

A Multi-Center Diagnostic Study of Automated Breast Ultrasound System (ABUS) for Breast Cancer in China

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Objective: To evaluate the effectiveness of Hand Held Ultrasound (HHUS) and ABUS by comparing it with Mammography (MAM).

Methods: This hospital-based non-inferior clinical diagnostic study has 3 cancer hospitals and 2 tertiary general hospitals. Women aged 30 to 69 who visited breast surgeons for the first time without visible, suspicious signs of breast cancer and signed Informed Consent Form were eligible for HHUS and ABUS, and women aged 40-69 (older group) also received MAM. All images were interpreted by certified doctors based on BI-RADS independently. BI-RADS Category 3 lesions underwent MRI. BI-RADS 4-5 indicate positive which requires biopsy. MRI or pathological results were served as golden standard. The sensitivities, specificities, diagnostic accuracies were calculated to assess the reliability of HHUS, ABUS and MAM.

Findings: 1382 eligible women were enrolled in this report. By taking unilateral breast as the unit of analysis, we have acquired 2764 results for HHUS and ABUS, and 1756 results for MAM. Of all 356 breast cancer lesions in whole group, 338 were detected by HHUS and 319 were detected by ABUS. Of all 287 breast cancer lesions in the older group, ABUS detected 256 and MAM detected 247. In whole group, the sensitivities of HHUS and ABUS were 94.94% and 89.61%, the specificities were 94.23% and 95.18%, and diagnostic accuracies were 94.32% and 94.46% respectively ($P > 0.05$). In the older group, the sensitivities of HHUS, ABUS and MAM were 94.77%, 89.2% and 86.06% ($P < 0.05$). The specificities were similar (94.08%, 94.76% and 95.58%), and no difference was observed in diagnostic accuracies ($P > 0.05$).

Interpretation: HHUS is a better primary screening tool than MAM for breast cancer in China. ABUS may be an alternative modality in rural areas, taking advantage of its automated system, high reproducibility and less operator dependence.

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