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Screening Ultrasound in Women with Negative Mammography: Outcome Analysis

Ji-Young Hwang[1,2], Boo-Kyung Han[1], Eun Young Ko[1], Jung Hee Shin[1], Soo Yeon Hahn[1], and Mee Young Nam[1]

[1]Department of Radiology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul;
[2]Department of Radiology, Kangnam Sacred Heart Hospital, Hallym University College of Medicine, Seoul, Korea.

Purpose: To show the results of an audit of screening breast ultrasound (US) in women with negative mammography in a single institution and to analyze US-detected cancers within a year and interval cancers.

Materials and Methods: During the year of 2006, 1974 women with negative mammography were screened with US in our screening center, and 1727 among them had pathologic results or any follow up breast examinations more than a year. We analyzed the distribution of Breast Imaging Reporting and Data System (BI-RADS) category and the performance outcome through follow up.

Results: Among 1727 women (age, 30–76 years, median 49.5 years), 1349 women (78.1%) showed dense breasts on mammography, 762 (44.1%) had previous breast US, and 25 women (1.4%) had a personal history of breast cancers. Test negatives were 94.2% (1.627/1727) [BI-RADS category 1 in 885 (51.2%), 2 in 742 (43.0%)]. The recall rate (=BI-RADS category 3, 4, 5) was 5.8%. Eight cancers were additionally detected with US (yield, 4.6 per 1000). The sensitivity, specificity, and positive predictive value (PPV1, PPV2) were 88.9%, 94.6%, 8.0%, and 28.0%, respectively. Eight of nine true positive cancers were stage I or *in-situ* cancers. One interval cancer was stage I cancer from BI-RADS category 2.

Conclusion: Screening US detected 4.6 additional cancers among 1000. The recall rate was 5.8%, which is in lower bound of acceptable range of mammography (5–12%), according to American College of Radiology standard.

Key Words: Breast neoplasms, diagnosis; breast neoplasms, ultrasonography; cancer screening

INTRODUCTION

Mammographic screening is the only proven modality to reduce mortality of breast cancer, with the rates ranging from 10 to 30%.[1-4] Screening breast ultrasound (US) is known to have a substantial role in the detection of early breast cancer in high risk women or women with dense breasts.[5-10] In 2009, a law was first enacted in the state of Connecticut requiring all mammography reports to inform patients of the availability of screening breast US and MRI to women with dense breasts. Subsequently, many facilities in Western countries have experienced a marked increase in the number of screening breast US.[11] In addition to its ability to be effective in dense breasts, US has several other advantages over mammography, including no ionizing radiation, no patient discomfort, and ease in performing real time intervention (i.e., US guided aspiration or biopsy).[12] Although MRI has a definite detection benefit, this diagnostic method is not applicable for screening purposes to women with unelevated risk of breast cancer due to its high cost. Screening US, however, has been devaluated due to its operator dependency, dubious cost-effectiveness, and relatively high false positive rate.[13-16]

There are several single center and multicenter studies on the value of screening US to depict small, node-negative breast cancers that are occult on mammography in women with dense breasts or women at an elevated risk of breast cancer.[7,8,17-20] The American College of Radiology Imaging Network (ACRIN)

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Corresponding author: Dr. Boo-Kyung Han, Department of Radiology, Samsung Medical Center, Sungkyunkwan University School of Medicine, 81 Irwon-ro, Gangnam-gu, Seoul 135-710, Korea.
Tel: 82-2-3410-0517, Fax: 82-2-3410-0084, E-mail: bkhan@skku.edu

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6666 multicenter trial reported that combined screening using both mammography and US could detect an additional 4.2 cancers per 1000 women.[21]

However, there is still a need for outcome data from variable groups to benchmark the performance of US screening and there is lack of discussion on false negative (FN) cases that were missed on screening US and false positive cases that could be related to excessive recalls. To ensure that the screening examinations are clinically relevant and appropriate, auditing US examinations per each unit as well as per larger regional base at regular intervals is essential, not to mention comparing this data with a general range of screening, if any. To our knowledge, the acceptable range of the performance of mammography plus US screening has not yet been established.

Therefore, the purpose of this study is to show the result of an annual audit of supplementary screening US in a high-volume single institution and to analyze screening-detected cancers within a year and interval cancers.

MATERIALS AND METHODS

The Institutional Review Board approved of this retrospective study and informed consent was waived.

Institution and examinee characteristics

In our screening center, the volume of screening mammography exceeded 8000 women per year and the rate of the supplemental use of breast US reached 20% of total screening women in 2005, and these values have increased up to 15000 women and 70% in 2010.

During the year of 2006, a total of 8320 asymptomatic women, aged at least 30 years, underwent mammograms for breast screening at our screening center. Women who complained of signs or symptoms of breast cancers were excluded. Among them, 520 (6.3%) had positive mammographic results, [Breast Imaging Reporting and Data System (BI-RADS) category 0, 3, 4, 5] and 18 women (0.22% of the total, 3.5% of positive mammograms) were diagnosed as breast cancers based on mammographic findings. Among the 7800 women with negative mammographic results (BI-RADS category 1, 2), 1974 (25.3%) underwent supplemental screening US. US was performed in women who requested them, regardless of their risk factors. Among the 1974 women with mammography plus US screening, 1727 (87.5%) had pathologic data or follow-up breast imaging (US and/or mammography) performed at least one year after the screening examination of this year until the year 2011 (Fig. 1).

Screening procedure

US was performed including bilateral whole breasts and both axillary areas using US units (HDI 5000, Advanced Technology Laboratories, Bothell, WA, USA; IU22, Philips Healthcare, Bothell, WA, USA; Logic 700, General Electric Medical systems, Milwaukee, WI, USA), equipped with 5–12-MHz linear-array transducers. All US examinations were performed by one of five board-certified breast radiologists with at least 5 years of experience in breast US. In our institution, mammography was performed before US. The mammography was reviewed by the radiologists who performed US prior to examination. During US examinations, any abnormality including cysts, solid nodules, distortion-like abnormalities, or focal heterogeneity was sought and stored as representative images. If no abnormalities were seen, the representative normal parenchymal pattern of any plane was imaged quadrant-by-quadrant. US scans. Each US examination took approximately 10 minutes (range, 5–20 minutes). US findings were reported using BI-RADS US descriptors and the final assessment of the most suspicious lesions were scored according to the expanded 7 point BI-RADS scale: 1, negative; 2, benign; 3, probably benign; 4A, low suspicion; 4B, intermediate suspicion; 4C, moderate suspicion; 5, highly suggestive of malignancy.[22,23] BI-RADS 3 lesions included circumscribed masses, fat necrosis-like lesions, complicated or complex cyst-like lesions, artifact shadowing-like lesions, and scar-like lesions. The BI-RADS 2 assessment was given when the US performers ensured that the lesions were cysts, calcified fibroadenomas, or simple duct ectasia, or when any BI-RADS 3 lesions showed stability for more than 2 years since the previous screening examination. In addition, when the hypo- or isoechoic nodules were circumscribed, numbered more than 3 in one or both breasts, and similar appearances in shape and echogenicity to each other, some radiologists put the lesions into the BI-RADS 2 category.

Bilateral four-view mammograms were obtained using digital mammographic units (Senographe DS, General Electric Medical Systems, Milwaukee, WI, USA; Lorad Selenia, Hologic, Danbury, CT, USA). Mammographic reports included breast parenchymal composition and the mammographic BI-RADS

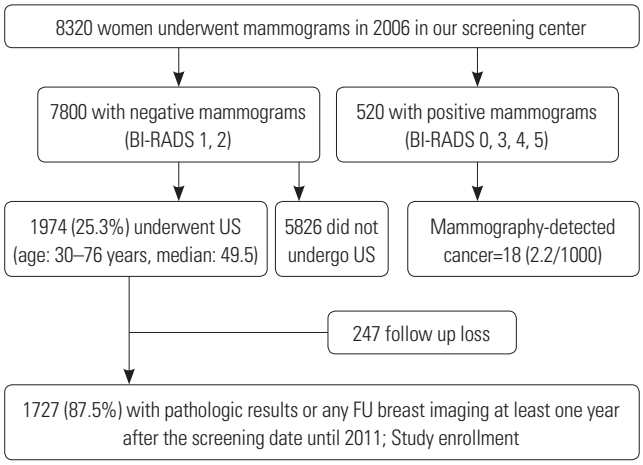

Fig. 1. Study population. BI-RADS, Breast Imaging Reporting and Data System; US, ultrasound; FU, follow up.

category. The visually-estimated overall mammographic breast composition was recorded according to the 4-point scale based on BI-RADS as follows: 1, almost entirely fat (<25% fibroglandular tissue); 2, scattered fibroglandular tissue (25–50% fibroglandular tissue); 3, heterogeneously dense (51–75% fibroglandular tissue); and 4, extremely dense (>75%). Composition grades 3 and 4 were defined as dense breasts. Mammographic BI-RADS category scores were given from 0 to 5.

Study parameters and statistics

Demographic data including age, a family history of breast cancers, personal history of previously treated breast cancers, mammographic parenchymal composition, and presence of previous breast US within 3 years in our institution were collected in these 1727 women using medical and radiologic records. The US BI-RADS category and the US findings of US-detected and interval cancers were reviewed through the radiologic database. The pathologic results of US-guided biopsy or subsequent surgery of the breast related with the screening results of the study year were investigated. To find out interval cancers, we linked our study list with the breast biopsy database for 2006 and 2007 and hospital's disease encoding system in our institution and searched for the cancers that appeared within a year (=365 days) after negative US results. We included the cancers that were revealed at the next screening 11 full months (=330 days) after the initial screening in the next screening-round detected cancers, and not into the interval cancer groups.

To audit US outcomes, BI-RADS 1 and 2 assessment was regarded as test-negative and BI-RADS 3, 4, or 5 assessment was regarded as test-positive. The recall rate was defined as BI-RADS 3, 4, and 5. The Reference standard for positive and negative outcomes was a combination of pathology and follow-up breast imaging until the year 2011. The most severe pathologic results represented the reference standard.

The positive outcomes were defined as a cancer diagnosed by a test-positive or a cancer diagnosed within 12 months after a test-negative. Sensitivity, specificity, and positive and negative predictive values (PPV, NPV) were calculated. PPV1 was defined as cancers among the recalled cases, and PPV2 was defined as outcomes of tissue diagnoses that result from positive screening examinations.[23] Minimal cancer was defined as invasive cancer ≤1 cm or ductal carcinoma *in situ* (DCIS).

We analyzed the US and pathologic findings of US-detected cancers and interval cancers.

RESULTS

Demographic data

The median age of the 1727 women was 49.5 years (age range: 30–76 years). The majority of the women were in their forties (n=763, 44.2%) or in their fifties (n=693, 40.1%), and the rest were in their sixties (n=143, 8.3%), 30's (n=107, 6.2%), and seventies (n=21, 1.2%) (Fig. 2). Among them, 23 (1.1%) women had a family history of breast cancer and 29 (1.5%) had a previous operation for breast cancer. At least one previous breast US within the previous three years were available in 762 of the 1727 (44.1%) women. Of the total subjects, 1349 (78.1%) showed dense mammographic composition. Dense breasts appeared in 88.8% (95/107) of women under the age of 40 years, 91.9% (701/763) of women aged 40 to 49 years, 69.7% (483/693) of women aged 50 to 59 years, 46.9% (67/143) of women aged 60 to 69 years, and 14.3% (3/21) of women aged 70 and over (Fig. 3).

BI-RADS category and performance

Among a total of 1727 women, BI-RADS 1 was found in 885 (51.2%), BI-RADS 2 in 742 (43.0%), BI-RADS 3 in 75 (4.3%), BI-RADS 4 in 25 (1.5%), and BI-RADS 5 in none (0%). Among the 25 lesions with BI-RADS 4, 24 were BI-RADS 4A and 1 was BI-RADS 4B (Table 1). Test-negative results occurred in 1627 (94.2%) and the recall rate was 5.8% (100/1727).

Among the 25 women with a BI-RADS 4 assessment, 19 underwent US-guided core needle biopsy, and 7 of them were to be determined carcinomas and 12 were benign (4, fibroadenomas; 6, fibrocystic changes; 2, adenosis). The remaining 6 pa-

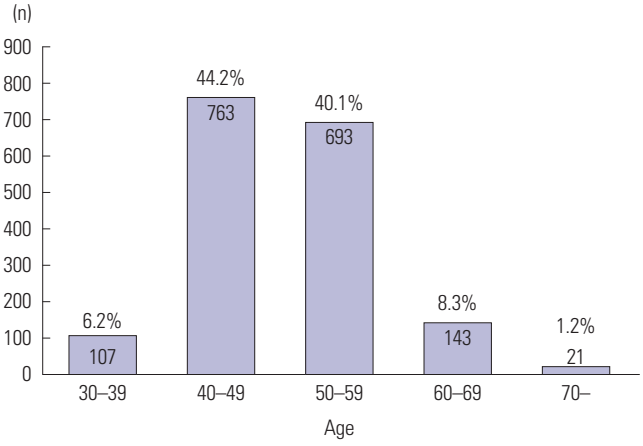

Fig. 2. Age distribution of study population.

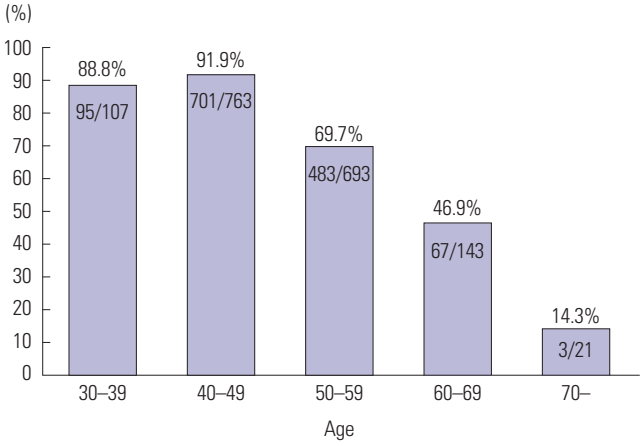

Fig. 3. Proportion of dense breasts according to the women's age.

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tients returned for imaging follow-up in 6 months, at which point their assessments were downgraded into benign US BI-RADS categories, and were further confirmed as benign with imaging follow-up for more than 1 year. Among the 75 women with BI-RADS 3 assessment, one out of 18 who received core needle biopsies within 8 months was ultimately confirmed as a cancer, and the remaining 57 were followed up with US or returned for subsequent screening at least once until January 2011. The 1626 women with BI-RADS 1 and 2 returned for subsequent screenings at least once until January 2011. One false-negative cancer (from BI-RADS 2) was diagnosed as cancerous within a year after the screening US.

The sensitivity, specificity, PPV1 and PPV2, and NPV were 88.9%, 94.6%, 8%, 28%, and 99.9%, respectively. The supplemental cancer detection yield was 4.6/1000 (8/1727). The minimal cancer rate and lymph node positivity were 62.5% (5/8) and 12.5% (1/8), respectively. The FN rate was 0.06% (1/1627) and the rate of interval cancers was 0.6/1000 (1/1727) (Table 2).

US-detected and interval cancers

Eight US-detected carcinomas were invasive ductal cancers (IDCs); 7 were ductal carcinoma *in situ*, and intraductal papilloma in 1 (Fig. 4, case 2 in Table 3). There were 6 stage I-cancer (T1N0 or T1N1mi) and 1 stage II-cancer (T2N0) under the AJCC 7th edition classification.[24] One US-miscategorized interval cancer was a stage I IDCs without lymph node metastasis (Table 3).

The size of malignant lesions on US ranged from 0.5 cm to 2.4 cm (median, 0.9 cm). All the US-detected carcinomas were accompanied by multiple (more than 3) nodules; six cases in bilateral and two in ipsilateral breasts. All the cancers were different from the accompanying benign-appearing nodules; 5 were different in both size and shape, two were different in size only, and one was different in shape only. The size difference between suspicious and the largest non-suspicious nodule was 0.1–1.8 cm (median; 0.45 cm) and a difference 0.2 cm or greater was regarded as being significant when a nodule was less than 1 cm. Five had previous US; 3 carcinomas newly appeared and 2 carcinomas (initial category 3 and 4a) increased since the previous screening US. One carcinoma initially assessed as BI-RADS category 3 has changed in its shape and size (from 0.8 cm to 1.2 cm) at the follow-up US 182 days after the initial US date (Fig. 5, case 8 in Table 3). Four had suspicious BI-RADS descriptors on the original report; microlobulated margin (n=1), irregular shape (n=2), and non-parallel orientation (n=1). Four had an oval shape on the report, but they showed an interval change in three and a complex cyst in one later.

One FN was initially assessed as BI-RADS category 2 because it was thought to be one of multiple fibroadenomas, as the patient had a prior history of multiple excisional biopsies due to benign masses and had the present mass was accompanied by multiple (more than 3) similar appearing nodules in bilateral breasts. However, it became palpable and US 188 days after the screening US date showed a size change from 0.7 cm to 1.7 cm (case 9 in Table 3). The cancerous nodule had shown a microl-

Table 1. US BI-RADS Category and Follow-Up Results in 1727 Women with Negative Mammography

BI-RADS category	No. (%)	Short-term FU (≤6 months)	US guided biopsy (≤6 months)	Cancer diagnosis
1	885 (51.2)	0	0	0
2	742 (43.0)	0	1	1
3	75 (4.3)	34	18	1
4	25 (1.5)	6	19	7
Total	1727 (100)	40	38	9

US, ultrasound; BI-RADS, Breast Imaging Reporting and Data System; FU, follow up.

Table 2. Comparison of Our Results with an Acceptable Range of Mammography on BI-RADS 2013

n=1727	US results	Acceptable ranges of diagnostic mammography performance
Recall rate	5.8% (100/1727)	5–12%
Supplemental cancer detection yield per 1000 cases	4.6	≥2.5
Sensitivity	88.9% (8/9)	≥75%
Specificity	94.6% (1626/1718)	88–95%
PPV1	8.0% (8/100)	3–8%
PPV2	28.0% (7/25)	20–40%
NPV	99.9% (1626/1627)	
Tumors found-stage 0 or 1	75% (6/8)	
Tumors found-minimal cancer*	62.5% (5/8)	>50%
Node-negative invasive cancers	87.5%	>80%

PPV, positive predictive values; NPV, negative predictive values; BI-RADS, Breast Imaging Reporting and Data System.
*Minimal cancer is invasive cancer ≤1 cm or ductal carcinoma *in situ*.

obulated margin (retrospectively, much different from the others) and it newly appeared since previous imaging.

Of the nine women with confirmed breast cancer within a year, six were 40–49 years old and three were 50–59 years, and all of them had heterogeneously or extremely dense breast parenchyma. Five of them had previous US examinations within 3 years and four did not. The cancer rate was not different between the women who had (6.6 per 1000) and did not have previous US (4.1 per 1000) (p=0.51).

DISCUSSION

Our study shows that screening US detected 4.6 additional cancers among 1000 women with negative mammography, a 4.3% rate of probable benign findings and a 5.8% recall rate in the population, 44.1% of whom had previous breast US. Our cancer detection yield is within the yield on the previous reports which was 2.7 to 5.3 cancers per 1000 women.[25] The cancer incidence might be different whether it is first-round screening or subsequent screening and according to the risk of different breast cancers. Berg, et al.[26] reported an average 4.3 cancer yield per 1000 for each of the 3 rounds of annual screening in the women, nearly 54% of whom had a personal history of breast cancers, which is one of the intermediate risk factors. Even though our patient group had much lower proportion of

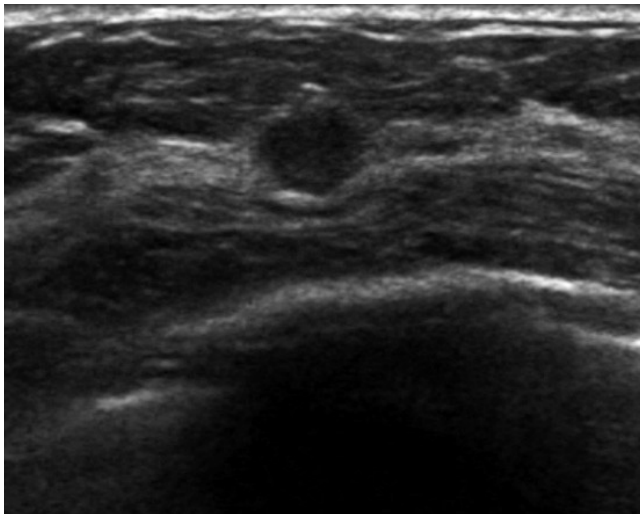

Fig. 4. A US-detected cancer in a 49-year-old woman that was initially assessed as BI-RADS category 4A (case 2 in Table 3). US shows an ill-defined oval hypoechoic mass in right breast and it was assessed as category 4A. The pathologic diagnosis was invasive ductal cancer with ductal carcinoma *in situ*. US, ultrasound; BI-RADS, Breast Imaging Reporting and Data System.

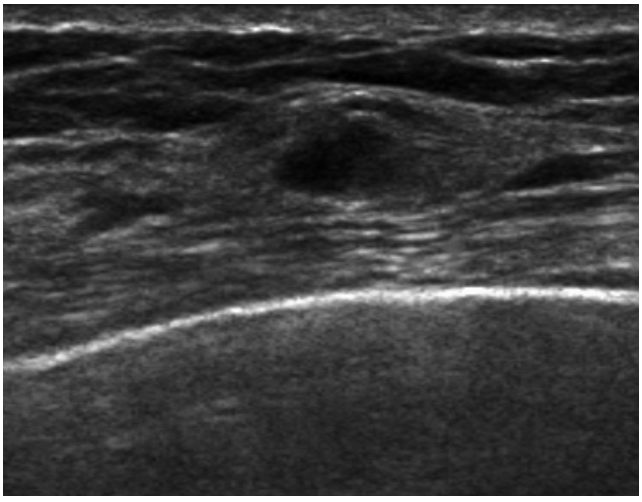

Fig. 5. A supplementary screening US detected cancer case in a 40-year-old woman that was initially assessed as BI-RADS category 3 (case 8 in Table 2). Initial supplementary screening US was assessed as BI-RADS 3 due to multiple small oval isoechoic nodules in both breasts. Diagnostic US after 6 months revealed that the mass in right breast increased in size up to 1.1 cm, and it was still not palpable. Both initial and follow-up mammograms were negative (not shown here). The pathologic diagnosis was invasive ductal cancer. US, ultrasound; BI-RADS, Breast Imaging Reporting and Data System.

Table 3. Analysis of 8 US-Detected (True-Positive) and 1 US-Miscategorized (False-Negative) Cancer

True Positive					
Case no.	**Age (yrs)**	**BI-RADS category**	**Previous US (yes/no)**		**Final pathology***
1	45	4a	No		Stage 0, 0.2 cm DCIS in intraductal papilloma
2	49	4a	Yes		Stage IB, 0.4 cm IDC with 1.5 cm DCIS, LN (1+, micrometastasis 700 um)
3	50	4a	No		Stage IA, 0.9 cm IDC, LN (-)
4	46	4b	No		Stage IA, 1 cm IDC, LN (-)
5	51	4a	Yes		Stage IA, 1.2 cm IDC, LN (-)
6	57	4a	Yes		Stage IIA, 3.4 cm IDC, LN (-)
7	46	4a	Yes		Stage IA, 0.9 cm IDC, LN (-)
8	40	3	No		Initial size on US (0.8 cm), Stage IA 1.1 cm IDC, LN (-): diagnosed after 182 days
False Negative					
Case no.	**Age (yrs)**	**BI-RADS category**	**Previous US (yes/no)**	**Initial size of mass on US**	**Final pathology**
9	41	2	Yes	0.7 cm	After 188 days, Stage IA 1.9 cm IDC, LN (-)

IDC, invasive ductal cancer; DCIS, ductal carcinoma *in situ*; LN, lymph node; BI-RADS, Breast Imaging Reporting and Data System.
*Staging complied with AJCC 7th edition.[24]

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women at intermediate risk, the cancer yield was similar.

One interval cancer had been miscategorized as BI-RADS 2. Because screening US was used as a supplemental test to enforce mammographic sensitivity and mammographically-evident cancers were excluded from the study population, the cancers had subtle, not overt, suspicious findings. Because these subtle findings are easily overlooked, clinicians should be attentive to interval appearance and interval growing. According to the recent report by Berg, et al.,[26] there were more interval cancers that were clinically detected or by MRI.

According to the ACRIN study, it is recommended that single or multiple oval hypoechoic masses, when identified on baseline screening, are included in BI-RADS category 3.[21] On the contrary, we put some of these lesions into BI-RADS category 2, if the radiologists observed no suspicious findings or no interval change since prior US and were assured of benignity. Moreover, 44.1% of our study population had undergone previous US. As a result, our recall rate was 5.8% and C3 rate was 4.3%, which was much lower than that of supplemental screening US in the published Western data which was between about 40–55%.[6,17,21,27,28] Heywang-Köbrunner, et al.[29] state that, due to the very high specificity and good reproducibility of mammography, no other method is accepted or used for screening of breast masses, which is supported by many other studies. However, results of this study show that screening US has a high specificity of 94.6%, which approximates the specificity range (88–95%) reported in mammography, supporting its role as a supplement to mammography. In addition, as reported in a recent study, the reproducibility of screening US may be enhanced by applying automated breast US or computer-aided detection.[30] Further prospective studies regarding the performances of screening US and application of these new techniques are anticipated in the future. In fact, the validation on the efficacy of US may depend on juggling between cost-effectiveness and diagnostic accuracy. Highly probable benign finding rates or false positive rates may be a barrier when the screening US is tested as one of clinical pathways.

Our study has several limitations. First, we excluded the women who did not visit our institution until December 2011 and the women with mammographic BI-RADS categories 0 and 3. Therefore, there could be more interval cancers which were misclassified as test-negatives in the women who underwent mammography plus US screening but were excluded. Second, almost half of our group had baseline screening US and all US examinations were performed by experienced radiologists, which may result in favorable screening US outcomes. The cost of handheld US is not so attractive to patients. Third, the benefit of screening US was only for the detection of early cancers, and did not consider mortality reduction. Multicenter, randomized, prospective studies are required to validate US efficacy as a second line screening tool, and the large-scale data are needed to establish the screening guideline.

In conclusion, screening US can detect 4.6 additional cancers per 1000 women whose breasts are mammographically dense. It showed satisfactory audit results, as compared with a mammography audit. The recall rate is acceptable when there is a baseline screening US.

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