SBI ACR Breast Imaging Symposium, April 2020

AI Analysis of Ultrasound Images Could Decrease Benign Breast Biopsies
Retrospective Study of Biopsied BI-RADS 4 and 5 Lesions

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- **AI decision support could have improved ultrasound diagnostic accuracy of lesions that were assessed as BI-RADS 4 or 5**
- **37% of benign biopsies could have been avoided without materially impacting sensitivity**

Objective

To determine if computer-aided ultrasound (US) diagnosis could have reduced the number of biopsies performed on BI-RADS 4 and 5 lesions that were ultimately found to be benign.

Clinical Relevance

False positives in breast cancer screening lead to unnecessary biopsies and follow up, which result in patient inconvenience, anxiety, complications and cumulative healthcare costs of $4 billion per year.

Materials and Methods

- IRB-approved, retrospective study of 500 patients with BI-RADS 4 or 5 lesions imaged with two orthogonal US views, successful biopsy, and confirmation of final diagnosis by pathology (290 benign, 210 malignant).

- US images were anonymized and then analyzed by the AI software system (Koios DS Breast). The system automatically assesses lesion risk based on B-mode imaging only. The system output was then evaluated against ground truth and compared to the radiologists' BI-RADS assessments.

Results

- The AUC of the system was found to be 0.85 (0.81 – 0.87).

- When analyzed categorically, the software correctly identified malignant lesions in 202/210 cases for a sensitivity of 96.19% (92.63% – 98.34%).

- Due to the retrospective nature of this study on lesions that were already biopsied, physician sensitivity was 100% (98.26% – 100%).

- Of the biopsied lesions that proved benign, the system contraindicated biopsy as the preferred clinical management decision 37% of the time.

CONCLUSION

AI software can provide an additional and complimentary clinical input for radiologists in lesion risk assessment. This additional information could potentially reduce the number of unnecessary breast biopsies without any significant adverse impact on sensitivity.