Blinded, Prospective Observational Study Evaluating the Performance of Artificial Intelligence-based Analysis of Breast Thermal Imaging for the Detection of Breast Cancer, at a Tertiary Care Cancer Hospital, India.

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Introduction

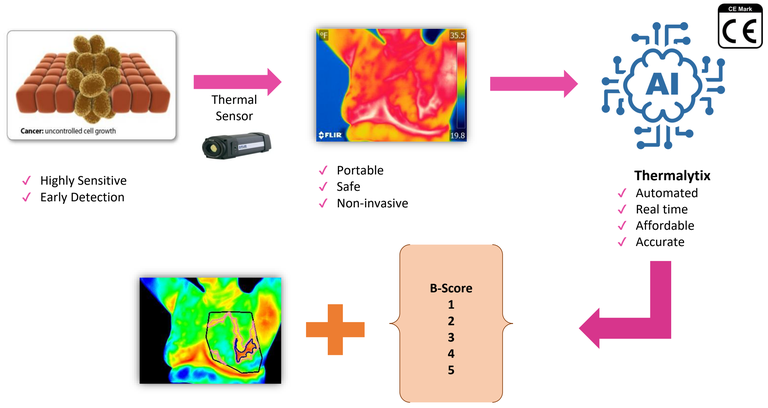
- Breast cancer is a growing public health challenge in India, as in many low- and middle-income countries (LMICs).
- Mammography-based screening is difficult to implement in resource-constrained settings.
- Further, a recent study reported a mammography screening rate of just 1.3% among eligible Indian women.
- To address this gap, there is growing interest in developing novel breast cancer detection tools that are not only clinically effective but also accessible, affordable, and acceptable, and do not require highly skilled operators.
- This prospective blinded study evaluates the clinical performance of Thermalytix in comparison with mammography and ultrasound, using histopathology as the reference standard where available.

Materials and Methods

- **Study Site:** This prospective, observational study is being conducted at a regional tertiary cancer center in Bengaluru, India.
- **Total Recruitment:** A total of 406 women have been recruited between July 2023 and July 2024 for this study
- **Exclusion Criterion:** 157 were excluded as they were pregnant or lactating or had a previous breast cancer history
- **Enrolled Participants:** 249 women aged 18-80 years, either symptomatic or asymptomatic, were enrolled.
  - Median age: 52 years (20% under 45 years)
  - 72.7% postmenopausal; 76.3% symptomatic
- **Study Procedure:** Each participant underwent the Thermalytix test, followed by standard-of-care imaging (mammography and/or ultrasound). Interpreting Radiologists were blinded to Thermalytix results and vice versa. Histopathology was used as the reference standard whenever available; otherwise, a combined radiological assessment from standard imaging tests was used.

Thermalytix

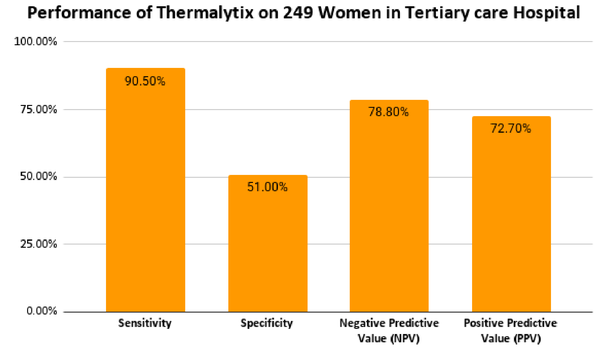
- Thermalytix is a novel, non-contact, radiation-free, AI-based screening tool that analyzes thermal patterns of the breast to identify abnormalities.
- Earlier studies have shown good clinical efficacy and economic feasibility of Thermalytix for community screening [1-2].



Results

- Among 249 women, 147 were determined to be malignant by reference standard (56% confirmed by biopsy and rest were radiologically positive)
- Thermalytix demonstrated a sensitivity of 90.5%, specificity of 51.0%, PPV of 72.7% and a NPV of 78.8% on these high-risk women at the tertiary care hospital.
- Of the 82 participants with biopsy confirmed malignancy, 77 (93.9%) were correctly identified as positive by Thermalytix.
- Hormone receptor profiling revealed 51 ER-positive, 55 PR-positive, 22 ER-negative, and 18 PR-negative cases, with 12 cases being ER-/PR-. HER2 status was positive in 18, negative in 43, and equivocal in 9 participants.
- Notably, all 9 triple-negative breast cancer cases were accurately identified as positive by Thermalytix.

Results



- Thermalytix detected malignancies included ductal carcinoma in situ, invasive ductal carcinoma, papillary carcinoma, and one poorly differentiated carcinoma

Conclusion

- Thermalytix demonstrates high diagnostic sensitivity across a broad range of breast cancer subtypes, including triple-negative disease, and correctly identifies majority of biopsy-confirmed cases.
- Its non-invasive, radiation-free, and portable design makes it highly suitable for deployment in tertiary care and resource-limited settings.
- These interim findings highlight the potential of AI-driven thermal imaging to complement existing screening programs and expand early detection access in underserved populations.
- Prospective analysis will continue for another year, and this larger cohort analysis will further validate the role of Thermalytix for breast cancer detection programs in LMICs.

References

[1] Kakileti et al. Observational study to evaluate the clinical efficacy of Thermalytix for detecting breast cancer in symptomatic and asymptomatic women. JCO Global Oncology. 2020 Oct;6:1472-80.

[2] Adapa K, Gupta A, Singh S, Kaur H, Trikha A, Sharma A, Rahul K. A real world evaluation of an innovative artificial intelligence tool for population-level breast cancer screening. npj Digital Medicine. 2025 Jan 2;8(1):2.