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A new risk stratification score for the management of ultrasound-detected B3 breast lesions

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Abstract

To develop a predictive scoring system for ultrasound-detected B3 lesions at ultrasound-guided core needle biopsy (US-CNB). A total of 2724 consecutive US-CNBs performed in our Institution (January 2011 to December 2014) were retrospectively reviewed. Inclusion criteria were as follows: (a) histopathological examination of the entire lesion or (b) availability of radiologic follow-up (FUP) ≥24 months. Patient- and lesion-related variables—patients' age, lesion consistency, lesion size, vascularization, BI-RADS category, and US-CNB result—were analyzed. Positive predictive values (PPVs) for malignancy were calculated correlating US-CNB results with excision histology or FUP. A scoring system for underlying malignancy was developed using risk factors weighting. A total of 102 B3 lesions were included: 27 atypical ductal hyperplasia (26.5%), 5 lobular intraepithelial neoplasia (4.9%), 32 radial scar (31.4%), 37 papillary lesions (36.3%), and 1 fibroepithelial lesion (0.9%). Surgery was performed on 71/102 (69.6%) lesions, and 22/71 were malignant; the remaining 31/102 lesions (30.4%) were unchanged at FUP. The overall PPV for malignancy was 21.6%. Patients' age (odds ratio [OR] = 3.63, P = 0.008), lesion consistency (OR = 5.96, P = 0.001), BI-RADS category (OR = 17.52, P < 0.001), and CNB result (OR = 3.6, P = 0.008) were associated with a higher risk of malignancy underestimation and selected as risk factors in the score definition. Two risk groups were identified: low (0-2 points) and high risk (3-5 points), with significantly different risk of malignancy underestimation (8.0% vs 59.3%, P < 0.001). The proposed score helps to predict the risk of malignancy underestimation and choose the management of B3 lesions at US-CNB.

KEYWORDS
B3 lesions, borderline breast lesions, breast ultrasonography, core needle biopsy, malignancy underestimation

1 | INTRODUCTION

Percutaneous imaging-guided core needle biopsy (CNB) is a valid alternative to surgical biopsy for the diagnosis of suspicious breast lesions, especially in nonpalpable ones, and the use of CNB has significantly increased the preoperative diagnosis rate.[1]

The CNB results are classified using the B code, and most of them are recognized as normal (B1) and benign (B2) on one hand or suspicious (B4) and malignant (B5) on the other hand.[2] However, there are also a number of lesions that cannot fit clearly in these categories and are so reported as B3 ("lesions of uncertain malignant

potential"). The B3 category is a heterogeneous group of lesions with a borderline histological spectrum at core needle biopsy (CNB).[3,4] It includes the following: (a) atypical intraductal epithelial proliferation (AIDEP) including atypical ductal hyperplasia (ADH) and flat epithelial atypia (FEA); (b) lobular intraepithelial neoplasia (LIN) including both atypical lobular hyperplasia (ALH) and lobular carcinoma in situ (LCIS); (c) radial scar/complex sclerosing lesion (RS/CSL); (d) papillary lesion (PL); and (e) "other entities" including fibroepithelial lesion with cellular stroma (FE) and "mucocele-like" lesion.[5,6]

B3 category is a histopathological result on CNB and should not be confused with BI-RADS 3 which is the probably benign category of Breast Imaging Reporting and Data System (BI-RADS) established by the American College of Radiology.[7]

B3 lesions are a relatively small proportion of all CNBs, ranging from 4% to 14%,[3,5,8] but they are considered a significant problem because of the risk of malignancy underestimation, which ranges from 20% to 35%, due to diagnostic or sampling errors.[6,9,10] For this reason, most of them are referred to surgery to examine the entire lesion and to establish the definitive diagnosis, thus resulting in a relatively great number of benign excision biopsies.[11,12]

Most of the studies in the literature discuss the outcome of B3 lesions following a stereotactic biopsy because they usually manifest as microcalcifications or architectural distortions recognized on mammography or digital breast tomosynthesis during breast screening.[9,12,14]

Sometimes, B3 lesions are ultrasound-visible; in these cases, ultrasound (US) is the preferred first-line mode for breast biopsy because it is quick, less costly, well accepted, performed in real time, with direct needle visualization, and with no scarring on subsequent mammograms.[15] However, when a CNB returns a B3 result, open surgery or therapeutic vacuum-assisted biopsy (VAB) are always suggested, according to the type of B3 lesion on histology.[16]

The aim of our study was to develop a predictive scoring system based on clinical-radiologic-pathologic data helpful to choose the most appropriate management in US-detected B3 lesions.

2 | MATERIALS AND METHODS

2.1 | Study design and patient population

The Institutional Review Board granted permission for this retrospective study. Informed consent was obtained from each patient for biopsy procedure.

A total of 2724 consecutive US-CNBs performed in our Institution, from January 2011 to December 2014, were retrospectively reviewed, and 141 B3 histological results were retrieved.

The inclusion criteria were as follows: (a) histologically confirmed borderline B3 lesions diagnosed on US-CNB; (b) diagnostic surgical excision performed at our hospital with histopathological examination of the entire lesion; or (c) availability of radiologic follow-up (FUP) ≥24 months. A total of 102 B3 lesions were finally included.

In our Institution, all biopsies with a B3 diagnosis are discussed in a breast multidisciplinary meeting that includes radiologists, pathologists, and surgeons to decide if refer the patient to surgery or imaging FUP.

2.2 | Biopsy technique

Biopsies were performed by 5 experienced (>5 years' experience) breast radiologists with the patient in a supine position, under US guidance.

US examinations were performed with an Acuson S2000 echograph (Siemens Healthcare, Erlangen, Germany) or with an Aplio 500 echograph (Toshiba Medical Systems Corporations, Otawara-shi, Tochigi-ken, Japan), equipped with a 6.2- to 12-MHz and a 5.5- to 18-MHz linear transducers, respectively, with freehand positioning technique.[17,18]

Lesions were divided into three groups according to needle size used: a 14-G semi-automated needle (Precisa 14G × 70 mm; HS Hospital Service SpA, Aprilia, Italy), a 16-G automated needle (Bio-Pince 16G × 10 cm; Argon Medical Devices, Athens, TX, USA), or a 18-G automated needle (BioPince 18G Argon 10 cm; Argon Medical Devices). The choice of needle size is predominantly determined by radiologist's preference; for each lesion, only one needle size was used. Direct visualization of the needle tip, before and after firing, was routinely performed.[19] A minimum of three specimens per lesion was obtained.[20] 5 mL of local anesthetic (mepivacaine hydrochloride) was intradermally administered on the access site.

2.3 | Data collection and images evaluation

The following patient- and lesion-related variables were analyzed:

- Patients' age, years
- Lesion consistency (mass | non-mass)
- Lesion size (≤10 mm | >10 mm)
- Vascularization (intra/perilesional | absent)
- BI-RADS category
- CNB histological result

According to lesion consistency, we distinguished "mass" and "non-mass" lesions because, even if "non-mass" lesions are not included in the BI-RADS US lexicon,[7] they may be more histologically heterogeneous and CNB may be less accurate.[21] An US-visible "mass lesion" is a space-occupying lesion, seen on multiple different US images, while a "non-mass lesion" is a hypoechoic area with an indistinct margin.[22] Lesion size is routinely assessed according to the maximum lesion diameter. The CNB results were categorized as B3 lesions without atypia (B3a: PL, RS/CSL, FE, and "mucocele-like" lesion) and B3 lesions with atypia (B3b: ADH, FEA, and LIN), as previously published.[23,24]

2.4 | Data analysis

Core needle biopsy results were correlated with excision histology or imaging FUP (stable/in agreement or changed/suspicious). We

calculated the referral rate as the percentage of B3 subtypes which were actually followed by surgical excision. The positive predictive value (PPV) for malignancy (based on surgical excision or imaging FUP) was calculated as follows: PPV (%) = number of malignant lesions/total of lesions × 100. PPVs for malignancy were also calculated as a function of patient- and lesion-related variables as described above. Statistical analysis was performed to identify which of these factors were correlated with a higher risk of underlying malignancy. After that, a points scale was assigned to each identified risk factor on the basis of its statistical weight and a scoring system for predicting the risk of malignancy underestimation was defined.

2.5 | Statistical analysis

All data were analyzed with a dedicated software (SPSS for Windows, version 22.0; IBM, Chicago, IL, USA). Continuous variable was evaluated by Kolmogorov-Smirnov test and Shapiro-Wilk test, which showed normal distribution of examined variables. The association between each patient- and lesion-related variable and PPVs for malignancy was investigated. Student's t test was applied for continuous variables analysis and chi-square test for categorical variables. For patients' age, the "cutoff" value was assessed through the analysis of receiver operating characteristics curve (ROC curve). A logistic regression model including all patients' and lesions' variables was used to compute odd ratios (ORs) and 95% confidence intervals (95% CIs) as estimate of malignant breast cancer risk. Chi-square test was also used to compare the defined risk groups with malignancy underestimation. A P-value <0.01 was considered significant.

3 | RESULTS

A total of 102 B3 lesions were identified in US-CNB samples of 94 women with a median age of 48.5 years and included the following results: 27 AIDEP (26.5%), 5 LIN (4.9%) (2 ALH and 3 LCIS), 32 RS/CSL (31.4%), 37 PL (36.3%), and 1 FE (0.9%).

Among the 102 US-CNB included, 44 (43.1%) were performed with a 14-G, 12 (11.8%) with a 16-G, and 46 (45.1%) with an 18-G needle, respectively.

Surgery was performed on 71/102 (69.6%) B3 lesions, and 22/71 (31%) were upgraded to malignant lesions: seven ductal carcinoma in situ (DCIS) (4 grade 1, 1 grade 2, 2 grade 3) and 15 invasive carcinomas (6 invasive ductal carcinomas grade 1, 2 invasive ductal

carcinomas grade 2, 2 invasive ductal carcinoma grade 3, 3 invasive lobular carcinomas grade 1, 1 invasive tubular carcinoma grade 1, and 1 invasive papillary carcinoma grade 1). The correlation between US-CNB results and surgical excision histological findings is shown in Table 1. The remaining 31/102 lesions (30.4%) were unchanged at imaging FUP and then considered benign.

The overall PPV for malignancy was 21.6% (22/102).

The device-specific PPV for malignancy was 30.0% (13/44) for 14G US-CNB, 16.7% (2/12) for 16G US-CNB, and 15.2% (7/46) for 18G US-CNB, without significant differences among the three needle size groups (P = 0.232).

The PPVs for malignancy according to patients' and lesions' characteristics are shown in Table 2, and for each variable, ORs from logistic analyses (95% CIs and P values) are reported. Among the examined variables, patients' age (P = 0.008), lesion consistency (P = 0.001), BI-RADS category (P < 0.001), and categorized CNB result (P = 0.008) were found associated with a higher risk of malignancy underestimation also at the logistic regression and then selected as risk factors to include in the score definition.

For categorical variables (lesion consistency, BI-RADS category, and categorized CNB results), the points were assigned according to the risk of associated malignancy as follows:

- Lesion consistency (mass lesion, score 0; non-mass lesion, score 1)
- BI-RADS category (BI-RADS 3, score 0; BI-RADS 4, score 1; BI-RADS 5, score 2)
- Categorized CNB results (B3a, score 0; B3b, score 1)

For patients' age, the ROC curve analysis revealed an area under the curve (AUC) of 0.659, showing acceptable discriminative capacity; "cutoff" value that best stratified the risk of underlying malignancy was 50 years so the points assigned were as follows: age<50 years, score 0; age ≥50 years, score 1.

Therefore, the score scale ranged between 0 and 5 points. Two different risk stratification groups were identified as follows: low- (score 0-2) and high-risk score (score 3-5) with a significantly different risk of malignancy underestimation (Table 3; Figures 1 and 2).

4 | DISCUSSION

Management of B3 lesions provides a challenge to the multidisciplinary team as diagnostic surgical excision is no longer the only

TABLE 1 Surgical excision histological findings of different B3 lesions and associated PPVs for malignancy

B3 category	US-CNB results (%)	Surgical excision	Referral rate, %	Benign/high-risk	Malignant	PPV, %
AIDEP	27 (26.5)	23	85.2	18	9	33.3
LIN	5 (4.9)	5	100.0	2	3	60.0
RS/CSL	32 (31.4)	16	50.0	28	4	12.5
PL	37 (36.3)	27	73.0	31	6	16.2
FE lesion	1 (0.9)	0	0.0	1	0	0.0

AIDEP, atypical intraductal epithelial proliferation; FE lesion, fibroepithelial lesion with cellular stroma; LIN, lobular intraepithelial neoplasia; PL, papillary lesion; PPV, positive predictive value; RS/CSL, radial scar/complex sclerosing lesion; US-CNB, ultrasound-guided core needle biopsy.

TABLE 2 PPVs for malignancy according to patients' and lesions' characteristics

US-CNB	Surgical excision/FUP			Logistic analysis		
	Benign/high-risk	Malignant	PPV (%)	Odds ratio	95% CI	P-value*
Age group						
<50 y	54	8	12.9	3.63	1.35-9.75	0.008
≥50 y	26	14	35.0			
Lesion type						
Mass	73	14	16.1	5.96	1.86-19.09	0.001
Non-mass	7	8	53.3			
Calcifications						
Present	10	5	33.3	2.05	0.62-6.82	0.230
Absent	70	17	19.5			
Lesion size						
≤10 mm	46	11	19.3	1.52	0.57-4.08	0.530
>10 mm	34	11	24.4			
Vascularization						
Intra/Perilesional	30	10	25.0	1.39	0.53-3.61	0.499
Absent	50	12	19.4			
BI-RADS						
3	27	0	0.0	1.13	1.02-1.24	0.066
4	46	6	11.5	17.52	5.12-59.95	<0.01
5	7	16	69.6			
US-CNB results						
B3a	60	10	14.3	3.60	1.35-9.59	0.008
B3b	20	12	37.5			

PPV, positive predictive value.
*P values from Fisher's exact tests.

TABLE 3 Risk stratification groups and associated PPVs of malignancy

Risk group	Score	Malignant	PPV, %	P-value*
Low risk (n = 75)	0-2	6	8.0	<0.0001
High risk (n = 27)	3-5	16	59.3	

PPV, positive predictive value.
*P values from Fisher's exact tests

available treatment.[11,16,25] Our study analyses our personal series of patients with only US-detected lesions with a B3 diagnosis at US-CNB with the aim of identifying parameters associated with an increased risk of malignancy underestimation and to develop a predictive scoring system useful in common practice to choose the right management in US-detected B3 lesions, considering clinical, radiologic, and pathologic data.

In our series, we found a relatively high percentage of papillary lesions (36.3%) if compared with previous studies,[3] probably due to the fact that this lesion usually manifests as a mass that can be easily detected by US. However, the number of ADH and RS/CSL, which usually manifest as microcalcifications and architectural distortions, is not so low as expected (26.5% and 31.4%, respectively): This could be related to the advances in US technology with an increased detection of "non-mass-like" lesions.

In our study, 22/102 (21.6%) B3 lesions were found to be malignant at surgical biopsy: This value is compatible with the current reported series, ranging from 12.7% to 35%.[26,27]

We did not find differences in terms of malignancy underestimation among the three needle size groups (P = 0.232; not significant). It has been previously emphasized that the amount of tissue available for pathologic examination is a decisive factor in determining the accuracy of the histological diagnosis, especially in B3 lesions.[26,28] Our result might be explained by the peculiar analysis of only US-visible lesions with a specific distribution of B3 subtypes (prevalence of PL). In these kinds of target lesions, biopsies are usually aimed at discrete solid masses where could be easier to obtain a specimen that is representative of the lesion, also thanks to the real-time needle visualization during US-guided biopsy.

In agreement with previous reports,[3–6,8] our results demonstrated that "high-risk" B3 lesions (AIDEP and LIN) have a significant increased risk of associated malignancy at surgical excision compared with "low-risk" B3 lesions (PL, RS/CSL, and FE) (37.5% vs 14.3%, respectively; P = 0.008). So our results support the proposed subcategorization of B3 lesions into two subgroups (without and with atypia).[4,23,24]

On the other hand, the only use of a "histologically based" distinction to guide the management decisions in B3 lesions is not sufficient.
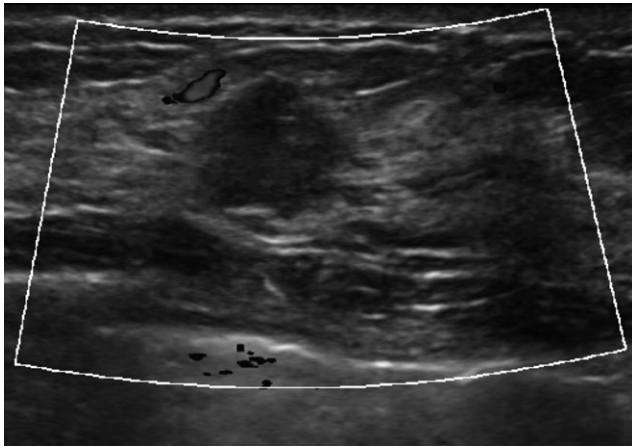
FIGURE 1 Example of low-risk B3 lesion. Patient's age: 31 y, points: 0; Lesion consistency: mass, points: 0; BI-RADS category: 4, points: 1; CNB result: papillary lesion, points: 0. Final B3-score: 1, low risk: indication to FUP. The lesion was unchanged after 2 y
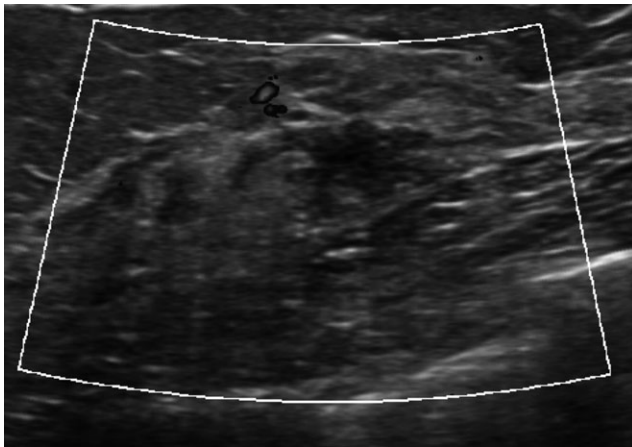

FIGURE 2 Example of high-risk B3 lesion. Patient's age: 55 y, points: 1; Lesion consistency: non-mass, points: 1; BI-RADS category: 4, points: 1; CNB result: atypical ductal hyperplasia, points: 1. Final B3-score: 4, high risk: indication to surgery. Excision histology: grade 3 DCIS

Based on independent risk factors of patients' age (1point), lesion consistency (1 point), BI-RADS category (1 point for BI-RADS 4 and 2 points for BI-RADS 5), and categorized CNB result (1 point), as derived from multiple logistic regression modeling, the estimated risks for associated malignancy among B3 lesions in the two risk stratification groups were 8.0% and 59.3%, respectively ($P < 0.0001$).

The proposed categorization tries to allow a unified strategy in the diagnostic or therapeutic approach (FUP, second-line VAB, or open surgical biopsy) according to the classification of a lesion. If prospectively validated on large series, it could be argued that conservative management of "low-risk" category (score 0-2, Figure 1) is acceptable, while first-line open surgical excision should be recommended in the high-risk category (score 3-5, Figure 2).

Our study has certain limitations, first, the retrospective nature of the study; second, the small sample size; and third, 30.4% of B3

lesions underwent imaging FUP, with no possibility to correlate the CNB result with the final excision histology. However, volumetric stability of a lesion for at least 24 months has been previously used as a reliable criterion of benignity.[29] At least, B3 results at CNB without subsequent surgical excision or at least 2 years of FUP have been excluded. Therefore, a selection bias may exist.

In conclusion, our study proposes a personalized strategy in every individual patient with a B3 diagnosis at US-CNB, taking into account the patient demographics, imaging features, and pathologic results. If confirmed on larger series and prospectively validated, this score could help to select the right management in B3 lesions diagnosed at US-CNB, reducing the frequency of benign surgical excision, which would benefit the patient and save on health care costs.

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