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● *Original Contribution*

1000-CASE READER STUDY OF RADIOLOGISTS' PERFORMANCE IN INTERPRETATION OF AUTOMATED BREAST VOLUME SCANNER IMAGES WITH A COMPUTER-AIDED DETECTION SYSTEM

Xiaojing Xu, Lingyun Bao, Yanjuan Tan, Luoxi Zhu, Fanlei Kong, and Wei Wang
Department of Ultrasound, First People's Hospital of Hangzhou, Affiliated Hangzhou Hospital of Nanjing Medical University, Nanjing.261 Huansha Road, Hangzhou 310006, China

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Abstract—The objective of our study was to assess, in a reader study, radiologists' performance in interpretation of automated breast volume scanner (ABVS) images with the aid of a computer-aided detection (CADe) system. Our study is a retrospective observer study with the purpose of investigating the effectiveness of using a CADe system as an aid for radiologists in interpretation of ABVS images. The multiple-reader, multiple-case study was designed to compare the diagnostic performance of radiologists with and without CADe. The study included 1000 cases selected from ABVS examinations in our institution in 2012. Among those cases were 206 malignant, 486 benign and 308 normal cases. The cancer cases were consecutive; the benign and normal cases were randomly selected. All malignant and benign cases were confirmed by biopsy or surgery, and normal cases were confirmed by 2-y follow-up. Reader performance was compared in terms of area under the receiver operating characteristic curve, sensitivity and specificity. Additionally, the reading time per case for each reader was recorded. Nine radiologists from our institution participated in the study. Three had more than 8 y of ultrasound experience and more than 4 y of ABVS experience (group A); 3 had more than 5 y of ultrasound experience (group B), and 3 had more than 1 y of ultrasound experience (group C). Both group B and group C had no ABVS experience. The CADe system used was the QVCAD System (QView Medical, Inc., Los Altos, CA, USA). It is designed to aid radiologists in searching for suspicious areas in ABVS images. CADe results are presented to the reader simultaneously with the ABVS images; that is, the radiologists read the ABVS images concurrently with the CADe results. The cases were randomly assigned for each reader into two equal-size groups, 1 and 2. Initially the readers read their group 1 cases with the aid of CADe and their group 2 cases without CADe. After a 1-mo washout period, they re-read their group 1 cases without CADe and their group 2 cases with CADe. The areas under the receiver operating characteristic curves of all readers were 0.784 for reading with CADe and 0.747 without CADe. Areas under the curves with and without CADe were 0.833 and 0.829 for group A, 0.757 and 0.696 for group B and 0.759 and 0.718 for group C. All differences in areas under the curve were statistically significant (*$p < 0.05$*), except that for group A. The average reading time was 9.3% (*$p << 0.05$*) faster with CADe for all readers. In summary, CADe improves radiologist performance with respect to both accuracy and reading time for the detection of breast cancer using the ABVS, with the greater benefit for those inexperienced with ABVS. (E-mail: jttj571@sina.com) **© 2018 World Federation for Ultrasound in Medicine & Biology. All rights reserved.**

Key Words: **Automated, Ultrasound, Computer-aided detection, Image interpretation.**

INTRODUCTION

Breast cancer is the most common form of malignant tumor among women worldwide. The early detection and accurate diagnosis of breast cancer have been improved with better diagnostic techniques (Bock et al. 2011).

Mammography is the primary modality for breast cancer screening. However, its sensitivity in detecting breast cancer in dense breasts is lower in approximately 35% to 40% of the screening population with dense breasts. The majority of Chinese women have small, dense breasts. In addition, women with dense breast tissue have an up to four- to sixfold increased risk of developing breast cancer compared with women with fatty breast tissue (Boyd et al. 2011; Martin et al. 2010; Pisano et al. 2008; Yahgjyan et al. 2011). To improve cancer detection and diagnosis in women with dense breasts, breast ultrasonography (US) is a

Address correspondence to: Lingyun Bao, Department of Ultrasound, First People's Hospital of Hangzhou, Affiliated Hangzhou Hospital of Nanjing Medical University, Nanjing.261 Huansha Road, Hangzhou 310006, China. E-mail: jttj571@sina.com

well-established adjunct modality (Kelly et al. 2010). Ultrasound has been reported to improve breast cancer detection in women with dense breast tissue (Hooley et al. 2012). But there are a broad range of skill levels in performing handheld ultrasound, with operator variability and dependence and a lack of standardization, which may lead to an increased number of false-positive results. One study reported that operator dependence can be reduced through standardization of the imaging technique and operator training (Berg et al. 2012). However, without standardization and improvements in workflow, widespread integration into the screening environment is not feasible (Giger et al. 2016). The automated breast volume scanner (ABVS) can scan the entire breast in a standard manner and send all images to an ABVS workstation. The images acquired in the transverse plane are reconstructed in three dimensions to allow interpretation in the coronal plane, which has proved valuable in diagnosis and differential diagnosis in breast cancer. The ABVS has been found to have benefits in standardization of image acquisition and quality, high reproducibility for lesion characterization and ease of understanding for clinicians (Jiang et al. 2015; Tozaki and Fukuma 2012). However, the interpretation of ABVS images remains associated with certain degree of missed diagnoses and false-negative interpretations (Dromain et al. 2013) influenced by artifacts, viewing area and visual fatigue and distraction of the radiologist.

Computer systems can aid radiologists in both detection and diagnosis. A computer-aided detection (CADe) system has the potential to help readers quickly locate potential lesions without sacrificing specificity (Singh et al. 2011). CADe systems have been developed extensively for mammography and 2-D ultrasound (Kuroki et al. 2008; Meeuwis et al. 2010; Wei et al. 2012). Previously, CADe systems developed for the ABVS achieved a standalone sensitivity ranging from 0.65 to 0.81 at one false positive per volume (Kozegar et al. 2017; Tan et al. 2013; van Zelst et al. 2017). The purpose of our study was to compare the performance of readers in classifying breast lesions as malignant or benign with and without CADe in interpretation of ABVS images.

METHODS

This study was approved by the institutional review board of the First People's Hospital of Hangzhou and is compliant with the Health Insurance Portability and Accountability Act. Informed consent was waived. Study authors had sole control of the study data.

Automated breast volume scanner

The automated breast volume scanner (ABVS, Siemens Healthcare, Siemens Medical Solutions,Mountain View, CA, USA) acquires B-mode ultrasound images by scanning a linear transducer in an automated fashion over the breast to obtain 3-D volumetric data. The transducer has 768 elements and operates in the frequency range of 6–14 MHz. The transducer has a width of 15.4 cm, automatically scans a distance of 16.8 cm and images up to a depth of 5.4 cm. The scan time is 1 min for one pass. Two to three passes per breast were acquired depending on the size of the breast. Up to 350 2-D B-mode images are obtained from each scan pass, and these images are reconstructed and presented on a computer workstation with a standard-resolution flat panel display in transverse, coronal and sagittal slices. The image acquisition parameters are automatically set by the system; the operator chooses only the breast size based on cup size, and the system sets the scan depth accordingly. In our hospital, the ABVS system is checked and recalibrated annually by a third party to maintain quality.

CADe system for automated breast ultrasound

The CADe system used in this study was the QVCAD system from QView Medical, Inc. (Los Altos, CA, USA). It is designed to aid radiologists in identifying suspicious areas in ABVS images. The CADe results are presented to the reader simultaneously with the ABVS images; that is, the radiologist reads the ABVS images concurrently with the CADe results.

The CAD-generated output from the CADe system is presented in two forms:

1. A CADe Navigator image of each ABVS volume or view, which is a modified minimum-intensity projection of the coronal image data with certain areas of interest highlighted by enhancement of dark areas and/or radial spiculations and retraction patterns, so that lesions appear as dark holes and spiculations and retraction patters appear as bright lines on the Navigator image. The enhancements may include both malignant and benign lesions.
2. CADe marks are colored circles around areas of interest and displayed over the CADe Navigator image and over the corresponding original ABVS images. CADe marks are intended to highlight potentially malignant lesions. The sensitivity threshold of the CADe marker is set at 0.2 false-positive marker per volume or view. In this configuration, 0.2 false-positive marker per volume means that the CADe system is configured so that, on average, it marks two regions that are false positives for every 10 normal volumes.

The user is instructed to use both the CADe Navigator image and the CADe marks in support of their review of the ABVS case. See Figures 1 and 2 for examples of a CADe Navigator image and CADe marks.

The CADe Navigator image is a static roadmap displayed concurrently with the original ABVS images