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Original Article

Evaluation of an AI-powered Portable Thermal Imaging Solution as a Pre-screening Tool for Breast Cancer

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Abstract

Background and objectives: Breast cancer is one of the greatest global health concerns for women, with rising incidence rates and mortality projections, while affordability and access to mammography screening and diagnosis, especially in low- and middle-income countries, remain a challenge. This retrospective clinical validation study evaluated a breast cancer pre-screening solution (BCPS) based on a commercially available smartphone with a thermal imaging sensor powered by artificial intelligence. The purpose was to measure the performance of the BCPS tool compared to mammography, the gold standard for first-pass examination in breast cancer screening.

Methods: The evaluation was conducted in the Erebouni Medical Center Breast Unit in Armenia over a period of six months. We tested a cohort of 478 women of whom 45 were finally diagnosed with breast cancer after biopsy. Participants were first screened with the BCPS before undergoing the standard breast screening pathway. After studying the mammography results, if malignancy was discovered, a biopsy was performed and taken as the ground truth when comparing with BCPS artificial intelligence results.

Results: When combined with patient-reported or clinical symptoms, the BCPS tool achieved a sensitivity of 89% and a specificity of 83% compared to mammography. When clinical or patient-reported symptoms were not taken into account, sensitivity was considerably lower (60%), while specificity was higher (88.2%).

Conclusions: The BCPS tool, in combination with basic clinical exams and patient-reported symptoms, may serve as a robust triaging tool for breast cancer detection where mammography is not available or affordable, identifying the majority of women who need further diagnostic assessment.

Introduction

Breast cancer is the most common cancer among women globally. In 2020, around 2.2 million women were diagnosed with breast cancer of whom 684,000 succumbed to the disease.[1] By 2040, these numbers are predicted to increase to over 3 million new cases and 1 million deaths every year. Breast cancer incidence rates are highest in countries that have undergone economic transition, but currently transitioning countries carry a disproportionate share of breast cancer deaths due to their larger populations.[2,3] The current gold standard for screening and early detection of breast cancer is mammography based on a mortality reduction of up to 41% for women regularly participating.[4] While ultrasound and magnetic resonance imaging (MRI) are available as additional screening tools for early breast cancer detection, their utilization for this specific purpose is limited due to various constraints.[5,6] Moreover, breast cancer screening programs are not implemented in every country and even if implemented not all women have access to

Keywords: Breast cancer; Medical imaging; Artificial intelligence; Screening; Sensitivity; Specificity.

Abbreviations: AI, artificial intelligence; AUC, area under the curve; BCPS, breast cancer pre-screening; CI, confidence interval; ROC, receiver operating characteristic.

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regular screening, especially in low- and middle-income countries. Generally, the problem is more prominent in rural areas, where it is next to impossible to access mammograms and ultrasound examinations due to the lack of adequate personnel and equipment. With the growing cancer mortality rate, researchers are exploring new innovative imaging technologies for breast screening combined with AI to help with early detection, which is crucial for survival.[7–11]

Breast thermography, as its name suggests, produces an image of the breast by highlighting temperature variations. Unlike methods that depict the physical structure of breast tissue, thermography creates a functional image by visualizing temperature changes on the skin's surface and was first used for screening breast cancer in 1956.[12] In 1982, the United States Food and Drug Administration granted approval, acknowledging its role as a complementary adjunct tool to mammography for breast cancer screenings. Thermal imaging works by detecting heat emitted from the body, and as cancerous tumors often have a higher metabolic rate than normal tissue, they emit more heat. This can be seen as a difference in temperature on a thermal image compared to normal tissue.[13–15] In the past, thermal imaging cameras were large and expensive, and had low sensitivity, making them impractical for breast cancer screening.[16,17] However, recent advances in thermal technology have made it possible to create smaller and more affordable thermal imaging sensors. These sensors such as FLIR Lepton (as used in this study) are already embedded in some smartphones, making them even more accessible. Another recent development is the use of artificial intelligence (AI) in thermal imaging. AI can be used to improve the analysis of thermal images and identify potential abnormalities in breast tissue temperature. This can help to reduce human error and subjectivity in interpreting thermal images, as has already been seen in the interpretation of mammograms.[18]

A Swedish life science company has combined existing smartphone-based thermal sensors and their own developed AI, creating a breast cancer pre-screening (BCPS) tool for primary care personnel. The company's mission is to address the issue of delayed detection of breast cancer on a global scale. The BCPS solution is designed to be user-friendly and accessible to individuals who may not have specialized medical knowledge but work as nurses in primary care. It offers insights into the overall health of the chest, whether a person is experiencing symptoms or not, by focusing on metabolic information. Furthermore, the BCPS solution holds the potential to alleviate various obstacles that hinder women from accessing mammography screening. These barriers encompass factors such as fear, psychological concerns, financial constraints, limited availability, lack of awareness, and cultural factors.[19]

BCPS uses AI to analyze thermal images of the breast area at the pixel level. The BCPS can be performed in the first line of healthcare by a non-specialist. The AI gives a risk prediction score, and if the risk is high, the patient is recommended to visit a breast cancer specialist. The algorithm identifies abnormal temperature patterns that could be indicative of malignant tumor development as cancer is characterized by a significant increase in cell metabolism and hypervascularization.[20,21] Both of these phenomena are accompanied by a local increase in the temperature of the breast tissue in the affected region, which can be recorded via smartphone-based thermal sensors. The AI then analyzes the thermal image and identifies abnormal subtle changes that the human eye will not be able to see. New generation thermal sensors in consumer smartphones have a standard high resolution of 160x120 and 19.200 pixels and can detect temperature differences of 0.050°C (https://www.flir.com/products/lepton/?model=500-0771-01&vertical=microcam&segment=oem).

Combining these high-resolution thermal images with AI reduces human subjectivity in analyzing thermal images through automated interpretation. Machine learning algorithms are deployed to analyze thermal images and produce scores by analyzing medically interpretable parameters that depict the metabolic activity occurring within the breast tissue, thus providing insights into the potential presence of malignancies. This aligns with the prevailing trend in the realm of AI implementation in digital mammography. In this domain, the utilization of machine learning algorithms has demonstrated clinical advantages. These algorithms aid in extracting, detecting, characterizing, and categorizing radiomics features present in mammograms.[22–24] The principles underlying AI-enhanced breast thermography closely resemble those of digital mammography. Currently, there is a renewed interest in evaluating the role of AI-enhanced breast thermography as an adjunct modality for screening. This evaluation is being carried out across different medical centers that have all contributed to the discourse on this topic.[25–27]

The objective of this six-month retrospective clinical validation study in a breast unit in Armenia was to evaluate the detectability of breast cancer development using a smartphone-based thermal sensor and AI. The study will compare the results of the BCPS, an AI-powered thermal imaging test, to the gold standard screening method, mammography, in terms of determining the accuracy of BCPS (sensitivity, specificity). The results of this study will provide important information about the potential of BCPS to be used for breast cancer screenings.

Materials and methods

Study design

This study was a retrospective clinical validation where we evaluated a cohort of women who visited the local breast center for diagnostic and screening examinations during six months in the Erebouni Medical Center Breast Unit in Armenia. This study followed the methodology of Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).[28] The study period lasted from 1 Dec 2022 to 31 May 2023 and the participants were 478 women. The study was conducted in a widespread cohort design. Enrollment criteria were women, over 20 years old, and visiting the breast unit for breast examination, both symptomatic and asymptomatic. Exclusion criteria were women who refused to participate, were pregnant or breastfeeding, or who had previous or ongoing breast cancer treatment, surgery, or radiation therapy. Patients who agreed to participate after receiving information about BCPS and the study itself signed a written consent document.

Screening protocol

The initial evaluation step involved the patient exposing their upper body, allowing the skin to cool down for 10 minutes, and subsequently replying to health-related questions. This process aimed to bring the patient's body to a state of thermal equilibrium, a state where temperature is uniform and stable. This thermal equilibrium is crucial as it helps to accentuate any temperature irregularities, enabling the detection of potential abnormalities, such as tumors, with greater accuracy during thermal imaging. For the correct and systematic acquisition of thermal images via smartphone, the examiner was trained in working with the device and used a floor guidance tool to secure optimal imaging angles. The pre-screening with three thermal images (frontal, left, and right) of the patient's

chest according to BCPS protocol did not alter the standard of care in the clinical pathway for any participant and is integrated as the first step before mammography, ultrasound, and possibly biopsy. For comparison, we used the results of mammography, and in the case of malignancy, the biopsy was taken as the ground truth. We then compared those results with the results of BCPS (thermal images combined with AI models and a health questionnaire, which the patient completed before BCPS began). To ensure data protection, all thermal images and personal data were anonymized for statistical evaluation. No optical sensor in the smartphone was utilized, except for the thermal imaging sensor, which captures heat emitted from the patients' chest for analysis.

Screening device

BCPS was performed with a CAT S62 Pro smartphone, with the Teledyne FLIR Lepton 3.5 thermal sensor as a standard component. The sensor provides a resolution of 160x120 (19.200 pixels) and can detect 0.050°C temperature changes. An Android application was installed in the smartphone, which was used during the retrospective clinical validation for data collection of thermal images together with other health and personal data. The same application was used to study the structured and labeled data in preparation for delivery to medical statisticians and machine learning engineers.

Artificial intelligence

In this chapter, we introduce our AI-driven methodology designed to analyze thermal images derived from original frontal, left, and right chest scans, culminating in the prediction of risk scores. The devised solution unfolds through a series of distinct stages, commencing with automated breast segmentation followed by the identification of abnormal regions. Subsequently, interpretable features are constructed for the detected abnormal regions, which are then used to assign an abnormality score for each of the regions. The regions with the highest abnormality scores are then used to train an ensemble of Random Forest Classifiers.

The training dataset consisted of thermal images of 829 patients, collected 1 year prior to this validation study. Moreover, the medical team has identified and annotated the tumor regions on the thermal images for the 69 disease-positive patients in the training dataset. As explained below, we used these annotations for training a model that assigned an abnormality score for each of the detected regions.

Automated breast segmentation

We used a deep learning approach for segmenting breast regions from the original chest scans. Specifically, we adopted the well-established U-Net architecture for this task.[29] To ensure the model's robustness and accuracy, we trained it on a dataset annotated by our team. The annotation process was facilitated by the open-source labeling tool "LabelMe" (http://labelme2.csail.mit.edu/Release3.0/index.php). Our automated breast segmentation model achieved a good segmentation accuracy, as evidenced by the Intersection over Union score of 95% on our dedicated test dataset.

Abnormal region detection

Following the segmentation of breast regions from the chest scans, our next objective was the detection of abnormal regions within these segmented breast areas. These abnormal regions are characterized by elevated temperatures when compared to the surrounding tissue. To achieve this task, we developed a region growing segmentation algorithm tailored to the specific characteristics of the breast thermography images. This algorithm initiates the process by identifying high-temperature points within the breast regions. Subsequently, it expands these regions iteratively, examining the temperature gradient at each step. The growth process continues until the temperature gradient becomes smaller than a predefined threshold value, signifying the boundaries of the abnormal region.

Feature construction

Following the detection of abnormal regions, our next step involved the construction of diverse temperature and shape-based features to comprehensively describe these regions.

Temperature-based features

Temperature Delta: This feature quantified the temperature variation within an abnormal region by calculating the difference between the maximum and minimum temperatures observed within that region.

Relative Temperature

We computed the mean temperature difference between the abnormal region and the surrounding healthy breast tissue, providing insights into the localized temperature variations within the breast.

Relative Temperature with Contralateral Comparison

To identify temperature asymmetries that can be indicative of potential abnormalities, we introduced a feature that measures the mean temperature difference between the abnormal region and the corresponding region on the contralateral breast.

Shape-based features

Fractal Dimensionality

In line with findings that highlighted the association between malignancy and higher fractal dimensionality due to irregular tumor boundaries, we incorporated fractal dimensionality as a feature to describe the irregularity of the abnormal region boundaries.[30]

Irregularity

To further characterize the shape of abnormal regions, we introduced a feature that identifies the hottest point within the region and computes the maximum distance from this point to the region's boundary. This distance is then normalized by the area of the abnormal region, providing a quantifiable measure of irregularity.

These temperature and shape-based features collectively offered a comprehensive and informative representation of abnormal breast regions, facilitating the identification and assessment of potential anomalies in our thermographic breast imaging.

Abnormality scoring for multi-region breast abnormality assessment

In the context of breast thermography, it is common to encounter multiple abnormal regions within each breast and view. To address this complexity, we had to either aggregate features across these regions, as demonstrated in prior studies, or select the most prominent abnormal region and extract its features.[31] In our approach, we chose the latter strategy, guided by precise annotations of tumor locations within our dataset. We trained a Random Forest classifier to assign an abnormality score to each of the abnormal regions. This score was instrumental in ranking the abnormal regions within each view, with the region bearing the highest abnormality score selected for subsequent analyses. Our algorithm thus enabled the precise identification and prioritization of abnormal regions within

Table 1. Distribution of study population characteristics

Attribute	Participants	Number of Cancers	Rate (95% CI)
Total Number	478	45	9.4 (7.1–12.4)
Age < 50 Years	256 (53.6)	16	6.2 (3.9–10.0)
Age ≥ 50 Years	222 (46.4)	29	13.1 (9.3–18.3)
Palpable Mass	69 (14.4)	32	46.4 (36.0–59.8)
No Palpable Mass	409 (85.6)	13	3.2 (1.9–5.4)
Pain	67 (14.0)	10	14.9 (8.4–26.4)
No Pain	411 (86.0)	35	8.5 (6.2–11.7)
Family History of Breast Cancer	64 (13.4)	9	14.1 (7.7–25.8)
No Family History of Breast Cancer	414 (86.6)	36	8.7 (6.4–11.9)

CI, confidence interval.

the breast thermography images, enhancing the accuracy and efficiency of the breast abnormality assessment.

Feature aggregation

After identifying the abnormal region with the highest abnormality score, we proceeded to construct the final feature set crucial for our predictive model. For each of the four breast views, left/right frontal view and left/right side view, we incorporated the features extracted from the selected abnormal region, thus facilitating a comprehensive analysis. These features were then complemented by a set of features describing the temperature variations between each of the views themselves, such as the median temperature difference between the left and right frontal breast regions.

By aggregating these diverse features, we created a robust and comprehensive feature set for our final predictions. This approach enabled our AI model to leverage spatial and temporal characteristics, to enhance the accuracy of breast thermography abnormality assessment.

Final prediction

In our final phase, we used an ensemble of four random forest classifiers, which were trained using a 4-fold cross-validation technique on our training dataset. The input to each of these classifiers was the feature set detailed earlier, which encapsulated information encompassing spatial, temperature-related, and patient-specific attributes. The output generated by each classifier represented the probability of the patient having breast cancer. To arrive at a unified prediction, we calculated the final risk score by taking the simple mean of these four probabilities. This approach ensured that the final prediction was both robust and statistically sound, contributing to the accuracy and reliability of our breast cancer risk assessment.

Statistical analysis

In this medical study, statistical analysis was conducted by an independent statistician, Sona Hunanyan, affiliated with Yerevan State University. The study's sample size was determined using a two-sided 95% confidence interval (CI), with an assumption of an 80% sensitivity and a desired confidence interval width of 0.3. The calculation was performed using the Clopper-Pearson interval (exact) method. Given a previously estimated breast cancer prevalence of 8% based on our prior data, we anticipated recruiting approximately 400 women for the study.

To assess the performance of our models in detecting breast malignancy, we computed sensitivity and specificity values. All statistical analyses were carried out using R Software version 4.2.2.

Results

Study population characteristics

A total of 478 eligible women who met the inclusion criteria and provided informed handwritten consent were incorporated into the data analysis. Among this cohort, 256 participants were below the age of 50, while 222 were aged 50 or older. All participants enrolled in the study underwent initial BCPS thermal imaging assessments prior to undergoing screening via mammography. Among the cohort, 45 individuals (comprising 9.4% of the sample) were identified as having a positive disease status through a combination of mammography and ultrasonography results or biopsy examinations. Notably, 32 out of these 45 women (constituting 71% of the positive cases) exhibited palpable breast masses. In contrast, among the 433 patients classified as disease-negative based on screening outcomes, only 37 individuals were found to have palpable breast masses. We present a detailed distribution of different characteristics of the study cohort in Table 1.

Evaluation

In the following, we present the outcomes of our BCPS tool. We investigate two distinct models: one reliant solely on thermal imaging predictions and another that incorporates these predictions in conjunction with the detection of palpable breast masses. We shall henceforth refer to these models as "Thermal Only" and "Thermal + Palpable Mass" respectively. The latter model's predictions are considered positive either when the Thermal Only model yields a positive result or when there exists a palpable mass on the breast. Detailed findings are summarized in Table 2.

The overall sensitivity of the Thermal Only model was determined to be 60% (95% CI, 47.3–6.2%), accompanied by a specificity of 88.2% (95% CI, 85.2–91.3%). However, upon integrating thermal imaging predictions with the identification of a palpable mass, the overall sensitivity exhibited a notable increase to 88.9% (95% CI, 80.2–98.6%), while maintaining a specificity of 80.1% (95% CI, 77–88.4%). Detailed receiver operating characteristic (ROC) curves and the corresponding area under the curve (AUC) values for both tests are presented in Figure 1. The Thermal Only model yielded an AUC score of 0.76, while the combined model

Table 2. Evaluation of 2 models on different population cohorts

Cohort	Thermal Only		Thermal + Palpable Mass	
	Positive Predictions (Number of Cancers)	Negative Predictions (Number of Cancers)	Positive Predictions (Number of Cancers)	Negative Predictions (Number of Cancers)
Total	78 (27)	400 (18)	126 (40)	352 (5)
Age < 50 Years	29 (7)	227 (9)	64 (14)	192 (2)
Age ≥ 50 Years	49 (20)	173 (9)	62 (26)	160 (3)
Palpable Mass	21 (19)	48 (13)	69 (32)	0 (0)
No Palpable Mass	57 (8)	352 (5)	57 (8)	352 (5)

achieved an AUC score of 0.88.

It is noteworthy that the performance of the Thermal Only model remains consistent across the cohorts of women with and without palpable breast masses. As indicated in the table, the model demonstrates sensitivities of 59.4% (with a specificity of 94.6%) and 61.5% (with a specificity of 87.6%) for the respective cohorts with and without palpable masses.

The thermal imaging predictions exhibit a notable disparity in performance between women aged 50 years and older, as compared to their younger counterparts. Specifically, the sensitivity among younger women is notably lower, measuring 43.8% (with a specificity of 90.8%). In contrast, for patients aged 50 and above, the sensitivity is considerably higher at 69% (with a specificity of 85%). We attribute this discrepancy to a limitation inherent in our study protocol, specifically, the relatively brief waiting period of only 10 minutes for thermal equilibrium onset. Our dataset reveals that younger women tend to exhibit more pronounced thermal patterns due to heightened hormonal activity. Therefore, it is plausible that extending the waiting time to 15 minutes may yield improved thermal equilibrium onset for younger patients. We intend to address this issue comprehensively in our forthcoming studies.

It is worth noting that even taking into account the above-mentioned limitation, the combined model's performance is robust. For both age groups, the combined model demonstrates a sensitivity of 87.5% with a specificity of 79.2% for the younger population and a sensitivity of 89.7% with a specificity of 81.3% for patients aged 50 years and older. This suggests that the integration of thermal imaging predictions with the detection of palpable masses continues to offer substantial diagnostic value across both age groups.

In Table 3 we present the model performances across different cancer characteristics. Namely, we present the sensitivities depending on the tumor size and tumor type.

Tumor size

In our study, we identified 10 malignant tumors with a size below 2 cm (T1). The Thermal Only model detected 5 of these tumors

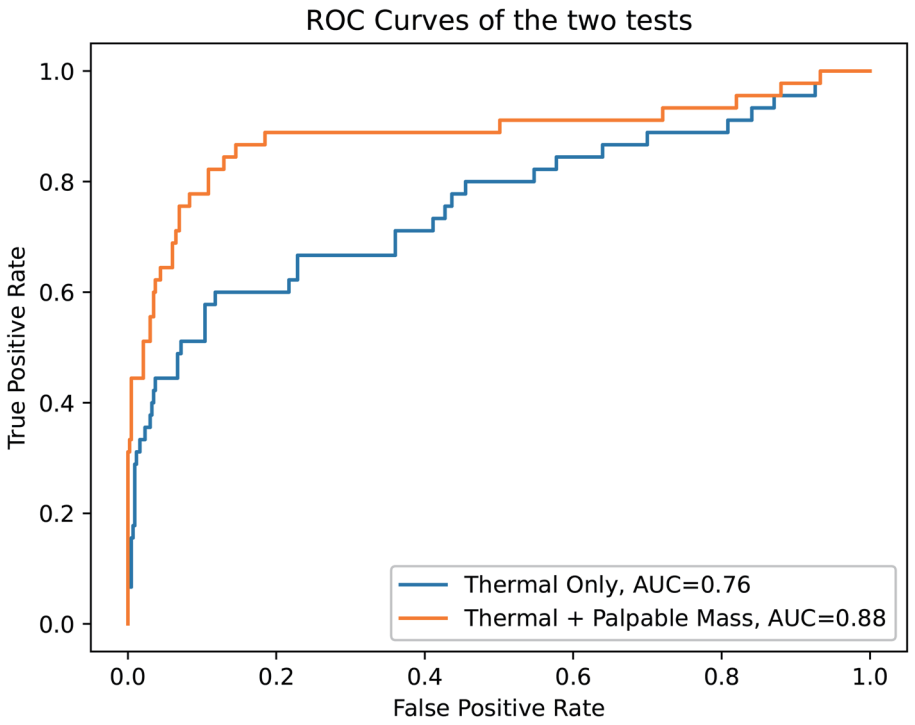

Fig. 1. ROC curves comparing the diagnostic performance of 2 models for breast cancer detection. AUC, area under the curve; ROC, receiver operating characteristic.

Table 3. Sensitivity of 2 models across different cancer characteristics

Characteristic	Number of Cancers	Thermal Only Sensitivity (%)	Thermal + Palpable Mass Sensitivity (%)
Tumor Size			
Below 2 cm	10	50	70
Above 2 cm	35	62.9	94.3
Tumor Type			
Non-specific tumor type	15	60	86.7
Luminal A	13	61.5	84.6
Luminal B	10	60	90
Luminal Her 2 or Her 2 Positive or Triple Negative	7	57.1	100

(50% sensitivity), while the combined model detected 7 of them (70% sensitivity). As expected, the model performance is better for larger tumors: among the 35 tumors exceeding 2 cm in size, the Thermal Only model detected 22 of them, yielding a sensitivity of 62.9%, while the combined model detected 33 of them, corresponding to a sensitivity of 94.3%.

Tumor type

Our analysis, presented in Table 3, reveals that the performance of the Thermal Only model exhibits consistent results across various tumor types. Of the 30 cases where biopsy tests were conducted, 13 were categorized as Luminal A, 10 as Luminal B, and 7 encompassed Luminal Her 2, Her 2 positive, or Triple-Negative tumors. Regardless of tumor type or whether a biopsy test was conducted, the Thermal Only model consistently demonstrated a sensitivity of approximately 60%, ranging from 57.1% to 61.5%.

In contrast, the performance of the combined model displayed a notable correlation with tumor aggressiveness. For Luminal Her 2, Her 2 positive, and triple-negative cases, the combined model detected all the tumor cases and exhibited strong performance for Luminal B tumors, with a sensitivity of 90%. These findings underscore the potential of the combined model to excel in detecting more aggressive tumor types, offering enhanced diagnostic capabilities in cases of heightened malignancy.

Discussion

Breast cancer remains a global health challenge with increasing incidence rates, and to address this issue, access to early screening and detection tools is critical, especially in low- and middle-income countries where resources for standard screening methods such as mammography are limited, leading to significant mortality projections. In this context, the development of portable and affordable pre-screening and pre-diagnostic tools such as BCPS show promising potential. BCPS utilizes thermal imaging and AI to identify potential abnormalities in breast tissue temperature based on the higher metabolism found in tumorous tissue. This innovative approach has several advantages, including non-invasiveness, absence of radiation exposure, and cost-effectiveness, and this study, conducted in the breast unit of a hospital in Armenia, provides insights into the effectiveness of implementing BCPS for breast cancer screening and diagnosis.

While the sensitivity of thermal imaging alone was 60% compared to mammography it has the potential to be a useful pre-screening or pre-diagnostic tool for breast cancer, especially in women who may not have access to standard-of-care screening methods such as mammography. When combined with self-reported or clinical symptoms, the sensitivity increased significantly to 88.9%. By using BCPS to stratify patients for further investigation, we can focus our resources on those who are most likely to have cancer and reduce the number of unnecessary mammograms.

The study also provides insights into the performance of BCPS based on patient age and clinical characteristics, suggesting that BCPS may be more effective in detecting breast cancer in women over 50 years of age. This is evidenced by the higher cancer detection rate in this group, and one possible explanation for this finding is that it may be more difficult to reach thermal equilibrium in younger women due to increased tissue activity. Thus, further research is needed to investigate this possibility and to identify ways to improve the effectiveness of BCPS in younger women. This might be achieved through a longer cooling time or a different thermal sensor that is better suited for younger women.

Overall, the study provides preliminary support for the potential of BCPS as a pre-screening tool, especially in settings where access to standard screening methods is limited. However, the study has several limitations. First, the sample size is relatively small, with a low number of cancer cases; therefore, it was not possible to calculate statistically significant differences for tumor subtypes. This is because examinations were performed in only one center with a limited capacity. Second, the cohort of female participants comprised both diagnostic and screening cases. We separated the participants based on the presence or lack of symptoms under the assumption that examinations of symptomless women were screening. Third, we did not have access to a cancer registry; thus, we could not track interval cancers and could only compare BCPS to cancers found by mammography and biopsy-proven or specimen-proven cancers. Fourth, subgroup evaluation was limited due to small sample sizes in all subgroups. Despite these limitations, our study provides valuable insights into the potential of BCPS as a pre-screening tool. Future studies with larger sample sizes, more representative cohorts, and access to cancer registries are needed to confirm our findings and address the limitations of our study. At present, BCPS technology which is a combination of thermal imaging and AI is only applicable to breast cancer pre-screening, but in the future, there could be further applications such as monitoring neoadjuvant therapy effects for breast cancer.

Conclusions

This study provides evidence that the BCPS tool using a smart-

phone-based thermal imaging sensor and AI in combination helps to detect breast cancers earlier, especially in settings where mammography as a standard of care is not available or accessible as a first-pass screening or diagnostic tool. This is particularly relevant for low- and middle-income countries. BCPS can also be used in high-income countries to pre-screen women outside of the recommended screening age range who seek primary care as a first step as well as to provide a pre-screening option for women who currently do not wish to undergo mammography for various reasons such as fear, psychological concerns, financial constraints, limited availability, lack of awareness, and cultural factors and are thus being missed by healthcare. Further studies are needed to validate these findings. In the future, more studies should be performed for different use cases such as the investigation of pathological lymph nodes. Also, it might be useful to compare the device to other modalities used in breast cancer screening and detection such as POCT (Point-of-Care Testing), MRI, and CEM (contrast-enhanced mammography).

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Conflict of interest

NB, AG, KDE, and AL are shareholders of Thermaiscan Technology AB. HS is a consultant working at Labz.ai. The rest of the authors have no conflict of interest.

Author contributions

Study concept and design (NB, AG, HS, HGK, AL), acquisition of data (LS, AGG), drafting and writing the manuscript (NB, AG, HS, KDE, AL), critical revision of the manuscript for important intellectual content (HS, AG, HGK), provided statistical data analysis and prepared the tables of data (HS, SA), administrative support (AL), funding acquisition (AL), study supervision (AG, HGK), software (HS, AL). All authors have read and agreed to the published version of the manuscript. The authors confirm that the article is not under consideration for publication elsewhere.

Ethical statement

This retrospective clinical validation study was carried out in accordance with the ethical principles of the Declaration of Helsinki (as revised in 2013). The institutional review board at Yerevan State Medical University approved the study protocol and granted ethics approval under Nr N3-5/22 (dated 2022-11-24). All participants involved in the study signed a written informed consent form.

Data sharing statement

The dataset used in support of the findings of this study is included within the article.

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