RSNA Press Release

AI Tops Density in Predicting Breast Cancer Risk

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At A Glance

- An AI model for predicting the five-year risk of breast cancer provided stronger and more precise risk stratification than breast density assessment.
- The model was applied to over 245,000 screening mammograms from five U.S. sites and one European site.
- Women in the high-risk AI group had more than a fourfold higher cancer incidence than women in the average-risk group, while breast density alone showed only modest separation.

CHICAGO – An image-only artificial intelligence (AI) model for predicting the five-year risk of breast cancer provided stronger and more precise risk stratification than breast density assessment, according to a new study being presented next week at the annual meeting of the Radiological Society of North America (RSNA).

Constance D. Lehman, M.D., Ph.D.

Christiane Kuhl, M.D., Ph.D.

Senior author Constance D. Lehman, M.D., Ph.D., professor of radiology at Harvard Medical School in Boston, Massachusetts, said traditional methods of assessing a woman's risk for breast cancer, including age, family history, genetics and breast density, are inadequate.

"Over two million women are diagnosed with breast cancer annually, and for most, it comes as a complete shock," she said. "Only 5 to 10% of breast cancer cases are considered hereditary, and breast density alone is a very weak predictor of risk."

Clairity Breast, the first FDA-authorized image-only AI breast cancer risk model, was trained on 421,499 mammograms from 27 facilities in Europe, South America and the U.S. Using mammograms both from women who developed cancer and women who did not develop cancer over the subsequent five years helped the AI model to learn the patterns and differences in breast tissue that predict cancer risk. The model was calibrated on an independent test set using a deep convolutional neural network to generate five-year risk probabilities.

"The model is able to detect changes in the breast tissue that the human eye can't see," Dr. Lehman said. "This is a job that radiologists just can't perform. It's a separate task from detection and diagnosis, and it will open a whole new field of medicine, leveraging the power of AI and untapped information in the image.

The model was applied to a study group of 236,422 bilateral 2D screening mammograms from five U.S. sites and 8,810 from one European site. The mammograms were acquired between 2011 and 2017. Radiologist-reported breast density (dense versus not dense) and five-year cancer outcomes were extracted from medical records and tumor registries, respectively. AI-predicted risks were categorized using National Comprehensive Cancer Network thresholds: average (less than 1.7%), intermediate (1.7-3.0%) and high (greater than 3.0%).

The researchers compared the risk categories using statistical models that account for follow-up time and censoring.

Accounting for breast density, women in the high-risk AI group had more than a fourfold higher cancer incidence than women in the average-risk group (5.9% vs. 1.3%). By contrast, breast density alone showed only modest separation (3.2% for dense vs. 2.7% for non-dense).

"The results of this large-scale analysis demonstrate that AI risk models provide far stronger and more precise risk

stratification for five-year cancer prediction than breast density alone," said first author and presenter Christiane Kuhl, M.D., Ph.D., director, Department of Diagnostic and Interventional Radiology at University Hospital RWTH Aachen, in Germany. "Our findings support the use of image-only AI as a complement to traditional markers supporting a more personalized approach to screening."

The American Cancer Society currently recommends that women at average risk have the option to start annual breast cancer screening with mammography at age 40. However, women under 40 are the fastest-growing group being diagnosed with breast cancer and advanced disease.

"An AI image-based risk score can help us identify high-risk women more accurately than traditional methods and determine who may need screening at an earlier age," Dr. Lehman said. "We already screen some women in their 30s when they are clearly at high risk based on family history or genetics. In the future, a baseline mammogram at 30 could allow women with a high image-based risk score to join that earlier, more effective screening pathway."

Breast density legislation enacted in 32 states requires healthcare providers to inform women undergoing a screening mammogram of their breast density.

"We'd like to see women given information on their breast density and their AI image-based risk score," Dr. Lehman said. "We can do better than just looking at a mammogram and saying, 'It is dense or not dense' to inform women of their risk."

Other co-authors are David Miller, Mark Scully, Emily Hipp, Elizabeth A. Morris, M.D., Toni W. Vomweg, M.D., Lora D. Barke, D.O., Louie Enriquez, M.D., J.D., and Philippe Raffy, Ph.D.

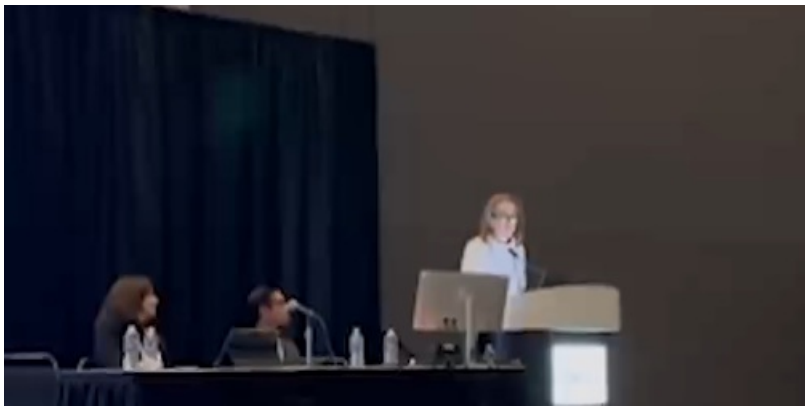
Note: Copies of RSNA 2025 news releases and electronic images will be available online at *RSNA.org/press25*.

RSNA is an association of radiologists, radiation oncologists, medical physicists and related scientists promoting excellence in patient care and health care delivery through education, research and technologic innovation. The Society is based in Oak Brook, Illinois. (*RSNA.org*)

Editor's note: The data in these releases may differ from those in the published abstract and those presented at the meeting, as researchers continue to update their data right up until the meeting. To ensure you are using the most up-to-date information, please call the RSNA Newsroom at 1-312-791-6610.

For patient-friendly information on breast imaging, visit *RadiologyInfo.org*.

Video (MP4):



B-Roll
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Video 1. Woman with radiologic technologist during screening mammography exam.
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Video 2. Radiologic technologist capturing mammography images.
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Video 3. Constance D. Lehman, M.D., Ph.D., discusses her research on how an image-only AI model provides stronger and more precise breast cancer risk stratification than breast density assessment.
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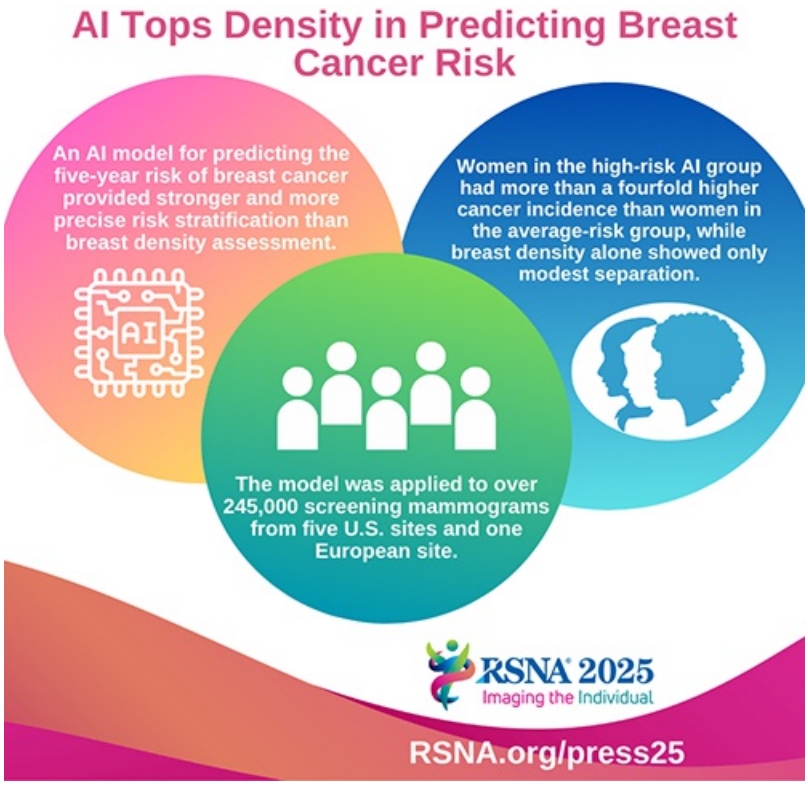
Images (JPG, TIF):



Infographic

Figure: Observed 5-Year Breast Cancer Incidence by AI-Predicted Risk and Breast Density

	Not Dense	Dense	All Exams
Average (<1.7%)	1.2% (60,112)	1.5% (50,794)	1.3% (110,906)
Intermediate (≥1.7–3.0%)	2.6% (33,578)	2.8% (35,936)	2.7% (69,514)
High (≥3.0%)	5.7% (32,723)	6.2% (32,201)	5.9% (64,924)
All Exams	2.7% (126,413)	3.2% (118,931)	2.9% (245,344)

Figure 1. This figure compares cancer incidence when women are grouped by AI-predicted 5-year risk versus by breast density. The table shows that AI risk categories separate women much more clearly: those in the high-risk AI group had more than a fourfold higher cancer incidence than women in the average-risk group (5.9% vs. 1.3%). By contrast, breast density alone showed only modest separation (3.2% for dense vs. 2.7% for non-dense).

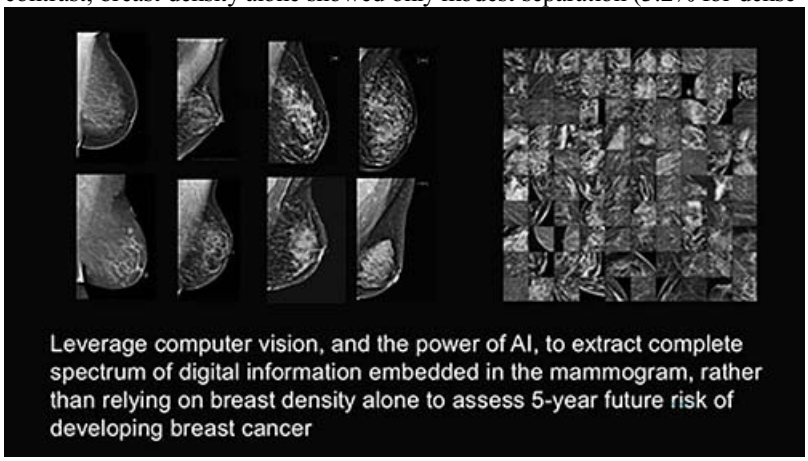


Figure 2. This figure illustrates how artificial intelligence can extract the full spectrum of predictive information directly from a mammogram, moving beyond the single measure of breast density. While breast density has long been used as a risk factor, it captures only limited information. By contrast, AI analyzes the entire image to provide a personalized 5-year risk score, offering a more precise and comprehensive approach to identifying women at

increased risk of breast cancer.

Resources:

Abstract