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The Temperature Reading on Thermography

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The Food and Drug Administration (FDA) has recently issued a warning to the public, stating that thermography should not be used as a sole screening tool for breast cancer and that it is not an effective alternative to mammography (U.S. Food and Drug Administration and Center for Drug Evaluation and Research, 2019a). In order for a screening examination to be effective, it must detect disease early, reduce mortality from the disease, and be widely accessible, affordable, and safe. It is widely known that mammography is an effective breast cancer screening tool and detects approximately four to six cancers per 1000 women screened. Mammography has decreased breast cancer mortality rates by approximately 41.6% in women aged 40 to 84 years by detecting cancers early when they are small and treatable (Surveillance Epidemiology and End Results (SEER) Program, 2017). Furthermore, a recent study demonstrated that mammographic screening and improved treatment resulted in a 45.3% to 58.3% reduction in breast cancer mortality in 2018 and averted 384,046–614,484 cumulative breast cancer deaths since 1989 (Hendrick et al., 2019). Early breast cancer detection lessens a patient's stage at diagnosis leading to a more favorable prognosis (Saadatmand et al., 2015). In addition, early-stage breast cancers often require less extensive surgery and may not require chemotherapy, which can have side effects (Plecha et al., 2014). Screening mammography is easily accessible and largely covered by medical insurance including Medicare. Mammography is also highly regulated under the MQSA (Mammography Quality and Standards Act), which ensures quality and safety through routine auditing and sets national benchmarks for breast imaging facilities and radiologists.

According to the American College of Radiology, annual screening mammography is recommended for the average risk woman beginning at age 40 years and should continue as a function of the patient's health status and overall life expectancy (Monticciolo et al., 2018). If available, tomosynthesis should be performed in all women and has shown to decrease recall rates by 15% and increase cancer detection rates by 41% when compared to digital mammography (Friedewald et al., 2014). High-risk women, such as those with a strong family history of breast cancer should begin annual mammography earlier, 10 years before the age of a first-degree relative's diagnosis (Monticciolo et al., 2018). Those with an even greater lifetime risk, such as BRCA mutation carriers, should begin annual screening mammography by age 30 years but no sooner than 25 years (Monticciolo et al., 2018). African-American women are also considered to be at high risk as they are more likely to die from breast cancer, are more likely to have aggressive triple-negative breast cancers, and are more likely to carry a BRCA mutation (Monticciolo et al., 2018). Therefore, the American College of Radiology advocates a risk assessment for African-American women at age 30 years to determine whether they qualify for earlier and more robust screening (Monticciolo et al., 2018).

By contrast, thermography does not have the rich support of multiple scientific studies to prove it as effective as mammography for screening for breast cancer. That is why the FDA has put out their most recent warning. The FDA is aware that health care facilities, such as health spas, mobile units, and homeopathic clinics, have been marketing thermography inappropriately (U.S. Food and Drug Administration, 2019a). On February 22, 2019, the FDA issued a letter warning Total Thermal Imaging, Inc. in La Mesa, California, to stop making inappropriate claims about thermography. This is not the first time the FDA has issued a warning to companies promoting thermography. Letters have been written to Thermogram Assessment Services, Nature's Treasures, Meditherm, Dr. Mercola's Natural Health Center, and Central Coast Thermography (U.S Food and Drug Administration and Center for Drug Evaluation and Research, 2019b).

Thermography has been around since the 1950s and is based on the principle that metabolic activity increases in precancerous tissues and cancer. During the cancer process, new vessels are created (angiogenesis), existing vessels are recruited, and there is an overall increase in metabolic activity causing the premalignant tissue or malignant lesions to grow. This typically causes an increase in temperature compared to the surrounding tissue, which can be mapped. Thermography uses a heat-sensing imaging device and records the emitted heat from the surface of the body. The different levels of heat emitted are displayed with a color scale for interpretation.

Thermography is performed in the erect position with the patient's arms above the head. Initially, the patient is in a heat-controlled room for 15 minutes for the body to reach a steady-state equilibrium. An infrared camera captures the images, and the

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images are sent to a computer for interpretation by a board-certified clinical thermologist. The study is not covered by Medicare.

A study published in 1990 looked at the efficacy of thermography. The study involved 10,238 participants between the ages of 40 and 65 years. All the women had a thermographic and clinical breast examination and were followed for the next 5 years. If there was an abnormality in either examination, the woman was referred for a mammogram. The study showed that the sensitivity for thermography was 61% and the specificity was 74%. Furthermore, 71% to 76% of the women who subsequently developed breast cancer within the 5-year period had a normal thermogram. The study concluded that thermography is not an adequate tool to detect breast cancer, nor is it useful to predict the development of breast cancer within 5 years (Williams et al., 1990).

Patients can opt for breast thermography; however, there is no scientific evidence to support its use as a standalone examination for breast cancer screening or diagnosis. Thermography has been cleared for use by the FDA but only when performed in addition to mammography. Thermography has unacceptable false-negative rates leading to delayed breast cancer diagnoses and high false-positive rates resulting in more follow-up examinations.

Health care providers need to be aware of medical facilities that are in “hot water” for misinforming the public on thermography's efficacy as a safe or superior alternative to mammography as highlighted in the recent FDA safety communication. Serving as patient advocates, it is the responsibility of health care providers to transmit appropriate and evidence-based information to patients. Thermography is not a replacement screening or diagnostic tool for mammography and should only be utilized in addition to routine mammography. Mammography continues to “stand the heat” by significantly reducing mortality from breast cancer and remains the gold standard for breast cancer screening and diagnosis.

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