Infrared Thermography Not a Useful Breast Cancer Screening Tool

Mammography Remains the Gold Standard

Abstract: Does Infrared Thermography Predict the Presence of Malignancy in Patients with Suspicious Radiologic Breast Abnormalities?

May 4, 2012, Phoenix—Infrared thermography, a non-radiation based imaging modality that measures thermal abnormalities in breast tissue, is not a reliable breast cancer screening tool, according to a new study presented this week at the American Society of Breast Surgeons (ASBrS) Annual Meeting. Researchers conclude that mammography should remain the standard of care for screening, and patients with suspicious radiologic findings requiring biopsy should be referred for the procedure.

“Today, large numbers of patients are requesting breast imaging exams that do not involve radiation and inquiring about thermography in particular,” comments researcher Cara Marie Guilfoyle, MD, Breast Fellow, Bryn Mawr Hospital. “This research sought to evaluate the effectiveness of this relatively new technology.”

The study examined 178 patients with abnormal results on mammography, ultrasound or MRI imaging, signaling a possible cancer, who were undergoing minimally invasive breast biopsy for further evaluation. Patients’ affected breasts were scanned using the No Touch Breast Scan (NTBS) infrared thermography system prior to minimally invasive biopsy. All results were compared with pathology findings, following biopsy.

In addition, the normal opposite breasts of all study participants were screened using infrared thermography.
“In our study, the NTBS high specificity mode missed 50% of all cancers, while the high sensitivity mode delivered an unacceptable number of false positives,” Dr. Guilfoyle comments.

In the high specificity mode, of the 52 patients later identified with cancer, infrared imaging failed to pick up 26 (sensitivity 50%). Sensitivity was lower with early-stage DCIS than with invasive cancer. Of the 132 negative biopsies, 42 presented with positive findings on infrared (specificity 67%). The positive predictive value of infrared thermography was only 37%, while the negative predictive value was 77%.

Initially patients were evaluated using the NTBS high specificity computerized analysis setting, which attempts to minimize the number of false positive cancer results, lowering identification of abnormalities that do not reflect cancer. Because this modality failed to pick up a large number of patients whose pathology results were positive, researchers switched to the high sensitivity mode in the later part of this screening to optimize accurate cancer identification. Scans from the early part of the study were re-analyzed using the NTBS high sensitivity mode.

In the high sensitivity mode, infrared thermography correctly identified 44 of the 46 positive breast biopsies (sensitivity 87%). Of the 116 negative biopsies, 61 were incorrectly identified as positive (specificity 48%). Twenty-two patients were excluded due to uninterpretable thermography scans. Overall, the positive predictive value of infrared thermography was 40%, while the negative predictive value was 90%. No significant difference was found in sensitivity between invasive and in situ cancers.

In the high specificity mode, when 173 normal contralateral breasts were scanned, 42 (24%) had positive results. In the high sensitivity mode, 72 of the 151 normal breasts (47%) had positive results. To date, no cancers have been found in these breasts through routine radiologic screening.

Lead researcher Andrea Barrio, MD, FACS, Breast Surgeon, Bryn Mawr Hospital explains that infrared thermography measures heat generated by tissue, which reflects blood flow patterns in the area being evaluated. Through a process known as angiogenesis, rapidly growing cancer lesions typically have an increased blood supply, resulting in higher temperature. Thermal data acquired during a scan undergoes computer analysis for temperature abnormalities, and the device presents doctors with the results.

Dr. Barrio says that few studies have been conducted to evaluate the usefulness of infrared thermography. While some research has found the technology to be more accurate in detecting cancer, she notes that the patient populations examined may have been significantly different.
“Certainly, these findings fail to point out a useful role for infrared thermography in our patient population. In the contralateral normal breasts, we were faced with 72 patients found positive on thermography but who showed no mammographic abnormalities,” she says. “Therefore, our research shows infrared thermography cannot be used as a successful adjunct to mammography nor can it replace any of the screening modalities in standard practice today. Mammography remains the gold standard.”
Abstract

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Title: Does infrared thermography predict the presence of malignancy in patients with suspicious radiologic breast abnormalities?

Objectives: The No Touch Breast Scan (NTBS) is a non-invasive non-radiation based imaging tool that measures and compares thermal abnormalities in breasts using dual infrared cameras and computer analysis. The NTBS generates a score reflective of blood flow patterns based on the theory of tumor angiogenesis. We evaluated NTBS screening as a predictor of breast cancer in patients undergoing minimally invasive breast biopsy for suspicious mammogram, ultrasound, or MRI findings.

Method: Following IRB approval, 181 female patients with 187 abnormal radiologic findings were prospectively evaluated from October 2009 to May 2011. Each patient had an NTBS prior to tissue biopsy. Final tissue pathologies were compared to corresponding NTBS scan results. Each breast was interpreted as positive or negative based on computer analysis of thermal abnormalities. The contralateral breast was scanned in all patients. Prior to October 15, 2010, patients were initially scanned using a “high specificity” mode termed NTBS1. Subsequently a “high sensitivity mode”, termed NTBS2, was used to minimize false negative results. Following initial data analysis, all patients were retrospectively re-evaluated in the NTBS2 mode. We are reporting both sets of results.

Results: Of the 181 patients prospectively evaluated, 3 patients were excluded due to a nonductal or lobular breast malignancy, for a total of 178 patients. 50 patients had 52 positive breast biopsies and 128 patients had 132 negative biopsies. Of the 52 positive biopsies, only 26 had a positive NTBS (sensitivity 50%). The sensitivity of NTBS was lower in the 20 in situ cancers compared with the 32 invasive cancers (35% vs. 59%, respectively). Of the 132 negative biopsies, 88 showed a negative NTBS scan (specificity 67%). The positive predictive value of NTBS was 37% and the negative predictive value was 77%. 173 normal contralateral breasts were scanned; 42 (24%) had a positive NTBS scan. Of the 178 patients retrospectively evaluated using NTBS2, 22 were excluded secondary to an uninterpretable scan, resulting in a total of 156 patients. 44 patients had 46 positive breast biopsies and 112 had 116 negative biopsies. Of the 46 positive biopsies, 40 had a positive NTBS (sensitivity 87%). There was no appreciable difference in sensitivity between in situ and invasive cancers in the NTBS2 mode (88% vs. 86%, respectively). Of the 116 negative biopsies, 55 showed a negative NTBS (specificity 48%). The positive predictive value of NTBS2 was 40% and the negative predictive value was 90%. 151 normal contralateral breasts were scanned; 72 (47%) had a positive reading.

Conclusions: NTBS does not accurately predict malignancy in women with radiologic abnormalities requiring biopsy. The higher sensitivity mode (NTBS2) results in an unacceptable number of false positives, precluding its use. Infrared screening cannot be used as a successful adjunct to mammography, nor can it replace any of the screening modalities that are standard practice. Mammography remains the gold standard for breast cancer screening.

Table 1. Clinical characteristics of 181 patients undergoing NTBS followed by minimally invasive biopsy

| Total Number of Radiologic Abnormalities | 187 |
| Median Age at Diagnosis (years)         | 52.5 |
Radiologic Abnormalities, n (%)  
Calcifications 77 (41%)  
Mass\(^a\) 104 (56%)  
Abnormal enhancement 5 (3%)  
Diffuse skin thickening 1 (<1%)  

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<th>Type of Biopsy, n (%)</th>
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<tr>
<td>Stereotactic 90 (48%)</td>
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<tr>
<td>Ultrasound Guided 73 (39%)</td>
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<tr>
<td>MRI Guided 7 (4%)</td>
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<tr>
<td>Biopsy without image guidance(^b) 13 (7%)</td>
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<tr>
<td>No target(^c) 4 (2%)</td>
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NTBS No Touch Breast Scan  
\(^a\) Includes patient with architectural distortion seen on mammogram  
\(^b\) Includes fine needle aspiration and core biopsy  
\(^c\) Target lesion not identified on day of biopsy