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Automated Breast Ultrasound (ABUS)

Author

Prof. Dr. **Mathias Goyen**

HealthManagement Editorial Board

Member – Industry Adviser, Academic Research Director

GE Healthcare

mathias.goyen@ge.com

Key Points

- 1 in 8 women will be diagnosed with breast cancer in their lifetime.
- Dense breast tissue increases cancer risk by a factor of 4 – 6.
- Screening mammography is an accepted approach to breast cancer mortality reduction. Breast cancer mortality reduction ranges from 20-44%.
- Effectiveness of screening mammography:

  All Women - Sensitivity: 85%
  Women with Dense Breasts - Sensitivity 65%
  → More than 1/3 of breast cancers not mammographically visible in women with dense breasts.

- Studies indicate that addition of ABUS results in the discovery of about 30% more cancers in women with dense breasts.

In 2013 the American Cancer Society estimates that there will be about 232,340 new cases of invasive breast cancer diagnosed in the United States alone. In 2013 about 39,620 women in the U.S. will die from breast cancer, exceeded only by lung cancer (American Cancer Society 2013). Survival rates in women with breast cancer are much higher when the cancer is detected at an early stage, and this is why routine screening mammograms are recommended by the American Cancer Society for women 40 years of age and older (American Cancer Society 2013; Duffy et al. 2002).

Breast Density

Screening mammography has long been the mainstay in detecting nonpalpable breast cancer while it is the most curable. However, while the accuracy of mammography is high in fatty breasts, breast density is a major limitation to the sensitivity of mammographic screening, prompting researchers to look for alternative methods to improve detection in these women.

Breast density is a strong independent risk factor for the development of breast cancer. In several studies, women with the highest levels of breast density were found to have a four- to six-fold increased risk of breast cancer compared with women with the lowest density classification (Boyd et al. 2007). Breast density has also been shown to increase a women's lifetime risk for developing breast cancer. About 40% of women have some dense breast tissue, and visualisation of cancers in dense breast tissue with mammography is sometimes limited, as radiographic images of dense breast tissue appear similar to cancer (American Cancer Society 2013; Boyd et al. 2007; Kolb et al. 1998; Brubaker 2013). The result is missed cancers or the discovery of later-stage cancers in women which may require more aggressive treatment options (Duffy et al. 2002). According to a peer-reviewed study by Boyd et al., published in the New England Journal of Medicine, "Women with dense tissue in 75%

or more of the breast have a risk of breast cancer four to six times as great as the risk among women with little or no dense tissue" (Boyd et al. 2007).

Automated Breast Ultrasound (ABUS)

While mammography remains the gold standard for breast cancer screening, clinical studies have shown improved early detection of breast cancer when ultrasound is used as an adjunct to mammography for women with dense breast tissue. However, like mammography, ultrasound has its own set of limitations, as the process is very user dependent and scanning the breast is difficult, inconsistent and time-consuming. These issues led to the development of a new ultrasound technology that addressed some of the limitations, leading to the birth of automated breast ultrasound (ABUS). Advantages with the ABUS technology include a reduction in the time of procedure and operator dependency, as the equipment utilises transducer technology that automatically scans the breast in several seconds, acquiring volumetric image data that can address the issue of dense breast tissue.

This i s d ifferent t han r outine u ltrasound of the breasts since the images from ABUS allow you to see in projections that routine ultrasound cannot, which results in detecting more breast cancers and less false negatives. After the exam the 3D ultrasound images are sent to a workstation where the radiologist interprets the ABUS scan along with the women's mammogram and clinical history. All together, the result is a more accurate way of detecting breast cancer in women with dense breasts. Even women with prior cancer, breast surgery or implants benefit from the additional information ABUS offers.

Several vendors market ABUS Systems, including Siemens with the S2000 ABUS, U-Systems with the somo-v ABUS and SonoCine. However, while there is an increased growth of traditional ultrasound systems dedicated to women's healthcare and for breast imaging applications over the years, the healthcare community is taking a 'wait and see' approach to the ABUS technology. This is mainly due to questions related to the expense associated with having an ultrasound system d edicated s olely t o b reast imaging, workflow adaptations and issues of reimbursement for this application (Brubaker 2013).

In 2012, U-Systems' somo-v ABUSdevice was approved by the FDA as an adjunct to mammography for breast cancer screening in asymptomatic women for whom screening mammography findings are normal or benign (BI-RADS® Assessment Category 1 or 2), with dense breast parenchyma (BI-RADS® Composition/Density 3 or 4), and have not had previous clinical breast intervention (U.S. Food and Drug Administration 2012). Part of the datagathering process for FDA-clearance came from an ROC (Receiver Operating Characteristic) Reader Study conducted by the University of Chicago (Drukker et al. 2013; Giger et al. 2012).

The addition of ABUS demonstrated increased interreader agreement when used i n c ombination w ith m ammography compared to mammography alone for women with dense breasts, The addition of ABUS resulted in the discovery of about 30% more cancers in women who had a normal mammogram, a normal physical examination, and dense breasts. About 4% of lesions found were false-positives. 93% of the cases with cancers detected with mammography and ABUS were invasive cancers. These results suggest that the addition of ABUS to screening mammography is expected t o y ield a benefit to patients with dense tissue by providing earlier detection of breast cancers that might be missed by mammography alone.

As procedure volumes grow and issues of reimbursement become clear, investment in ABUS technology will become more economically feasible, resulting in increased ABUS activity in the market.

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