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Application of Artificial Intelligence in the Mammographic Detection of Breast Cancer in Saudi Arabian Women

Rowa Aljondi [1,*], Salem Saeed Alghamdi [1], Abdulrahman Tajaldeen [1], Shareefah Alassiri [2], Monagi H. Alkinani [3] and Thomas Bertinotti [4]

[1] Department of Applied Radiologic Technology, College of Applied Medical Sciences, University of Jeddah, Jeddah 23218, Saudi Arabia; salghamdi@uj.edu.sa (S.S.A.); aatajaldeen@uj.edu.sa (A.T.)
[2] Ministry of Health, Administration of Public Health, Breast Cancer Screening Programmer, Jeddah 22246, Saudi Arabia; sh.alassiri@gmail.com
[3] Department of Computer Science and Artificial Intelligence, College of Computer Science and Engineering, University of Jeddah, Jeddah 22246, Saudi Arabia; malkinani@uj.edu.sa
[4] Therapixel, 75014 Paris, France; tbertinotti@therapixel.com
* Correspondence: rmaljondi@uj.edu.sa

Abstract: Background: Breast cancer has a 14.8% incidence rate and an 8.5% fatality rate in Saudi Arabia. Mammography is useful for the early detection of breast cancer. Researchers have been developing artificial intelligence (AI) algorithms for early breast cancer diagnosis and reducing false-positive mammography results. The aim of this study was to examine the performance and accuracy of an AI system in breast cancer screening among Saudi women. **Materials and Methods:** This is a retrospective cross-sectional study that included 378 mammograms collected from 2017 to 2021 from government hospitals in Jeddah, Saudi Arabia. The patients' demographic and clinical information were collected from files and electronic medical records. The radiologists' assessments of the mammograms were based on Breast Imaging Reporting and Data System (BIRADS) scores. Follow-up or biopsy reports verified the radiologists' findings. The MammoScreen system was the AI tool used in this study. Data were analyzed using SPSS Version 25. **Results:** The patients' mean age was 50.31 years. Most patients had breast density B (42.3%) followed by A (27.2%) and C (25.9%). Most malignant cases were invasive ductal carcinomas (37.3%). Of the 181 cancer cases, 36.9% were BIRADS category V. The area under the curve for the AI detection (0.923; 95% confidence interval [CI], 0.893–0.954) was greater than that for the radiologists' interpretation (0.838; 95% CI, 0.796–0.881). The AI detection agreed with the histopathological result in 167 positive (91.3%) and 182 negative cases (93.3%). The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of the AI system were 92.8%, 91.9%, 91.3%, 93.3%, and 92.3%, respectively. The radiologist's interpretation agreed with the pathology report in 180 positive (73.8%) and 134 negative cases (100%). Its sensitivity, specificity, PPV, NPV, and accuracy were 100%, 67.7%, 73.8%, 100%, and 83.1%, respectively. **Conclusions**: The AI system tested in this study had better accuracy and diagnostic performance than the radiologists and thus could be used as a support diagnostic tool for breast cancer detection in clinical practice and to reduce false-positive recalls.

Keywords: artificial intelligence; breast cancer; mammography; radiology

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1. Introduction

Breast cancer stands out as the most common type of cancer in Saudi Arabian women, with an annual incidence rate of 14.8% and a mortality rate of 8.5% [1]. According to Saudi Cancer Registry (SCR) statistics, the incidence rate of breast cancer among women in Saudi Arabia has been increasing, accounting for 28.7% of all reported cancers among women of all ages [2]. Early and accurate diagnosis of breast cancer could improve patient survival and clinical outcomes [2]. Thus, appropriate screening methods are important for detecting the early signs of breast cancer [3].

Mammography is one of the most important imaging modalities for the early diagnosis of breast cancer [3]. Human-based diagnosis of breast cancer using mammography screening detection has drawbacks such as a high false-positive rate, overdiagnosis, and overtreatment, which are costly and have negative psychological impacts on patients [4–6]. In addition, it can lead to a missed diagnosis rate of 15%–35% for breast cancers that are not detectable on breast imaging [7].

Computer-aided detection (CAD) systems have been widely used in clinical practice to assist radiologists in identifying potential breast cancers by mammography [8]. However, CAD does not improve diagnostic accuracy in mammography for breast cancer detection or increase biopsy recommendations [8,9]. In addition, more research is needed to address the current obstacles to the development of breast cancer CAD systems [10]. Therefore, researchers have developed artificial intelligence (AI) algorithms for the early detection of breast cancer and to improve the interpretation of mammograms for breast cancer screening by reducing false-positive results [11–19]. AI techniques for cancer imaging in health care have recently been investigated, developed, and evaluated as support technologies for disease detection, prognosis, and clinical decision making [8,11,20]. This has enhanced the accuracy and efficiency of breast cancer detection, assisting radiologists with breast cancer screenings and reducing the workload of second readers [14,17,18,21–23]. Current evidence has highlighted that the use of AI-based tools has improved radiologists' breast cancer detection by mammography without the additional reading time required [17,24].

To the best of our knowledge, previously, there were limited studies that investigated the potential role of an AI system in detecting breast cancer on mammography among Saudi women [23,25,26]. Most of these published studies use different image processing techniques to improve the diagnostic performance of the computerized breast cancer detection methods and classification of breast lesions [23,25,26]. In a pilot study using a digital mammographic breast cancer database from Saudi Arabia, the machine learning (ML) method based on a CAD system was used for tumor segmentation [23]. Their proposed technique needs to use the radiologist's knowledge to draw the tumor borders and to have a more accurate and efficient classification process [23]. Similarly, in other studies performed on datasets from Qassim province, Saudi Arabia, their proposed methods used several pre-processing steps to achieve better performance of their proposed methods [25,26]. However, in our study, we proposed to evaluate the benefits of using automated AI-based tools for digital mammographic imaging in the detection of breast cancer in terms of diagnostic performance and efficiency.

AI software has been used in radiology to improve the diagnostic efficiency of radiologists. This software can be used as a decision support tool to help radiologists confirm the incidence of breast cancer early in women and avoid errors while interpreting the signs of breast cancer in images. The results of this study will contribute to achieving the goals of the Kingdom's Vision 2030 for improving the quality and efficiency of health care services [27]. Given the considerable interest in using automated AI methods for breast cancer detection on medical imaging, the present study aimed to examine the performance and accuracy of an automated AI system in breast cancer screening in Saudi women.

2. Methods

2.1. Study Design, Population, Period, Setting, and Ethical Consideration

This is a cross-sectional study that included 378 screening examinations of mammographic digital images. Data were retrospectively collected over 5 years (2017–2021). The cases were obtained from different government hospitals in Jeddah, Saudi Arabia (King Abdul-Aziz Hospital and Oncology Center, King Abdullah Medical Complex, and East Jeddah General Hospital). This study was approved by the institutional review board of the Ministry of Health in Saudi Arabia (IRB approval number: A01215). The personal information of the patients was obtained with strict confidentiality and their clinical data and radiological images were anonymized exclusively for the purpose of this research. The need for patient consent was waived owing to the observational and retrospective nature of the investigation.

2.2. Eligibility Criteria

The inclusion criteria for all cases were women aged > 40 years who had undergone screening digital mammographic examinations. The exclusion criteria were patients who had undergone breast reduction or implant augmentation, were currently breastfeeding, had a history of breast cancer, or had received post-neoadjuvant chemotherapy. The flowchart of the selection of the study population is shown in Figure 1.

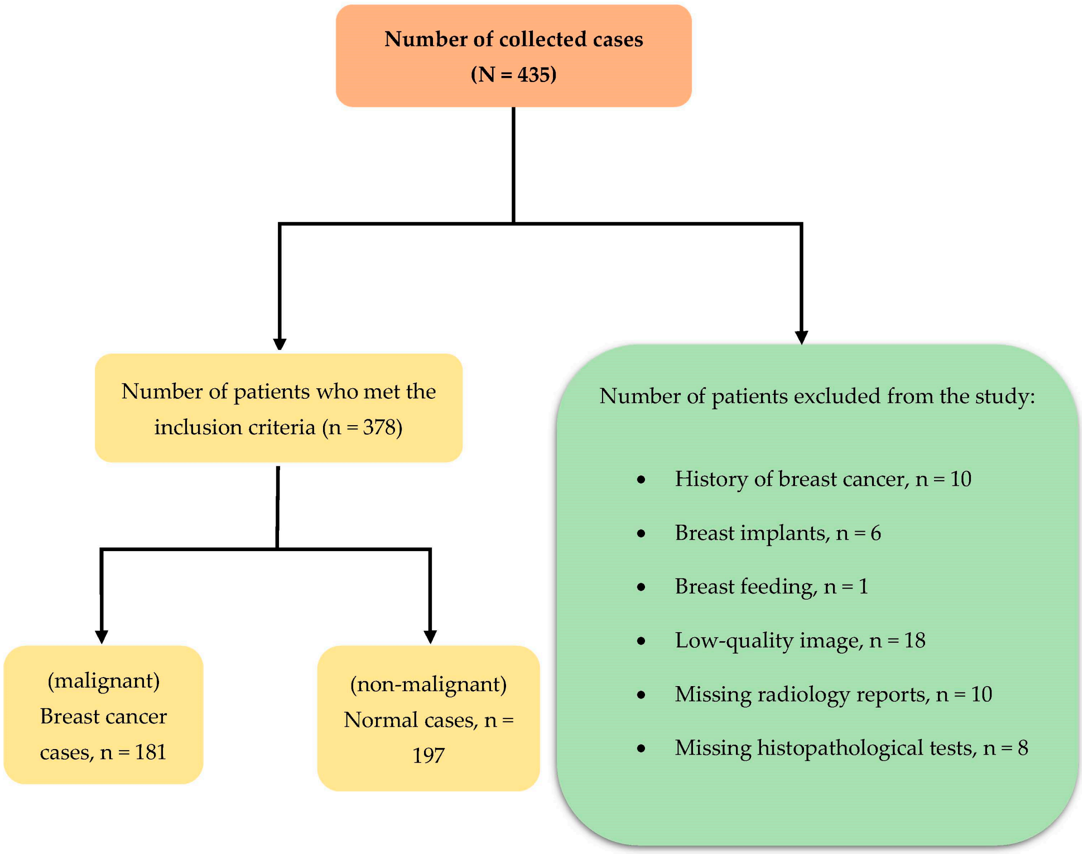


Figure 1. Flowchart of the selected dataset.

2.3. Data Collection Procedures

Digital 2D mammographic screening tests were performed using a mammography machine. As cases were obtained from different governmental hospitals, multiple mammographic machines were used for breast screening. The collected data were then stored in DICOM format and images were taken in two views (craniocaudal [CC] and mediolateral oblique [MLO]). All cases were anonymized using the DICOM Anonymizer tool_version 1.0.2 before applying the AI system. The patients' demographic and clinical characteristics were retrospectively extracted from their files and electronic medical records. Data were collected by the research coordinator and cross-checked by the research investigators.

The collected data were interpreted by the radiologists and confirmed by follow-up screening or biopsy. Malignant findings were considered true-positive results if the histological analysis of biopsy samples had positive results. When non-malignant findings were reported, the ground truth of the presence or absence of breast cancer was confirmed either by histopathological analysis or at least one year of follow-up examination [24]. The follow-up examinations resulted in negative malignant findings, reduced recall bias, and determined the A system's ability and reliability.

2.4. Radiological Score Assessment

The assessments of the malignant lesions were described as microcalcifications, irregularly shaped masses, infiltrative masses, nipple traction, and skin thickening. In addition, the Breast Imaging Reporting and Data System (BIRADS; scale of 1–6) was used for grading the mammogram reports as follows [28]:

BI-RADS 0: Incomplete examination; need additional imaging evaluation.

BI-RADS I: Negative.

BI-RADS II: Benign.

BI-RADS III: Probably benign. A short-interval follow-up is recommended: 4 months for masses and 6 months for microcalcifications.

BI-RADS IV: Suspicious abnormality: A biopsy should be considered.

BI-RADS V: Highly suggestive of malignancy. A biopsy or surgery should be performed.

BI-RADS VI: Biopsy-proven malignancy. Imaging is performed for cancer staging or evaluation after chemotherapy.

In the present study, the radiologists' assessment scores were classified into positive and negative malignancy based on a screening scenario threshold of BI-RADS $\geq$ 3 as there was a recall for follow-up screening or suggested biopsy.

2.5. AI System for Mammogram Analysis

In our study, we used the MammoScreen software package as the AI system which was designed to identify suspicious regions of breast cancer by digital mammography and assess their likelihood of malignancy (MammoScreen V1; Therapixel, Nice, France). This system has been validated for two-dimensional mammography and received US Food and Drug Administration (FDA) clearance in April 2019 [29]. The implemented AI system combines two groups of deep convolutional neural networks (CNN) with an aggregation module [17].

The pre-processing steps for the MammoScreen software package have a selection algorithm from DICOM tag; typical screening images are selected for CC and MLO views. If multiple CC or MLO views are found for the same patient, the most recent images were used with the assumption that the most recent images should have the best quality. By delivering a visual report summarizing the algorithm's results, the system accepts the CC and MLO views for each breast as inputs and outputs the location of the lesions with a suspicion score ranging from 1 (benign) to 10 (malignant). The closer the score to the extremes (1 or 10), the more certain the estimate [30]. The MammoScreen software detects and characterizes suspicious findings on a screening mammogram, as illustrated in Figure 2. Lesions are categorized into three main categories: red (7–10), highly suspicious lesions; yellow (5–6), lesions suspected of malignancy; and green (1–4), lesions with low suspicion. Green lesions are not displayed by default on the MammoScreen interface; these lesions can be displayed using the filtering button at the bottom left corner of the interface.

2.6. Statistical Analysis

The data were analyzed using the statistical package of social sciences (SPSS) program (Version 25). After the normality homogenous test, the parametric variables identified were expressed in descriptive statistics, namely frequencies, percentages, and mean $\pm$ standard deviation (SD). A cross-tabulation test was used to calculate the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy. In addition, the area under the receiver operating characteristic (AUROC) curve was used to test the differences between the AI system's and radiologists' assessment scores. The confidence intervals (CIs) were considered at 95%, and a p-value of <0.05 was considered statistically significant.

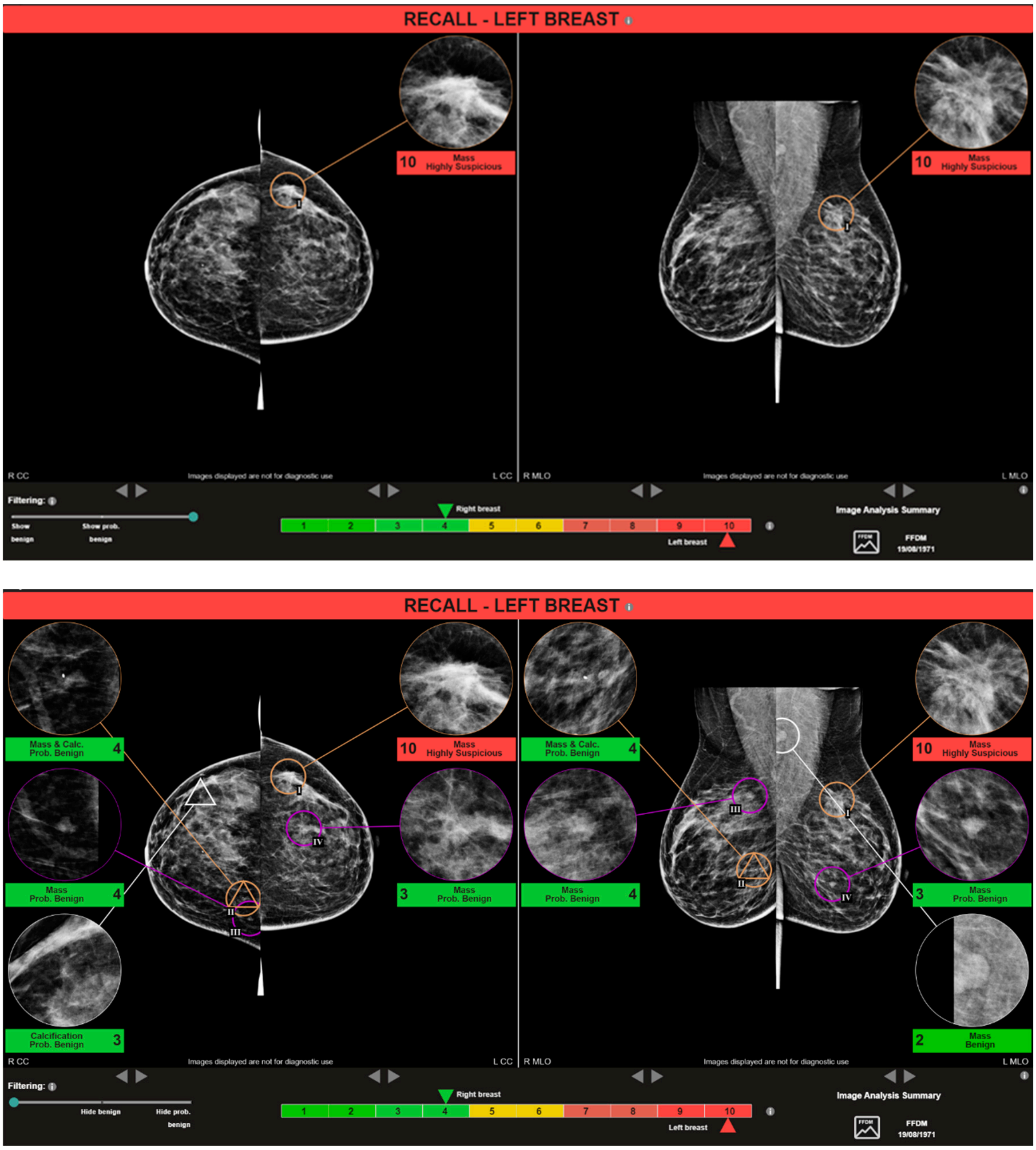


Figure 2. The detection and characterization of suspicious lesions on mammograms using the MammoScreen software. The lesions are categorized into three main categories: red, highly suspicious lesions; yellow, lesions suspected of malignancy; and green, lesions with low suspicion of malignancy. The green lesions are not displayed by default on the MammoScreen interface but can be displayed using the filtering button at the bottom left corner of the interface.

3. Results

Three hundred and seventy-eight mammograms, radiology reports, and pathological findings were reviewed. The patients' mean age was 50.3 years (range, 43–57 years); median breast thickness, 57 mm; and median glandular dose, 6.6 mGy. Most patients had breast density B (42.3%) and a breast imaging reporting and data system (BIRADS) classification V (36.9%) or II (20.9%). Most patients diagnosed with cancer had invasive ductal carcinoma (35.5%). Of the patients, 10.05% had no evidence of malignancy and 42.06% showed no evidence of malignancy after follow-up for at least 6 months. The results presented in Figure 1 and Tables 1 and 2 were from Clearfield.

Table 1. Demographic and clinical characteristics of the study population and selected digital mammograms (n = 378).

Characteristic	Value
Age (y), mean ± SD	50.31 ± 10.5
Breast thickness (mm), median (interquartile range)	57.0 (48–66)
Glandular dose (mGy), median (interquartile range)	6.6 (4.7–10.4)
Breast density category, n (%)	
A	103 (27.2)
B	160 (42.3)
C	98 (25.9)
D	17 (4.5)
BI-RADS categories	
0	34 (9.0)
I	21 (5.6)
II	79 (20.9)
III	38 (10.1)
IV	70 (18.5)
V	136 (36.9)
Mean MammoScreen score, median (interquartile range)	6.03 (4–9)

BI-RADS = Breast imaging reporting and data system.

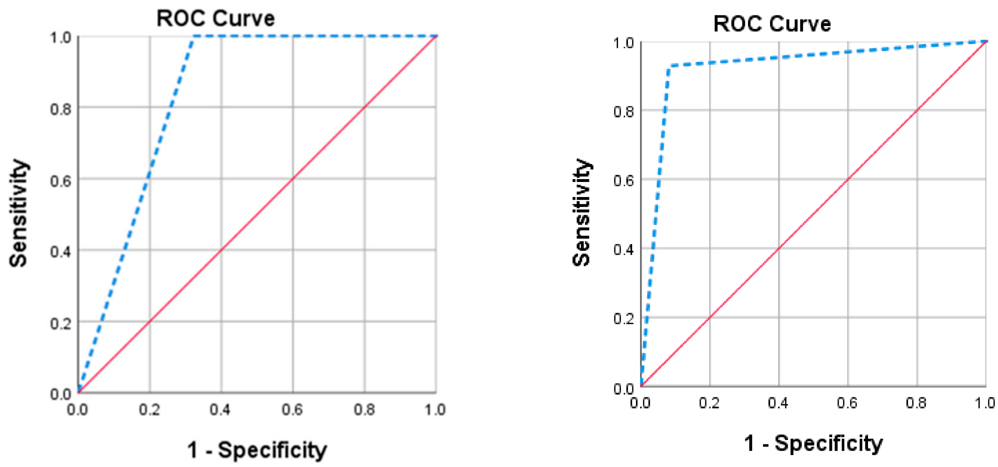
Table 2. Characteristics of the patients with breast cancer in the selected dataset (n = 181).

Histological Type	No. of Cases, n (%)
Invasive ductal carcinoma	141 (37.3)
Metastatic carcinoma	12 (3.17)
Ductal carcinoma in situ	10 (2.6)
Invasive lobular carcinoma	7 (1.85)
Other types	11 (2.91)

The AI system and radiologists were compared in terms of their overall assessment performance of the mammograms. The area under the curve (AUC) value of the AI system (0.923; 95% CI, 0.893–0.954) was higher than that of the radiology assessment (0.838; 95% CI, 0.796–0.881), as shown in Table 3. The AUC difference was 0.085, which was slightly higher for the AI system. The average ROC curves are displayed in Figure 3. As shown in Tables 4 and 5, the AI system agrees with the ground truth results to diagnose 167 cases (91.3%) as positive findings and 182 cases (93.3%) as negative findings. On the other hand, the AI system does not agree with the ground results that 16 negative results (8.7%) in the histopathological analysis of biopsy samples were positive results (false-positive results). Furthermore, 13 positive results (6.7%) in the histopathological analysis of biopsy samples were diagnosed as negative results with the AI system (false-negative results). The sensitivity, specificity, PPV, NPV, and accuracy of the AI system were 92.8%, 91.9%, 91.3%, 93.3%, and 92.3%, respectively.

Table 3. Comparison of AUC values between the AI system and radiologists' assessment results.

Variable	AUC	p-Value	95% CI
Artificial intelligence system assessment results	0.923	0.001	0.893–0.954
Radiologists' assessment results	0.838	0.001	0.796–0.881



(**A**) ROC curve of radiologists' assessment results (**B**) ROC curve of the AI results

Figure 3. (**A**) Receiver operating characteristic (ROC) curves of the radiologists' and (**B**) artificial intelligence (AI) system assessment results.

Table 4. Cross tabulation between the AI system and radiologists' assessment (RA) with ground truth results.

Variable	Categories	Ground Truth		Total
		Negative *n* (%)	Positive *n* (%)	
AI categories	Negative	182 (93.3)	13 (6.7)	195 (100)
	Positive	16 (8.7)	167 (91.3)	183 (100)
Radiologists' assessment (RA)	Negative	134 (100)	0 (0)	134 (100)
	Positive	64 (26.2)	180 (73.8)	244 (100)

Table 5. Accuracy measures for the AI system's assessments and Radiologists' assessment (RA).

Variable	Sensitivity	Specificity	PPV	NPV	Accuracy	AUROC
AI categories	92.8%	91.9%	91.3%	93.3%	92.3%	0.923
Radiologists' assessment (RA)	100%	67.7%	73.8%	100%	83.1%	0.838

As shown in Tables 4 and 5, the radiologists' assessment results agree with the ground truth results to diagnose 180 cases (73.8%) as positive findings and 134 cases (100%) as negative findings. On the other hand, the radiologists' assessment results do not agree with the ground truth results that 64 negative results (26.2%) in the follow-up examinations with either an additional screening or a histopathological analysis of biopsy samples were positive results according to the radiologists' assessments (false-positive results). The sensitivity, specificity, PPV, NPV, and accuracy of the radiologists' assessment were 100%, 67.7%, 73.8%, 100%, and 83.1%, respectively.

4. Discussion

AI applications play a significant role in oncoradiology in terms of the early detection and precise diagnosis of breast cancer. Early cancer detection increases the likelihood of effective treatment in different types of malignancy [31]. Recently, the implementation of digital mammographic screening programs is the most essential method to reduce cancer morbidity and mortality that has led to improvements in patient survival [29]. Owing to the increased interest in AI in radiology applications, various modern deep learning-based algorithms have been created and applied to digital mammography. Preliminary research has shown that the use of AI systems to provide concurrent mammographic interpretations can increase radiological efficiency in terms of time, sensitivity, and specificity [22,32]. AI systems based on CAD neural network algorithms are useful in the detection of breast lesions and in reducing the false-positive rate. On the other hand, radiologists' performance in mammography screening has a high false-negative rate, especially in cases with dense breast parenchyma [33–39].

The histopathological test results in the present study show that invasive ductal carcinoma was the most common type of cancer among the patients. This finding is consistent with previously published reports that invasive ductal carcinoma is the most common type of breast cancer among Saudi women, accounting for more than 80% of the most common malignancy lesions [40,41]. This breast cancer is diagnosed at an average age of <50 years. This indicates the urgency for the implementation of breast screening programs and an accurate diagnostic system [41].

In our study, a dataset of digital mammograms, including those of different types of breast abnormalities and normal breasts, were identified using the MammoScreen AI system. This AI system is based on CNNs which are the most frequently used neural networks in radiological studies. By observing the overall tendency of all ROC curves, we demonstrated in this study that the AI system outperformed the radiologists in detecting breast cancer. The AI system had a slightly higher AUC value than the radiologists, with a difference of 0.085 (0.923 vs. 0.838). The results of several previous studies are consistent with our results [17–19,24,42,43]. According to McKinney et al., the AUC for the AI system was greater than the average for six radiologists by an absolute margin of 11.5% [20]. Similarly, Rodriquez-Ruiz et al. investigated the performance of radiologists with and without the support of an AI system and found statistically significant higher AUC values for readings with AI support (0.89) than for unaided readings (0.87) [42]. The same group published a subsequent study to examine the stand-alone performance of an AI system compared with that of 101 radiologists who evaluated nine different cohorts of digital mammogram examinations from four different manufacturers. The results showed that the average AUC was 0.814 for the radiologists and 0.840 for the AI system so that the AI system outperformed 61.4% of the radiologists in terms of AUC [24]. Important results were achieved by Pacilè et al. (2020) who demonstrated an improvement in the average AUC across 14 radiologists with and without the MammoScreen AI system, with AUC values of 0.769 and 0.797, respectively. The average difference in AUC was 0.028 based on the investigation research [17]. These results suggest that the AI system had better performance in detecting breast cancer than radiological assessment.

The results of the present study demonstrate a false-positive rate of 8.7% for the AI system and 26.2% for the radiologists. On the basis of these results, the AI system agrees with the ground truth results confirmed by biopsy or follow-up imaging which achieved high specificity and accuracy for detecting breast cancer and had fewer callbacks for benign findings. These findings are consistent with those of previous studies that demonstrated the high accuracy of the AI system in breast cancer detection [17–19,24,42,43]. Fewer false-positive markings on mammograms were also found when the AI system was used [17,19,44]. In the United States and Europe, the performance of the AI system exceeded that of a single radiologist with regard to sensitivity (56% vs. 48%) and specificity (84% vs. 81%) [18]. Like other population-based studies, our study included all types of mammograms, including those of normal breasts, benign lesions, and breast cancer cases, to obtain optimal data as similar as possible to those obtained from routine screening. By enhancing diagnostic accuracy, this AI program would enable more women to obtain a benign diagnosis without unnecessary callbacks, imaging, or biopsies [17,19,21,44]. This could also help physicians read images with a high degree of confidence and less time interpreting normal mammograms; thereby, patients could receive their results faster.

The AI system used in this study had a cutoff suspicion score of ≤6 (AUROC = 0.967; sensitivity, 92.8% and specificity, 91.9%) which reflects its high accuracy in detecting breast cancer (see Supplementary Results, Figure S1 and Table S1). These results are similar to the those of an American study presented of the Society of Breast Imaging (SBI) in 2021 [45]. MammoScreen was used to analyze 16,004 screening mammograms in a recent US study presented at the 2021 SBI conference and the results revealed that the MammoScreen cutoff suspicion score was 6, the middle point of the MammoScreen lesion suspicion score and the best compromise in terms of sensitivity and specificity. By using the MammoScreen AI system, 27% of breast cancer cases were found 1 year earlier and 21% were found 2 years earlier, with a minimal increase in recall rate [45]. However, further longitudinal research studies are needed to determine the usefulness of the MammoScreen AI system for detecting early-stage breast cancer in the Saudi women cohort.

One limitation of the present study is the limited follow-up time of the patients for defining the ground truth, which may provide no false-negative results for patients with normal breast findings. As for normal cases, this provided high specificity to the radiologists' performance in the present study. Further studies are needed with a longer follow-up period of 18 months to allow the detection of intervals and flag cancer cases earlier using the AI program. In addition, the radiologists' performances were categorized on the basis of their BI-RADS scores determined using a screening scenario threshold of BI-RADS category ≥ II which was considered positive when the cases were recalled for follow-up. If a probability of malignancy (POM) was determined by radiologists, it was preferred over the BI-RADS because it provides better samples from the ROC space and is an ordinal scale.

In the same context, the AI system and radiologists improved the quality of mammographic breast cancer detection without prolonging the overall reading time [17,46]. However, our study used a dataset without a matched control group. Collaboration with radiologists using the AI system is needed to obtain a more sensitive diagnostic performance. Currently, hospitals lack AI algorithm systems and AI professionals. We believe these limitations did not affect the outcome of this study. Future studies should include additional controls such as merging mammographic data with radiologists-aided AI algorithm systems.

The main advantages of AI systems are that they can improve the diagnosis and detection of breast cancers, which can be achieved without additional workload, time, and effort. This has important impacts on the reduction in recall and false-positive rates and many economic and social benefits [44]. Moreover, AI systems are noninvasive techniques that can be superior to human experts in predicting prognosis and detecting breast cancers in the early stages and thus can be used by radiologists as a diagnostic support tool [19]. Visual interpretation by radiologists is still a suitable method when AI software is not available.

5. Conclusions

The AI system used in this study had good sensitivity and specificity compared with the radiologists and thus could be used to improve the diagnosis and detection of breast cancers. By enhancing radiologists' specifications, the MammoScreen AI might enable more women to obtain a benign diagnosis without unnecessary callbacks, biopsies, or imaging. This could help physicians read images with a high degree of confidence and with less time interpreting mammograms; thereby, patients could obtain their results faster. Further studies are needed to confirm these results by incorporating Saudi radiologists' performance in reading mammograms using an AI system.

Supplementary Materials: The following supporting information can be downloaded at https://www.mdpi.com/article/10.3390/app132112087/s1. Supplementary results for the cutoff points of the artificial intelligence program (MammoScreen suspicion score results). Figure S1: Area under the ROC curve for AI MammoScreen_score; Table S1: Accuracy measures of the cutoff points ≥ 5.

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Informed Consent Statement: The need for patient consent was waived owing to the observational, retrospective nature of the investigation.

Data Availability Statement: Not applicable.

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Conflicts of Interest: T.B. is an employee of Therapixel company. All other authors declare no competing interest.

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