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Invasion prediction with artificial intelligence in ductal carcinoma in situ (DCIS) patients: a proof-of-concept study

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Abstract

Background Ductal carcinoma in situ (DCIS) is a heterogeneous precursor lesion with variable invasive potential. Current predictive parameters for invasion risk offer limited utility for personalized assessment. This study aims to evaluate artificial intelligence (AI)-assisted mammography analysis as a tool for predicting invasion risk in DCIS patients.

Methods In this retrospective cohort study, 74 patients with pathologically proven DCIS by preoperative biopsy were analyzed using a deep learning-based AI system (Transpara version 1.7.4). The AI system classified patients into low-risk and high-risk groups, which were validated against postoperative histopathological findings. Statistical analysis included sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy calculations.

Results Invasion was detected in 19 (25.7%) patients, with 18 (94.7%) classified as high-risk by the AI system. The model demonstrated 94.7% sensitivity, 45.5% specificity, 37.5% PPV, and 96.2% NPV. In patients aged ≥ 50 years and those with lesions ≥ 3 cm, the NPV reached 100%. A significant relationship was found between necrosis and invasion ($p = 0.004$).

Conclusions The high NPV suggests AI-assisted mammography analysis could serve as an effective rule-out tool for invasion in DCIS patients, potentially identifying candidates for less aggressive surgical treatment. Further validation in larger, multi-center studies is necessary to confirm these findings.

Keywords Ductal carcinoma in situ, Artificial intelligence, Deep learning, Mammography, Invasion prediction, Risk assessment

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Background

Ductal Carcinoma In Situ (DCIS) is defined as a noninvasive, heterogeneous precursor lesion of breast cancer that remains confined within the basement membrane of the breast ducts [1, 2]. While some DCIS cases progress to invasive cancer, a significant portion of them are indolent and due to the heterogeneity in lesion biology, DCIS treatment is gradually evolving towards more patient-specific approaches [3].

Current histopathological and clinical parameters employed to predict the invasive potential of DCIS offer limited utility; however, they remain inadequate for comprehensive personalized risk assessment [4, 5]. Consequently, the incorporation of artificial intelligence (AI) algorithms into radiological imaging analysis presents a promising framework for predicting the biological behavior of DCIS lesions. A comprehensive review of the literature reveals that while numerous studies have investigated AI applications in mammography interpretation and DCIS management, there remains a notable paucity of research specifically addressing the prediction of DCIS invasion potential through AI methodologies [6]. To the best of current knowledge, this study represents one of the initial investigations to evaluate invasion risk stratification in DCIS patients through the application of artificial intelligence and machine learning techniques in breast imaging assessment.

Artificial intelligence and deep learning algorithms have the potential to support radiologists in the diagnostic process by systematically analyzing suspicious lesions and microcalcification patterns in mammography images. Recent research has shown that artificial intelligence-assisted mammography evaluation can play a complementary role in clinical decision-making processes and offer more personalized approaches according to patients' risk profiles [7].

In this study, we aimed to evaluate the performance of artificial intelligence-assisted mammography analysis in predicting the risk of invasion in patients diagnosed with DCIS and to contribute to the identification of low-risk patients.

Materials and methods

Study design and patient selection

This retrospective cohort study included 74 patients with pathologically proven Ductal Carcinoma In Situ (DCIS) by preoperative biopsy who presented to the study center between January 2022 and December 2024. All radiological examinations were performed at a single dedicated breast imaging center under standardized protocols to ensure consistency in image acquisition and interpretation. Patients underwent multidisciplinary evaluation including ultrasound and/or MRI when clinically indicated. Suspicion of microinvasion was documented for cases where imaging features suggested possible invasion, but preoperative biopsy results confirmed only DCIS. Inclusion criteria included having a pathologically confirmed diagnosis of DCIS by preoperative biopsy, availability of complete histopathological, radiological, and clinical data, and presence of imaging data of sufficient quality for artificial intelligence analysis. Patients were excluded if they had missing or insufficient histopathological and radiological data, were diagnosed with conditions other than DCIS, had a history of invasive breast cancer, or had cases unsuitable for artificial intelligence analysis due to low image quality. The study was approved by the Scientific Research Ethics Committee of Sancaktepe Şehit Prof. Dr. İlhan Varank Training and Research Hospital of University of Health Sciences (Decision No: 2025/23, Date: 22.01.2025) and was conducted in accordance with the principles of the Declaration of Helsinki.

Data collection

A standardized data collection protocol is applied for all patients presenting to the study center. In this process, demographic information, medical and family history, risk factors, and physical examination findings are recorded. The study center maintains a comprehensive database where all clinical, radiological, and pathological data of patients are stored. All imaging data are archived in the center's PACS (Picture Archiving and Communication System) system. For this study, the radiological characteristics (DCIS size, presence of microcalcification, mammographic density, BI-RADS score) and histopathological data (nuclear grade, presence of necrosis, presence and type of invasion) of the patients were obtained retrospectively from this system.

Artificial intelligence analysis

All mammograms from patients presenting to the study center are analyzed using a commercially available, CE-marked, and FDA-cleared deep learning-based artificial intelligence (AI) system (Transpara version 1.7.4, ScreenPoint Medical, Netherlands) as part of the center's routine clinical protocol for breast cancer detection. This system automatically processes digital mammography images and provides risk assessments based on convolutional neural networks. The AI solution has been validated on large-scale mammography datasets and quantifies the likelihood of malignancy by analyzing morphological features and tissue patterns, offering standardized risk scores to support radiological interpretation[7]. The results from the AI analysis were obtained through the standard clinical workflow, and no additional processing was performed specifically for this study.

In this study, Transpara was applied specifically to predict invasion risk in DCIS patients. Through systematic

Table 1 Baseline characteristics by AI risk group

Variables		*N* (*n* = 74)	High Risk (*n* = 48)	Low Risk (*n* = 26)	*P*-Value
Age		48.7 ± 8.6	48.2 ± 9	49.7 ± 7.8	0.470
BMI		24.6 ± 3.7	24.4 ± 3.2	25 ± 4.5	0.505
Type of Biopsy	Tru-cut	38 (51.4)	23 (47.9)	15 (57.7)	0.757
	Vacuum	33 (44.6)	23 (47.9)	10 (38.5)	
	FNA	3 (4.1)	2 (4.2)	1 (3.8)	
DCIS Size (cm)	< 3	36 (48.6)	20 (41.7)	16 (61.5)	0.165
	≥ 3	38 (51.4)	28 (58.3)	10 (38.5)	
Microcalcification		63 (85.1)	43 (89.6)	20 (76.9)	0.178
Density of Mammography	A	2 (2.7)	1 (2.1)	1 (3.8)	0.807
	B	15 (20.3)	11 (22.9)	4 (15.4)	
	C	44 (59.5)	28 (58.3)	16 (61.5)	
	D	13 (17.6)	8 (16.7)	5 (19.2)	
Mass Formation		12 (16.2)	9 (18.8)	3 (11.5)	0.522
BI-RADS Score	4	68 (91.9)	42 (87.5)	26 (100)	0.085
	5	6 (8.1)	6 (12.5)	0 (0)	
Suspicious of Microinvasion		16 (21.6)	14 (29.2)	2 (7.7)	0.065
Nuclear Grade I		1 (1.4)	0 (0)	1 (3.8)	0.351
Nuclear Grade I-II		1 (1.4)	0 (0)	1 (3.8)	0.351
Nuclear Grade II		15 (20.3)	8 (16.7)	7 (26.9)	0.456
Nuclear Grade II-III		5 (6.8)	3 (6.2)	2 (7.7)	1.000
Nuclear Grade III		50 (67.6)	36 (75)	14 (53.8)	0.111

AI Artificial Intelligence;*BMI* Body Mass Index, *DCIS* Ductal Carcinoma In Situ, *FNA* Fine Needle Aspiration, *BI-RADS* Breast Imaging-Reporting and Data System

accuracy analyses, a 70% score threshold was identified as optimal, yielding 94.7% sensitivity and 58.1% accuracy.

Statistical analysis

All statistical analyses were performed using R statistical software (Version 4.1.0, R Foundation for Statistical Computing, Vienna, Austria). Descriptive statistics were presented as mean ± standard deviation or median (interquartile range) for continuous variables, and as number (percentage) for categorical variables.

For comparisons between groups, Student's t-test was used for continuous variables showing normal distribution, Mann-Whitney U test for continuous variables not showing normal distribution, and Chi-square or Fisher's exact test for categorical variables.

To evaluate the invasion prediction performance of the artificial intelligence system, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy rates were calculated. Logistic regression analysis was used to determine the relationship between artificial intelligence risk scoring and histopathological and clinical findings. The level of statistical significance was accepted as $p < 0.05$.

Table 2 Postoperative histopathological findings according to AI risk classification

Variable		*N* (*n* = 74)	High Risk (*n* = 48)	Low Risk (*n* = 26)	*P*-Value
Necrosis		51 (68.9)	39 (81.2)	12 (46.2)	0.004
Invasion		19 (25.7)	18 (37.5)	1 (3.8)	0.004
Invasion Subtypes	Microinvasion	4 (5.4)	4 (8.3)	0 (0)	0.526
	Her2 positive	3 (4.1)	3 (6.2)	0 (0)	0.526
	Luminal A	5 (6.8)	5 (10.4)	0 (0)	
	Luminal B	3 (4.1)	3 (6.2)	0 (0)	
	Luminal B Her-2 positive	3 (4.1)	2 (4.2)	1 (3.8)	
	Triple negative	1 (1.4)	1 (2.1)	0 (0)	
Invasive Tumor T Stage	T1mi	4 (5.4)	4 (8.3)	0 (0)	1.000
	T1a	13 (17.6)	12 (25)	1 (3.8)	
	T1b	2 (2.7)	2 (4.2)	0 (0)	
DCIS Architectural Subtypes	Solid	43 (58.1)	32 (66.7)	11 (42.3)	0.075
	Cribriform	50 (67.6)	31 (64.6)	19 (73.1)	0.628
	Micropapillary	17 (23)	11 (22.9)	6 (23.1)	1.000
	Papillary	21 (28.4)	11 (22.9)	10 (38.5)	0.252
	Apocrine	6 (8.1)	3 (6.2)	3 (11.5)	0.659
	Comedo	32 (43.2)	24 (50)	8 (30.8)	0.178
	Flat	10 (13.5)	8 (16.7)	2 (7.7)	0.478
Focality		13 (17.6)	8 (16.7)	5 (19.2)	0.760
LCIS		5 (6.8)	4 (8.3)	1 (3.8)	0.651
Immunohistochemical Features	ER	44 (59.5)	27 (56.2)	17 (65.4)	0.679
	PR	39 (52.7)	23 (47.9)	16 (61.5)	0.430
	HER2	10 (13.5)	7 (14.6)	3 (11.5)	1.000
Surgical margin	< 2 mm	11 (14.9)	8 (16.7)	3 (11.5)	0.737
	≥ 2 mm	63 (85.1)	40 (83.3)	23 (88.5)	
Metastatic Lymph Node		1 (1.4)	1 (2.1)	0 (0)	1.000

AI Artificial Intelligence, *DCIS* Ductal Carcinoma In Situ, *T* stage, Tumor stage according to the TNM classification system, *LCIS* Lobular Carcinoma In Situ *ER* Estrogen Receptor, *PR* Progesterone Receptor, *HER2* Human Epidermal Growth Factor Receptor 2, *mm* Milimeter

Results

The demographic and clinical characteristics of the 74 patients included in the study are shown in Table 1. The mean age of the patients was 48.7 ± 8.6 years, and the mean body mass index (BMI) was 24.6 ± 3.7 kg/m². According to the artificial intelligence risk classification, 48 patients (64.9%) were evaluated in the high-risk group, and 26 patients (35.1%) in the low-risk group.

The postoperative histopathological findings according to AI risk classification are presented in Table 2. In histopathological examination, invasion was detected in 19 (25.7%) of 74 patients. Necrosis was detected in 51 patients (68.9%), with a statistically significant relationship between the presence of necrosis and invasion ($p = 0.004$). Of the patients with necrosis, 39 (81.2%) were in the high-risk group, and 12 (46.2%) were in the low-risk group. The distribution of invasion according to AI

risk classification is shown in Table 3. Of the patients with invasion, 18 (94.7%) were classified as high-risk by artificial intelligence. The relationship between risk groups and the presence of invasion was found to be statistically significant ($p = 0.004$).

The performance metrics of the artificial intelligence system in predicting invasion based on various characteristics are presented in Table 4. The system showed 94.7% sensitivity, 45.5% specificity, 37.5% positive predictive value (PPV), and 96.2% negative predictive value (NPV) in detecting invasion. The overall accuracy rate was calculated as 58.1%.

Detailed analysis of the false-negative case revealed a 46-year-old premenopausal woman with 1.5 cm high-grade DCIS presenting with microcalcifications, BI-RADS 4 classification. The DCIS showed mixed architectural patterns including solid, cribriform, and comedo subtypes with necrosis. Despite these high-risk pathological features, there was no clinical suspicion of microinvasion on biopsy. The AI system assigned a score below the 70% threshold, classifying this as low-risk. Final pathology revealed pT1a invasive carcinoma, Luminal B HER2-positive subtype.

Table 3 Distribution of invasion according to artificial intelligence risk classification

Variable		*N* (*n* = 74)	Yes (*n* = 19)	No (*n* = 55)	*P*-Value
AI Risk Classification	High Risk	48 (64.9)	18 (37.5)	30 (62.5)	0.004
	Low Risk	26 (35.1)	1 (3.8)	25 (96.2)	0.004

AI Artificial Intelligence

In subgroup analyses, the performance of the artificial intelligence model was evaluated according to age, BMI, DCIS size, and presence of microcalcification. In patients aged 50 and older, sensitivity was 100%, specificity 54.5%, NPV 100%; in patients younger than 50, sensitivity was 90.9%, specificity 39.4%, NPV 92.9%. In patients with DCIS size 3 cm and above, sensitivity was 100%,

Table 4 Performance metrics of AI system in predicting invasion based on various characteristics

Variable	N	TP	FP	TN	FN	Prevalence (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
All	74	18	30	25	1	25.7	94.7	45.5	37.5	96.2	58.1
Age											
< 50	44	10	20	13	1	25.0	90.9	39.4	33.3	92.9	52.3
≥ 50	30	8	10	12	0	26.7	100.0	54.5	44.4	100.0	66.7
BMI											
< 25	40	12	15	13	0	30.0	100.0	46.4	44.4	100.0	62.5
≥ 25	34	6	15	12	1	20.6	85.7	44.4	28.6	92.3	52.9
DCIS Size (cm)											
< 3	36	7	13	15	1	22.2	87.5	53.6	35.0	93.8	61.1
≥ 3	38	11	17	10	0	28.9	100.0	37.0	39.3	100.0	55.3
Microcalcification											
0	11	2	3	6	0	18.2	100.0	66.7	40.0	100.0	72.7
1	63	16	27	19	1	27.0	94.1	41.3	37.2	95.0	55.6
Density of Mammography											
A	2	0	1	1	0	0.0		50.0			50.0
B	15	3	8	4	0	20.0	100.0	33.3	27.3	100.0	46.7
C	44	13	15	15	1	31.8	92.9	50.0	46.4	93.8	63.6
D	13	2	6	5	0	15.4	100.0	45.5	25.0	100.0	53.8
Mass Formation											
0	62	15	24	23	0	24.2	100.0	48.9	38.5	100.0	61.3
1	12	3	6	2	1	33.3	75.0	25.0	33.3	66.7	41.7
BI-RADS Score											
4	68	14	28	25	1	22.1	93.3	47.2	33.3	96.2	57.4
5	6	4	2	0	0	66.7	100.0	0.0	66.7		66.7
Suspicious of Microinvasion											
0	58	7	27	23	1	13.8	87.5	46.0	20.6	95.8	51.7
1	16	11	3	2	0	68.8	100.0	40.0	78.6	100.0	81.2
Surgical Margin											
< 2 mm	11	2	6	2	1	27.3	66.7	25.0	25.0	66.7	36.4
≥ 2 mm	63	16	24	23	0	25.4	100.0	48.9	40.0	100.0	61.9

N Count, *TP* True positiv, *FP* False positive, *TN* True negative, *FN* False negative, *PPV* Positive predictive value, *NPV* Negative predictive value, *BMI* Body Mass Index; *DCIS* Ductal Carcinoma In Situ, *BI-RADS* Breast Imaging-Reporting and Data System, *mm* Milimeter

specificity 37.0%, NPV 100%, while in lesions smaller than 3 cm, sensitivity was 87.5%, specificity 53.6%, NPV 93.8%.

Discussion

The presented study serves as a proof of concept regarding the potential of artificial intelligence-assisted mammography analysis in predicting the risk of invasion in patients diagnosed with ductal carcinoma in situ (DCIS). Prior research typically emphasizes conventional histopathological and clinical parameters when assessing the invasion potential of DCIS; however, these conventional approaches often exhibit limitations in providing personalized risk assessments. Although artificial intelligence algorithms designed for the analysis of radiological imaging data have shown promise in cancer diagnosis and prognosis in recent years, their specific application in evaluating the invasive potential of DCIS remains underexplored. A notable finding in this preliminary study was the high negative predictive value (NPV) of 96.2%. This result suggests a potentially high probability of no invasion in patients classified as low-risk by the AI system, positioning this approach as particularly promising as a rule-out test for invasion in DCIS cases. In the context of this study, this indicates that when the AI system categorized a DCIS patient as low-risk, invasive disease was generally absent, though validation in larger cohorts is needed.

In the current cohort, the observed invasion rate in the final pathology of patients initially diagnosed with DCIS was 25.7%, which aligns with previously reported rates of 20–30% within contemporary literatüre [5, 8]. The high NPV represents a substantial advancement in predictive tools from a clinical perspective, particularly in the management of DCIS cases. Identifying low-risk patients poses a significant challenge in clinical practice, where avoiding unnecessary treatments is paramount [9, 10]. Existing studies indicate that a considerable proportion of DCIS cases do not progress to invasive cancer, underscoring the insufficiency of traditional risk factors in identifying these patients [3, 11, 12]. Accordingly, a model with a high NPV serves as an effective rule-out test for invasion and could be instrumental in stratifying patients suitable for active surveillance strategies. When using the AI system to rule out invasion, a low-risk classification provides clinicians with strong evidence that invasive disease is absent, creating a reliable foundation for less aggressive management approaches.

Significantly, subgroup analyses also yielded comparable high NPV values. Specifically, the NPV was 100% in patients aged 50 years and older, as well as in lesions measuring 3 cm and above. These findings suggest that the model may exhibit enhanced reliability within specific patient demographics, with the 100% NPV in lesions ≥ 3 cm potentially reflecting the greater imaging data available for AI analysis in larger lesions, enabling better characterization of tissue patterns. This observation is consistent with research conducted by Kim et al. (2020), which reported variations in AI model performance based on factors such as age and lesion size [13].

Furthermore, the study demonstrated a high sensitivity value of 94.7%, indicating that the model effectively detects DCIS cases with invasive potential. However, limitations were noted, as evidenced by a specificity of 45.5% and a lower PPV of 37.5%. Retrospective analysis of mammographic features revealed that while clinical suspicion of microinvasion achieved only 57.9% sensitivity versus 94.7% for the AI system. This substantial difference underscores AI's value as a complementary tool to clinical assessment. As highlighted by Zeng et al. (2024) in a recent systematic review, AI systems often produce false positive results to achieve high sensitivity [14]. This phenomenon has the potential to lead to overdiagnoses, potentially diminishing the clinical benefits derived from diagnostic applications. Nonetheless, the high NPV value associated with this model mitigates the clinical ramifications of these limitations, establishing it as a valuable tool, particularly for identifying low-risk patients.

An important finding of this study was the statistically significant relationship between the presence of necrosis and invasion (p = 0.004). Notably, 81.2% of patients with necrosis were classified as high-risk by the artificial intelligence algorithm, corroborating literature that emphasizes necrosis as a crucial prognostic marker in DCIS [15, 16]. This correlation indicates that the AI algorithm effectively captures histopathological risk factors and identifies significant biological relationships based on imaging data.

The high NPV of 96.2% observed in this study offers considerable clinical potential for ruling out invasion in DCIS patients. High NPV is the critical performance metric for clinical tests designed to exclude a condition, making these findings particularly relevant. As emphasized in current literature, AI-assisted risk classification systems can play a transformative role in personalizing treatment [17, 18]. With this high NPV, clinicians could potentially identify patients with a very low probability of invasive disease who may be suitable candidates for less aggressive treatment approaches or active surveillance strategies, thus supporting treatment de-escalation decisions in appropriate clinical contexts. This approach has the potential to reduce morbidity associated with unnecessary treatments and enhance the effective utilization of healthcare resources. The high NPV particularly suggests utility in guiding sentinel lymph node biopsy decisions, as patients classified as low-risk might safely avoid this procedure when undergoing breast-conserving surgery, pending prospective validation.

Looking forward, this AI approach aligns with emerging active surveillance protocols for low-risk DCIS. The ability to reliably identify patients with minimal invasion risk could support ongoing trials such as COMET, LORD, and LORIS [19–21]. We are currently expanding our dataset and welcome multicenter collaborations to validate these promising initial findings in the context of personalized DCIS management.

This proof-of-concept study has several limitations. The sample size was restricted to 74 patients from a single institution, which may limit generalizability. While the AI system showed promising results with high sensitivity (94.7%) and negative predictive value (96.2%), the relatively low specificity (45.5%) could potentially lead to overdiagnosis if used as the sole decision-making tool. It is also important to note that the AI system employed was originally designed for general breast cancer detection rather than specifically for predicting invasion in DCIS. Before clinical implementation can be considered, these initial findings require validation through larger, multicenter studies.

Conclusion

The presented proof of concept study demonstrates that artificial intelligence-assisted mammography analysis in DCIS patients can serve as a valuable rule-out tool for invasion, with its high negative predictive value providing reliable exclusion of invasion in low-risk patients. This approach may facilitate the identification of candidates for less aggressive surgical treatment plans and personalization of management strategies. Despite the limitations of this proof-of-concept study, our findings represent an important step toward personalized DCIS management, where AI will play a crucial role in individualizing treatment decisions. Future research should prioritize validating these findings within larger and multicenter patient populations, addressing the methodological limitations identified in this initial study.

Supplementary Information

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Supplementary Material 1.

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Authors' contributions
AG (Adnan Gundogdu): Conceptualization, methodology, investigation, data curation, writing - original draftCSW (Ceyda Sonmez Wetherilt): Methodology, validation, formal analysis, writing - review & editingAA (Ayhan Alpar): Investigation, resources, data curationSA (Sangar Abdullah): Investigation, data curationOCY (Osman Cem Yilmaz): Supervision, validation, visualizationLC (Levent Celik): Supervision, project administration, writing - review & editing.

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Data availability
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by the Scientific Research Ethics Committee of Sancaktepe Şehit Prof. Dr. İlhan Varank Training and Research Hospital of University of Health Sciences (Decision No: 2025/23, Date: 22.01.2025). The need for informed consent was waived by the Ethics Committee due to the retrospective nature of the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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