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NEWS

IMAGE-ONLY AI MODEL COMPARED WITH BREAST DENSITY FOR IDENTIFYING WOMEN AT 5-YEAR INCREASED RISK OF BREAST CANCER: MULTICENTER U.S.-EUROPEAN ANALYSIS

PURPOSE

To compare an image-only AI model performance with that of breast density in stratifying 5-year breast cancer risk, and to assess whether AI-derived risk adds predictive value beyond density in a large, diverse international screening population.

METHODS AND MATERIALS

The AI model was trained on 421,499 mammograms from 27 facilities in Europe, South America, and the U.S., using a deep convolutional neural network and calibrated on an independent test set to generate 5-year risk probabilities. We applied the model to a cohort of 245,344 bilateral 2D screening mammograms (236,442 from five U.S. sites; 8,810 from one European site) acquired from 2011-2017. Radiologist-reported breast density (dense vs. not dense) was extracted from medical records and five-year cancer outcomes from tumor registries. AI-predicted risks were categorized using NCCN thresholds: average (<1.7%), intermediate (>1.7-3.0%), and high (>3.0%). Univariable and multivariable time-to-event models accounting for interval censoring were fit to obtain hazard ratios (HRs) for AI risk and breast density.

RESULTS

Breast density alone was associated with modestly increased cancer risk (HR 1.16, 95% CI 1.11-1.22). Relative to average risk, HRs were 2.06 for intermediate (95% CI 1.93-2.20) and 4.49 for high risk (95% CI 4.24-4.76), regardless of density. When both factors were considered together, the increased risk for breast density adjusted for AI risk was 1.12 (95% CI 1.07-1.17), and the increased risks for AI intermediate and high-risk categories adjusted for density were 2.04 (95% CI 1.92-2.18) and 4.47 (95% CI 4.22-4.73), respectively. Thus, accounting for breast density, shifting from average to intermediate AI risk is associated with a twofold increase in cancer risk, while moving to high risk increases risk more than fourfold. In contrast, the increased risk for breast density adjusting for AI risk is minimal.

CONCLUSIONS

While breast density remains an important factor in breast cancer screening, particularly for its role in masking cancers, this large-scale analysis shows that an image-only AI model offers more precise risk stratification for 5-year cancer prediction and provides additional predictive value, including in dense-breasted women. These findings support its use as a complement to traditional markers for guiding personalized screening.

CLINICAL RELEVANCE/APPLICATIONS

AI-derived image-based risk assessment can enhance decision-making in screening programs by identifying women at increased 5-year risk, including those with dense breasts, where cancer risk and detection challenges often coexist. Used alongside density, this approach may better inform supplemental imaging and prevention strategies.