow-up interval / downgrading into BI-RADS 2 (black dashed line, women younger than 50) and upgrading into BI-RADS 4 (gray dashed line, older women with a past history of breast cancer) are highlighted.

* further research is necessary

Table 1

Distribution of BI-RADS descriptors among the 23 malignant lesions found in 4,941 diagnostic mammography examinations assigned BI-RADS 3.

Descriptor	n	remarks
mass shape		
Round	2	
Oval	3	
Lobular	0	
Irregular	0	
mass margin		
Circumscribed	2	
Indistinct	1	overall, mass descriptors present in 12 lesions
Microlobulated	0	
Spiculated	0	
Obscured	3	
mass density		
Fat	0	
Hypodense	2	
Isodense	5	
Hyperdense	1	
asymmetric density	7	additional finding in 5 mass lesions, 2 lesions asymmetric densities only
architectural distortion	1	
<u>calcification morphology</u>		
Eggshell	0	
Amorphous	0	
Pleomorphic	2	
Dystrophic	0	
Lucent	0	
Punctuate	6	overall, calcification descriptors present in 8 lesions, 2 lesions were assigned 2 morphology descriptors
fine-Linear	2	
Round	0	
Popcorn-like	0	
Milk	0	
Rodlike	0	
Skin	0	
Suture	0	
Vascular	0	

Descriptor	n	remarks
<u>calcification distribution</u>		
Diffuse	0	
Clustered [†]	7	
Linear	1	
Regional	0	
Segmental	0	

[†] In the 5th edition of the BI-RADS lexicon, "clustered" is not used anymore. Instead, the descriptor "grouped" was added to the lexicon.

Table 2

Distribution of predictive variables among our study population (n=4,941 patients).

variable	n benign (overall 4,918)	n malignant (overall 23)
age		
younger than 50	2005 (40.8%)	1 (4.3%)
50 – 64	1815 (36.9%)	13 (56.5%)
older than 64	1098 (22.3%)	9 (39.1%)
personal history of breast cancer		
yes	825 (16.8%)	14 (60.9%)
no	4093 (83.2%)	9 (39.1%)
family history of breast cancer		
none	2782 (56.6%)	8 (34.8%)
minor	1045 (21.2%)	6 (26.1%)
major	940 (19.1%)	6 (26.1%)
missing	151 (3.1%)	3 (13.0%)
breast density		
I	456 (9.3%)	2 (8.7%)
II	1918 (40.0%)	12 (52.2%)
III	2010 (40.9%)	6 (26.1%)
IV	534 (10.9%)	3 (13.0%)
additional benign findings		
yes	1273 (25.9%)	7 (30.4%)
no	3645 (74.1%)	16 (69.6%)
additional malignant findings		
yes	130 (2.6%)	2 (8.7%)
no	4788 (97.4%)	21 (91.3%)

Table 3

Results from the univariate logistic regression models in 4,941 patients with mammographic BI-RADS 3 rating. A malignant outcome is recorded in 23 patients.

variable	odds ratio	95% confidence interval	P-value
age			
base level: <50 yrs			
50 – 64 yrs	14.36	2.85 – 261.02	P<0.05
>64 yrs	16.43	3.08 – 303.28	P<0.01
personal history			
	7.72	3.37 – 18.58	P<0.001
family history			
base level: none			
minor	1.99	0.66 – 5.74	P=0.201
major	2.22	0.73 – 6.40	P=0.141
breast density			
base level: I			
II	1.43	0.39 – 9.19	P=0.643
III	0.68	0.16 – 4.66	P=0.638
IV	1.28	0.21 – 9.76	P=0.787
additional benign findings			
	1.25	0.48 – 2.94	P=0.62
additional malignant findings			
	3.51	0.56 – 12.12	P=0.09

Table 4

Results from the multivariate logistic regression model in 4,941 patients with mammographic BI-RADS 3 rating. A malignant outcome is recorded in 23 patients.

variable	odds ratio	95% confidence interval	P-value
age			
base level: <50 yrs			
50 – 64 yrs	12.44	2.29 – 232.00	P<0.05
>64 yrs	10.93	1.73 – 213.91	P<0.05
personal history			
	5.53	2.21 – 14.53	P<0.001
family history			
base level: none			
minor	2.10	0.68 – 6.14	P=0.175
major	1.73	0.56 – 5.05	P=0.321
breast density			
base level: I			
II	1.14	0.29 – 7.54	P=0.864
III	0.83	0.17 – 5.91	P=0.822
IV	3.04	0.47 – 24.37	P=0.241
additional benign findings	1.19	0.44 – 2.97	P=0.712
additional malignant findings	1.06	0.06 – 5.47	P=0.957