International Journal of Community Medicine and Public Health
Manjunath G et al. Int J Community Med Public Health. 2022 Dec;9(12):4634-4640
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20223225

Original Research Article

Feasibility and outcomes of using a novel artificial intelligence enhanced breast thermography technique, Thermalytix, in screening for breast abnormalities at primary health centres at the community level in South India

Geetha Manjunath[1], Himanshu Madhu[1], Nirmala Buggi[2], Anasuya Suggaiah[2], Revathi Muthanna[1], Charitha Gangadharan[1]*, Jilsy M. Joy[1], Sathiakar Collison[1], Lakshmi Krishnan[1]

[1]Niramai Health Analytix, Data Science, Bangalore, Karnataka, India
[2]Bruhat Bengaluru Mahanagara Palike Hospital, Bangalore, Karnataka, India

Received: 14 October 2022
Revised: 21 November 2022
Accepted: 22 November 2022

***Correspondence:**
Dr. Charitha Gangadharan,
E-mail: charitha.g@niramai.com

ABSTRACT

Background: Women from low-income families have poorer health-seeking behavior, particularly when it comes to cancer screening. A community health initiative was launched by Niramai in collaboration with city officials in Bangalore as a pilot to increase awareness and make breast health screening available to all. This study describes a community-level breast screening for underprivileged women in south India adopting Thermalytix, a thermography-based artificial intelligence device.
Methods: This observational study was conducted at 25 municipal primary health centers where women over 18 years of age were enrolled. The project started on 14 November 2017 and is ongoing. Procedures include a brief meeting on camp procedures, identification of eligible candidates, health education, and Thermalytix testing.
Results: A total of 6935 women underwent artificial intelligence (AI)-powered Thermalytix screening in 25 Bruhat Bengaluru Mahanagara Palike (BBMP) hospitals. The median age was 42 (range 18-86) of the 5248 women enrolled as per inclusion. Among the 5248 women recruited, 62 (1.18%) women were detected with some abnormalities in Thermalytix. Out of the women who underwent follow-up investigations (11/62), eight were positive on radiological evaluation, further histopathological evaluation confirmed one ductal carcinoma *in situ*.
Conclusions: Community participation with the engagement of the local government health officials enabled us to develop screening strategies for underprivileged women. Thermalytix could be a potential screening tool in resource-constrained settings and the portable equipment enabled easy movement across different primary health centers (PHCs). Since it is a privacy-aware test, there was less refusal to participate in the test.

Keywords: Artificial intelligence, Breast neoplasms, Mammography, Early detection of cancer, Thermography

INTRODUCTION

Breast cancer is a major public health concern in India, accounting for approximately 25% of all female cancer cases.[1] It is estimated that the prevalence of breast cancer in India is 92.6 per 100,000 population with a mortality rate of 12.7 per 100,000 population.[2] Breast cancer incidence is rising rapidly in low- and middle-income countries (LMICs); Over a 26-year period, the age-standardized incidence rate of breast cancer in India

increased by 39·1% (95% UI 5·1–85·5) from 1990 to 2016, with an increase observed in every state of the country.[3]

Breast cancer screening identifies signs of breast cancer among women even before the symptoms appear and systematic breast cancer screening is associated with a reduction in cancer deaths across many studies.[4] Guidelines for the screening, diagnosis, and treatment of breast cancer exist in the developed world, but economic and health systems barriers preclude the implementation of many of these recommendations in resource-limited countries and the screening modality that is appropriate for India and other LMICs remains undetermined.[5] Community-level mammographic screening is not the most effective approach in LMICs as it is a complex undertaking involving substantial resources and infrastructure and results obtained in western countries are unlikely to be replicated in poorer countries.[6] Hence it is recommended that there should be a "mixed" portfolio of tools to reduce breast cancer mortality with mammography reserved only for those sub-populations that meet the criteria.[7,8]

Self-breast examination, clinical breast examination, and ultrasound are the cancer screening methodologies that are most frequently used in the absence of comprehensive mammographic screening. Breast self-examination is probably the least expensive method but is likely to reduce mortality only if competently performed and if backed up with an appropriate diagnostic follow-up. However, at the community level, it is not feasible to ensure women perform well.[9] Clinical breast examination refers to the conventional method of a healthcare practitioner physically inspecting the breast to detect any symptoms and its sensitivity range from 28% to 54% and is depending on the skill of the healthcare workers.[10] In a recent study, Mittra et al 2021 found that clinical breast examination conducted every two years by primary health workers significantly down staged breast cancer at diagnosis and led to a non-significant 15% reduction in breast cancer mortality overall.[11] However, the success of its use for early screening has not been widely established.[12,13] Ultrasonography could offer a low-cost way to improve sensitivity and detection rates of early cancers in women with dense breasts, but the use of ultrasound has also been restricted in India due to the pre-conception and pre-natal diagnostic techniques act, of 1994. It is therefore not a feasible option for community-based breast cancer screening programs in India.[14]

In 1982, the United States Food and Drug Administration (FDA) approved thermography as a supplement to mammography to help detect breast cancer. Digital infrared thermal imaging (DITI) has resurfaced in this era of modernized computer technology, and several authors have revisited the use of breast thermography as a cost-effective technique to detect breast anomalies in the community.[15-18] Modern high-resolution thermal cameras can detect temperature differences of 0.025°C and when combined with computer algorithms for thermal analysis may reduce subjectivity and enable automated quantitative interpretation thereby making the interpretation process more factual.[19] The use is not intended to replace the mammogram for breast screening but rather to use it as a complementary tool as part of more efficient earlier detection strategies contributing to decreasing mortality rates.

The CE marked Thermalytix™ uses machine learning, image processing, and computer vision techniques to give an automated interpretation of the breast thermal images, and is a potentially low-cost, portable, non-invasive, and non-contact thermal screening modality. In a recent publication of a multisite study of 470 asymptomatic and symptomatic women, it has been validated to have a sensitivity of 91.0%, specificity of 82.4%, and an negative predictive value (NPV) of 97.9% for the detection of breast malignancy.[20] It is effective on women of all ages, but especially on younger women with dense breasts. This is a low-cost, accurate, automated, easily portable cancer screening device that is painless, non-touch, and radiation-free.

This paper aims to describe a community-level breast screening for underprivileged women in south India adopting Thermalytix, a thermography-based artificial intelligence device.

METHODS

This is an observational study of an ongoing screening program conducted at primary health centers of the Bruhat Bengaluru Mahanagara Palike (BBMP), which is the administrative body of the Bangalore metropolitan area, using artificial intelligence based breast thermography CE-marked Thermalytix technology to screen asymptomatic women for breast abnormalities in conjunction with Niramai Health Analytix, the manufacturer of Thermalytix.

On 14 November 2017, the state government of Karnataka launched a community public health initiative to raise breast health care awareness and make breast screening available to all BBMP hospitals and affiliated primary health centers (PHCs) offering Niramai's Thermalytix screening tool. Currently, breast screening is not available at any of these screening locations. Every month, on selected days according to a preplanned schedule, Niramai-trained technicians screen women who walk in at BBMP healthcare centers (Figure 1). The awareness training, recruitment, screening, and follow-up procedures are described below.

Participant selection

Participants were women over the age of 18 who were enrolled as outpatients. Pregnant and lactating women were excluded from the study. Voluntary recruitment was done following community-based awareness activities;

other subjects were recruited from the villages by accredited social health activists (ASHA) workers.

Sample size

Since this is an ongoing public health initiative in collaboration with BBMP, the exact formal sample size calculation was not performed.

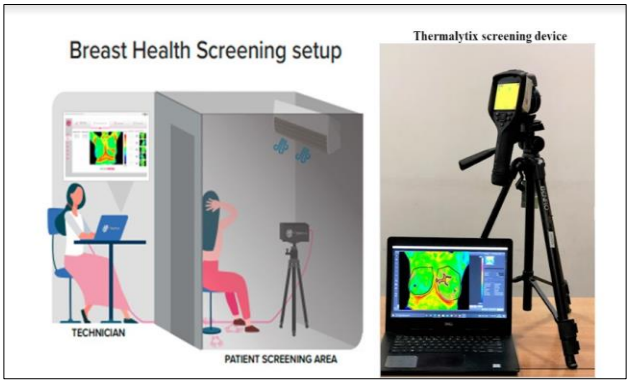

Figure 1: Camp screening set-up at BBMP facilities and Thermalytix breast screening device.

Training of field staff/technicians

For the technicians and community participants, a well-organized field training program was implemented as part of the project. The staff received two days of training covering how to use and troubleshoot the device, as well as information about breast cancer, study inclusion criteria, and recruitment requirements. Local support groups received the additional training, so they could counsel and direct a patient to the screening camp. Several breast health awareness activities were planned for health professionals and different levels of community leaders, including ASHAs. Women who visit health clinics were invited to undertake the Thermalytix screening as part of this project. As per the previously planned schedule, there were two technicians at the BBMP affiliated PHC. Every six months, refresher training is provided.

Resources used

Each center uses one Thermalytix device and two qualified technicians on a scheduled day. Thermalytix devices consist of a cooler, thermal camera, tripod, Thermal printers, a laptop to capture the thermal images, and a rotating stool. An image of the Thermalytix breast screening device is represented in Figure 1.

Screening methodology

Women who visit the BBMP health clinics are given a summary of the camp processes, as well as registration for the camp. Written informed consent is obtained. After obtaining the informed consent, screening starts with documentation, which includes demographics and relevant medical history. The Thermalytix screening is then initiated by providing the participants with the relevant instructions (Figure 2). Before taking the thermal images, the person is pre-cooled with the help of a cooler. A skilled technician captures five thermal images of the chest region: frontal, left-oblique, left-lateral, right-oblique, and right-lateral views.[21]A representative case is displayed in Figure 3 with breast images taken from five different views. The Thermalytix software was then used to upload these pictures. The asymmetry in the structural, vascular, and thermal properties of the observed abnormality allows Thermalytix software to automatically analyze the uploaded images to find abnormal patterns. The automated analysis of the thermal image generates a screening report that recommends the next step: follow-up with breast ultrasound and/or further investigations if the abnormal thermal activity is detected (triaged as red), or routine screening if no abnormal thermal patterns are detected (triaged as green). The Thermalytix test takes about 15 minutes to complete. Women who are diagnosed with a breast anomaly (triaged as red) are referred for additional testing and follow-up.

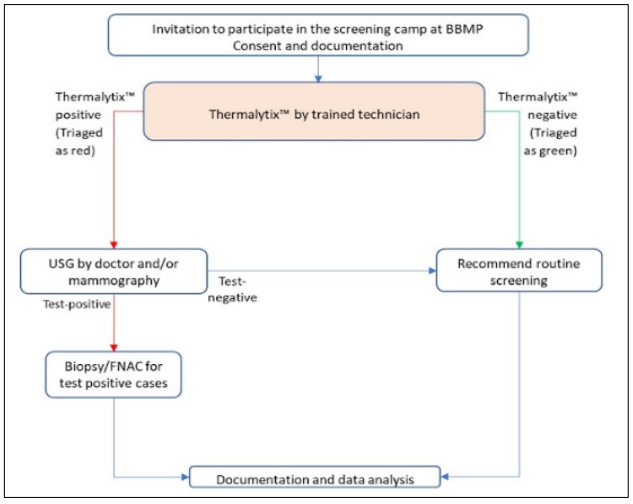

Figure 2: Schematic diagram of the screening process at BBMP facilities.

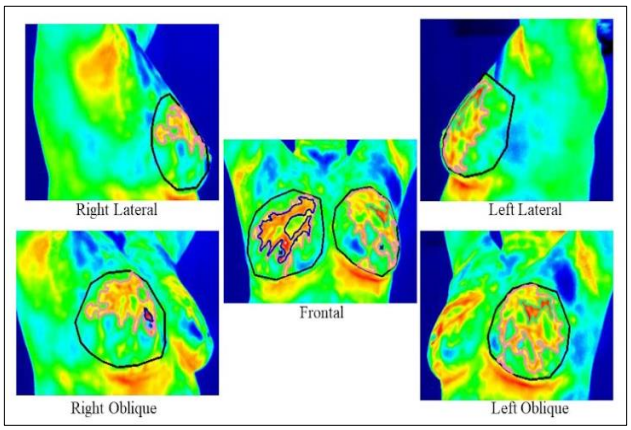

Figure 3: The five views of the breast captured in the Thermalytix device.

Informed consent

Informed written consent was obtained from the participants.

RESULTS

A total of 6935 women underwent AI-powered Thermalytix screening in 25 different BBMP hospitals with mean age (±SD) of 42.81 (±11.64), and a median age of 42 (Table 1). 62.63% of the women screened were pre-menopausal. The majority (n=4706/5248, 89.67%) were asymptomatic. A total of 62 women were assessed to be at high risk after scoring with the Thermalytix software (62/5248=1.18%). The positivity rate of the Thermalytix test (version 4.9) in this community setting thus was 1.18%.

Table 1: Demographics of the population studied.

Variables	Frequency of eligible screened participants (n=5248) (%)	Frequency of Thermalytix screened red (n=62) (%)
Age (years)		
≤20	64 (1.22)	0
21-30	737 (14.04)	17 (27.42)
31-40	1623 (30.93)	18 (29.03)
41-50	1642 (31.29)	15 (24.19)
51-60	822 (15.66)	3 (4.84)
61-70	306 (5.83)	8 (12.90)
71-80	51 (0.97)	1 (1.61)
>80	3 (0.06)	0
Menopausal status		
Premenopausal	3287 (62.63)	37 (59.68)
Postmenopausal	1961(37.37)	25 (40.32)
Symptoms		
Lump in breast	90 (1.71)	8 (12.90)
Breast pain	431 (8.21)	15(24.19)
Nipple discharge	16 (0.30)	0
Skin discharge	5 (0.10)	1 (1.61)

Among the 62 women characterized as being at high risk after thermal screening (Figure 4), 11 participants out of 62, who underwent follow-up investigations and submitted the reports and identified with abnormal breast tissues, one was diagnosed with ductal carcinoma in situ (DCIS) and eight had benign breast lesions, one participant had a normal report and one participant's reports were unavailable to conclude.

The overall test positivity rate of Thermalytix in this cohort was 1.18% and the positive predictive value with radiological positivity as reference was found to be 9/11=81.81%.

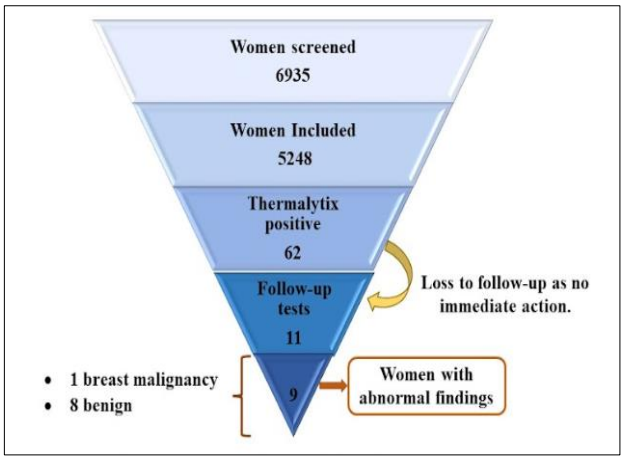

Figure 4: Summary of the participants in the project.

DISCUSSION

This work demonstrates the potential of a novel breast cancer early detection technique in a low- and middle-income country within a limited resource setting. In this paper, we have reported the feasibility and results of utilization of portable, radiation-free breast thermography enhanced by computer-aided machine learning algorithms, to detect breast anomalies among asymptomatic women with no access to other more conventional screening methods.

Organized national mammographic screening has been adopted as the gold standard for early detection of breast cancer in western countries; however, screening for breast cancer in LMICs presents a paradoxical dilemma. On one hand, no screening would lead to increased odds of presentation at advanced-stage diseases for which treatments are unavailable, unaffordable, and cost-ineffective. On the other hand, LMICs are not equipped to both implement a screening campaign effectively and deal with the downstream consequences of screening-detected lesions, most of which end up not being cancer. The optimal method of screening in LMICs is not known, and a "mixed" portfolio of tools is recommended. As noted by Anderson et al, 2011 it is necessary to look very closely at any given country to best direct that particular country's screening program.[22] Resource-stratified guidelines for the early detection of breast cancer were developed as a framework by the Breast Health Global Initiative (BHGI).[23] It was suggested to consider various organizational levels of countries in relation to breast cancer. Specifically, at the basic level, breast self-examination is encouraged, whereas diagnostic ultrasound and mammography are available at a limited level. At the increased level, patients have access to diagnostic mammography with opportunistic breast screening, and at the maximum level, the population undergoes organized screening for breast cancer.[23]

In the absence of comprehensive mammographic screening, several groups in LMICs have investigated

alternate techniques to improve breast screening coverage. Breast cancer screening can be delivered by mobile mammography units which were first introduced to increase geographical access but also to reach deprived women. Population studies have shown mobile mammography programs to be effective at increasing rates of breast cancer screening, although it is less cost-effective than conventional stationary mammography.[24] The results of screening programs based on clinical breast examination have been more encouraging. A recent study by Mittra et al 2021 indicated that clinical breast examinations performed by primary health professionals every two years considerably reduced the stage of breast cancer at diagnosis and resulted in a non-significant 15% decrease in overall breast cancer mortality.[11] In contrast, another large randomized study to compare CBE with no screening conducted in India could not demonstrate mortality reduction of CBE.[25] In women with dense breasts ultrasonography could be a low-cost way to improve sensitivity and detection rates of early cancers, though it is limited by operator dependency. If used for screening rather than for the assessment of palpable disease, it has the potential for a high false-negative rate.[26] Conventional hand-held breast ultrasound has been evaluated as a screening tool, either alone or as an adjunct to mammography. But it is highly operator-dependent and necessitates the presence of a radiologist. A meta-analysis has demonstrated that in women with dense breasts ultrasound detects additional four breast cancer cases per 1000 mammography-negative women but nearly doubles the referral rate to further assessment.[27]

By contrast, high-frequency automated breast three-dimensional ultrasound (ABUS) is less operator-dependent, requires less time, can be performed by trained nurses or technicians and the results are more reproducible.[28] Victoria Mango and colleagues 2022 have used the portable intelligent iBreastExam, a handheld screening device based on elastography, to evaluate women aged 40 years or older who were symptomatic or at high risk with a family history of breast cancer and found that in the diagnostic detection algorithm, the iBreastExam would be suitable as a pre-screening device.[29]

With a better resolution of current infra-red cameras, there has been a recent resurgence of interest in breast thermography in the detection of breast lesions. Singh et al 2019 have recently reviewed the role of image thermography in early breast cancer detection.[30] Harnessing the advantage of current high-resolution thermal cameras with computer algorithms for thermal analysis may lessen subjectivity and enable automated quantitative interpretation. The aim is not to replace mammography with this method of breast screening, but rather to use it as an adjunct modality with other earlier detection methods that are more effective and help reduce mortality rates.

We believe that Thermalytix is well suited for breast screening in LMICs, and this report brings out some of the strengths of the technique. Breast screening in LMICs is often non-existent due to a host of patient, economic and system-level barriers that impact screening rates among disadvantaged populations, such as lack of awareness, no knowledge about breast cancer, fear of the results of tests, scared of undergoing mammography, the stigma of getting cancer, financial pressure, lack of time/privacy, accessibility to treatment facilities and presence of male health workers.

Thermalytix removes some of these barriers. It is a non-contact, non-invasive, no breast compression test that is privacy aware, uses no radiation, and is an affordable, portable, and light small screening device. As a portable device, it improves access to care. It is affordable and hence, is available for all socio-economic groups. The test can be made available at the remotest of health centers, bridging geographical distances, and can be conducted by low-skilled healthcare workers. The cost is lower than standard imaging modalities due to two main reasons-firstly the infrastructure involved in setting up the test is lower than standard imaging modalities; secondly, it can be performed by a trained paramedical thus reducing the burden on specialists.

Hence, it is associated with high levels of patient satisfaction. Women who are shy and sensitive to the touch of private parts can use the test without inhibition.

Limitations

Certain limitations of our study warrant acknowledgment. This was a purely observational study and the results obtained were not compared to another but a similar cohort of women undergoing screening by either CBE or mammography.

CONCLUSION

In conclusion, it is believed that this technique, Thermalytix, is a promising technique to increase access to breast screening in LMICs. Further larger population-based studies are warranted to establish its place in the clinical pathway of breast cancer detection. This pilot program has the potential of being replicated on a national scale to create awareness about breast cancer and downstage its presentation.

ACKNOWLEDGEMENTS

The authors acknowledge the support from BBMP health workers for conducting the camp and mobilizing the participants in the camp and BBMP management for providing the permission to conduct the screenings on their premises.

Funding: Niramai Health Analytix
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Malvia S, Bagadi SA, Dubey US, Saxena S. Epidemiology of breast cancer in Indian women. Asia Pac J Clin Oncol. 2017;13(4):289-95.
2. Jacques F, Soerjomataram I, Dikshit R, Eser S, Mathers C, Rebelo M, et al. "Latest world cancer statistics – GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012–IARC." Available at: https://www.iarc.who.int/news-events/latest-world-cancer-statistics-globocan-2012-estimated-cancer-incidence-mortality-and-prevalence-worldwide-in-2012/. Accessed on 08 September 08 2022.
3. Dhillon PK, Mathur P, Nandakumar. India State-Level Disease Burden Initiative Cancer Collaborators. The burden of cancers and their variations across the states of India: the Global Burden of Disease Study 1990-2016. Lancet Oncol 2018;19:1289-306.
4. Duffy SW, Tabár L, Yen AM, Dean PB, Smith RA, Jonsson H, et al. Mammography screening reduces rates of advanced and fatal breast cancers: Results in 549,091 women. Cancer. 2020;126(13):2971-9.
5. Singh S, Shrivastava JP, Dwivedi A. Breast cancer screening existence in India: A nonexisting reality. Indian J Med Paediatr Oncol. 2015;36(4):207-9.
6. Negi J, Nambiar D. Intersectional social-economic inequalities in breast cancer screening in India: analysis of the National Family Health Survey. BMC Womens Health. 2021;21(1):324.
7. Mishra GA, Pimple SA, Mittra I, Badwe RA. Screening for breast cancer: Cost-effective solutions for low- & middle-income countries. Indian J Med Res. 2021;154(2):229-36.
8. Li J, Shao Z. Mammography screening in less developed countries. Springerplus. 2015;4:615.
9. Hackshaw AK, Paul EA. Breast self-examination and death from breast cancer: a meta-analysis. Br J Cancer. 2003;88(7):1047-53.
10. Albert US, Schulz KD. Clinical breast examination: what can be recommended for its use to detect breast cancer in countries with limited resources? Breast J. 2003;9(2):S90-3.
11. Mittra I, Mishra GA, Dikshit RP. Effect of screening by clinical breast examination on breast cancer incidence and mortality after 20 years: prospective, cluster randomised controlled trial in Mumbai. BMJ. 2021;372:n256.
12. Ngan TT, Nguyen NTQ, Van Minh H, Donnelly M, O'Neill C. Effectiveness of clinical breast examination as a 'stand-alone' screening modality: an overview of systematic reviews. BMC Cancer. 2020;20(1):1070.
13. Kiely BE, Goodwin A. Is it time to abandon clinical breast examination? Med J Aust. 2021;215(10):458-9.
14. Mani S. Guidelines for ultrasound owners and owners of clinics, diagnostic centres, nursing homes and hospitals. Indian J Radiol Imaging. 2012;22(2):125-8.
15. Khan AA, Arora AS. Thermography as an Economical Alternative Modality to Mammography for Early Detection of Breast Cancer. J Healthc Eng. 2021;5543101.
16. Krishna S, George B. An affordable solution for the recognition of abnormality in breast thermogram. Multimed Tools Appl. 2021;80:28303-28.
17. Singh D, Singh AK, Tiwari S. Early Thermographic Screening of Breast Abnormality in Women with Dense Breast by Thermal, Fractal, and Statistical analysis. Research Square. 2022.
18. Omranipour R, Kazemian A, Alipour S, Najafi M, Alidoosti M, Navid M, et al. Comparison of the Accuracy of Thermography and Mammography in the Detection of Breast Cancer. Breast Care (Basel). 2016;11(4):260-4.
19. Kakileti ST, Manjunath G, Ramprakash HV. Advances in Breast Thermography. In (Ed.), New Perspectives in Breast Imaging. IntechOpen. 2017.
20. Kakileti ST, Madhu HJ, Krishnan L, Manjunath G, Sampangi S, Ramprakash HV. Observational Study to Evaluate the Clinical Efficacy of Thermalytix for Detecting Breast Cancer in Symptomatic and Asymptomatic Women. JCO Glob Oncol. 2020;6:1472-80.
21. Schwartz RG, Brioschi M, Pittman J, Rind B. Guidelines for Breast Thermography. Pan Am J Med Thermol. 2021;2(1):26-34.
22. Anderson BO, Cazap E, El Saghir NS, Yip CH, Khaled HM, Otero IV, et al. Optimisation of breast cancer management in low-resource and middle-resource countries: executive summary of the Breast Health Global Initiative consensus, 2010. Lancet Oncol. 2011;12:387-98.
23. Anderson BO, Shyyan R, Eniu A, Smith RA, Yip CH, Bese NS, et al. Breast cancer in limited-resource countries: an overview of the Breast Health Global Initiative 2005 guidelines. Breast J. 2006;12(1):S3-15.
24. Vang S, Margolies LR, Jandorf L. Mobile Mammography Participation Among Medically Underserved Women: A Systematic Review. Prev Chronic Dis. 2018;15:E140.
25. Sankaranarayanan R, Ramadas K, Thara S, Muwonge R, Prabhakar J, Augustine P, et al. Clinical breast examination: preliminary results from a cluster randomized controlled trial in India. J Natl Cancer Inst. 2011;103(19):1476-80.
26. Scheel JR, Lee JM, Sprague BL, Lee CI, Lehman CD. Screening ultrasound as an adjunct to mammography in women with mammographically dense breasts. Am J Obstet Gynecol. 2015;212(1):9-17.
27. Rebolj M, Assi V, Brentnall A, Parmar D, Duffy SW. Addition of ultrasound to mammography in the case of dense breast tissue: systematic review and meta-analysis. Br J Cancer. 2018;118(12):1559-70.

28. Brem RF, Tabár L, Duffy SW, Inciardi MF, Guingrich JA, Hashimoto BE, et al. Assessing improvement in detection of breast cancer with three-dimensional automated breast US in women with dense breast tissue: the SomoInsight Study. Radiology. 2015;274(3):663-73.
29. Mango VL, Olasehinde O, Omisore AD, Wuraola FO, Famurewa FC, et al. The iBreastExam versus clinical breast examination for breast evaluation in high risk and symptomatic Nigerian women: a prospective study. Lancet Glob Health. 2022;10(4):e555-63.
30. Singh D, Singh AK. Role of image thermography in early breast cancer detection- Past, present and future. Comput Methods Programs Biomed. 2020;183:105074.

Cite this article as: Manjunath G, Madhu H, Buggi N, Suggaiah A, Muthanna R, Gangadharan C, et al. Feasibility and outcomes of using a novel artificial intelligence enhanced breast thermography technique, Thermalytix, in screening for breast abnormalities at primary health centres at the community level in South India. Int J Community Med Public Health 2022;9:4634-4640.