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Original research

Evaluation of digital infra–red thermal imaging as an adjunctive screening method for breast carcinoma: A pilot study

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HIGHLIGHTS

- Breast thermography has been researched for over 50 years, and over 800 peer-reviewed breast thermography studies.
- Studies suggest that an abnormal thermogram is 10 times more significant than a first order family history of the disease.
- When used along with clinical examination and mammography it can significantly improve screening of breast cancer.
- The present study was motivated by the need to evaluate the technique in Indian scenario.
- Our study results confirm that thermography is a good screening modality for breast cancer.

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ABSTRACT

Background: Early screening plays a pivotal role in management of breast cancer. Given the socio-economic situation in India, there is a strong felt need for a screening tool which reaches the masses rather than waiting for the masses to reach tertiary centers to be screened. Digital infra-red thermal imaging (DITI) or breast thermography as a screening test offers this possibility and needs to be carefully assessed in Indian scenario.**Methods**: The study involved 1008 female patients of age 20–60 years that had not been diagnosed of cancer of breast earlier. All the subjects in this population were screened for both the breasts using DITI. Based on the measured temperature gradients (ΔT) in thermograms, the subjects were classified in one of the three groups, normal ($\Delta T \leq 2.5$), abnormal ($\Delta T > 2.5$, <3) and potentially having breast cancer ($\Delta T \geq 3$). All those having ($\Delta T > 2.5$) underwent triple assessment that consisted of clinical examination, radiological and histopathological examination. Those with normal thermograms were subjected to only clinical examination. **Results**: Forty nine female breasts had thermograms with temperature gradients exceeding 2.5 and were subjected to triple assessment. Forty one of these which had $\Delta T \geq 3$ were proven to be having cancer of breast and were offered suitable treatment. Eight thermograms had temperature gradients exceeding 2.5 but less than 3. Most of these were lactating mothers or had fibrocystic breast diseases. As a screening modality, DITI showed sensitivity of 97.6%, specificity of 99.17%, positive predictive value 83.67% and negative predictive value 99.89%. **Conclusion**: Based on the results of this study involving 1008 subjects for screening of breast cancer, thermography turns out to be a very useful tool for screening. Because it is non-contact, pain-free, radiation free and comparatively portable it can be used in as a proactive technique for detection of breast carcinoma.

1. Introduction

The incidence of breast cancer is rapidly rising and it accounts for about 25% to 33% of all cancers in women in India [1]. Management of this growing problem requires effective screening

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modalities. The widely accepted screening modality for breast cancer is the triple assessments, which comprises of self-examination or regular visits and follow ups for clinical examination, ultrasonography and mammography and biopsy [2]. However, the prevalence of these screening programs in India is rather limited because of several factors, including lack of awareness and lack of screening facilities. According to WHO's latest world health statistics, less than 5% women, aged 50–69, underwent screening by mammography in India between year 2000 and 2003 [3]. That is why over 50% of breast cancer patients in India present at late stages 3 and 4, which impedes the effective management of the cancer.

This situation might improve if a screening test is made available that is able to reach the masses rather than waiting for the masses to reach tertiary centers to be screened. Digital infra-red thermal imaging (DITI) or breast thermography as a screening test offers this possibility and needs to be carefully assessed in Indian scenario. This approach is based on detecting the heat produced due to increased blood circulation as a result of neo-angiogenesis, and metabolic changes associated with a tumor's genesis and growth. In contrast mammography, ultrasound, MRI, and other imaging tools are primarily based on differences in the scattering/transmission characteristics of tumor with respect to the normal tissue.

Infrared thermography has been in use in medical diagnostics since the 1960s, and in 1982 was approved by the US Food and Drug Administration (FDA) as an adjunctive tool for the diagnosis of breast cancer [4]. Still its use as a screening tool is rather limited at least in India. With the continued improvements in thermal imaging camera technology and the image processing capability of the present day computers, DITI looks even more attractive as a portable, non-invasive diagnostic tool. Therefore, to assess the feasibility and efficacy of DITI we conducted a pilot study at a government tertiary care centre in central India.

2. Study design

The study involved 1008 female patients of age 20–60 years that were being screened and had not been diagnosed of cancer of breast earlier. Pre examination written consent, in accordance with declaration of Helsinki, was obtained. Further, 95.15% of the subjects included were asymptomatic females, 3.67% had unilateral or bilateral mastalgia, 0.69% had breast lump but did not seek any treatment and 0.49% female complained of discharge.

3. Thermography methodology

The examination was performed in a cool carpeted room, with ambient temperature maintained around 21–25 °C, with patient sitting disrobed up to waist in front of an infra-red camera, after at least 15 min of no physical activity. This infra-red camera (Flir, Thermo vision A-20) detects signal over the spectral range of 7.5–13 μm and had image resolution of 160 × 120 pixels. Its operating temperature range is from −20 °C up to 90 °C with temperature resolution ~ 0.1 °C. The software supplied with the camera was used to find areas of the breasts having different temperature gradients by generating a color-coded, processed image of the breasts showing suspicious foci. According to the magnitude of temperature gradient all images were divided in 3 classes; normal ($\Delta T \leq 2.5$), abnormal ($\Delta T > 2.5$, <3) and potentially having breast cancer ($\Delta T \geq 3$). All those having $\Delta T > 2.5$ underwent triple assessment that consisted of clinical examination, radiological and histopathological examination. Those with normal thermograms were subjected to only clinical examination.

4. Results

Out of the 1008 females screened, $\Delta T > 2.5$ was observed for 49 cases. Out of these 41 subjects had ($\Delta T \geq 3$). On subsequent examination by triple assessment all these breasts (having $\Delta T \geq 3$) were found to be the cases of breast cancer. Eight cases had $\Delta T > 2.5$ but less than 3. Of these 3 were lactating mothers, 5 had fibrocystic disease (fibroadenosis-4, fibroadenoma-1) as shown in Table 1. Those with insignificant thermographic abnormality were excluded for malignancy [4]. Some representative thermograms with $\Delta T \geq 3$ indicating of a suspicious foci suggesting unilateral breast cancer are shown in Fig. 1a,b & c (details are given in figure legends). Thermogram, in Fig. 2 with $\Delta T > 2.5$ and <3 shows lactating engorged breast with bilateral symmetrical vascular signs. Thermograms in Fig. 3, with $\Delta T \leq 2.5$, shows bilateral fibroadenoma with normal thermal image suggestive of a benign pathology and ruling out malignancy which otherwise would have needed an invasive procedure like fine needle aspiration cytology or biopsy.

Based on the subjects included in this study, sensitivity of breast thermography to detect malignancy came out to be 97.6% with 1 case being false negative. Specificity was 99.17%, positive predictive value came out to be 83.67% and negative predictive value 99.89% as shown in Table 2.

5. Discussion

The risk of getting breast cancer has tripled over the last half-century due to change in life style and other factors [5]. Therefore it is necessary to detect breast cancer early for better management of this growing menace. For decades, breast self-examination and mammography have been used as the screening techniques of choice. However, there have been concerns about the safety of mammography [6–8]. These concerns have led to a recent revision

Table 1
Details about the subject examined in study and their outcomes.

No. of subjects	Thermography	Triple assessments	Remarks
959	$\Delta T < 2.5$	• Clinical examination normal	Negative for malignancy
8	$\Delta T > 2.5$ but <2.9	• 5 patients had suspicious lump on clinical examination. • All 8 mammograms were normal. • Biopsy confirmed fibrocystic disease in 5 patients.(fibroadenosis-4,fibroadenoma-1)	Negative for malignancy
41	$\Delta T > 3$	• All patients had clinically palpable lump on examination. • 38 patients had abnormal mammography Biopsy:25 patients had Infiltrating Ductal Carcinoma • 14 patients had Ductal Carcinoma in situ • 1 patient had phylloidestumour • 1 patient had inflammatory carcinoma of breast	3 patients had normal mammography but were found to be infiltrating ductal carcinoma.

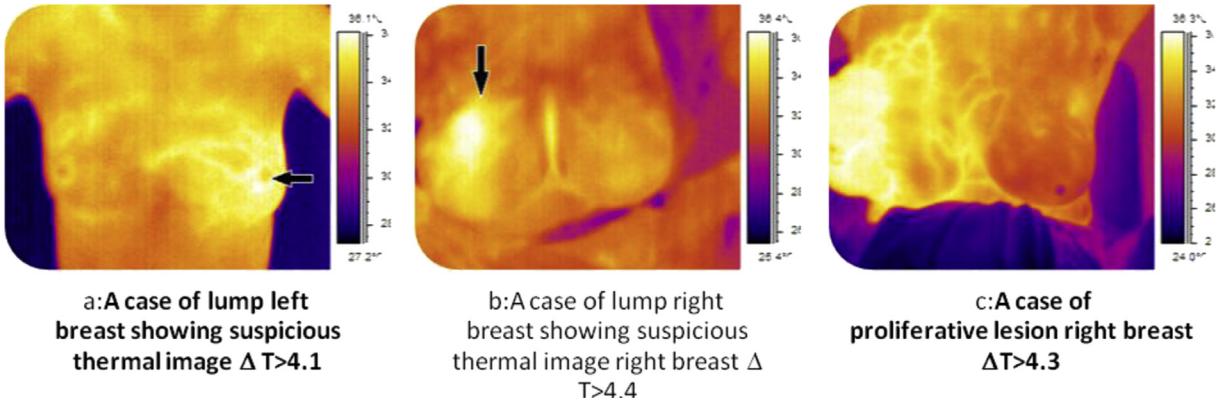

Fig. 1. a,b,c: Black arrows denote areas of suspicion or hotspots having temperature gradient >3 suggestive of unilateral breast cancer.

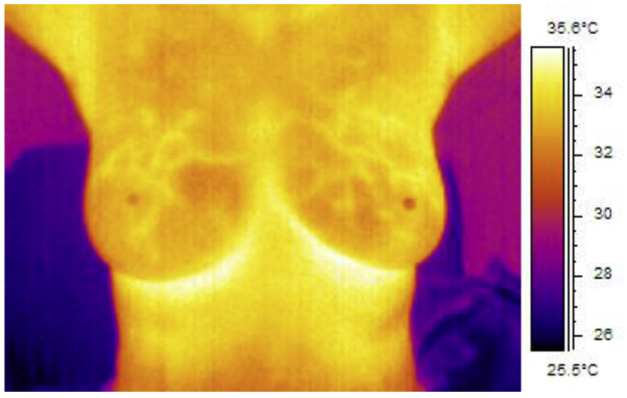

Fig. 2. A thermogram of lactating mother showing bilateral symmetrical thermal signs $\Delta T = 2.5–2.9$.

in the guidelines for mammography i.e., waiting until the age of 50 to get the first screening and then only get one every two years [9].

Thermography, on the other hand, has received interest as a contact free, pain-free and radiation-free tool for screening breast cancer. Breast thermography has been researched for over 50 years, and over 800 peer-reviewed breast thermography studies exist in the index-medicus. These studies suggest that an abnormal thermogram is a very important marker for developing breast cancer [10], 10 times more significant than a first order family history of the disease [11], and when used as part of a multimodal approach (clinical examination + mammography + thermography) it can significantly improve screening of breast cancer [12]. Although the

Table 2
Test results.

Screening test results	Diagnosis		Total
	Diseased	Not diseased	Breasts
Positive	A (true positive) = 41	B (false positive) = 8	A + B = 49
Negative	C (false negative) = 1	D (true negative) = 958	C + D = 959
Total	a+c = 42	b + d = 966	1008

results of one of the first large-scale study, Breast Cancer Detection and Demonstration Project performed during 1973–1979 in United States, were mixed, these have been attributed to the design of the study, lack of laboratory environmental controls and established reading protocols [13]. Now, with the availability of much more sophisticated infrared detectors and reading protocols for the thermograms, significant improvements have been reported [14]. For example, use of DITI on 92 patients for whom a breast biopsy was recommended based on prior mammogram or ultrasound showed a sensitivity of up to 97% [15]. The relatively poor specificity observed in this study was attributed to the fact that some benign conditions like infection or inflammation of breast parenchyma can also alter temperature distribution and lead to fast positive findings. The results presented in this report suggest that DITI is a valuable adjunct to mammography and ultrasound; especially in women with dense breast parenchyma [15]. Similarly high sensitivity has been reported by other workers [16,17]. The use of this approach, especially in developing countries, could be well suited because of lower cost, relatively easier instrumentation along with other advantages [18,19].

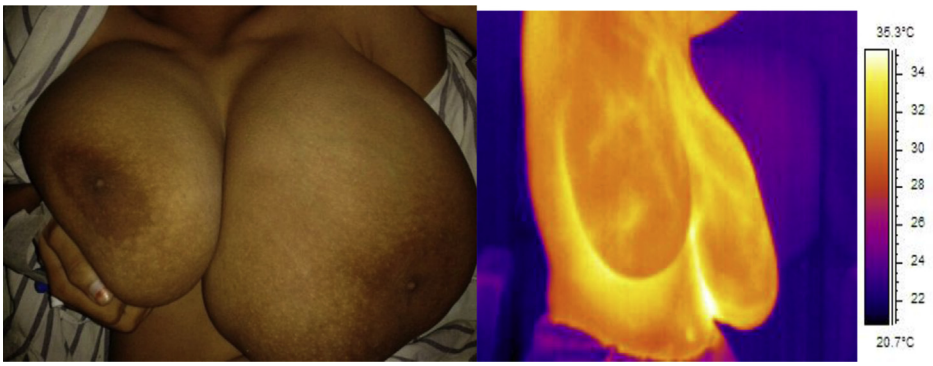

Fig. 3. A case of benign hypertrophy of breast. On thermography it is clearly evident that no abnormal thermal signs are present.

The present study was motivated by the need to evaluate the technique in Indian scenario. Although some clinical studies have been carried out in India by IGCAR, in association with Madras Medical College & SRM Medical College, on the use of thermography for screening of breast cancer no detailed scientific report exists, The reports published in newspapers suggest that a sensitivity of ~98 per cent and the specificity ~ 96 per cent in well-established breast cancers and about 85 per cent in the case of early lesions (about 1 cm size) were achieved in these studies [20].

Results obtained in our study suggest that the sensitivity of thermography appears to exceed that of mammography, meaning that a normal thermogram has a smaller chance of missing cancer when compared to a normal mammogram. Therefore the results of our study also confirm that breast thermography is a good screening modality for breast cancer. It is pertinent to reemphasize that thermography exploits the heat produced by increased blood circulation due to neo-angiogenesis for diagnosis and does not have the ability to pinpoint the location of a tumor [21].

Consequently, breast thermography has a role for screening and not for locating tumor. It can serve as a very important adjuvant modality to clinical examination for screening breast cancer [22].

6. Conclusion

In this pilot study, conducted at our institute, DITI has shown promising results with sensitivity 97.6%, specificity 99.17%, positive predictive value 83.67% and negative predictive value 99.89%. Being a non-contact, pain free, radiation free and portable procedure it received a good patient response and high acceptability.

From our study we conclude that DITI is well suited as a screening tool and its use in combination with other laboratory and outcome assessment tools, can lead to significant improvement in the management of breast cancer in India. This can be used to improve the current scenario in India where because of late diagnosis considerable amount of patients suffering from breast cancer suffer death. More over it can lead to easy and acceptable screening in rural areas also where mammography and biopsy studies are still a distant dream.

Ethical approval

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Conflict of interest

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Manuscript preparation							

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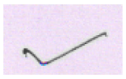
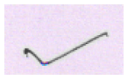
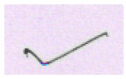
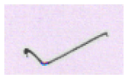
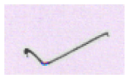
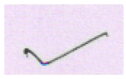
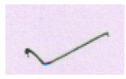
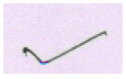
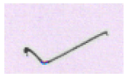
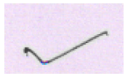
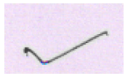
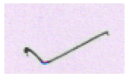
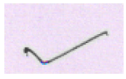
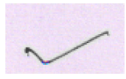
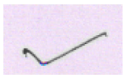
Manuscript editing							
Manuscript review							
Guarantor		–	–	–	–	–	–

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