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BREAST

BI-RADS categorisation of 2708 consecutive nonpalpable breast lesions in patients referred to a dedicated breast care unit

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Abstract
Objectives To determine the malignancy rate of nonpalpable breast lesions, categorised according to the Breast Imaging Reporting and Data System (BI-RADS) classification in the setting of a Breast Care Unit.
Methods All nonpalpable breast lesions from consecutive patients referred to a dedicated Breast Care Unit were prospectively reviewed and classified into 5 BI-RADS assessment categories (0, 2, 3, 4, and 5).
Results A total of 2708 lesions were diagnosed by mammography (71.6%), ultrasound (8.7%), mammography and ultrasound (19.5%), or MRI (0.2%). The distribution of the lesions by BI-RADS category was: 152 in category 0 (5.6%), 56 in category 2 (2.1%), 742 in category 3 (27.4%), 1523 in category 4 (56.2%) and 235 in category 5 (8.7%). Histology revealed 570 malignant lesions (32.9%), 152 high-risk lesions (8.8%), and 1010 benign lesions (58.3%). Malignancy was detected in 17 (2.3%) category 3 lesions, 364 (23.9%) category 4 lesions and 185 (78.7%) category 5 lesions. Median follow-up was 36.9 months.
Conclusion This pragmatic study reflects the assessment and management of breast impalpable abnormalities referred for care to a specialized Breast Unit. Multidisciplinary evaluation with BI-RADS classification accurately predicts malignancy, and reflects the quality of management. This assessment should be encouraged in community practice appraisal.

Keywords Biopsy/needle/methods · Breast neoplasms/diagnosis · Breast diseases/classification · Mammography/classification · Breast diseases/ultrasound · Ultrasound · Mammary/classification

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Introduction

The widespread introduction of individual and national screening programs for breast cancer has led to a significant increase in the detection of nonpalpable breast lesions. In 1993, this prompted the American College of Radiology (ACR) to develop a Breast Imaging Reporting and Data System (BI-RADS) quality assurance tool which includes a lexicon for standardising mammography reporting, an assessment structure for findings, and recommended specific courses of action. The first BI-RADS atlas was initially available for lesions detected by mammography, and was updated and extended to ultrasound and magnetic resonance imaging (MRI) in 2003 [1]. On the basis of the level of suspicion, lesions detected by mammography and

ultrasound are allocated to one of seven BI-RADS assessment categories, six of them being final. The assessment categories include "Need additional imaging evaluation" (category 0), "Normal" (category 1), "Benign finding" (category 2), "Probably benign finding" (category 3), "Suspicious abnormality" (category 4), "Highly suggestive of malignancy" (category 5), "Known biopsy-proven malignancy" (category 6). Its predictive value has been validated in several studies in different types of populations undergoing surgical biopsies [2, 3] diagnosis or screening mammographies and ultrasounds [4, 5], and ultrasound masses [6]. On 492 surgical biopsies, Liberman [2] found carcinoma in 34% of 355 category 4 lesions, and 81% of 129 category 5 lesions. No malignancy was found in 8 category 3 lesions. Out of 1312 mammographically guided needle localizations, Orel [3] found positive predictive values (PPV) for BI-RADS of 13% in category 0 (2/15), 0% in category 2 (0/50), 2% in category 3 (3/141), 30% in category 4 (279/936), and 97% in category 5 (165/170). In a follow-up study mixing 955 diagnostic, 1807 screening mammographies, and additional 655 ultrasounds, Zonderland [4] found the following PPV: BI-RADS 1: 0.3% (5/1542), BI-RADS 2: 0.6% (6/935), BI-RADS 3:3.9% (6/154), BI-RADS 4: 52.7% (39/74), and BI-RADS 5: 100% (57/57). Kim [5] prospectively evaluated 4668 breast ultrasounds; in 3596 nonpalpable lesions, PPV was 0.05% in category 1 (1/2098), 0.8% in category 3 (4/520), 16.8% in category 4 (54/321), 92.6% in category 5 (25/27). In the retrospective review published by Raza [6], out of 926 palpable and nonpalpable masses, assessed by ultrasonography only (n=410), or ultrasonography and mammography (n=516), malignancy rates were 0.8% (3/356) in category 3, 16.2% (85/524) in category 4, and 93.4% (43/46) in category 5.

However, in current practice, the BI-RADS classification might be lacking, or there might be a discrepancy between assessment and recommendations [7], though this trend was shown to decrease over the years. Additionally, there can still be substantial interobserver variability in its application [8–12]. Of note, BI-RADS, though useful, remains a radiological classification, and does not take into account detailed previous history, prognosis and clinical factors that may also widely influence management [13, 14]. In France, in 2002, the 4th American BI-RADS lexicon for mammography was translated into French by the Health Authority (HAS, former ANAES). It additionally suggested a list of radiological examples for each BI-RADS category [15, 16]. The first MRI and ultrasound BI-RADS edition were then translated and their use became mandatory in 2004.

To date, no routine study validated in routine the use of this translated classification to predict malignancy in purely nonpalpable lesions. To ensure the breast biopsy programme and imaging reviewing quality, we systematically referred nonpalpable breast lesions to a multidisciplinary panel, in the setting of a dedicated reference Breast Care Unit. The purpose of the study was to evaluate the accuracy of the panel's assessment of the lesions with BI-RADS classification, and to compare the observed malignancy rates with the theoretical expected rate.

Materials and methods

Patients

Study patients were all referred to our Breast Care Unit between May 2, 2001 and March 9, 2007 by breast cancer screening programme medical staff, general practitioners, gynaecologists, or outside radiologists. In-house physicians could also refer patients if they were already being followed in the breast care unit. In all the cases, patients had to be referred by a physician. The panel imaging review was performed for all nonpalpable breast lesions, but not specifically for the study. All patients with reported BI-RADS 3 to 5 lesions were prospectively included in the study, and from 2004, BI-RADS 0 were also included. Patients in whom BI-RADS classification was missing on reports were also included if the imaging was considered BI-RADS 3 or upper category. None of the patients was excluded. Patient data were recorded on a standard collection form giving demographic information, relevant medical history, risk factors for breast cancer and radiographic findings. A panel of radiologists, breast-dedicated oncologists and gynaecologists reviewed all images (mammography, ultrasound and MRI) unblinded to the existing report. When the reported BI-RADS category was not confirmed by the panel, the panel's assessment overruled the reported assessment. When members of the panel disagreed, the worst BI-RADS grade of those proposed was registered, and a final review was performed with histopathological results.

A multidisciplinary team decision was taken for each patient with regard to BI-RADS recommendations (need for additional imaging studies, routine interval mammography, short-term follow-up and biopsy). The study was performed in accordance with the ethical standards laid down in the 1964 declaration of Helsinki. No informed consent was required, but information was provided to patients. (For a monocentric observational study, French law does not require approval by an ethic committee, irrespective of the prospective or retrospective nature of the study).

Imaging guidance and tissue sampling

Additional imaging was not routinely performed, unless required by the panel. When masses detected by outside

mammography were not seen on ultrasound or when ultrasound was not performed, we performed it focusing on the area of interest. All lesions were sampled in the Radiology Unit. If the abnormality was visible on ultrasound, ultrasound-guided sampling was used, either fine needle aspiration cytology (FNAC) with a 22 G needle for a cyst or mixed lesion, or a core needle biopsy with a 14 or 16 G automated gun for a solid mass.

If microcalcifications were present, stereotactic vacuum-assisted core needle biopsy (VAB) was performed using an 11 G device (Mammotome® MR biopsy system, Ethicon Endo-Surgery, Cincinnati, USA) on patients lying in a prone position on a dedicated table. A localising clip was placed if the lesion seen at mammography had been completely removed or if a large area had been sampled and the precise biopsy site had to be documented. Radiographs of the tissue specimens were obtained to confirm the presence of microcalcifications. In cases of architectural distortions, asymmetric densities, or a large area of amorphous calcifications, surgical biopsy without previous diagnostic biopsy was usually proposed.

Histology

All histopathology results were read by the same breast pathologist. Ductal carcinoma in situ (DCIS) and invasive carcinoma were classified as malignant. In surgical cases, the final diagnosis was given by examination of the excised specimen. In other cases, such as the detection of a benign lesion on diagnostic biopsy, the final diagnosis was based on follow-up mammograms.

Follow-up

After sampling, whether surgical or biopsy, the follow-up protocol was not predefined. The first imaging was generally performed 6 to 9 months after a benign result, and the follow-up was performed at the discretion of the physician. When no sampling was decided upon, the first mammographic follow-up interval was defined by the panel, ranging from 4 to 12 months in BI-RADS 3 lesions. Lesion changes during follow-up prompted BI-RADS reassessment and possibly delayed biopsy or surgery. A lesion occurring in another breast quadrant during follow-up was classified as a second lesion.

Data handling and analysis

Data were entered into Excel spreadsheets (Microsoft®, Redmond, USA). Malignancy rate according to the BI-RADS category was calculated by dividing the number of breast cancers by the total number of lesions per category.

Results

Patients' characteristics

The study included 2521 patients with 2708 nonpalpable breast lesions. Patient characteristics are summarised in Table 1. Median age was 55 years (range: 27–87), 61.2% of patients were postmenopausal, 14.2% had a personal history of breast cancer (DCIS n=60, invasive n=299, not specified n=58) and 32.6% had a familial history of breast cancer. Median follow-up was 36.9 months (range 9–93 months).

Lesions detected

Of the 2708 lesions referred to the interdisciplinary panel, 1938 (71.6%) were detected by mammography alone, 237 (8.7%) by ultrasound alone, 527 (19.5%) by ultrasound plus mammography, and 6 (0.20%) by MRI alone. The imaging findings of the 1938 lesions detected by mammography alone were as follows: 72.6% with foci of microcalcifications, 17.1% masses, 1.8% microcalcifications associated with a mass, and 8.5% architectural distortions or asymmetric densities (Table 2).

Table 1 Patient characteristics

	Number*	
Personal mammary history		
– None	1497	(59.4)
– Benign disease	550	(21.8)
– High risk disease	58	(2.3)
– Breast cancer	359	(14.2)
Familial history of breast cancer		
– No	1689	(67.0)
– Yes	796	(31.6)
Pregnancies		
– No	595	(23.6)
– Yes	1896	(75.2)
Oral contraceptive pill use		
– Yes	1152	(45.7)
– No	1297	(51.4)
Menopausal status		
– Postmenopausal	1543	(61.2)
Hormone replacement therapy		
No	763	(30.3)
Yes	764	(30.3)
– Premenopausal	953	(37.2)
Total	2521	

*data are number of patients unless otherwise specified, with percentages in parentheses. In some cases, data were not specified: personal mammary history (n=57), family history of breast cancer (n=36), pregnancies (n=30), oral contraceptive use (n=72), menopausal status (n=25), HRT use (n=16)

A total of 1732 lesions were biopsied either promptly (n=1637) by core needle biopsy (n=309), vacuum-assisted biopsy (n=807) or open breast biopsy (n=521) or during follow-up (n=95) when needed by BI-RADS reassessment. Open breast biopsy was gradually superseded by percutaneous procedures during the study. It accounted for about 40.0% of procedures until 2003, but for only 22.1% in 2004, 11.7% in 2005, and 5.7% in 2006 and 2007. Histology revealed 32.9% malignant tumours, 8.8% high-risk lesions and 58.3% benign lesions. Details relating to these lesions are given in Table 3. Fine needle aspiration cytology was performed for 117 lesions (Table 4).

Overall malignancy rates

There were 56 BI-RADS 2 lesions (2.1%), 742 BI-RADS 3 lesions (27.4%), 1523 BI-RADS 4 lesions (56.2%), 235 BI-RADS 5 lesions (8.7%) and 152 BI-RADS 0 lesions (5.6%). The malignancy rate according to aspects on imaging and BI-RADS category is given in Table 5. The malignancy rate was 24.7% for masses and 21.1% for microcalcifications detected by mammography alone. It was 13.5% for masses detected by ultrasound alone. Malignancy rates for either masses or microcalcifications detected by mammography alone were similar within each BI-RADS category. Overall malignancy rates by category are summarised in Table 6 and detailed below.

BI-RADS category 2 lesions

Of the 56 BI-RADS 2 lesions, 6 (10.7%) were sampled because of concomitant breast cancer or mammary surgery (3 biopsies, 3 aspiration procedures). No carcinoma was found.

BI-RADS category 3 lesions

Prompt histology or cytology was performed in 140 (18.9%) of the 742 BI-RADS category 3 lesions because of a personal (12.9%) or familial (25.0%) history of breast cancer, hormone replacement therapy use (17.9%), or staff decision to simplify follow-up (44.3%). Aspiration of 49 lesions revealed 28 benign lesions or cysts. Twenty-one aspirates were acellular. Follow-up of these 21 patients did not reveal any signs of malignancy. Biopsy of 91 lesions detected 6 malignancies (2 invasive carcinomas, 4 DCIS), 4 high-risk lesions, and 81 benign lesions. The remaining 602 lesions (81.1%) were followed up by short-interval imaging. Of these 602 lesions, 52 underwent morphological changes during follow-up. On sampling, 11 proved to be malignant and 4 high-risk. The overall malignancy rate for BI-RADS 3 lesions was thus 2.3% (17/742). Among the 11 malignancies, there were 4 invasive ductal carcinomas (IDC), 4 DCIS, and 2 invasive lobular carcinomas (ILC), which were detected after a median delay of 16.5 months [9–54 months]. Nine out of ten imaging findings were related to microcalcifications. Tumour size ranged from tiny clusters of carcinoma to extensive disease (more than 50 mm), 2 patients had node involvement. The 11th malignancy was considered to be unrelated to the lesion being followed up. It was an ultrasound mass in the right breast, classified BI-RADS 3, that yielded an acellular aspirate, and was excised at the time of contralateral cancer surgery. The histology report mentioned a fibroadenoma. Two years later, a palpable mass was found in the right breast in the same site and was identified as an IDC on histology. It seems likely that the excised ultrasound mass corresponded to the fibroadenoma, although a failure in needle localisation cannot be excluded. Overall, two-thirds (11/17) of malignant BI-RADS category 3 lesions were microcalcifications.

BI-RADS category 4 lesions

A total of 1386 of the 1523 BI-RADS category 4 lesions (91.0%) were sampled. A conclusive histological diagnosis was obtained for 1280 lesions (84.0%): 26.4% were malignant, 10.6% high-risk and 63.0% benign. Of 364 malignancies, the prompt biopsy yielded a benign diagnosis in 7 cases. Rebiopsy was decided upon promptly in 4 cases, and during follow-up in 3 cases. The false-negative rate in

Table 2 Radiology findings

	Number	%
Mammography	1938	71.6
– Mass (ultrasound negative)	332	12.3
– Microcalcifications	1407	52.0
– Mass + microcalcifications	35	1.3
– Architectural distortions, and asymmetric densities	164	6.1
Ultrasound	764	28.2
– Mass (ultrasound alone)	237	8.7
– Mass (ultrasound and mammography)	527	19.5
MRI	6	0.2
Total	2708	

Table 3 Final Histopathological findings in 1732 biopsies

	Number	
Benign lesions	1,010	(58.3)
– Fibrocystic changes	267	
– Fibrosis	37	
– Ductal ectasia	16	
– Fibroadenoma	210	
– Blunt duct adenosis	229	
– Radial sclerosing lesion	29	
– Papilloma	28	
– Ductal epithelial hyperplasia	103	
– Inconclusive	34	
– Other (lipoma, intramammary node, lymphocytic mastitis)	57	
High-risk lesions	152	8.8
– Atypical ductal hyperplasia (ADH)	73	
– Atypical lobular hyperplasia (ALH)	44	
– carcinoma in situ (LCIS)	35	
Malignancies	570	32.9
• Ductal carcinoma in situ (DCIS)*	195	
• Invasive cancer	375	
– Invasive ductal carcinoma (IDC)	263	
– Intraductal carcinoma with microinvasion	18	
– Microinvasive breast carcinoma	18	
– Lobular carcinoma	46	
– Lobular and ductal carcinoma	3	
– Tubular carcinoma	11	
– Tubulolobular carcinoma	8	
– Mucinous carcinoma	6	
– Other	2	
Total	1,732	

Atypical ductal hyperplasia on biopsy upgraded to DCIS at surgery was classified as a DCIS in Table 1

this category was 1.9%. Diagnosis by biopsy was inconclusive for 50 lesions (4.3%) (Normal breast tissue, n=7; atrophy, n=8; too small sample, n=19; adipose or fibroadipose tissue, n=16) of which 13 were resampled during follow-up and found to be benign. Short- term follow-up of the 37 other biopsied lesions revealed no signs of malignancy. A total of 56 aspiration procedures were performed. The results were benign for 36 lesions and inconclusive for 20 lesions. Sampling was not carried out in 135 cases (8.8%) because of technical problems (n=33), patient refusal or progressive disease at another site (n=69), or downstaging of the lesion at the time of the scheduled biopsy (n=35). Biopsies were performed at a later date in 5 patients and were benign. The overall malignancy rate for this category was 23.9% (14.9% for BI-RADS-4a; 39.3% for BI-RADS 4b).

BI-RADS category 5 lesions

A total of 226 (96.2%) out of 235 lesions in this category were sampled (9 patient refusals) by biopsy (n=226) or by aspiration followed by biopsy (n=9). The distribution was 184 malignancies (78.7%), 10 high-risk lesions (4.2%) and 32 benign lesions (13.6%). The benign lesions were in fact cases of fat necrosis (n=3), sclerosing adenosis (n=15), radial scars (n=2), fibroadenoma (n=6), fibrocystic changes (n=4), lipoma (n=1) and amylosis (n=1). No additional malignancies were detected over a median follow-up of 40 months.

BI-RADS category 0 lesions

These 152 lesions were reclassified as BI-RADS 4 (n=7, of which 4 were malignant) or downgraded to BI-RADS 2 and 3 after additional imaging (n=147). The 5 biopsies performed during follow-up were benign.

Discussion

Our study of 2708 consecutive nonpalpable breast lesions correlates imaging findings with histopathological data, according to BI-RADS French classification. It differs from most previous studies on BI-RADS categorisation in several major respects.

Firstly, our study is the only one which prospectively validates the French adaptation of the American BI-RADS on a large population. The American translation into French might raise language issues, as pointed by Stines [17]. Additionally, the American lexicon does not explicitly states which features should be included in the various final assessment categories. In contrast, a table of breast abnormalities was added as a suggestion for each BI-RADS category in the French classification [16], as also did German authors [18].

Table 4 Fine Needle aspiration cytology findings

	Number	%
Fibrocystic changes	58	53.7
Acellular, inconclusive or haemorrhagic	38	35.2
Fibroadenoma	4	3.7
Lymph node	2	1.9
Epithelial hyperplasia	2	1.9
Ductal ectasia	1	0.9
Benign	3	2.8
Malignant cells[a]	9	8.3
Total	117	

[a] followed by histology (also included in Table 3)

Table 5 Malignancy rates by radiological aspect and BI-RADS category

	Lesions (N)	Malignancies by BI-RADS category[a]							Malignancy rate
		2	3	4	4a	4b	5	0	
Mammography									
– Mass (ultrasound negative)	332	0/12	2/94 (2.1)	4/15 (26.7)	10/60 (16.7)	25/52 (48.1)	40/52 (76.9)	1/47 (2.1)	24.7
– Microcalcifications	1407	0/21	11/414 (2.7)	21/75 (28.0)	90/504 (17.9)	104/265 (39.2)	70/92 (76.1)	1/36 (2.8)	21.1
– Mass + microcalcifications	35	…	0/6	0/1	2/11 (18.2)	4/8 (50.0)	6/6 (100.0)	0/3	34.3
– Architectural distortions, asymmetric densities	164	0/6	1/37 (2.7)	14/41 (34.1)	5/28 (17.9)	11/25 (44.0)	13/22 (59.1)	1/5 (20.0)	27.4
Ultrasound									
– Mass (ultrasound only)	527	0/14	3/141 (2.1)	3/25 (12.0)	14/204 (6.9)	30/76 (39.5)	21/25 (84.0)	0/42	13.5
– Mass (ultrasound + mammography)	237	0/3	0/46	5/20 (25.0)	8/61 (13.1)	13/51 (25.5)	35/38 (92.1)	1/18 (5.5)	26.2
MRI	6	…	0/4			1/1		0/1	16.7
	2708								

[a] Data are number of malignant lesions/total number of lesions, with percentages in parentheses

Secondly, previous studies were impaired by small sample size [19], or retrospective design [20, 21]. Others were limited because they are performed only on surgical biopsies [2, 3, 22] – a technique disappearing over time-, or because these studies evaluated a single biopsy technique, (VAAB [23–25] or core needle biopsy [21, 26]) , or a single breast abnormality (mass[14, 24] or microcalcifications[27]). As opposed to the latter, our report concerns patients who have been referred to our dedicated breast care unit by community physicians and does not describe the experience of a single radiology unit. The study thus reflects the lesions that are routinely encountered in organised or personalised screening programs by breast practitioners. Additionally, it analysed abnormalities detected by all screening methods (mammography, ultrasound and MRI).

Thirdly, it focused on purely impalpable breast lesions. Many authors do no distinguish between palpable and nonpalpable lesions [4–6, 26] or this statement might not be specified [3]. BI-RADS assessments and recommendations are more accurate in impalpable lesions than for the palpable ones, particularly in categories 0 and 3 [28]. It is emphasized in the literature that radiological evaluation of palpable and occult lesions should be interpreted in a different manner [29]. In our study, all the patients went through a medical consultation with a breast specialized practitioner, including a physical exam, which guarantees the nonpalpable character of the lesions analysed.

The concern of the variability in BI-RADS assessment has been largely depicted [8–11]. The multidisciplinary assessment by the panel reached satisfying malignancy rates and a low false negative rate. Although this statement is difficult to quantify, the common reviewing of breast imaging increased the radiologist's knowledge of breast pathology and management, and clinician's ability to interpret mammography, ultrasound and MRI. Of note, this assessment was not performed exclusively for the study, and it demonstrates its feasibility in clinical daily practice.

The overall malignancy rate of 32.9% (IDC and DCIS) on sampled lesions is consistent with published findings. An Italian study of over 4000 core needle biopsies of both palpable and occult breast lesions found that about one-third were malignant [26]. Breast cancer prevalence seems to be slightly higher in Western Europe (55% in the Dutch COBRA study [30], 63.2% in an Austrian study [21]) than in the United States (46% in Liberman et al. [2]). Recall rates and negative findings of biopsies have previously been shown to be twice as numerous in the USA as in the UK, with same cancer detection rates [31]. Thus, BI-RADS malignancy rates per category, notably in category 4, may widely vary according to biopsy program and health policy.

Benign lesions are often the most difficult to manage. A BI-RADS category 3 lesion is reputed to have a 2% or lower probability of malignancy [1]. This probability is

Table 6 Malignancy rates by BI-RADS category

BI-RADS category	Number of lesions (%)	Immediate sampling (N)	Total lesions sampled (%)	Histology during follow-up (N)	Malignant lesions (N)	Malignancy rate (%)
0	152 (5.6)	7	4.6	5	4	2.6
2	56 (2.1)	6	10.7		0	0.0
3	742 (27.4)	140	18.9	52	17	2.3
4	1523 (56.2)	1386	91.0	18	364	23.9
4 NS	177 (6.5)				47	26.6
4a	868 (32.1)				129	14.9
4b	478 (17.7)				188	39.3
5	235 (8.7)	226	96.2		185	78.7
Total	2708	1774		75	570	21

Category 0 : need additional imaging, category 2: benign findings, category 3: probably benign findings, category 4: suspicious abnormality (subcategories NS: not specified, 4a: benign result expected, 4b: malignant result expected), category 5: highly suggestive of malignancy

almost supported by our 2.3% malignancy rate for this category, slightly higher than defined in the BI-RADS. In the WHI prospective trial of 58,408 women, 5% of women with a baseline mammogram were recommended for short-term follow-up [32]. The incidence of cancer was 1% at 2 years. In a much smaller study of 737 women with a category 3 lesion, only 6 masses proved to be malignant (positive predictive value (PPV), 0.8%) [5]. However, the malignancy rate would seem to be higher in community practice [33]. It was 8.8% in community practice in the USA [34]. The PPV was 3.9% in a Dutch hospital population [4], and 2 of 35 (5.7%) BI-RADS 3 nonpalpable mammographic lesions proved to be malignant in the Greek experience [25]. Because the probability of cancer is low for category 3 lesions, it has been argued that it is possible to opt for short-term follow-up rather than sampling. However, we considered sampling in 18.6% of BI-RADS category 3 lesions, particularly in women with personal or familial breast cancer factors. It may reduce the rates of close monitoring, which might lead to potentials losts of follow-up, and can reduce patient anxiety. MRI could be of interest to reduce the sampling rate in this population, but further data are needed before performing it in routine current practice [35]. Delayed cancer diagnosis in the case of BI-RADS 3 lesions was mostly due to the presence of microcalcifications rather than masses. This finding is consistent with the previous work of Mendez, finding a 6.5% malignancy rate among BI-RADS category 3 microcalcifications [36]. Clustered microcalcifications are difficult to classify as BI-RADS category 3 or 4; scattered microcalcifications jeopardise the performance of vacuum-assisted biopsy [37]. The few delayed diagnoses encountered and the heterogeneity of the final histopathological results (from tiny clusters of DCIS to N + carcinoma) do not make it possible to draw firm conclusions. We therefore strongly recommend that patients be encouraged to comply with careful and extended follow-up, as the median delay in cancer diagnosis was 16 months.

Theoretically, BI-RADS 4 lesions are indeterminate, and malignancy rates can range from 2% to 95% [1]. These lesions are actually associated with a highly variable rate of cancers. Our malignancy rate was 23.9% (364/1523 lesions) and in line with published single-institution reports for this category of lesion. Liberman et al. found a malignancy rate of 34% (120/355 lesions) [2], Orel et al. found PPV of 30% (279/936 lesions) [3], Lacquement et al. 23% (n=234 biopsies) [38], Zonderland and Pope 52.7% (n=74 screening and diagnostic mammograms) [4], Raza et al. 16.2% (n=524 masses) [6], and Kim et al. 31.1% (161 out of 519 screening and diagnostic mammograms) [5]. In our study, 8.8% of the lesions failed to be sampled. This rate seems in agreement with other authors [24], and those patients warrant cautious and close follow-up. The subdivision of the category into 4a, 4b, and 4c, reflecting growing suspicion, is optional. During the course of the study, we made a subdivision into category 4a (rather benign), and category 4b (rather malignant) in order to facilitate management. Nomograms predicting malignancy could be of interest in this context, essentially for patient information, but cannot to date supersede biopsy procedure [39].

Our malignancy rate of 78.7% for BI-RADS category 5 was low but in agreement with some other published data (81%) of 492 surgical biopsies [2]; 73% of 366 vacuum-assisted biopsies [40], 17 of 20 (85%) BI-RADS 5 lesions [41] or 25 of 82 (44%) BI-RADS 5 microcalcifications [27]. The theoretical target of a 95% malignancy rate probably does not reflect practice. We encountered classical radiological traps such as adenosis, radial scars and necrosis. In addition, in our opinion, some of the items suggested in the French classification do not have 95% specificity in diagnosing carcinomas even when strict

criteria are applied [16]. Microcalcifications associated with a distortion can be necrosis (particularly in an operated breast), growing microcalcifications with a suspicious morphology can be adenosis, and a segmentary distribution of abnormalities is not always associated with cancer. These criteria alone do not warrant classification into category 5; the physician should have additional evidence and be convinced that carcinoma is present. A suitable alternative for highly suspicious lesions, compatible with benign radiological traps, would be the use of BI-RADS subcategory 4c.

The higher prevalence of personal or familial history of breast cancer than in the general population is due to our position as a reference Breast Care Unit, more likely to recruit "high-risk" women. Furthermore, in our population, BI-RADS 4 lesions were double those of BI-RADS 3 lesions. Outside physicians might be less likely to refer patients to a breast care unit in the event of a reassuring radiologist conclusion, or when a short follow-up interval imaging is proposed, than when an intervention is advocated.

Before September 2009, we did not report outside BI-RADS categorisation, mostly because of its lack on reports. The French-speaking radiological community had been using for decades the Le Gal classification to classify microcalcifications [42], and the switch to the BI-RADS was a lengthy process. In a future study, the percentages of changes in BI-RADS categorisation will be used to evaluate the benefit of this multidisciplinary approach by the ongoing panel.

The advantages of a dedicated structure are a comprehensive review of imaging, with complete medical history, collective decision-making, and patient follow-up. Indeed, we need to further assess the efficacy of the BI-RADS categorisation in the long term. Nonpalpable lesions management evolves continuously. With the widespread use of MRI, future prospects in breast imaging include the sampling of lesions detected only by MRI. These concerns are gradually solved by the development of MRI-guided breast biopsy techniques, now available in routine clinical practice in specialized radiology units [43]. Plus, biopsy procedures with larger cores such as the Intact® breast lesion excision system (BLES) (Elswood, Voorburg, Netherlands) are currently being evaluated [44], and may avoid some surgeries in the future.

In conclusion, this large-scale study of nonpalpable abnormalities is the first to validate the BI-RADS French classification, and it emphasizes the performance of multidisciplinary evaluation, as shown by proper BI-RADS malignancy rates in each category. Breast practitioners should perform similar audits in order to be able to evaluate quality of care and encourage improvement in the management of breast lesions.

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