Digital infrared thermal imaging (DITI) of breast lesions: sensitivity and specificity of detection of primary breast cancers

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AIM: To determine the sensitivity and specificity of digital infrared thermal imaging (DITI) in a series of women who underwent surgical excision or core biopsy of benign and malignant breast lesions presenting through the symptomatic clinic.

MATERIALS AND METHODS: DITI was evaluated in 63 symptomatic patients attending a one-stop diagnostic breast clinic.

RESULTS: Thermography had 90 true-negative, 16 false-positive, 15 false-negative and 5 true-positive results. The sensitivity was 25%, specificity 85%, positive predictive value 24%, and negative predictive value 86%.

CONCLUSION: Despite being non-invasive and painless, because of the low sensitivity for breast cancer, DITI is not indicated for the primary evaluation of symptomatic patients nor should it be used on a routine basis as a screening test for breast cancer.

Introduction

Advances in breast radiology have led to the increased detection of very small invasive and non-invasive cancers, particularly through screening and this is in part the reason for the fall in mortality from the disease. Despite this there are still problems screening patients at risk, particularly younger women, because of breast density and also concerns about multiple exposures to ionizing irradiation. Although focussed ultrasound can be very useful in determining the nature of an equivocal area, it is not recommended for routine surveillance on its own due to the risk of spread. Although focused ultrasound can be very useful in determining the nature of an equivocal area, it is not recommended for routine surveillance on its own due to the risk of spread. Magnetic resonance imaging (MRI) of the breast has been shown to be highly effective in detecting early breast cancer and is now recommended for routine use in screening specific high-risk groups and for pre-treatment assessment of the breast in some patients with known breast cancer to assess tumour size and extent. However, as MRI is relatively expensive, requires injection of intravenous contrast medium, and is often not widely available, there remains the quest to find alternative non-invasive breast imaging techniques to use as an alternative to conventional techniques.

Thermography, the measurement of heat emission from the breasts was investigated in the 1970s and 1980s and abandoned when it was found to be of low specificity and selectivity. Recent technological advances in infrared radiation detection together with improved computer software have led to the development of the digital infrared thermal imaging (DITI) system. Preliminary reports from rodent models suggest that the increased vascularity associated with early tumour development may be detected before there is mammographic evidence of an abnormality.
Furthermore this non-invasive system, which does not involve exposure to ionizing radiation, may be able to pick up ductal carcinoma in situ (DCIS). In a rat adenocarcinoma model, DITI was able to pick up very small, rapidly proliferating tumours. This could be potentially important in making an early diagnosis in younger women with breast cancer.

With such promising early results, this study was undertaken with the aim of determining the sensitivity and specificity of DITI in a series of women undergoing surgical excision or core biopsy of benign and malignant breast lesions presenting through the symptomatic clinic.

Materials and methods

Patients

After giving informed consent, selected symptomatic patients attending a one-stop breast clinic were subjected to DITI. The sole selection criterion was a complaint of unilateral symptoms and all patients were seen by one consultant breast surgeon (I.S.F.) between June 2006 and February 2007. The study was approved by the Research Ethics Committee.

Thermographic system

The Meditherm med2000 thermal imaging system (Meditherm, Beaufort, NC, USA) was used for the thermographic imaging. This system has two principal components: the camera and the thermal evaluation software. The camera contains a sensor sensitive to infrared radiation and is able to digitize the image data. The software is PC compatible and stores the data as a standard TIFF image file. The system uses the PC for camera control and image storage and retrieval.

The camera was positioned so that it was approximately centred on the area to be scanned, was appropriately focused, and connected to the PC with the installed software.

Patient preparation

The room temperature was kept stable at approximately 22 °C, so that the patient was comfortable, and not perspiring nor shivering. The examination room had no windows and the vents were muffled, pointing away from the patient. The ceiling lights were fluorescent and invariably kept well away from the scanned area.

Patients were asked to remove their clothes from their waist upwards and were left to equilibrate with ambient conditions for 10–15 min. Jewellery and gowns were also removed. Then, they were instructed to sit in the middle of a rotation stool without a back rest, positioned at approximately 100 cm from the thermographic camera.

Imaging

Patients were asked to position their hands on the top of their head and remain still. Three images were obtained from each patient: one face (0°) and one oblique on each side at 45° from middle line for optimal exposure of all aspects of the breasts. Images were then appropriately labelled and stored as TIFF images.

These colour images (thermograms) comprise colour pixels, each one reflecting a single temperature measurement. These measurements can vary from black (coolest) to white (warmest) with 14 “intermediate” colours (Fig 1).

Table 1
Grading of thermographic findings

<table>
<thead>
<tr>
<th>Colour difference from corresponding area of contralateral side (no of colours)</th>
<th>Diffuse lesion</th>
<th>Focal lesion (non-linear, excluding inframammary fold, axilla, or neck)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–5</td>
<td>0–3</td>
<td>4, 5</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

Table 2
Distribution of grading of thermographic images

<table>
<thead>
<tr>
<th></th>
<th>Contralateral breast</th>
<th>Ipsilateral breast</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1</td>
<td>T2</td>
</tr>
<tr>
<td>T1</td>
<td>40</td>
<td>0</td>
</tr>
<tr>
<td>T2</td>
<td>0</td>
<td>44</td>
</tr>
<tr>
<td>T3</td>
<td>0</td>
<td>16</td>
</tr>
<tr>
<td>T4</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>T5</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>65</td>
</tr>
</tbody>
</table>
Reporting

In order to assure consistency in the reporting of the thermal images, a breast thermal imaging scale was developed, based on the colour gradient between adjacent areas and differences between the two breasts (Table 1). Images were reported by a radiology consultant with extensive experience in breast imaging (R.W.) and by a senior surgical research fellow with experience in the use and interpretation of the technique (M.K.). The images were double-read with consensus reached on image classification.

Images were classified as T1 to T5, where T1/2 was indicative of normal tissue or benign changes, T3 lesion of uncertain malignant potential and T4/5 suspicious or highly suspicious of malignancy. T1/2 was defined as absence of focal, non-linear differences in temperature with four or more colours difference from surrounding area (neck, infra-mammary fold, and axilla excluded) and absence of diffuse lesions with six or more colours difference from the contra-lateral breast (Table 2).

Thermography results were compared with the final diagnosis and the sensitivity, specificity, positive and negative predictive values of the method were calculated. The diagnosis of cancer was routinely based on histology, whereas benign changes were diagnosed either from imaging or histology (Figs 2–4).

Results

In total, 126 breasts of 63 patients (58 females and five males) were examined. The mean age of the patients was 47.6 years (range 26–82 years). Cancerous lesions were finally diagnosed in 20 breasts and there were no bilateral cancers. Sixty one breasts were imaged with ultrasound and 90 by mammography.

As a thermographic grading of T3 would essentially instigate further diagnostic tests, this grading was deemed positive for the calculation of the sensitivity, specificity, positive and negative diagnostic values.

Thermography had 90 true-negative, 16 false-positive, 15 false-negative, and 5 true-positive results. Sensitivity was calculated as 25%, specificity 85%, positive predictive value 24%, and negative predictive value 86%. For the same group of patients, ultrasound had a sensitivity of 88%, specificity 91%, positive predictive value 79%, and negative predictive value 95% (U3 or more was deemed positive). For mammography the respective values were 84, 97, 89, and 96% (M3 or more was positive).

Discussion

A simple grading system (T1-5) was used, which was compatible with other components of the triple assessment of patients attending one-stop clinics with blinding of both the image acquirer and interpreter. This study has shown that digital infra-red thermography has a low sensitivity of 25% for detection of breast cancer in women presenting to a one-stop clinic. Despite the lack of discomfort for the patient and very low running costs of DITI, the excessive number of false-positive cases would have resulted in the unnecessary invasive assessment of women with T3/4/5 abnormalities.

In the Breast Cancer Detection Demonstration Project (BCDDP) carried out in the 1970s involving 16,000 thermograms, the sensitivity was 39% and the specificity 82%. This
suggests that despite technological improvement, DITI has lower sensitivity than the older technique of thermography. Parisky et al.10 conducted a five-centre study of DITI in the evaluation of 769 patients who were scheduled for breast biopsy because of mammographic or ultrasonic abnormalities. A total of 875 biopsies were performed and the sensitivity of DITI was 97% with a specificity of 14%. In a smaller but similar study of 94 biopsies Arora et al.11 reported a sensitivity of 97% and specificity of 44%. The authors concluded that this was a useful adjunct to mammography and ultrasound even though there was a high rate of false positivity.

Recently, Wishart et al.12 reported results of digital infrared thermography in 100 patients prior to core needle biopsy and analysed the results in four ways: screening report after DITI, neural network analysis, expert manual review, and using an artificial intelligence programme. The expert manual review was undertaken by an independent thermography expert blinded to the results but aware of the biopsy site. Sensitivity of both routine reporting and neural network analysis was low (53 and 48% respectively). The sensitivity of the expert manual review was 78% compared with 70% for the artificial intelligence analysis. These studies differed from the present study because, although blinded to the histological results, the thermographers were directed to the region of interest, which may explain the higher sensitivities and specificities reported.

The present study was not set up to determine whether changes in serial thermograms in high-risk patients with BRCA1/2 mutations or those who have had breast-conserving treatment for malignancy might be of value and this will require further investigation.

At present DITI should not be offered as a screening test for breast cancer in the absence of proof of efficacy.

Acknowledgements

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References