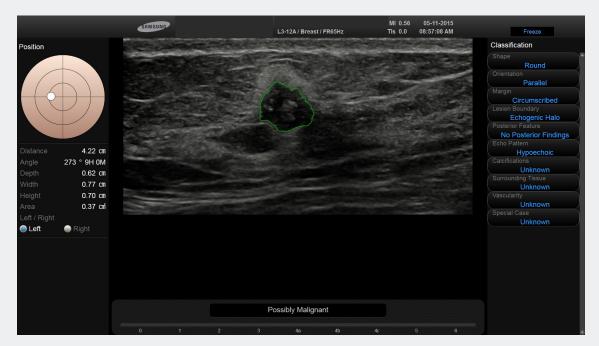
Evaluation of S-Detect as a screening tool for Breast Tumors

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"With its provided accuracy, S-Detect can certainly become a valuable tool in breast cancer screening, and even also assist beginners and non-experienced radiologists."

Introduction

Breast cancer is the most common cancer with high mortality rate in women internationally, including Vietnamese women. Therefore, an early detection of breast cancer is very crucial for better prognosis. Among diagnostic modalities, breast ultrasound is a useful screening tool in differentiating benign and malignant tumors. However, its limitation still depends largely on radiologist's experience.

Recently, for this reason, computer-aided diagnosis (CAD) systems have been rapidly entering the radiology mainstream, providing second opinion in assisting image interpretation. Based on the definitions in mass category of Breast Imaging Reporting and Data System developed by American College of Radiology 2013 ultrasound lexicon (BI-RADS)¹, Samsung Medison developed a CAD software called S-Detect to help physicians making an accurate decision. It is clearly finding its way to the clinical application.

In this study, 111 breast lesions were collected and they were reconfirmed of their pathology by biopsy at Medic Center, Ho Chi Minh City. With these results, S-Detect's efficacy was evaluated and the agreement between S-Detect and Conventional breast ultrasound examination was measured.

Method

First, a cross-sectional study was designed and all of the data were collected at ultrasound department of Medic Center, Ho Chi Minh City. Using sample size determination formula, with an expected margin of error at w = 0.05 and P_{dis} = 20/100,000 (prevalence of breast cancer in Vietnamese women population, according to Nguyen Chan Hung et al²), the minimum size of 73 cases was calculated. In addition, since observation occurs in different population, the number of cases must be 1.5 to 2 fold the minimum size needed. Therefore, a total number of cases needed were calculated 1.5 times the minimum (n = 73x1.5 = 110 cases).

Second, from April 2015 to June 2015, data of 111 breast lesions of 111 females patients whose BI-RADS scores were from 3 to 5 were acquired. Patients who disagreed to be a part of the research and/or patients with surgical and chemotherapy history were excluded from the study.

Lastly, the data were statistically analyzed using software SPSS 16.0 and p value < 0.05 was considered as significant.

Two radiologists whose experiences are 1 and 15 years in breast US investigated dedicated lesions using linear probe L3-12A in RS80A with Prestige (Samsung Medison Co., Ltd). Lesions were reported based on BI-RADS final assessment categories. S-Detect was applied to re-estimate the lesions. The specialized computer algorithm analyzed based on 6 features – shape, orientation, margin, lesion boundary, echo pattern, posterior feature. Finally, the system suggested a possibility of being benign or malignant. All lesions' final diagnosis were confirmed by biopsy results (FNAC, core biopsy, excisional biopsy).

Results & Discussion

1) Evaluation of S-Detect

	Malignant	Benign	Sum
Possibly malignant	57	19	76
Possibly benign	4	31	35

Table 3.1. S-Detect results compared with biopsy results (n = 111)

A total of 111 malignant lesions were included in series, and 61 were malignant (60 carcinoma, 1 sarcoma). Of these 61 cases, 57 were reported malignant by S-Detect (Figure 1 and 2). The sensitivity based on these results was 93.4%. The remaining 4 out of 61 malignant cases (6.65%) were cancerous tumors which software conveyed as benign. They were all subclinical lesions (< 1cm) with circumscribed border, and no signs of surrounding tissue infiltration.



Figure 1. A right breast mass classified as BI-RADS 5. S-Detect also proposed as possibly malignant. Biopsy revealed sarcoma.



Figure 2. A left breast mass in 48 years old patient, <1cm in diameter, speculated margin, vertical orientation, Halo sign(+). S-Detect and Conventional US both suggest malignant. Biopsy revealed Ductal Carcinoma in Situ (DCIS).

In addition, 3 of them were satellite lesions nearby large masses, and 1 was an early detected carcinoma. (Figure 3)

Among 50 benign masses, S-Detect reported correctly 31/50 making its specificity at 62% and accuracy at 79.3%. The misinterpreted were the cases of fat necrosis, breast abscess, infected simple cyst, tuberculous mastitis, fibroadenoma, and etc., which show varying hypoechoic to heterogeneous echo patterns, ill-defined border, vertical oriented and sometimes halo sign (+). Especially for tumors with ill-defined border or vertical orientated alone, S-Detect usually suggested malignancy. However, in these cases, the over-diagnosis was necessary to avoid false-negative. However, this software also has limitation. The existence of microcalcifications and neovascular pattern were not analyzed. Since they are valuable indicators for malignancy, S-Detect misses an interpreting information.



Figure 3. Satellite lesion with <1cm diameter, well-defined margin, horizontal orientation, halo sign(-). S-Detect suggested benign. Biopsy revealed Invasive Ductal Carcinoma (IDC)

2) Correlation between S-Detect and Conventional breast ultrasound

	Conventional US					
		Possibly benign	Possibly malignant	Sum		
S-Detect	Possibly malignant	31	4	35		
	Possibly benign	8	68	76		
	Sum	39	72	111		
kappa coefficient		0.76				

Table 3.2. Correlation between S-Detect and conventioanI US in diagnosis of breast cancer (n = 111)

To measure the agreement of these two methods, kappa coefficient was calculated at 0.76.

Using cited scale in Table 3.3, the kappa coefficient of 0.76 is in "Substantial agreement" range. As a result, it's implied that S-Detect has a high correlation with the alternative method. This supports S-Detect's application in daily clinical breast practice in assisting investigation of breast tumors.

	Poor	Slight	Fair	Moderate	Substantial	Almost perfect
Карра	0.0	.20	.40	.60	.80	1.0
	Карра	Agreement	Карра	Agreemen	t	
	<0	Less than chance agreement	0.41~(0.60 Moderate agi	Moderate agreement	
	0.01~0.20	Slightagreement	0.61~0).80 Substantial a	greement	
	0.21~0.40	Fair agreement	0.81~(0.99 Almost perfe	ct agreement	

Table 3.3. Interpreting Kappa Coefficient³

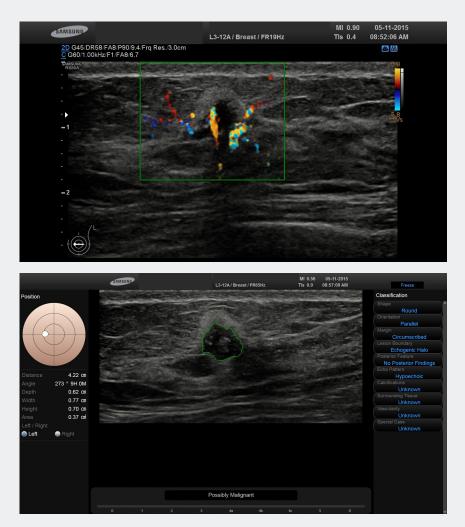


Figure 4. Early detected carcinoma, <1cm in diameter, vertically orientated, halo sign(+), suspicious of neovascular pattern, microcacification within mass. Both S-Detect and conventional US suggested malignancy.

Conlcusion

S-Detect is a promising tool in clinical application of breast imaging, based on BI-RADS¹ classifications. With substantial agreement to conventional method (k = 0.76), S-Detect contains clinical values in daily practice. Moreover, with its provided accuracy (sensitivity 93.4%, specificity 62%, accuracy 79.3%), S-Detect can certainly become a valuable tool in breast cancer screening, and even also assist beginners and non-experienced radiologists.

Supported Systems

- RS80A with Prestige
- RS80A
- HS70A

References

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- 3. Anthony J. Viera and Joanne M. Garrett , "Understanding Interobserver Agreement: The Kappa Statistic", Family