INFORMATION BRIEF (RAPID REVIEW)

NIRAMAI THERMALYTIX AS A BREAST CANCER SCREENING TOOL

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
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NIRAMAI THERMALYTIX AS A BREAST CANCER SCREENING TOOL

PURPOSE

To provide brief information on the effectiveness, safety, and cost-effectiveness of new emerging test device namely Niramai Thermalytix as a breast cancer screening tool based on request from Adult Health Sector, Family Health Development Division, Ministry of Health Malaysia.

BACKGROUND

Breast cancer is one of the most prevalent malignancies affecting women worldwide, including younger women under the age of 40. While breast cancer is more prevalent among postmenopausal women, its occurrence in younger women represents a significant public health concern due to unique challenges, including more aggressive tumour characteristics, delayed diagnosis, and the psychosocial and reproductive implications of treatment. Early detection of breast lesions is important for reducing mortality and improving recurrence-free survival period.[1,2]

Out of the total 2,296,840 breast cancer cases in females, 429,336 are estimated to be in women under 45 years of age, as per data from GLOBOCAN 2022.[1.3] Younger patients often present with advanced-stage disease, more aggressive subtypes (e.g., triple-negative and HER2-positive), and poorer overall survival rates compared to older women. Additionally, young women often face financial burdens due to prolonged treatment, career interruptions, and inadequate health insurance coverage. Family planning, childcare responsibilities, and social dynamics can further exacerbate the stress associated with their diagnosis and treatment.[3]

Technical features

Thermalytix is a new emerging test which is a non-invasive non-contact, radiation-free, painless tool that uses thermal radiomics and combines the thermal imaging with advanced artificial intelligence (AI) algorithms.[4] Niramai Thermalytix uses high-resolution infrared thermal imaging cameras to capture heat distribution patterns on the surface of the breasts. The system employs proprietary AI algorithms to analyse temperature variations and detect thermal abnormalities associated with breast tumors. It is designed to identify subtle temperature differences caused by increased vascularity and metabolic activity in malignant tissues. The system software generates a quantified risk score, providing actionable insights for clinicians. The device is designed as a portable tool and can be easily deployed in both urban and rural settings, including community health camps and primary care centers. Unlike mammography, this method is free from ionizing radiation. Also, Thermalytix provides results without being influenced by tissue density, which are less effective for women with dense breast tissue (common among younger women). It is a non-invasive procedure and ensures a pain-free experience. The system integrates cloud computing to store and process thermal images securely. [5] **(See Figure 1)**

Figure 1: Test device – Thermalytix and its accessories

Regulatory status

The Niramai Thermalytix breast cancer screening technology has achieved a regulatory milestones with clearance from U.S. Food and Drug Administration (US-FDA) in item called Niramai's SMILE-100 System. It received FDA 510(k) clearance, making it one of the few deep-tech health startups from India to achieve this. The SMILE-100 is a thermography-based device designed for adjunctive diagnostic imaging to identify thermal anomalies in the breast region. This clearance enables the system's use in the U.S. healthcare market, expanding its global reach.[6]

In addition, the Thermalytix solution also holds CE certification (CE mark), allowing it to be marketed within the European Economic Area. This approval confirms and demonstrated that this device meets European Union safety and performance standards under the Medical Device Directive (MDD 93/42/EEC).[7]

Subsequently, Niramai Thermalytix also received certification from ISO 13485 and MDSAP Certifications. These certifications confirm the device compliance with international medical device quality standards and regulatory requirements, facilitating adoption in multiple global markets, including Europe, Asia, and the Middle East.[7]

EVIDENCE SUMMARY

A total of 136 titles were retrieved from Google Scholar and from the general search engines. Six (6) titles are retrieved from the scientific databases such as Medline via OVID and PubMed. using the key word searched “thermalytix” or “Niramai”. No limits were applied to the search. The last search was run on 21 November 2024. **A total of two (2) studies** were found to be relevant and included in this review on Niramai Thermalytix, which comprised of one systematic review with meta-analysis and one prospective cohort study. Sample size for pooled for meta-analysis was 1187 participants and a total of 258 patients in the cohort study. The cohort study was conducted in India.

EFFICACY/ EFFECTIVENESS

Kakileti ST et al. (2024) evaluates the efficacy of Thermalytix, a non-invasive thermal imaging tool, for breast cancer screening in young women. The study used a meta-analysis approach, aggregating data from three (3) clinical studies. These studies included a total of 1187 women who underwent Thermalytix and compared with participants followed by a standard of care which included one or more of mammography, ultrasound, and biopsy. Thermalytix analyses high-resolution thermal images, using AI to identify radiomic features like hotspots, vascular patterns, and areolar characteristics to predict malignancy.[1]

Results

Out of the total 1187 women, 463 (39%) were under 45 years old and of these 463 young women, 268 (57.9%) did not have a valid mammography report due to inconclusive results or the test not being performed. This highlights the challenge of using mammography in younger women, often due to dense breast tissue. In the young women cohort (age <45), Thermalytix demonstrated a high negative predictive value (NPV) of 99.6%. This suggests that Thermalytix is particularly effective in ruling out malignancies in this age group, especially when mammography is inconclusive or not performed. Thermalytix showed a sensitivity of 90.7% (95% CI; 82.0% to 99.4%) and a specificity of 82.1% (95% CI; 78.5% to 85.8%) when raw data in this age group were aggregated. The PPV and NPV were 34.2% (95% CI; 25.5% to 42.9%) and 98.9% (95% CI; 97.7% to 100%). **See Figure 2**. Pooled performance on women younger than 45 years were performed, where, the study used a random-effects meta-analysis to account for variability and heterogeneity among the included studies. For women younger than 45 years, the pooled sensitivity and specificity were estimated as 96.0% (95% CI; 88.9% to 100%) and 82.3% (95% CI; 78.6% to 85.9%), respectively.[1]

In the overall population, Thermalytix demonstrated a sensitivity of 88.3% (95% CI; 83.3% to 93.2%) and a specificity of 84.7% (95% CI; 82.5% to 86.9%) in detecting malignancy when data from all the three studies are aggregated. The corresponding PPV and NPV were 47.7% (95% CI; 42.0% to 53.3%) and 97.9% (95% CI; 96.9% to 98.8%), respectively.[1]

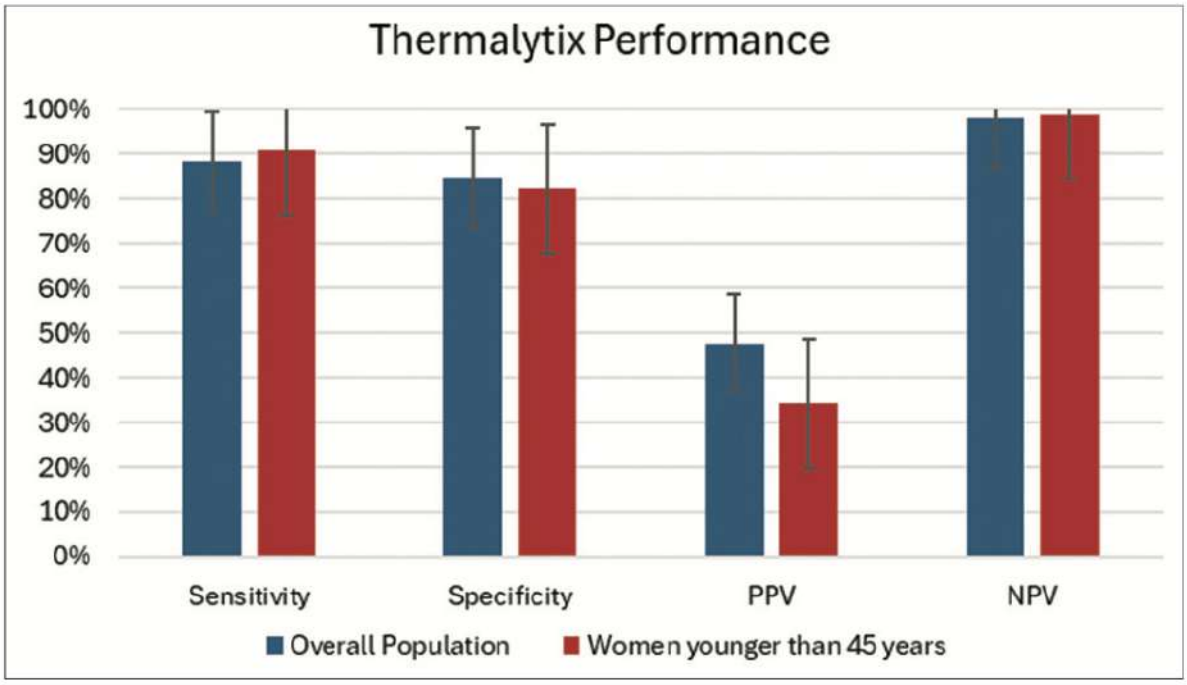

Figure 2: Aggregated performance of Thermalytix in the overall population (n=1187) and in women younger than 45 years (n=463)

From the study, its concluded that Thermalytix offers a viable, non-invasive, and radiation-free alternative for breast cancer screening in young women, particularly those with dense breast tissue where mammography is less effective, making it especially useful for younger women who may not benefit as much from traditional mammograms.

A multicentric study by **Singh A et al (2021)** evaluates the effectiveness of Thermalytix, as a novel artificial intelligence (AI)-driven thermography-based screening method, compared with standard breast cancer screening modalities such as mammography and clinical breast examination (CBE). This study was conducted across several centres, focusing on women with symptoms suggestive of breast cancer. Its aim to assess the diagnostic accuracy of Thermalytix.

In this study, its included **symptomatic women** referred for breast cancer screening. A prospective two (2) centres cohort study was conducted at cancer care centres, located in Bangalore, South India. All participants underwent Thermalytix screening, mammography, and CBE and the diagnostic outcomes from Thermalytix were compared with the gold standard i.e histopathological findings or biopsy results where applicable.[5]

Results

From this study, Thermalytix demonstrated sensitivity comparable to mammography, with higher specificity than CBE in detecting breast abnormalities. Among the cohort of (N=258) women, 63 women (24.4%) were diagnosed with malignant breast cancer. The median age of the cohort was 41 years with a range between 18 and 80 years. The median age among women diagnosed with cancer was 55 years (range: 26 to 78 years) compared with women without cancer, 40 years (range: 18 to 80 years), $p<0.001$. Among the cohort of 258 women, 149 women (57.8%) were aged <45 years, 92 women (35.7%) had attained menopause and 38 women (14.7%) had a family history of cancer.[5]

From the ROC curve, the test device were found: **(See Figure 3)**[5]

- sensitivity of = 82.5% (95% CI; 73.2 to 91.9) vs diagnostic mammogram (92%, 95% CI; 80.7 to 97.8)
- specificity of = 80.5% (95% CI 75.0 to 86.1) vs diagnostic mammogram (45.9%, 95% CI; 34.3 to 57.9)
- When using BI-RADS 3 (Breast Imaging-Reporting and Data System) was considered as test-positive.
- The overall area under the curve (AUC) was 0.845.
- **For women aged <45 years**, the test device had a sensitivity = 87.0% (95% CI; 66.4 to 97.2) and specificity = 80.6% (95% CI; 72.9 to 86.9).
- **For women aged ≥45 years**, the sensitivity= 80.5% (95% CI; 65.1 to 91.2) and specificity were = 86.5% (95% CI; 78.0 to 92.6).

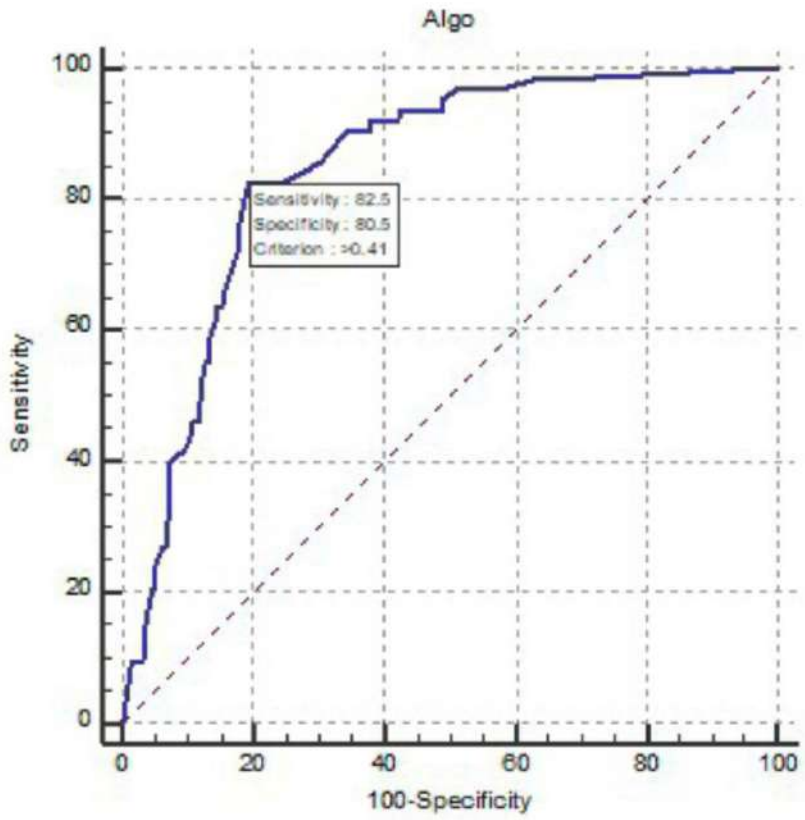

Figure 3: ROC Curve with sensitivity and specificity at a cut-off of >0.41 for Thermolytix score and the AUC was found to 0.845

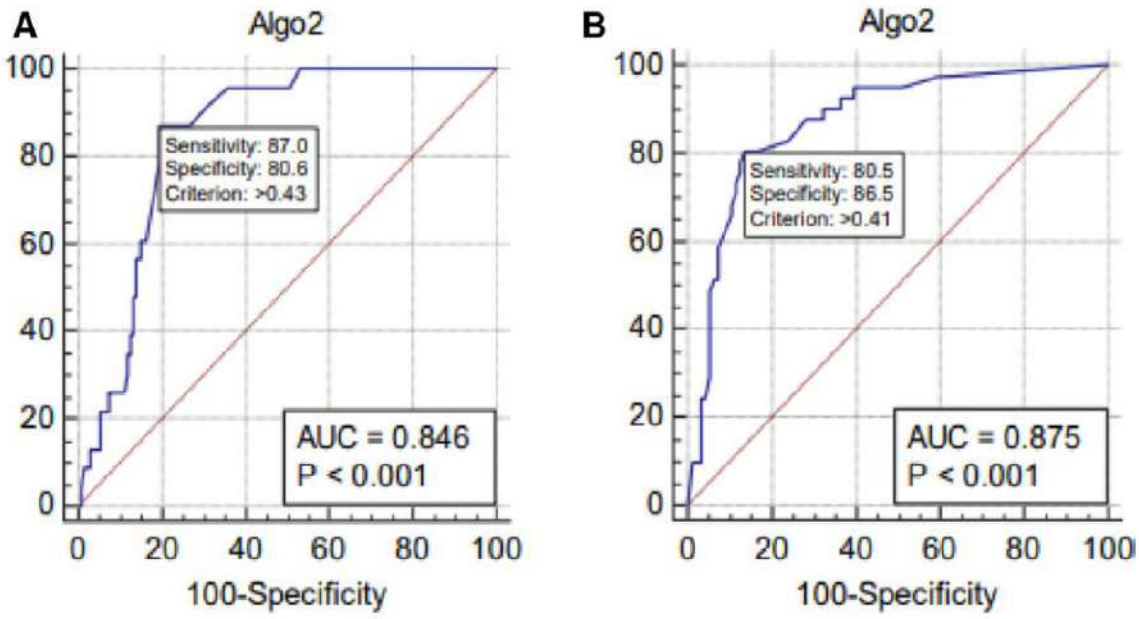

Figure 4: ROC curves find optimal cut-off points of Thermolytix score in women aged (A) 45 years or younger and (B) above 45 years

From the study, its concluded that Thermalytix offers promising potential as an AI-driven, non-invasive breast cancer screening method. Its performance is comparable to standard modalities and could serve as a practical solution in resource-limited settings where access to mammography is constrained. The authors advocate for further research to validate its long-term effectiveness and integration into routine clinical practice.

SAFETY

This technology is a non-invasive that uses thermography, which involves capturing thermal images of the body without any physical contact or insertion of instruments and using machine intelligence. This ensures patient comfort and eliminates risks associated with invasive procedures. It is radiation-free, unlike mammograms, which use X-rays and involve exposure to ionizing radiation, where Niramai Thermalytix relies on thermal imaging. Furthermore, the technology avoids compression of the breast, which is common in mammography and can cause discomfort or pain for some women. In addition, Niramai Thermalytix is suitable for all age groups compared with mammograms. In mammogram, it is generally recommended for women over 40 due to the density of younger women's breast tissue, which can lead to less accurate results. In contrast, Niramai Thermalytix works well for women of all ages, including younger individuals, because it doesn't rely on tissue density and since thermal imaging process does not require physical contact or the presence of a clinician.[8]

No retrieval evidence (study) related to safety was found in this review.

COST-EFFECTIVENESS

NIRAMAI's equipment is relatively low-cost compared to mammography machines, making it suitable for deployment in low-resource settings, including rural areas and smaller healthcare facilities. Since there is no need for expensive radiology infrastructure, the overall cost of screening is lower. By identifying cancer at an early stage, Niramai Thermolytix is able be used as early interventions which are often less expensive and more effective than late-stage cancer treatments. Hence, it may reduce treatment costs.[9]

No retrieval evidence (study) related to cost-effectiveness was found in this review.

LIMITATION AND CONSIDERATIONS

Although Niramai thermolytix demonstrated its efficacy and performance in diagnostic accuracy, it is not universally accepted as a stand-alone diagnostic tool yet as the reference standard is mammography. Its use is often integrated into broader diagnostic pathways. The accuracy of the system depends on the quality of thermal images and the robustness of the machine learning through its AI algorithm. Continuous improvements and validations are needed. While this technology is able to identify abnormalities, affordable and accessible follow-up diagnostic and treatment facilities are crucial to realise its full potential.

CONCLUSION

Based on the review Niramai Thermolytix demonstrated a high accuracy and performance where:

1. In Thermolytix vs standard of care which included one or more of mammography, ultrasound, and biopsy:
   - In the **overall population**, the sensitivity of 88.3% (95% CI; 83.3% to 93.2%) and a specificity of 84.7% (95% CI; 82.5% to 86.9%) in detecting malignancy.
   - For **women younger than 45 years**, the pooled sensitivity and specificity were estimated as 96.0% (95% CI; 88.9% to 100%) and 82.3% (95% CI; 78.6% to 85.9%).
   - When raw data were **aggregated from this young women cohort**, Thermalytix resulted in a sensitivity of 90.7% (95% CI; 82.0% to 99.4%), a specificity of 82.1% (95% CI; 78.5% to 85.8%), a PPV of 34.2% (95% CI; 25.5% to 42.9%), and an NPV of 98.9% (95% CI; 97.7% to 100%).

2. In a prospective cohort study in two centres, Thermalytix vs diagnostic mammogram resulted:
   - in a sensitivity of = 82.5% (95% CI; 73.2 to 91.9) vs (92%, 95% CI; 80.7 to 97.8)
   - specificity of = 80.5% (95% CI 75.0 to 86.1) vs (45.9%, 95% CI; 34.3 to 57.9)
   - The overall area under the curve (AUC) was 0.845.
   - **For women aged <45 years**, the test device had a sensitivity = 87.0% (95% CI; 66.4 to 97.2) and specificity = 80.6% (95% CI; 72.9 to 86.9).
   - **For women aged ≥45 years**, the sensitivity= 80.5% (95% CI; 65.1 to 91.2) and specificity were = 86.5% (95% CI; 78.0 to 92.6).

REFERENCES

1. Kakileti ST, Madhu HJ, Krishnan L, et al. Observational Study to Evaluate the Clinical Efficacy of Thermalytix for Detecting Breast Cancer in Symptomatic and Asymptomatic Women. JCO Glob Oncol. 2020 Oct;6:1472-1480, 2024)
2. Miller KD, Nogueira L, Mariotto AB, et al. Cancer treatment and survivorship statistics, 2019. CA Cancer J Clin 2019;69:363-85
3. Bray F, Laversanne M, Sung H et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer JClin 2024;74:229-63; International Agency for Research on Cancer. GLOBOCAN Cancer 2022. Lyon, France: IARC; 2022. Available from: https://gco.iarc. fr/. [Last accessed on 2024 Nov 21].
4. Health & Fitness. Jashley Ann Cruz. This new compact device can accurately detect breast cancer in women. Published On: April 14, 2023. Available from: http:// https://www.gmanetwork.com/lifestyle/health-fitness/100311/this-new-compact-device-can-accurately-detect-breast-cancer-in-women/story. [Last accessed on 2024 Nov 21]
5. Singh A, Bhat V, Sudhakar S, et al. Multicentric study to evaluate the effectiveness of Thermalytix as compared with standard screening modalities in subjects who show possible symptoms of suspected breast cancer. BMJ Open. 2021 Oct 19;11(10):e052098
6. Niramai Smile-100. Available from: https://catalogartifact.azureedge.net/publicartifacts/niramaihealthanalytixprivatelimited1700565517023.niramai-thermalytix-397a6186-59bf-4130-aef6 b28b1e7616e0/Artifacts/Documents/Smile100brochure.pdf (Last assessed on 2024 Nov 25)
7. Breast Cancer Detection. Deeptech healthcare company NIRAMAI receives CE Mark approval. April 07, 2021. Availavle at: http:// https://indiaai.gov.in/news/deeptech-healthcare-company-niramai-receives-ce-mark-approval. (Last assessed at 2024, Nov 25)
8. Niramai Thermolytix. Thermalytix: AI-Powered Breast Cancer Screening Test. Available at: http:// https://www.niramai.com/about/thermalytix/ (Last assessed at 2024, Nov 25)
9. Kakileti ST, Madhu HJ, Krishnan L, et al. Observational Study to Evaluate the Clinical Efficacy of Thermalytix for Detecting Breast Cancer in Symptomatic and Asymptomatic Women. JCO Glob Oncol. 2020 Oct;6:1472-1480

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