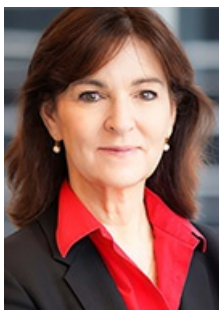


Changes in AI Mammogram Risk Scores over Time Help Predict Future Breast Cancer

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[Constance D. Lehman, M.D., Ph.D.](#)

OAK BROOK, Ill. – Using artificial intelligence (AI), researchers found that image-based risk scores for breast cancer derived from screening mammograms evolve over time and differ between women who develop cancer and those who do not, opening the door to a new era of dynamic breast cancer risk assessment. The new research was published today in [Radiology](#), a journal of the Radiological Society of North America ([RSNA](#)).

Deep learning models can now generate breast cancer risk scores directly from [screening mammograms](#), using the entire image rather than a limited, predetermined feature such as density. These models have demonstrated better performance than traditional risk models and breast density alone in estimating a woman's five-year breast cancer risk.

Most women diagnosed with [breast cancer](#) have no known genetic mutations or reported family history of the disease. Traditional risk models have limited discriminatory ability in population-based screening settings.

"Deep learning models have been primarily used to assess cancer risk scores at a static point in time," said lead researcher Constance D. Lehman, M.D., Ph.D., professor of radiology at Harvard Medical School and CEO of Clarity, Inc. "In this study, we evaluated longitudinal changes in the image-only deep learning breast cancer risk score using serial mammograms from a large screening cohort."

The study included women who underwent screening mammograms between 2009 and 2019 at six imaging sites spanning urban tertiary, community-based and rural practice settings. All exams were standard 2D bilateral full-field digital mammography screening exams acquired with or without digital breast tomosynthesis.

A total of 239,703 consecutive 2D screening mammograms from 89,882 patients were initially included in the study cohort. After exclusions, the final cohort included 54,014 women (median age 61) with 817 cancer patients and 53,197 cancer-free controls. Each woman contributed one index exam (defined as the final screening mammogram within the year prior to a breast cancer diagnosis or the final mammogram in the five-year study period for cancer-free controls) and up to six prior annual mammograms, for a total of 158,807 mammograms. The median number of screening mammograms per woman was three.

A validated, open-source image-only deep learning model was applied to all the mammograms to generate continuous five-year breast cancer risk scores. No demographic, clinical or historical imaging data were used.

A total of 817 women (1%) were diagnosed with breast cancer within 365 days of their index exam, including 451 (55%) with invasive cancer, 118 (14%) with ductal carcinoma in situ (DCIS), and 248 (30%) with an unknown cancer. Of these, 682 (83%) were screen-detected cancers, and 135 (17%) were interval cancers. The remaining 53,197 women (98%) were not diagnosed with breast cancer during follow-up and were categorized as cancer-free controls.

The researchers compared the risk scores of the 817 women diagnosed with invasive cancer or DCIS with the scores of the 53,197 cancer-free control individuals.

“We observed clinically relevant differences in risk trajectories between women who did and did not develop cancer,” Dr. Lehman said. “The increase in scores among cancer patients was detectable as early as six years prior to diagnosis and became more pronounced over time.”

Among the cancer patients, AI risk scores increased progressively over the six years preceding diagnosis, with the median score increasing from 2.1 in the first five to six years of the study period to 6.6 at the index exam. Cancer-free women exhibited stable scores across all time points, with medians ranging from 1.8 to 2.2 over the study period.

“These findings demonstrate signals, invisible to the human eye, in the image alone can predict future risk,” Dr. Lehman said. “This is exciting, because 85% of women diagnosed with breast cancer do not have a significant family history of breast cancer or known genetic mutations.”

Dr. Lehman noted that the majority of breast cancer cases are sporadic, meaning they’re not driven by familial inheritance or genetics.

“AI-derived risk scores can identify patients who are otherwise predisposed to the disease, and our findings demonstrate that image-based AI risk scores evolve over time and that changes in those scores may provide additional information about future breast cancer risk,” she said.

The risk score trajectory among cancer patients increased most steeply in the years immediately preceding the diagnosis. A gradual increase in scores in the early years of the study period was followed by a much steeper increase two years prior to the index exam. In contrast, the cancer-free trajectories remained essentially flat across the study period.

“These trends remained robust across subgroups defined by age and breast density, further supporting the generalizability of our findings,” Dr. Lehman said. “This is particularly relevant given persistent disparities in screening performance across patient populations. A dynamic biomarker approach grounded in the imaging data could mitigate some of these disparities by enabling risk-based personalization that does not rely on self-reported or inconsistent clinical data.”

Dr. Lehman said the study’s findings support the potential of image-based risk models as dynamic imaging biomarkers to guide personalized, risk-reduction strategies.

“With the power of AI, computer vision, and the ability to extract predictive data, we are able to apply the power of imaging to risk assessment and preventing disease from developing,” she said. “Having a dynamic risk score opens up a whole new domain of more effective preventive therapies for breast cancer, similar to how we screen for and treat patients with high cholesterol and hypertension.”

AI image-based risk scores are incorporated into the 2026 National Comprehensive Cancer Network guidelines. The guidelines recommend that beginning at age 35, women with an elevated five-year risk score (greater than 1.7%) consider breast MRI in addition to annual mammography.

An FDA-approved AI-based, image-based five-year risk-scoring model is currently in clinical use at select healthcare institutions across the U.S.

“Longitudinal Analysis of Changes in Deep Learning Image-based Breast Cancer Risk Scores Over Time.” Collaborating with Dr. Lehman were Sarah F. Mercaldo, Ph.D., Shadi Azam, Ph.D., Rulla M. Tamimi, Sc.D., Andrew Carney, M.S., Sarah M. Friedewald, M.D., and Leslie R. Lamb, M.D., M.Sc.

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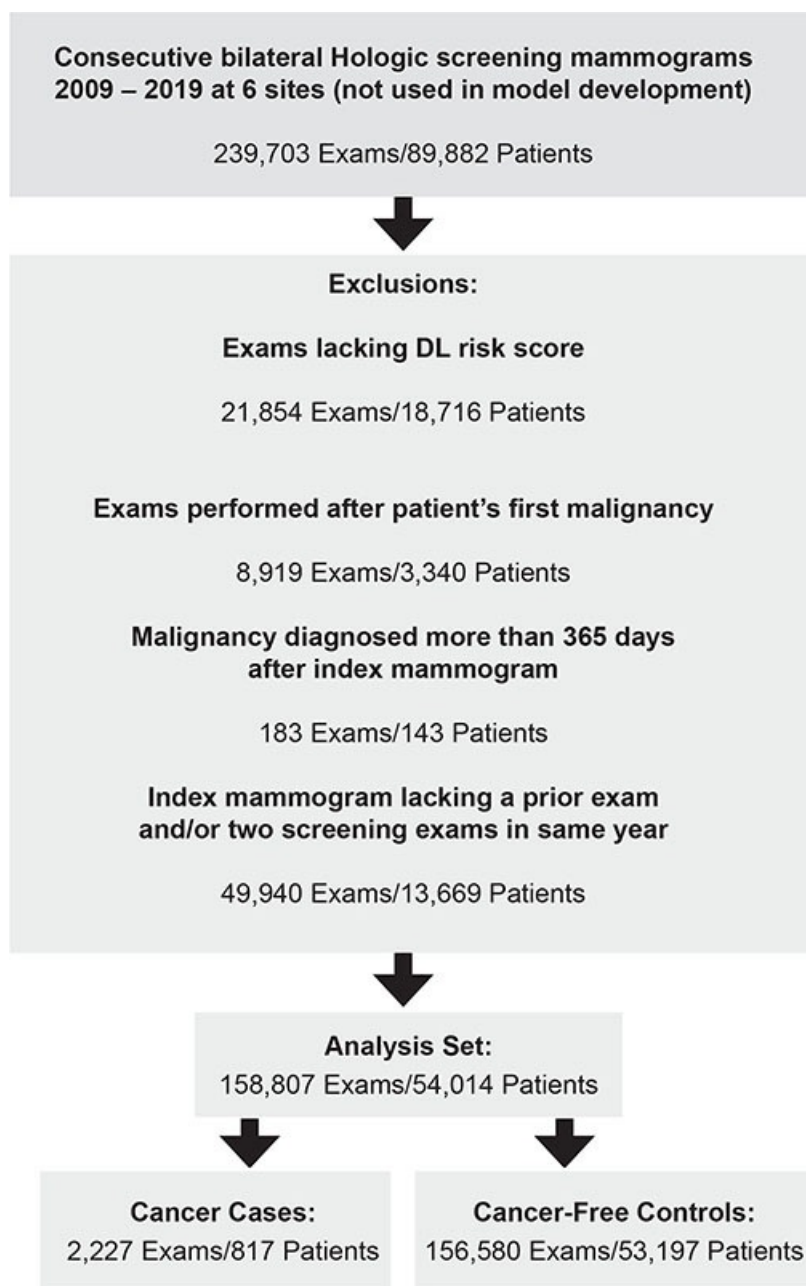


Figure 1. Flowchart of cohort selection. Consecutive bilateral Hologic screening mammograms (2009–2019; not used in model development) at six sites were included (239,703 examinations in 89,882 patients). Exclusions comprised examinations lacking deep learning (DL) risk scores (21,854 examinations in 18,716 patients), examinations performed after the patient's first malignancy (8,919 examinations in 3,340 patients), malignancies diagnosed more than 365 days after the index mammogram (183 examinations in 143 patients), and index mammograms lacking a prior examination or with two screening examinations in the same year (49,940 examinations in 13,669 patients). The final dataset included 158,807 examinations from 54,014 patients, comprising 2,227 examinations in 817 patients with cancer and 156,580 examinations in 53,197 cancer-free controls.

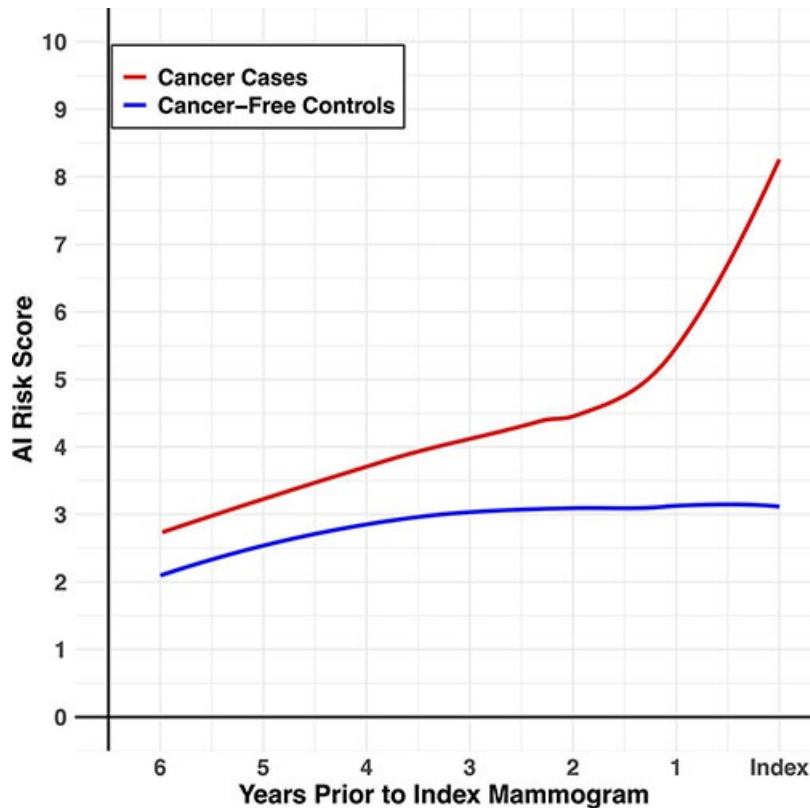


Figure 2. Line graph shows artificial intelligence (AI) risk score trends before the index examination in patients with cancer and cancer-free controls. Loess-smoothed AI risk scores are shown by year before the index mammogram. The red curve represents women diagnosed with breast cancer within 1 year following the index examination, and the blue curve represents cancer-free controls (confirmed with a 5-year follow-up). AI risk scores increased steadily in patients with cancer (slope, 1.13 per year [95% CI: 1.07, 1.18]; $P < .001$) and remained relatively stable in cancer-free controls (slope, 0.09 per year [95% CI: 0.08, 0.10]; $P < .001$).

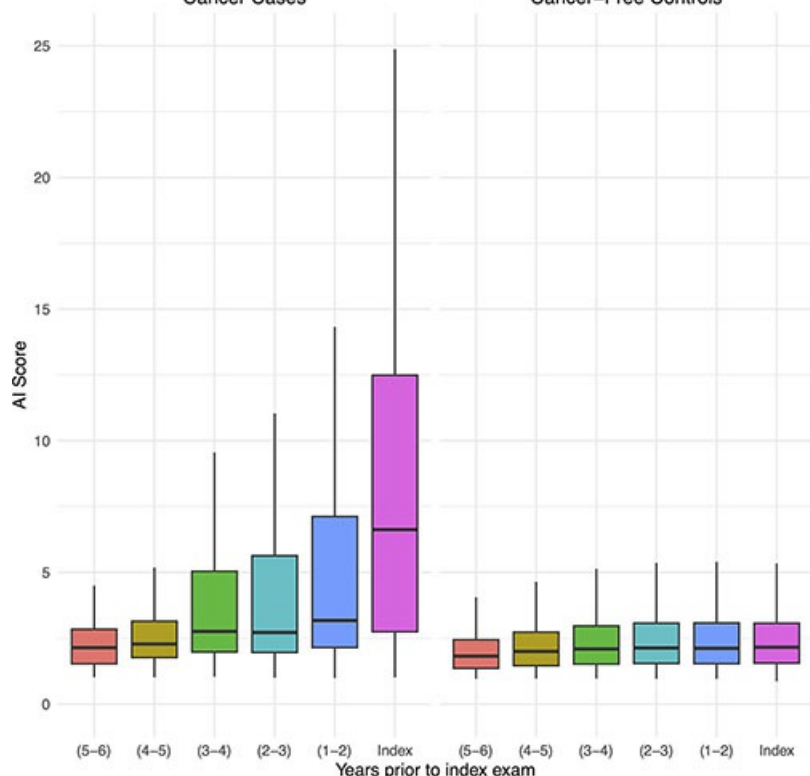


Figure 3. Median artificial intelligence (AI) risk scores at each time point in patients with cancer and cancer-free controls. Boxplots of the deep learning risk scores by year-group interval before the index examination, stratified by

cancer outcome, visualize score distributions over time for patients with cancer and cancer-free controls. Boxplots show the medians as the horizontal line within each box; box boundaries indicate the IQRs (25th–75th percentiles); whiskers indicate the range of values outside the IQRs.

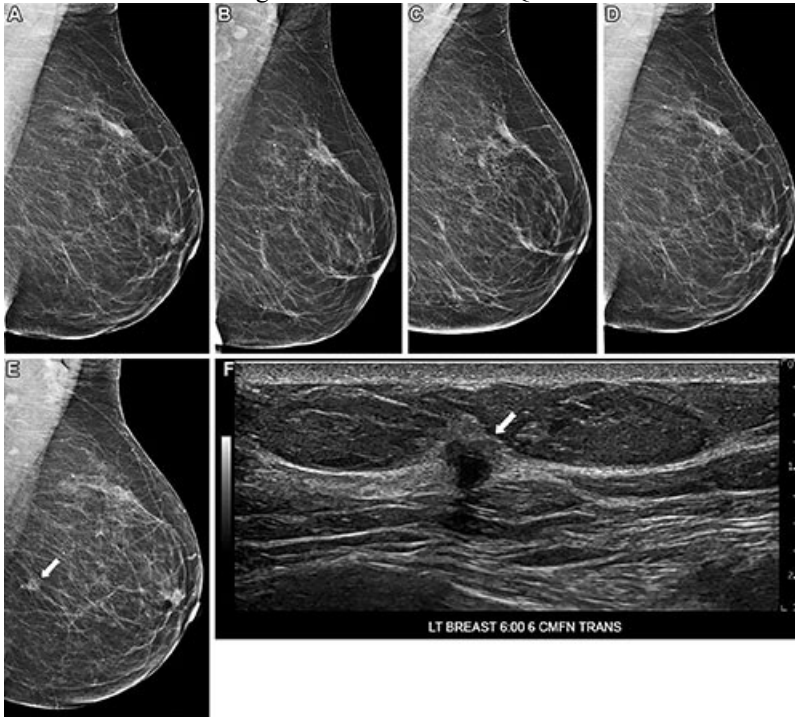


Figure 4. Images in a 75-year-old woman who underwent routine screening mammography in 2022. Left mediolateral oblique views shown from prior screening mammograms: **(A)** 2015, **(B)** 2018, **(C)** 2019, and **(D)** 2021. In **(E)** 2022, a new mass developed in the left breast at the 6-o'clock position (arrow), with a **(F)** corresponding irregular mass at US (arrow). Subsequent US-guided core needle biopsy yielded invasive ductal carcinoma, grade 2. The deep learning 5-year risk scores gradually increased from 2.0 (2015) to 2.1 (2018), 3.4 (2019), 3.6 (2021), and 15.3 (2022). CMFN = centimeters from nipple, LT = left, TRANS = transverse.

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