## RS80A

# S-Detect™ in Breast Ultrasound : Initial Experience

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#### Introduction

The use of breast Ultrasound Sonography (US) as an adjunctive screening tool to mammography has been widely increasing. Especially in women with dense breasts, or with a strong first-degree family history of breast cancer, or with presence of abnormal genes, further evaluation with breast US is recommended even in the negative mammographic findings.

While the number of breast US examination has been increasing rapidly, the number of experienced doctors who will perform the US examination has been still limited.

US is well known to be an operator dependent modality and the result of US varies according to the performing doctors. Since breast US showed unacceptably high operator dependence and reduced reproducibility more than other body part, the large number of false positive findings and unnecessary biopsy were pointed as limitations of screening breast US.

On these bases, objective and standardized assessment of lesions seen on US is necessary.



#### **Methods**

Three breast dedicated radiologists (from 7 year to 14 years of experience in breast US) performed breast US examinations of 34 breast masses in 30 patients using RS80A (Samsung Medison Co., Ltd, Seoul, Korea). Twenty two cases, which were prospectively enrolled, were candidates for breast biopsy. They were evaluated with US and underwent US-guided percutaneous biopsy on the same day.

As a control group, we collected twelve cases of proven benign lesions which had previous long-term follow up images or previous biopsy result.

After finishing the US examination, radiologists classified the masses according to their possibility of malignancy based on the US features into 5 BI-RADS® final assessment categories, from BI-RADS® category 2 to BI-RADS® category 4C or 5 in consensus. After making the final assessments, we applied S-Detect™ (Smart-Detect™ Samsung Medison Co., Ltd, Seoul, Korea) to the captured US images of the lesions and obtained the results. The application of S-detect™ program was done twice, to the transverse image and sagittal image. The results were recorded as possibly benign or possibly malignancy. If the result was different in both transverse and sagittal views, or possibly benign in one direction and possibly malignant in the other direction, the result was considered as possibly malignancy.

Final diagnosis was made by 14G core needle biopsy, vacuum-assisted biopsy or reviews of the previous US images more than 2 years. We compared the results of radiologists' final assessment with the results of S-Detect<sup>TM</sup>, and correlated with final diagnosis (Table 1).

| Diagnosis               | Histology                              | No. | Radiologists' assessment                             | S-Detect                                |
|-------------------------|--|-----|--|---|
| Benign lesion<br>(n=16) | Benign cysts /<br>Fibroadenomas        | 12  | BI-RADS® <b>C2 or 3</b> (Typical or probably benign) | 11 Possibly Benign 1 Possibly Malignant |
|                         |  | 4   | BI-RADS® C4A (low suspicion)                         | All Possibly Malignant                  |
| Malignancy<br>(n=13)    | 10 IDC<br>3 DCIS                       | 2   | BI-RADS® C4A (low suspicion)                         | Possibly Benign     Possibly Malignant  |
|                         |  | 4   | BI-RADS® C4B (intermediate suspicion)                | Possibly Benign     Possibly Malignant  |
|                         |  | 7   | BI-RADS® C4C or 5 (moderate suspicion or more)       | All Possibly Malignant                  |
| High risk lesion (n=5)  | 1 Radial Scar<br>2 Sclerosing Adenosis | 3   | BI-RADS® C4A (low suspicion)                         | All Possibly Malignant                  |
|                         | 1 IDP<br>1 IDP with ADH                | 2   | BI-RADS® <b>C4B</b> (intermediate suspicion)         | All Possibly Malignant                  |

**Table 1.** Abbreviations: ADH=Atypical ductal hyperplasia, B=Benign, C=Category, DCIS=Ductal carcinoma in situ, IDC=Invasive ductal carcinoma, IDP=Intraductal papilloma, M=Malignant

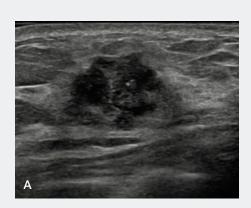


#### **RESULT**

Table 1 shows the results of radiologists' assessment, the results of S-detect<sup>™</sup> and final diagnosis. The final diagnoses of the lesions were malignancy in 13 cases, benign lesions in 16 cases, and high risk lesions in 5 cases. The mean size of the lesions was 1.2 cm (1.2  $\pm$  0.6 cm).

S-detect<sup>™</sup> assessed the lesions same with the consensus of breast dedicated radiologists in 31/34 cases (91.2%).

All highly suspicious lesions (BI-RADS® category 4C or 5) were interpreted as possibly malignant on S-detect™ and the pathologies were all invasive ductal carcinomas (IDC) (Figure 1).





**Figure 1.** A 63-years old woman with palpable mass in left breast. About 2.2cm sized a heterogeneous hypoechoic mass with irregular shape, indistinct and microlobulated margin was found with echogenic halo on US (A). Radiologist suggested BI-RADS® category 5 and S-detect™ also suggested possibly malignant (B). Biopsy proved IDC.

In thirteen cases of fibroadenomas, radiologists suggested low suspicion of malignancy (BI-RADS® category 4A) in 4 cases, and S-detect™ suggested possibility of malignancy in 5 cases (Figure 2).

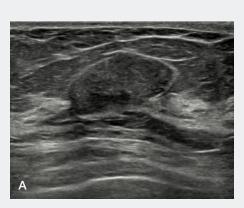




Figure 2. A 62-years old woman with palpable mass in left breast. US showed about 2.2cm sized an irregular shape, heterogeneous low echoic mass (A). Both radiologist and S-Detect™ assessed as possibly malignancy (B). But the result of core needle biopsy was a fibroadenoma.

All typical benign lesions were possibly benign (Figure 3). Otherwise, they were all suggested as a benign lesion by both radiologists and S-detect™ (Figure 4).

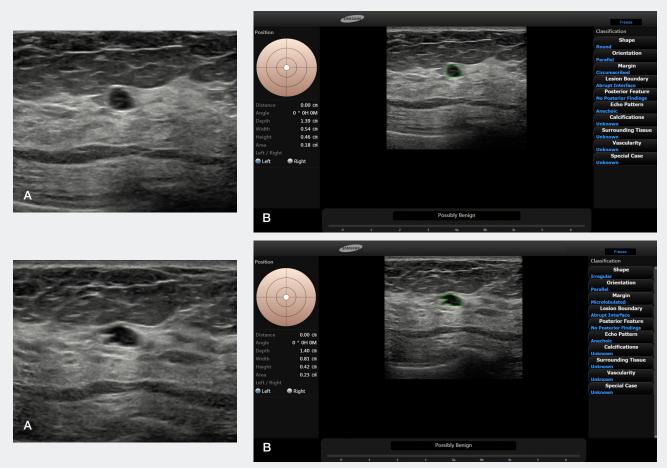
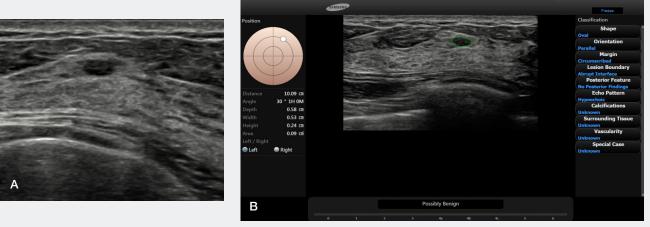


Figure 3. A 40-years old woman with screening US-detected lesion in left breast. On US, about 0.8cm sized a circumscribed anechoic mass was noted. The mass showed somewhat irregular shape, but the margin was circumscribed with thin echogenic line and abrupt interface (A). Radiologist suggested benign cyst with BI-RADS® category 2 and S-detect™ also suggested possibly benign (B). The lesions had been stable for more than 2 years.



**Figure 4.** A 38-years old woman with stable US-detected nodule in left breast. US showed about 0.5cm sized an oval shape, circumscribed isoechoic mass (A). Radiologists and S-Detect™ both assessed as probably benign (BI-RADS® category 3) and possibly benign lesion (B).

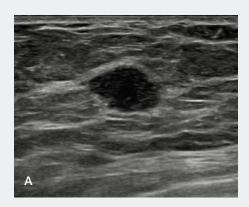
For the 5 high risk lesions, radiologists (n=3 and n=2) and S-detect<sup>™</sup> suggested possibility of malignancy in all cases (Figure 5). In 13 malignant cases, S-detect<sup>™</sup> missed one IDC and one ductal carcinoma in situ (DCIS), which showed relatively circumscribed masses on US.

In one case, the patient had abnormal nipple discharge and the other one was a newly developed mass on follow up screening mammography (Figure 6).





**Figure 5.** A 37-years old woman with screening US-detected lesion in left breast. US showed an irregular shape, 0.7cm sized isoechoic mass (A). Both radiologists and S-Detect™ assessed the lesions as suspicious malignancy (BI-RADS® category 4B) and possibly malignancy (B). Core needle biopsy and surgical excision revealed radial scar.





**Figure 6.** A 70-years old woman who had a newly developed mass on the screening mammography. About 1cm sized a low echoic mass with partially microlobulated margin, was noted on her lower outer breast on US (A). Radiologist assessed the mass as a suspicious malignant lesion (BI-RADS® category 4), but S-Detect™ assessed as probably benign lesion with circumscribed margin (B). Invasive ductal carcinoma was diagnosed after core needle biopsy.

#### **Discussion**

In this study, the sensitivity of S-detect™ was 84.6%. Two missed breast cancers were relatively circumscribed isoechoic and hypoechoic masses with suspicious clinical findings, such as abnormal nipple discharge and newly developed mass on screening mammography. S-detect™ is a program that analyzes the US features of the lesion only and assesses the possibility of malignancy based on the BI-RADS® US lexicon. Therefore, circumscribed malignant mass may be remained as limitation of S-detect™. Moreover, radiologists try to find out any subtle suspicious feature when they perform breast US examination of patients with suspicious clinical findings, but S-detect™ is not available to do such performance.

Nevertheless, the specificity of S-detect<sup>™</sup> was calculated to be 68.8%, except the high risk lesions that need to be biopsied but classified into benign lesion, which was similar to the specificity of radiologist (75%). The main cause which decreased specificity was irregular shaped fibroadenomas referred for biopsy, both radiologist and S-detect<sup>™</sup> assessed them as possibly malignancy.

### Conclusion

S-Detect<sup>TM</sup> showed excellent agreement (91.2%) with the assessment of breast dedicated radiologist in interpreting the breast mass. It is suggested as a good decision-making support, especially for the beginner or non-breast radiologist.

#### **Supported Systems**

(1) RS80A

#### References

(1) Mendelson EB, Böhm-Vélez M, Berg WA, et al. ACR BI-RADS® Ultrasound, In: ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology; 2013.