Jikeikai Med J 2010 ; 57 : 127-35

Reliability of Computer-aided Ultrasonographic Diagnosis of Breast Masses : Receiver Operating Characteristic Study of the Effect on Observers' Accuracy in Characterizing Breast Masses

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ABSTRACT

Purpose : To evaluate the effect of computer-aided diagnosis (CAD) systems on observers' diagnostic performance in discriminating malignant and benign breast masses on ultrasonographic images.

Methods : The subjects were 50 patients in whom ultrasonography had revealed breast masses. The masses consisted of 16 malignant and 34 benign lesions. We examined whether the differentiation of malignant masses from benign masses of the breast with the CAD system alone is reliable. Receiver operating characteristic analysis was done to compare the observers' performance with and without CAD output. The participants were 3 novices and 3 experts in charge of breast ultrasonography.

Results : The area under the best-fit receiver operating characteristic curves (Az) of the CAD system alone was 0.8963. The mean Az values for all observers were 0.8705 ± 0.06 and 0.8949 ± 0.012 before and after the use, respectively, of the CAD system and did not differ significantly ($p = 0.085$). In the novices, the mean Az values before and after the use of the CAD system were 0.7890 ± 0.035 and 0.8888 ± 0.012 and differed significantly ($p = 0.016$). In the experts, the mean Az values were 0.8903 ± 0.024 and 0.8981 ± 0.013 and showed no significant difference ($p = 0.931$).

Conclusion : The results of our experiments show that the use of a CAD system allows novices to diagnose breast masses as accurately as do experts. (Jikeikai Med J 2010 ; 57 : 127-35)

Key words : computer-aided diagnosis, receiver operating characteristic observer study, breast masses, ultrasound, Breast Imaging-Reporting and Data System classification

INTRODUCTION

The number of patients with breast cancer has recently increased in Japan[1]. The diagnostic imaging procedures used to detect breast masses include mammography, ultrasonography (US), computed tomography, and magnetic resonance imaging.

In Japan, mammography is used mostly for screening[2,3]. However, this procedure has low diagnostic accuracy in high-density breasts and in young patients, and, thus, its ability to detect masses is limited[4-8]. Muttarak et al have reported that the mean diameter of lesions on specimens detectable with mammography was 3.03 ± 1.97 cm ; on the other hand, the mean diameter of lesions not detectable with mammography was 1.6 ± 0.54 cm. Muttarak et al. concluded that their ability to detect small lesions with on mammography was inadequate[9].

Received for publication, September 21, 2010

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On the other hand, the accuracy of US for diagnosing breast masses is high[10–16]. This procedure facilitates the detection of breast cancers that cannot be detected with mammography[17,18]. In particular, breast cancer can be detected with US alone in many patients in whom mammography has shown high-density breasts[19]. Also, a study involving experimental screening with US has suggested that this procedure increases the detection rate of cancer[6,7,19]. However, there have been no previous studies of the screening of breast masses with US. In Japan, a large comparative study (Japan Strategic Anti-cancer Randomized Trial) was started in 2007 to evaluate the usefulness of US for screening[20].

However, US has limitations of its own. The diagnostic accuracy of US depends on the examiner's skills and is difficult to control. Also, due to the low specificity of US, false-positive results are more frequent than with mammography[21]. Furthermore, the number of staff needed to evaluate US images is insufficient in Japan. In general, sonographers in Japan undergo training in US of the breast. However, if US breast screening were to be performed for all Japanese women older than 40 years, each accredited ultrasonographer (accredited by the Japan Society of Ultrasonic in Medicine) would be required to examine approximately 100 patients per day[22].

On the basis of this background, several recent studies have investigated the usefulness of computer-aided diagnosis (CAD) for breast US[23–25]. Unfortunately few studies have examined the quality of the observers' performance when breast US is used as a diagnostic tool[26].

In the present study, we examined the usefulness of breast US with CAD, which included image assessment by 6 observers, in diagnosing breast masses.

METHODS

This study was approved by the institutional review board of The Jikei University School of Medicine.

The subjects were 50 patients in whom breast US revealed breast masses from April 2007 through April 2009. In all patients, pathological diagnoses were made at our hospital. The images for analysis were selected retrospectively by a single radiologist. The images had been obtained from 16 patients with malignant lesions and 34 patients with benign lesions. Of the 16 patients with malignant lesions, 6 had papillotubular carcinoma, 2 had scirrhous carcinoma, 4 had solid-tubular carcinoma, 2 had mucinous carcinoma, 1 had invasive lobular carcinoma, and 1 had ductal carcinoma *in situ* (DCIS). The 34 patients with benign lesions included 5 with fibroadenoma, 1 with intracystic papilloma, and 28 who did not show any changes during follow-up for at least 2 years. These 28 lesions were anechoic and well-circumscribed. Posterior acoustic enhancement was found in all lesions on B-mode imaging method. Color Doppler imaging method revealed no vascularity. These imaging findings suggested that these lesions were cysts. The mean lesion diameter was 1.46 ± 0.85 cm (range, 0.4–3.8 cm), and the mean age of patients was 51.4 years (range, 26–89 years).

Experiment 1 : Assessing the reliability of differentiating benign from malignant masses with the CAD system alone

We evaluated whether the differentiation of malignant from benign masses of the breast tissue with CAD system alone is reliable. The CAD system we used was the B-CAD system (Medipattern Corp., Ontario, Canada). When establishing the extent of the lesion and proceeding to "analysis," the following 8 features were analyzed according to the Breast Imaging-Reporting and Data System (BI-RADS) criteria on the CAD system for the classification of lesions (5 grades)[27]:

1. Shape (oval, round, irregular)
2. Orientation (parallel, not parallel)
3. Margin (circumscribed, not circumscribed; indistinct, angular, microlobulated, spiculated)
4. Lesion boundary (abrupt interface, echogenic halo)
5. Echo pattern (anechoic, hyperechoic, complex, hypoechoic, isoechoic)
6. Posterior acoustic features (no posterior acoustic features, enhancement, shadowing, combined pattern)

7. Surrounding tissue (duct changes, Cooper's ligament changes, edema, architectural distortion, skin thickening, skin retraction/irregularity)
8. Calcifications (macrocalcifications, microcalcifications outside of mass, microcalcifications in mass)

This system is summarized below (Fig. 1).

All US examinations were performed with the LOGIQ7 US scanner (GE Healthcare, Inc., Japan) with a 12-Mhz linear probe.

The images to be analyzed were chosen from a selection of US images by an independent radiologist who otherwise did not participate in the study. The lesions were classified according to the BI-RADS criteria. By comparing results and histopathological findings, we examined the reliability of the CAD system as a tool to differentiate benign and malignant breast masses.

Experiment 2 : An experiment involving image assessment by 6 observers

An experiment involving image assessment by 6 observers was performed with a 5-grade confidence-rating method based on US findings of the mammary gland evaluated according to the BI-RADS criteria and category classification.

The observers who participated in this experiment consisted of those who were not routinely in charge of breast US (novices : 2 sonographers and 1 radiology resident) and those who were routinely in charge of breast US (experts : 3 sonographers accredited by the Japan Society of Ultrasonics in Medicine).

The mean number of years of experience with breast US for novices and experts were 1.4 years (range, 0.2-2 years) and 5.7 years (range, 3-9 years), respectively. All observers assessed the ultrasonograms independently.

The US images were first presented without the CAD output. After each observer marked the initial category of confidence, the computer output for the results regarding the category was shown (results of Experiment 1). Then, each observer had the chance to change the previously indicated category level.

The observers were not informed of the patient's age, medical history, or history of pregnancy, because

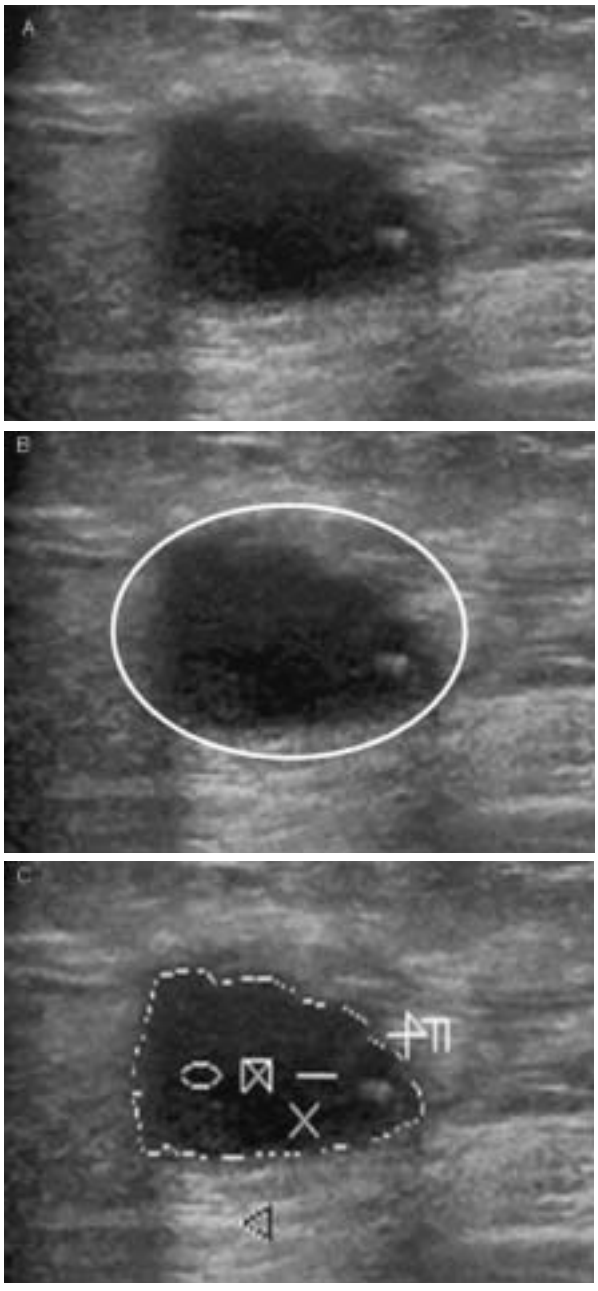

Fig. 1. Explanation of the CAD system
US images are input (A). When the extent of a lesion on a selected US image of the breast lesions is outlined (B), the candidate lesions are automatically visualized on the CAD system. As several candidate lesions are presented, the examiner must select the most accurate candidate. Simultaneously, if there are no adequate candidates, the examiner can manually adjust the outline on the CAD system. When the lesion extent has been established, US findings are analyzed with the CAD system (C).
Throughout the experiment, 1 radiologist selected the US image and outlined the lesion extent for CAD analysis.

these are possible risk factors for malignancy.

Statistical analysis

Receiver operating characteristic (ROC) analysis was performed to compare the observers' performance with and without CAD output in distinguishing benign from malignant breast masses. An ROC curve was prepared on the basis of the category chosen by the observers, employing the ROCKIT curve-fitting program (LABMRMC : Charles E. Metz, University of Chicago, Chicago, IL, USA) developed by Metz et al.[28]. The area under the best-fit ROC curves (Az) plotted in the unit square was calculated for each fitted curve. The statistical significance of the difference between the ROC curves obtained without CAD output and those obtained with CAD output was tested using the same computer program. The significance of the difference between the Az values was determined. The difference calculated was between the novices who performed assessments with or without the CAD system and the experts who performed assessments with the CAD system. The difference was also calculated between the novices and the experts who both performed the assessments without the CAD system. Evaluation of these differences was tested using the paired t-test. Statistical analyses were performed with a statistical software package (SPSS, version 11.0 ; SPSS Inc., Chicago, Ill, USA). P values of less than 0.05 were considered to indicate a significant difference.

We also calculated the sensitivity, specificity, and positive predictive values for the diagnosis of breast masses determined by all observers.

RESULTS

The mean size of the lesions selected for this experiment was 1.46±0.85 cm. The mean size of the 16 malignant lesions was 1.79±0.82 cm. On the other hand, the mean size of the 34 benign lesions was 1.32±0.85 mm.

First, we examined the database used in the experiments involving image assessment (Fig. 2A, B). Of the 34 benign lesions, 18 were misdiagnosed by 1 or more novices, and 18 were misdiagnosed by 1 or more experts. Of the 16 malignant lesions, 13 were misdiagnosed by 1 or more novices, and 3 were misdiagnosed by 1 or more experts.

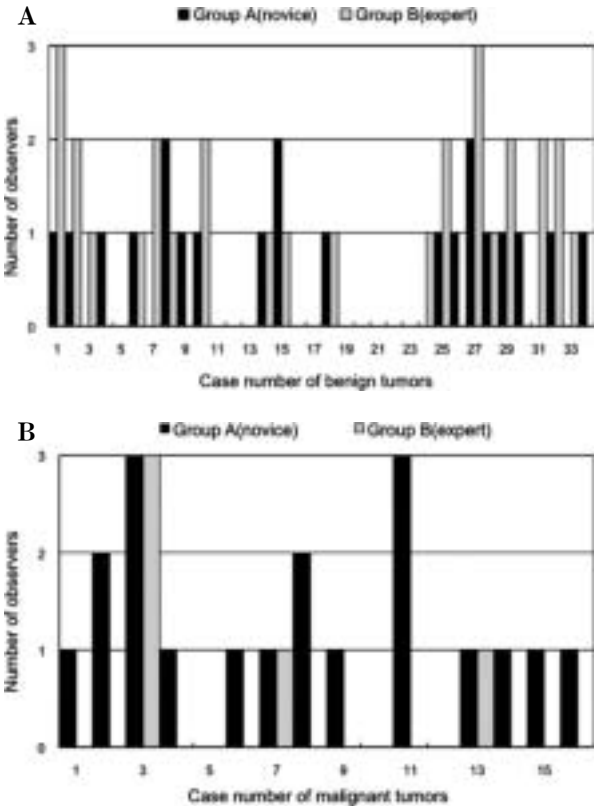

Fig. 2. Number of observers who could not accurately diagnose breast masses without the CAD system The graph shows the number of observers who incorrectly indicated 50 breast masses as 34 benign lesions (A) or 16 malignant lesions (B) without the CAD system.

Experiment 1 : Assessing the reliability of differentiating benign from malignant masses with the CAD system alone (*Table 1*)

When the CAD system alone was used, the sensitivity, specificity, and positive predictive value were 87.5%, 70.6%, and 58.3%, respectively. For differential diagnosis by all observers, they were 74.0%, 75.5%, and 60.1%, respectively. In the novices, the sensitivity, specificity, and positive predictive value were 58.3%, 79.4%, and 59.7%, respectively. In the experts, they were 89.6%, 71.6%, and 60.5%, respectively. When the CAD system alone was used, the Az value was 0.8963 (Fig. 3).

Table 1. Sensitivity, specificity, and positive predictive values for the observers Groups A/B, overall and the CAD system alone

Statistic	Group A (Novice)	Group B (Expert)	All observers	CAD System
Sensitivity	58.3	89.6	74.0	87.5
Specificity	79.4	71.6	75.5	70.6
Positive predictive value	59.7	60.5	60.1	58.3

Note. -All numbers are percentages.
-The number of cases is 50. The number of all observers is 6 (novice 3, expert 3).

Table 2. Az values of the observers (Groups A and B) before and after introduction of the CAD system

Observer	Az value without CAD Output	Az value with CAD Output
Group A (novice)		
1	0.8286	0.9033
2	0.7583	0.8765
3	0.7888	0.8859
Average*	0.7890±0.035	0.8888±0.012
Group B (expert)		
1	0.8672	0.8945
2	0.9147	0.9033
3	0.8889	0.8798
Average*	0.8903±0.024	0.8981±0.013
Average for all observers*	0.8705±0.06	0.8949±0.012

*Data are the mean ±standard deviation

Experiment 2 : An experiment involving image assessment by 6 observers (*Table 2*)

The mean Az values for all observers were 0.8705±0.06 and 0.8949±0.012 before and after, respectively, the use of the CAD system and did not differ significantly ($p=0.085$) (Fig. 3). In the novices, the mean Az values were 0.7890±0.035 and 0.8888±0.012 before and after, respectively, the use of the CAD system and showed a significant improvement ($p=0.016$) (Fig. 4A). In the experts, the mean Az values were 0.8903±0.024 and 0.8981±0.013, respectively, and did not differ significantly ($p=0.931$) (Fig. 4B).

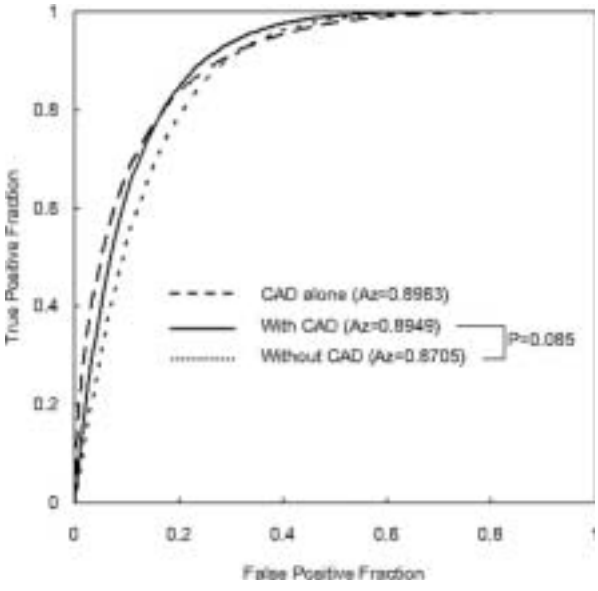

Fig. 3. Mean ROC curves for all observers ($N=50$ for each test)
Mean ROC curve for all observers who distinguished between benign and malignant breast masses with and without the CAD output and ROC curve for the CAD output alone.
The mean Az value for all observers increased from 0.8705±0.06 without the CAD system to 0.8949±0.012 with the CAD output. The difference was not significant ($p=0.085$). The Az value of the CAD system alone was 0.8963.

Discussion

The incidence of breast cancer has recently increased in Japan[1] and emphasizes the importance of breast cancer screening. In Japan, mammography is used mostly for breast cancer screening. However, the detection rate of breast cancer with mammography is low in young patients and patients with high-density breasts[4-8].

On the other hand, the sensitivity of breast US for

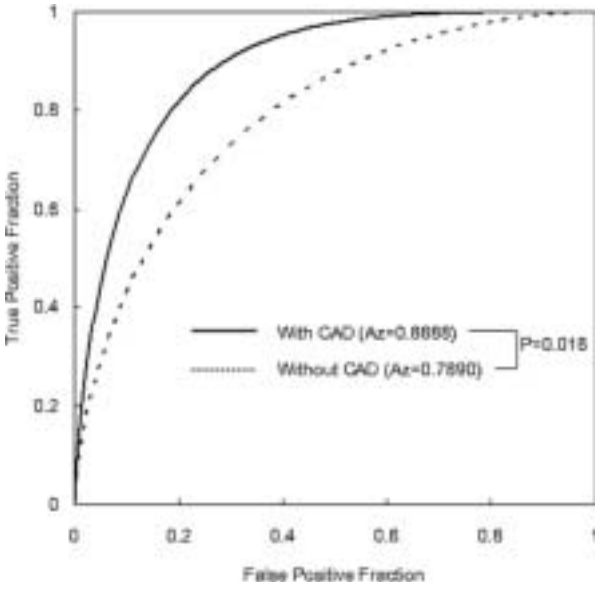

Fig. 4A. Mean ROC curves of novices ($N=50$ for each test)
Mean ROC curve for novices who distinguished between benign and malignant breast masses with and without the CAD output. The mean Az values obtained with and without the CAD output were 0.8888 ± 0.012 and 0.7890 ± 0.035, respectively. The difference was significant ($p=0.016$).

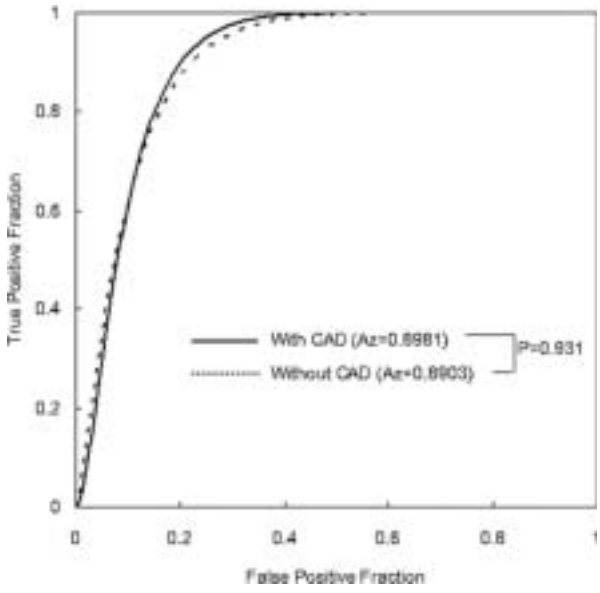

Fig. 4B. Mean ROC curves of experts ($N=50$ for each test)
Mean ROC curve for experts who distinguished between benign and malignant breast masses with and without the CAD output. The mean Az values obtained with and without the CAD output were 0.8981 ± 0.013 and 0.8903 ± 0.024, respectively. The difference was not significant ($p=0.931$).

breast masses is high[10–16], but its diagnostic capacity depends on the examiner's skills. The numbers of radiologists, physicians skilled in the US diagnosis of breast masses, and sonographers who are skilled in breast US are limited[22]. Under current conditions, breast screening with US in Japan may be impractical and as a result, an automatic breast examination device was recently developed[25,29]. The introduction of this device may contribute to the widespread application of breast US for screening.

We believe that the introduction of a CAD system is necessary for breast cancer screening by US in Japan to overcome the shortage of radiologist and skilled sonographers.

In our experiments, without the CAD system, of the 16 malignant lesions, 13 were misdiagnosed by 1 or more novices, and 3 were misdiagnosed by 1 or more experts. Therefore, the images selected in these experiments may have been technically difficult for the novices to diagnose. This can be explained by the small size of the lesions selected.

The mean size of lesions selected for this experiment was 1.46 ± 0.85 cm. The mean size of the 16 malignant lesions was 1.79 ± 0.82 cm, and that of the 34 benign lesions was 1.32 ± 0.85 cm. For these lesions, the CAD system alone showed a sensitivity of 87.5%.

In a series reported by Muttarak et al the mean diameter of lesions detectable with mammography was 3.03 ± 1.97 cm. On the other hand, the diameter of lesions that were not detectable with mammography was 1.6 ± 0.54 cm. They concluded that their ability to detect small lesions with mammography was inadequate[9].

Therefore, on the basis of our results, we believe that the use of US with the CAD system is superior to mammography as a screening method in terms of the qualitative diagnosis of small breast lesions.

The results of our experiments involving image assessment by 6 observers showed that the use of the CAD system improved the novices' diagnostic ability for breast masses but not that of experts. Therefore, the use of the CAD system may overcome to some

degree the limitation of accuracy control in US and shortage of staff.

On the other hand, when the experts used the CAD system, their diagnostic capacity was unchanged. In these experiments, a single US image was presented at a time to the observers. However, if the patient's background variables, such as age, reproductive history, parity, and breast-feeding history, are presented for image assessment, they may improve the observers' diagnostic capacity.

With regards to accuracy, the specificity and positive predictive value of the CAD system alone were low. It has previously been reported that the lesion border selected for CAD analysis affects the CAD output[24]. Therefore, the selection of the lesion outline on the image to be analyzed is important. In addition, our present experiment suggests that the results of analysis with the B-CAD system depends heavily on the shape and margin recognized. To improve the performance level of the CAD system alone, we must evaluate the US images by appropriately adjusting such parameters as gain, focus, and the grade of speckle reduction by spatial compounding condition.

In this experiment, changes in the outcome category influencing treatment were made by novices after using the CAD system for a mean of 6 lesions (range, 5 to 8 lesions). In contrast, experts made such changes for only a mean of 1 lesion (range, 0 to 2 lesions). On the basis of these results, we conclude that novices are more easily influenced by the results of the CAD output than are experts. In this experiment, the specificity for diagnosis with the CAD system alone was low, suggesting that the possibility of false-positive lesions may increase. This can be explained by the novices' tendency to increase sensitivity (so as not to miss a malignancy), resulting in more false-positives. These results suggest the necessity of considering not only the nature of the CAD system but also the screener's tendencies.

The present study had several limitations. One limitation was the observers' selection. In this study, sonographers and a radiology resident were included as observers. Another limitation was the image selection. The pathological diagnosis was not obtained for all lesions used in these experiments. A third limitation was the conditions of the experiments. In these experiments, a single US image was presented at a time without clinical information to the observers. The situation did not match the actual clinical setting. A fourth limitation was that we evaluated a few cases of DCIS, an early stage of breast cancer. DCIS is usually detected as a cluster of microcalcifications that do not create masses. However, the diagnostic accuracy of US for calcified lesions is low; therefore, in the present study, we evaluated several cases of DCIS. Although the purpose of screening is to detect cancers at an early stage, we should attempt to evaluate the diagnostic accuracy of the CAD system for images of DCIS.

Conclusion

The use of the CAD system significantly improves a novice's ability to diagnose breast masses but has no marked effect of the ability of an expert. Therefore, the use of the CAD system may be able to overcome, to some extent, the problem of manpower shortage for US breast screening and improve the overall quality of screening, especially by novices. The US diagnosis with the CAD system is also more sensitive than conventional mammography for small lesions.

To improve the performance of CAD systems and the ability of experts to diagnose breast masses, further investigation is needed. More detailed investigations into the effect of sonographers' tendencies, clear guidance on the use of the CAD system, and a second experiment with a larger sample size will give us a better understanding of the practicality of implementing the use of CAD systems clinically.

Acknowledgments: The authors are grateful to Dr. Lorenzo L. Pesce (Kurt Rossmann Laboratories for Radiologic Image Research, Department of Radiology, University of Chicago Medical Center, Chicago, IL, USA) for providing the computer program (LABMRMC, version 1.4B3) for statistical analysis and giving helpful advice regarding the statistics.

We also thank Dr. Kazuo Awai (Hiroshima University) and Dr. Tomohiro Kayama (The Jikei Uni-

versity School of Medicine) for their advice.

CONFLICT OF INTEREST STATEMENT

Authors have no conflict of interest.

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