Concurrent-Read CAD helps streamline Automated Breast Ultrasound (ABUS) interpretation

By Dr. Yulei Jiang

Screening mammography remains the main imaging modality for breast cancer screening in asymptomatic and average risk women. Its effectiveness, however, is reduced in women whose breast tissue is heterogeneously dense or extremely dense, because dense breast tissue makes it more difficult for breast cancer to be detected in mammograms. In the US, about 35 states have legislations that require health care providers to inform women about dense breast tissue. In this way women can be informed not only of the increased risk of cancerous lesions being missed in screening mammograms because of the masking effect of dense breast tissue, but also of the increased risk of developing breast cancer, associated with having dense breast tissue [1].

Breast ultrasound can be a supplement to mammograms in breast cancer screening of women with dense breast tissue [2, 3]. Screening breast ultrasound can detect breast cancers not seen in screening mammograms. However, hand-held breast ultrasound faces challenges for screening. Its operator dependence and increased demand on radiologists' involvement make it challenging in screening applications.

ABUS AS ADJUNCT FOR BREAST CANCER SCREENING

Automated breast ultrasound (ABUS) was first approved as an adjunct to mammography for breast cancer screening by the US Food and Drug Administration (FDA) in 2012. ABUS provides automated scanning of the patient, thereby eliminating operator dependence—a major constraint of hand-held breast ultrasound. Volumetric B-mode image datasets are obtained for each patient in about 15 minutes. Radiologists interpret ABUS images of the entire breast volume together with standard screening mammograms to identify potential abnormalities that need to be worked up.

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As an adjunct to screening mammography, ABUS has been shown to be able to increase the number of breast cancers detected from mammograms alone [4, 5]. A retrospective observer performance study of 17 Mammography Quality Standard Act (MQSA) certified US radiologists who interpreted 185 first-generation ABUS images (somo•v, GE Healthcare) showed that interpreting screening mammograms and ABUS images together significantly increased the area under the ROC curve (AUC, from 0.72 to 0.82, $p < 0.001$), indicating improvement in diagnostic accuracy. The sensitivity increased significantly from 58% to 74% for 52 cases with cancer in the study ($p < 0.001$). Specificity did not change significantly (from 78% to 76%, $p = 0.5$) for 133 cases without cancer in the study. Clinical studies have also shown that ABUS used as an adjunct to screening mammography increases cancer yield in screening [6-8].

CHALLENGES TO ABUS INTERPRETATION

Clinical and reader studies indicate that it takes 2.9 to 9.5 minutes to interpret an ABUS dataset [6, 7, 9, 10]. and this does not include comparison of any previous images. The volumetric nature of the images, the complexity of the B-mode image slices, and the efforts needed from radiologists to dismiss image artifacts and pseudo abnormalities, contribute to the length of time required to read ABUS cases. While this might be seen as an improvement over screening hand-held breast ultrasound if the radiologist scans the patient, it nonetheless represents a significant demand on radiologists' time and the clinical workflow.

CONCURRENT-READ CAD

Computer-aided diagnosis (CAD) devices were first introduced into clinical practice for interpretation of screening mammograms. Today, CAD devices are widely used in the interpretation of screening mammogram, and they are currently the subject of intense interest fuelled by recent advances in deep learning and artificial intelligence. QVCAD (from QView Medical, CA, USA) is a new CAD device for interpretation of screening ABUS images. The US FDA approved QVCAD for screening ABUS somo•v images in 2016 and subsequently approved QVCAD for screening ABUS Invenia images (GE Healthcare) in 2017.

CAD systems in clinical use today function typically as what is known as a "second reader." These systems are invoked after a radiologist completes the interpretation of the images, and the role of the CAD system is to make sure that the radiologist did not overlook suspicious findings that the computer has identified. The radiologist is then supposed to look at findings that the computer identifies to make sure that they are not suspicious.

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If a finding were indeed found to be suspicious, then the radiologist's interpretation would be changed because of the computer finding. In most situations, radiologists determine that findings identified by the computer are in fact not suspicious, and while it is easy to come quickly to this conclusion, nevertheless a look back at the images is still required.

QVCAD does not function in the same way as other second-read CAD systems. Instead, it is invoked as soon as a radiologist begins to interpret ABUS images. Case presentation begins with 2-dimensional synthetic images linked to the raw 3-dimensional ABUS volume dataset. These 2-dimensional images, are called navigator images and are a part of the QVCAD system. They provide the radiologist with a quick overview of the case without having to scroll through the 3-dimensional volumes. In addition, the computer findings are included in the navigator image, making them available to the radiologist at the outset.

Once the radiologist identifies potential areas of interest, he or she then goes into the 3-dimensional volumes to investigate focal areas. Case interpretation is possibly less dependent on meticulous survey of the 3-dimensional volumes than reading ABUS images without QVCAD. This is a fundamentally different workflow from second-read CAD systems. This concurrent-read paradigm makes it possible to save interpretation time, whereas with second-read systems reducing additional interpretation time is the best one could hope for.

In addition, for second-read CAD systems, radiologists must be vigilant against additional false-positives caused by not effectively dismissing non-lesion findings that the computer identifies.

For a concurrent-read CAD system, the effect on sensitivity is paramount. Because the computer findings are presented to radiologists at the outset of case review, thereby potentially influencing their expectation of the case, radiologists must guard against missing cancers that they otherwise would detect, to ensure that any benefit of the concurrent-read CAD system does not come at a cost of reduced sensitivity.

QVCAD HELPS ABUS INTERPRETATION: PERFORMANCE STUDY

To evaluate the effect of QVCAD on reader performance in interpreting screening ABUS cases, we conducted a retrospective observer performance study with 18 MQSA-certified US radiologists and 185 first-generation ABUS cases (somo•v) [11]. The study was designed to compare reader performance, in terms of both diagnostic accuracy and interpretation time, in reading screening ABUS cases with and without QVCAD. Screening mammograms were not included in this study. All cases were from screening of asymptomatic women with BI-RADS C (heterogeneously dense) or D (extremely dense) breast tissue density. The study included many more cancer cases than typically seen in a screening setting so that reader accuracy on cancer cases can be measured

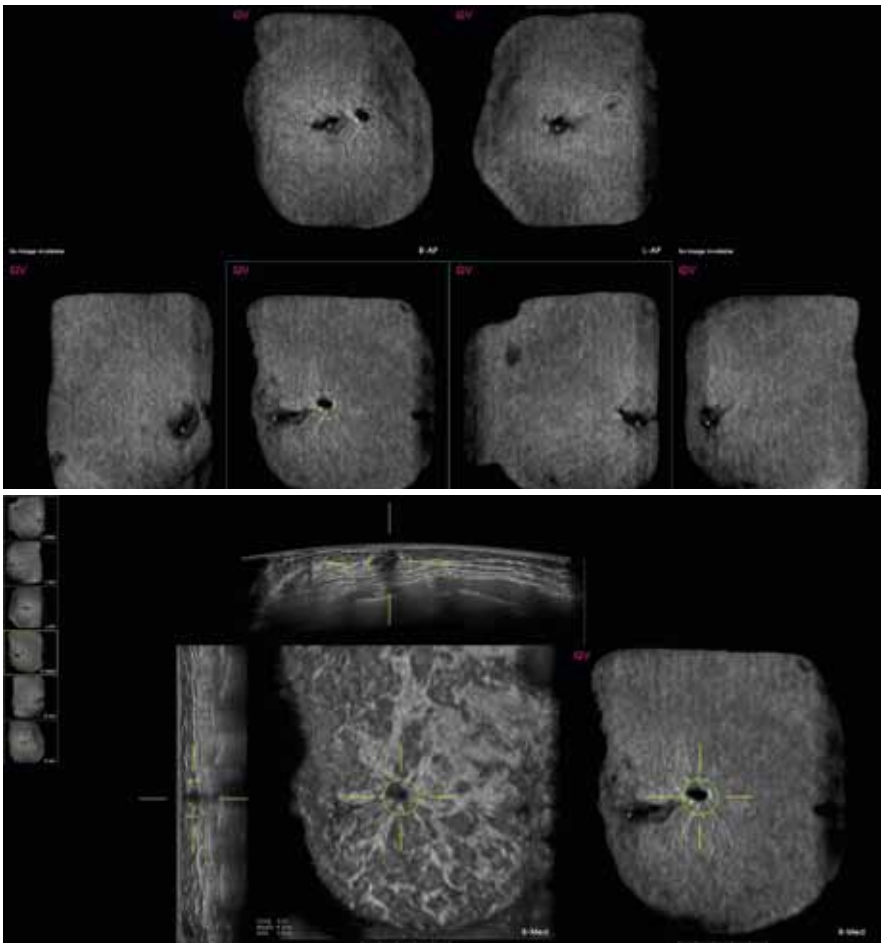

Figure1. QVCAD navigator images (top) showing a 2-dimensional summary of the raw 3-dimensional ABUS dataset superimposed with computer findings displayed as color circles and artificially dark areas of possible speculated lesions. Review of the volumetric slices are linked (bottom)

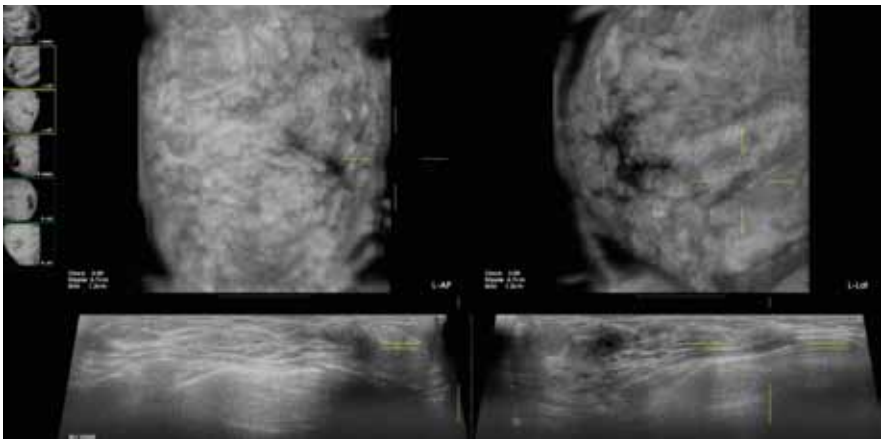

Figure 2. To review a 3-dimensional ABUS dataset without QVCAD, a radiologist review transverse, coronal, and sagittal slices of six volumes.

with reasonably good precision, as is commonly done in retrospective reader performance studies. Each reader read each case twice, once without and once with QVCAD, separated by about four weeks. Their interpretation accuracy with QVCAD was compared with their interpretation accuracy without QVCAD, and their interpretation time with QVCAD was compared with their interpretation time without QVCAD.

For diagnostic accuracy, measured in terms of AUC, the performance averaged across all readers was statistically non-inferior when readers interpreted ABUS cases with QVCAD as compared with when they read the same ABUS cases without QVCAD. The AUC value was 0.85 with QVCAD and 0.83 without QVCAD, with $p < 0.01$ for a non-inferiority test that the AUC value does not reduce by more than 0.05. Sensitivity and specificity did not changed significantly between without and with QVCAD.

"... Interpretation time was significantly shorter with QVCAD compared to without QVCAD...."

Interpretation time was significantly shorter with QVCAD compared to without QVCAD. The average interpretation time of all readers and all cases was 3 minutes and 33 seconds without QVCAD, and it reduced to 2 minutes and 24 seconds with QVACD, saving on average more than one minute per cases and reducing the interpretation time by 33%. Of course, this did not include time for comparison with any prior images or preparing clinical report.

CLINICAL RELEVANCE

The results of this retrospective reader study indicate that, used clinically to help improve the workflow in the interpretation of ABUS images, QVCAD will help streamline the interpretation process and reduce the time needed to read ABUS images. This should come as a helpful tool to radiologists who read screening ABUS cases. It is possible that radiologists may find the navigator images particularly helpful. Clinical experience with QVCAD is needed to confirm this expectation from the reader study.

This reader performance study was carried out with older ABUS images. Analysis of current ABUS images (e.g., Invenia) has since been performed and showed that QVCAD performs similarly, in terms of cancers identified by the computer and the number of its false-positive findings, as it does on older ABUS images (somo•v) [12]. This suggests that the benefit in reducing interpretation time observed in the reader performance study will likely persist with contemporary ABUS systems. This expectation awaits confirmation from clinical experience. With greater awareness of reduced effectiveness of screening mammograms for women with dense breast tissue, particularly through awareness raised via patient notification of having dense breast tissue, ABUS could see increased use in breast cancer screening, and QVCAD could be a welcome tool to help make ABUS more effective for breast cancer screening.

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