Article # WP201511-RS80A / Issue Date 30 Nov, 2015

Categorization of focal breast lesions according to the Ultrasound Breast Imaging Reporting and Data System (BI-RADS US) lexicon: Role of a computer aided decision making support (S-Detect™)

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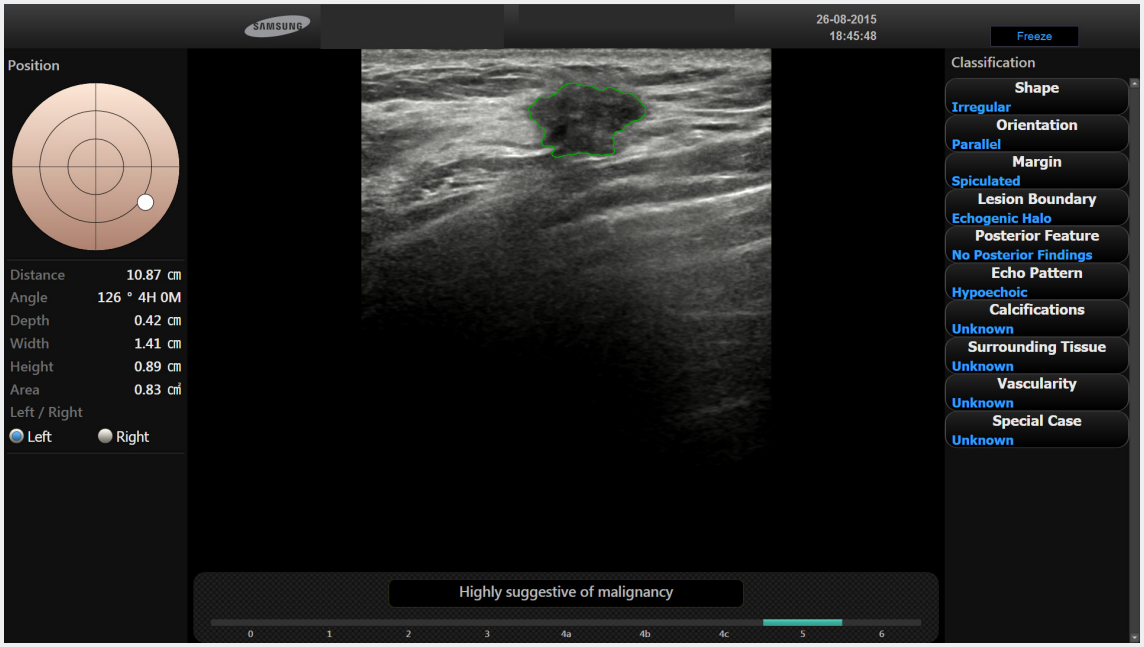

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Introduction

Breast ultrasound (US) is a widespread imaging tool, often used as an adjunct to mammography with the aim to characterize focal breast lesions (FBLs), thus improving cancer detection rates and reducing the number of false negatives for breast cancer diagnosis. However, breast US requires extensive experience, yielding it as an operator-dependent procedure and presents lower reproducibility, specificity and positive predictive value than mammography.

SAMSUNG

Breast Imaging-Reporting and Data System (BI-RADS) lexicon was first developed by the American College of Radiology (ACR) in 2003, providing descriptors for focal breast lesions (FBLs) on breast US imaging, which standardized the reporting terminology and clinical management.

Computer-aided detection (CAD) system, such as S-Detect™ by Samsung, has been developed as a supporting tool in classifying FBLs, allowing recording, processing and reviewing of US images seamlessly.

The aim of this study was to assess the role of a novel computer-guided decision-making support (S-Detect™) in the categorization of FBLs based on the BI-RADS US lexicon.

Method

CAD examination was performed on US images of 160 consecutive FBLs between December 2014 and June 2015. Indications for breast US included a palpable mass detected on physical examination, dense breasts or detected lesions from adjunct mammography examination, patients with mastodynia and young patients having family history or in a follow-up for benign breast nodules or cysts.

Two radiologists by consensus classified 160 FBLs (size range: 2.6 – 47.2 mm; mean: 11.5 mm ± 6.5 SD) in 123 patients (121 women and 2 men; age range: 13-98 years; mean 50.1 years ±14.4 SD) into 4 categories : (1) BI-RADS 2 benign; (2) BI-RADS 3 probably benign; (3) BI-RADS 4 suspicious; (4) BI-RADS 5 highly suggestive of malignancy. The classification was based on the BI-RADS US descriptors such as shape, orientation, margin of the mass, boundary, echo pattern and posterior acoustic feature. FBLs were detected by a high resolution ultrasound system, RS80A (Samsung Medison Co., Ltd, Seoul, Korea).

A third independent reader also assessed the same 160 FBLs off-line while using S-Detect™, a built-in dedicated US-BIRADS classification software which is capable of a semi-automated lesion extraction and guided classification based on the descriptors above. Patient's age, family or personal history of breast cancer and previous US investigations were available to the investigator in order to reproduce a more realistic clinical situation. Mammographic findings of FBLs were not taken into consideration for this BI-RADS US classification.

US-guided core-biopsy and fine-needle aspiration cytology (FNAC) served as a standard of reference (SOR) for all the FBLs classified as either BI-RADS 4 or 5. US findings at 6 months follow-up have been available for all the 45 lesions classified as BI-RADS 3 both before and after S-Detect™ assessment.

Sensitivity, specificity, positive and negative predictive values (PPV, NPV) were calculated while considering BI-RADS 4 and 5 FBLs as malignant and BI-RADS 2 and 3 FBLs as benign mass.

Results

Table 1 shows the differences in the BI-RADS categorization of the 160 FBLs assessed by the two radiologists in consensus and the third reviewer using S-Detect™.

BI-RADS CATEGORY	RADIOLOGISTS' ASSESSMENT (number of lesions)	S-Detect™ GUIDED ASSESSMENT (number of lesions)
BI-RADS 2	70	70
BI-RADS 3	54	51
BI-RADS 4	21	26
BI-RADS 5	15	13
TOTAL	160	160

Table 1. Categorization of 160 FBLs before and after S-Detect™ assessment. Concordance between S-Detect™ assisted radiologist and the two reviewers not performing S-Detect™ was 89.4 %.

S-Detect™-assisted radiologist changed the initial BI-RADS classification in 17 of 160 (10.6%) FBLs: 9 FBLs were upgraded from BI-RADS 3 to BI-RADS 4 (Figure 1) whereas 6 FBLs were downgraded from BI-RADS 4 to BI-RADS 3 (Figure 2), and 2 FBLs were downgraded from BI-RADS 5 to BI-RADS 4. No differences were noted in classification of FBLs BI-RADS 2.

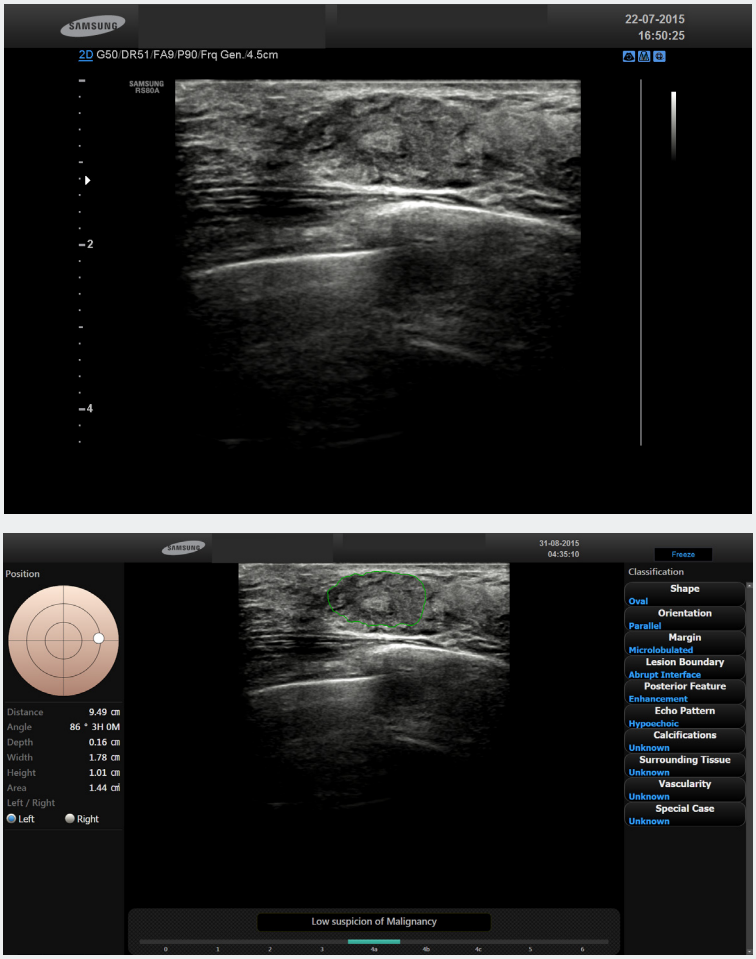

Figure 1. In a 57-year-old woman, B-mode US depicted an oval-shaped mass, slightly hypoechoic with a central area of hyperechogenicity, parallel orientation and a slightly posterior acoustic enhancement. The two reviewers assessed margins as circumscribed, S-Detect™ guided radiologist as microlobulated, thus the lesion was upgraded from BI-RADS 3 to BI-RADS 4A. Core-needle biopsy confirmed the lesion as an invasive ductal carcinoma.

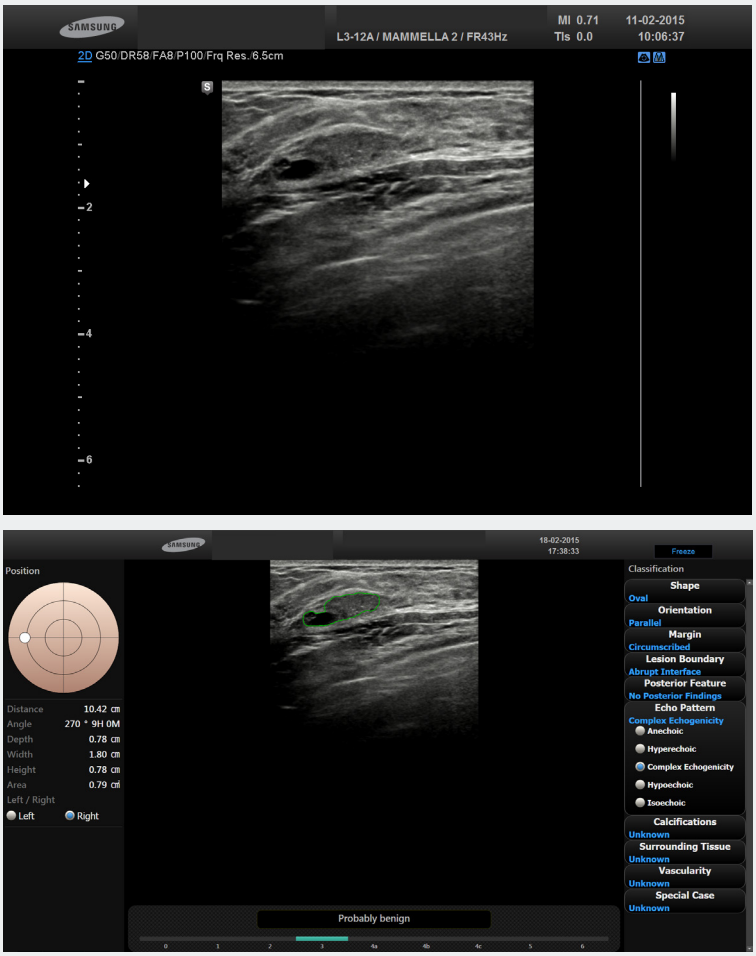

Figure 2. A 43-year-old woman with dense breasts undergone breast sonography. US image displays an isoechoic mass with an eccentric anechoic area, oval shape, parallel orientation and circumscribed margins. S-Detect™ assisted radiologist changed this FBL from BI-RADS 4 to BI-RADS 3. Core needle biopsy revealed a usual ductal hyperplasia (fibrocystic changes).

Histological diagnoses (Table 2) was obtained for 45 lesions classified as BI-RADS 4 or BI-RADS 5 with or without S-Detect™:

- 7 Benign lesions: fibroadenoma (2), usual ductal hyperplasia (2), granuloma (1), corpuscular cyst (1), abscess (1);
- 2 High risk lesions: atypical ductal hyperplasia (1), sclerosing adenosis (1);
- 36 malignant lesions: invasive ductal carcinoma (27), invasive lobular carcinoma (6), mucinous carcinoma (1), malignant phyllodes tumor (1), chondrosarcoma (1)

Diagnosis	Histology	No	Radiologists Assessment	S-Detect™	S-Detect™ Assisted Radiologist
Benign Lesion (n=7)	Fibroadenoma	2	BI-RADS 3 BI-RADS 4A	PM PB	1 BI-RADS 4A 1 BI-RADS 3
	Corpuscular cyst	1	BI-RADS 4A	PB	1 BI-RADS 3
	Granuloma	1	BI-RADS 4B	PM	BI-RADS 4C
	Usual Ductal Hyperplasia	2	BI-RADS 3 BI-RADS 4A	PM PB	BI-RADS 4 BI-RADS 3
	Abscess	1	BI-RADS 4A	PM	BI-RADS 4B
Malignancy (n=36)	Invasive ductal carcinoma	27	4 BI-RADS 3 23 BI-RADS 4 or 5	All PM 3 PB & 20 PM	All BI-RADS 4 or 5 All BI-RADS 4 or 5
	Invasive Lobular carcinoma	6	2 BI-RADS 3 4 BI-RADS 4 or 5	All PM	All BI-RADS 4 or 5
	Mucinous carcinoma	1	BI-RADS 4A	PB	BI-RADS 3
	Chondrosarcoma	1	BI-RADS 4B	PM	BI-RADS 4B
	Malignant Phyllodes tumor	1	BI-RADS 4A	PB	BI-RADS 3
High Risk Lesion (n=2)	ADH Sclerosing Adenosis	1 1	BI-RADS 3 BI-RADS 4A	PM PB	BI-RADS 4B BI-RADS 3

Table 2. PB= Possibly Benign; PM= Possibly Malignant; ADH= Atypical Ductal Hyperplasia

The two radiologists classified 160 FBLs as BI-RADS 2 (n = 70), BI-RADS 3 (n = 54), BI-RADS 4 (n = 21), BI-RADS 5 (n = 15), with Sensitivity, Specificity, PPV and NPV of 81.6%, 95.9%, 86.1% and 94.3%, respectively.

S-Detect™ assisted radiologist classified 160 FBLs as BI-RADS 2 (n = 70), BI-RADS 3 (n = 51), BI-RADS 4 (n = 26), BI-RADS 5 (n = 13), with Sensitivity, Specificity, PPV and NPV of 92.1%, 96.7%, 89.7% and 97.5% respectively.

In cases of malignancy, S-Detect™-guided re-classification was correct in 12 of 17 cases (70.6%): 6 of 9 malignant FBLs and 1 of 9 high risk FBLs were properly upgraded from BI-RADS 3 to BI-RADS 4, 3 of 6 benign FBLs were downgraded from BI-RADS 4 to BI-RADS 3. Furthermore, 2 FBLs were downgraded from BI-RADS 5 to BI-RADS 4, but the course of management for these cases wouldn't have undergone any variations.

On the other hand, 2 of 9 benign FBLs were erroneously upgraded to BI-RADS 4 and 2 of 6 malignant FBLs and 1 of 6 high risk FBLs were erroneously downgraded to BI-RADS 3.

Discussion

In this study, S-Detect™ assisted radiologist reached higher sensitivity, specificity, NPV and PPV when compared to the reviewers without S-Detect™.

Among 36 malignant FBLs, only 2 were interpreted as "probably benign" (BI-RADS 3) by the S-Detect™ assisted radiologist. Histological diagnosis for these cases were mucinous carcinoma and malignant phyllodes tumor, respectively. These masses showed relatively circumscribed margins, and the phyllodes tumor in particular, presenting with no more than three lobulation, was considered of oval morphology. S-Detect™ assisted radiologist classified only one high risk lesion as BI-RADS 3 for which pathologic diagnosis was sclerosing adenosis.

Six malignant (2 invasive lobular carcinoma and 4 invasive ductal carcinoma) and 1 high risk (atypical ductal hyperplasia) lesions missed by the two reviewer were correctly recognized as suspicious by radiologists' S-Detect™ assisted readings. These lesions showed non-irregular morphology and margins were not completely circumscribed, thus assessed as microlobulated.

The two benign lesions that were erroneously upgraded as BI-RADS 4 by the radiologist with S-Detect™ assistance were histopathologically proved to be one fibroadenoma and one usual ductal hyperplasia. In these two cases descriptors which led the radiologist to upgrade were shadowing as posterior acoustic finding and round morphology, respectively.

One abscess and one granuloma were the only two lesions inaccurately assessed as BI-RADS 4, both with and without performing S-Detect™. This is due to the presence of indistinct margins for the first lesion and non-parallel orientation for the second one.

Conclusions

Our experience validated S-Detect™ as an effective computer-aided decision-making tool for classification of FBLs as it improves breast cancer detection rate, specificity, NPV and PPV, even when compared with to the results of the experts.

Supported Systems

- RS80A with Prestige
- RS80A
- HS70A