Original Investigation

Breast Imaging Outcomes following Abnormal Thermography

Colleen H. Neal, MD, Kelsey A. Flynt, MD[1], Deborah O. Jeffries, MD, Mark A. Helvie, MD

Rationale and Objectives: The study aimed to determine the outcome of patients presenting for evaluation of abnormal breast thermography.

Materials and Methods: Following Institutional Review Board approval, retrospective search identified 38 patients who presented for conventional breast imaging following a thermography-detected abnormality. Study criteria included women who had mammogram and/or breast ultrasound performed for evaluation of a thermography-detected abnormality between January 1, 2000, and December 31, 2015. Patients whose mammograms and ultrasounds were initiated at an outside institution or who did not have imaging at our institution were excluded. Records were reviewed for clinical history, thermography results, mammogram and/or ultrasound findings, and pathology. Mammograms and ultrasounds were prospectively interpreted by one of 14 Mammography Quality Standards Act–certified breast imaging radiologists with 3–30 years of experience. Patient outcomes were determined by biopsy or at least 1 year of follow-up. Patient ages ranged from 23 to 70 years (mean = 50 years).

Results: Ninety-five percent (36 of 38) of patients did not have breast cancer. The two patients diagnosed with breast cancer had suspicious clinical symptoms including palpable mass and erythema. No asymptomatic woman had breast cancer. Negative predictive value was 100%. Of 38 patients, 79% (30 of 38) had Breast Imaging Reporting and Data System (BI-RADS) 1 or 2 assessments; 5% (2 of 38) had BI-RADS 3; and 16% (6 of 38) had BI-RADS 4 ($n = 5$) or BI-RADS 5 ($n = 1$) assessments. Two of six patients with biopsy recommendations were diagnosed with breast cancer (Positive predictive value 2 = 33.3%). All findings recommended for biopsy were ipsilateral to the reported thermography abnormality.

Conclusions: No cancer was diagnosed among asymptomatic women. The 5% of patients diagnosed with cancer had co-existing suspicious clinical findings. Mammogram and/or ultrasound were useful in accurately characterizing patients with abnormal thermography.

Key Words: Thermography; breast cancer; mammography.

INTRODUCTION

Breast cancer is one of the leading causes of death among women worldwide. Screening mammography is the most thoroughly researched and widely utilized examination for breast cancer detection. Screening mammography has repeatedly been shown to contribute to decreased breast cancer–associated mortality (1–6). Supplemental screening with ultrasound, tomosynthesis, and magnetic resonance imaging (MRI) are performed as clinically indicated, especially for higher risk women; these imaging modalities have all demonstrated effectiveness and safety in the detection of breast cancer. However, patients may seek alternative breast cancer screening methods such as breast thermography. Less is known about the efficacy of thermography for breast cancer detection. Breast thermography was originally developed in the late 1950s in Canada (7,8). Thermography was implemented as a breast cancer screening study in the 1960s. In 1977, Feig et al. compared mammography and thermography screening in 16,000 women and found thermography to have a sensitivity of 39% (9). Based on this low sensitivity, Feig concluded that thermography was not practical as a breast cancer screening tool. Following the results of the study by Feig, breast thermography was largely abandoned (10).

Since that time, thermal imaging technology has improved and breast thermography is regarded as an adequate method for breast cancer screening in some medical communities, which describe it as offering earlier breast cancer diagnosis relative to conventional imaging modalities and clinical examinations (11). Although the US Food and Drug Administration (FDA) has not approved thermography as a stand-alone modality for breast cancer screening or diagnosis (12), patients concerned with mammographic radiation or compression may seek thermography in lieu of screening mammography.

When a nonpalpable breast abnormality is detected, imaging guidance is required to localize the abnormality for diagnosis and treatment. Because thermographic guidance is not readily available, patients with thermography-detected abnormalities may be referred to conventional breast imaging centers for evaluation with mammogram and/or ultrasound. There is a paucity of literature guiding the radiologist's approach to

Acad Radiol 2017; ■:■■–■■

From the Department of Radiology, University of Michigan, C415 MIB SPC 5842, 1500 E. Medical Center Drive, Ann Arbor, MI, 48109. Received July 14, 2017; revised September 11, 2017; accepted October 19, 2017. [1]Permanent Address: St. Luke's Health System Breast Center, 4321 Washington Street Suite 1000, Kansas City, MO 64111. **Address correspondence to:** C.H.N. e-mail: hawleyc@med.umich.edu

https://doi.org/10.1016/j.acra.2017.10.015

patients who present with a clinical indication of "abnormal thermography." The purpose of the study was to evaluate the outcome of patients presenting for abnormal breast thermography to provide guidance to radiologists evaluating these patients.

MATERIALS AND METHODS

Institutional review board approval was obtained for this Health Insurance Portability and Accountability Act-compliant retrospective cohort study. No extramural funding was used. Informed consent was waived. Using institutional records, we retrospectively identified patients who had the words "thermogram," "thermography," or "thermascan" included in their breast imaging reports at our institution between January 1, 2000, and December 31, 2015. After the data acquisition, the study database was de-identified to complete the analysis. Our center is a National Cancer Institute-designated comprehensive cancer center and a National Comprehensive Cancer Network center. Breast thermography is not performed at our institution. Forty-five patients were identified from this records search. The study population included female patients who were referred for conventional breast imaging (mammogram and/or ultrasound) for evaluation of an abnormal thermography finding. We excluded cases that only referenced thermography in the report because thermography was discussed with the patient ($n = 4$), included clinical history of recent negative thermography ($n = 1$), and cases in which the standard breast imaging workup for thermography abnormality was initiated at an outside institution ($n = 2$). Abnormal thermography results were not further classified other than providers' referral. Thirty-eight patients who were referred for conventional breast imaging for evaluation of a thermography abnormality composed the patient cohort.

Medical records were reviewed to record data on side of reported thermography abnormality. The prospectively rendered mammogram and/or ultrasound findings and Breast Imaging Reporting and Data System (BI-RADS) assessment category were recorded (13). The size, laterality, in-breast location of imaging findings, and whether the patient had a screening mammogram within the 18 months before thermography were recorded. Patients' family and personal histories of breast cancer, age, menopausal status, and years of imaging follow-up were recorded. Family history was considered positive if there was a first-degree relative with breast cancer (i.e., sister, mother, and/or daughter). Presence or absence of personal history of breast cancer or prior high-risk lesion (e.g., lobular neoplasia) was recorded. Presence of concomitant clinical breast symptoms such as palpable mass or pain was also noted.

In women older than 30 years, diagnostic mammography +/− ultrasound was performed for evaluation of a clinical problem at our institution according to National Comprehensive Cancer Network guidelines (14). Women younger than 30 years were initially evaluated with focused ultrasound of the area of concern; diagnostic mammogram, if performed, was per radiologist recommendation. Mammography may not have been performed based on the patient's age or if the patient declined mammogram. Diagnostic mammograms routinely consisted of craniocaudal, mediolateral oblique, and lateral views, and were performed on either Senographe DMR systems (GE Healthcare) or Senographe Essential (GE Healthcare). Additional diagnostic views were performed at the discretion of the interpreting radiologist depending upon clinical situation. Digital breast tomosynthesis was not used during the study period. All mammograms were interpreted by one of 14 Mammography Quality Standards Act–certified breast imaging radiologists with 3–30 years of experience. Focused ultrasound was performed by the diagnostic radiologist using GE Logiq systems (GE Healthcare). Ultrasound was commonly performed if the location of the thermography abnormality was known based on thermography report or if a focal mammographic finding such as mass or asymmetry was identified. If biopsy was performed, biopsy method and pathological diagnosis were recorded. Patient outcomes were determined by biopsy or at least 1 year of imaging follow-up.

RESULTS

Ninety-five percent (36 of 38) of patients who presented for breast imaging evaluation following abnormal thermography did not have breast cancer. The two patients diagnosed with breast cancer had known co-existing suspicious clinical symptoms including palpable mass and erythematous breast. No asymptomatic woman referred for evaluation of a thermography abnormality was found to have breast cancer. Of the 36 patients without breast cancer, four had a breast biopsy with benign result and all others had clinical and/or imaging follow-up of at least 1 year.

The patients' ages ranged from 23 to 70 years, with a mean and median age of 51 years. Of the 38 patients, 79% (30 of 38) had BI-RADS 1 or 2 assessments; 5% (2 of 38) had BI-RADS 3; and 16% (6 of 38) had BI-RADS 4 ($n = 5$) or BI-RADS 5 ($n = 1$) assessments. The two cases with probably benign BI-RADS Category 3 findings were stable on follow up for greater than 2 years. Two of six patients with biopsy recommendations were diagnosed with breast cancer (Positive predictive value 2 = 33.3%). However, both patients diagnosed with breast cancer had ipsilateral suspicious clinical symptoms in addition to their reported thermogram abnormalities; both patients had a preexisting, known palpable mass and one of the patients had an erythematous ipsilateral breast. One of the palpable masses measured 15 mm, and the second patient who was diagnosed with breast cancer had multifocal palpable masses, the largest measuring 6 cm. This patient also had erythema and skin thickening involving the inferior half of her breast. Of all the patients, 34% (13 of 38) of patients had concomitant clinical symptoms in addition to the reported thermogram abnormality for which they were referred.

Fifty percent (3 of 6) of the conventional imaging findings recommended for biopsy were calcifications and 50% (3