

Purpose: We developed a computer-aided diagnostic tool (CADx) to analyze breast sonograms. The goals are to standardize reporting of findings with an electronic version of the ACR BI-RADS protocol and to improve accuracy and reproducibility of radiologists' interpretation. CADx (Breast Companion®, BC) addresses inter-radiologist variability and may reduce the number of unnecessary negative biopsies. Radiologist performance was examined in clinical use of BC and accuracy and reproducibility of the results were tested.

Methods: BC computes and reports numeric features of the mass, compares these to images in a reference database, uses Relative Similarity to retrieve instantaneously the most similar cases and provides numerical results including Computerized Lesion Assessment (CLA) following the ACR BI-RADS assessment category. We assembled 596 cases with confirmed findings (22% cancer, 28% simple cysts, 10% complicated cysts, 40% solid benign).

Results: In "stand-alone" mode BC accuracy and reproducibility are very high: ROC Area=0.98±0.02, Sensitivity=99.7%, Specificity=96.1%. On 125 cases (30% malignant) radial and anti-radial views of the same mass were analyzed. CLAs for the image pairs were highly correlated, equivalent by the two-tailed t-test ($p>.5$). 36 subjects (35% malignant) had two exams of the same mass within three weeks on two different scanners (GE, Siemens). ROC results were not significantly different and were substantially equivalent by kappa (0.72). Four experienced sub-specialty radiologists read the same set of 596 cases twice. In the first they followed normal practice completing an entire ACR BI-RADS hardcopy report. Four to six months later they read the same cases (randomized) using the structured reporting system of BC and while considering the CLA score. ROC Areas increased an average of 4.2% ($p=0.001$), Sensitivity was statistically unchanged ($p<0.5$) while Specificity increased an average of +15.1% (power=93%).

Conclusions: These significant results demonstrate that BC may help improve radiologist accuracy without negative impact on identification of cancer.

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