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Breast thermography review

The terms of reference for the thermography review (Fitzgerald and Berentson-Shaw. *Thermography as a screening and diagnostic tool: a systematic review*. NZMJ 9 March 2012) resulted in a specifically narrow "silo" of acceptable studies relating to breast cancer screening that eliminated most of the thermography literature. However, thermal imaging potentially identifies abnormal breast metabolism prior to oncogenesis. Sequential imaging of hyperthermia and vascular patterns can then show any responses to hormonal, lifestyle or other interventions.

Historically, abnormal thermograms have been associated with developing cancer. 1416 patients with persistently abnormal breast thermograms for 8 years had an actuarial breast cancer risk of 26% at 5 years.[2] In the 165 patients with non-palpable cancers, thermography was the only test that was positive when compared to mammography and ultrasound in 53% of these patients at initial evaluation. The authors concluded that a persistently abnormal thermogram, even in the absence of any other sign of malignancy, was associated with a high risk of developing interval cancer.[2]

Similarly, 1527 patients with abnormal thermograms were followed for 12 years and 40% developed malignancies within 5 years.[3] These so-called "false" positives gained further significance after an abnormal thermogram was associated with more rapidly growing tumours with a shorter disease-free interval.[4] Patients with hot tumours have significantly worse disease-free and specific survival than those with cold tumours;[5] as do younger women[6,7] where 367 of the 2654 breast cancer cases occurred in those ineligible for State-subsidised mammography (NZ National Statistics 2009).

Mammography is less specific with fibrocystic breasts with the cancer detection rate falling to 55% in Grade IV breast density.[8] Boyd discussing dense fibrocystic breasts concluded "Annual screening in women with extensive mammographic density is not likely to increase cancer detection rate (due to masking)…. Attention should therefore be directed to the development and evaluation of alternative imaging techniques for such women".[9] In this regard, thermography found 58 of 60 biopsy-proven breast cancers for a 97% sensitivity, 44% specificity, and a 82% negative predictive value in 92 women with dense breasts recommended for breast biopsy based on mammography or ultrasound evaluations.[10]

To quote Kennedy[8] "No single tool provides excellent predictability; however, a combination that incorporates thermography may boost both sensitivity and specificity. In light of technological advances and maturation of the thermographic industry, additional research is required to confirm the potential of this technology to provide an effective non-invasive, low risk adjunctive tool for the early detection of breast cancer."

The writer imported an American thermography system in 2002 and since 2009 has used the German InfraTec/InfraMedic computerised system registered as a medical device in the EU[1] and with MedSafe (WAND). The following results demonstrate clinical relevance:

- A 48-year-old woman with fibrocystic breasts and a normal mammogram and ultrasound (U/S) at age 44 requested a thermogram that revealed a large vascular complex in the upper right breast. Repeated mammography and U/S reported benign fibrocystic breasts. A year later the thermogram had deteriorated with higher contralateral temperatures. Mammography and U/S again reported benign fibrocystic breasts. A surgical opinion was sought and a guided core biopsy performed in some upper outer quadrant thickening. Histology confirmed a Grade 11 lobular carcinoma.

- A 53-year-old woman requested thermography. Mammography and U/S performed 2 weeks previously had identified fibrocystic changes and indeterminate micro-calcifications deemed inconclusive. The left breast revealed an abnormal vascular complex. Three months later, the thermal image had deteriorated. A repeated mammography and U/S were again reported as only consistent with fibrocystic changes with less obvious micro-calcifications. The thermal abnormality persisted with comparative imaging 6 months and a year later. After further discussion with the radiologist, the patient had magnetic resonance imaging following which an 8mm tumour was identified and confirmed as an infiltrating ductal carcinoma after excision.

- A 57-year-old woman developed a diffuse, bulky and mobile mass in the upper outer right breast. The mammogram (March 2007) stated: Both breasts show relatively dense stromal appearance with bilateral benign vascular calcification. In the area of clinical concern, there is a focal area of somewhat increased density with reasonably well defined margins.

  Ultrasound was performed and reported: A 1 ×1.5cm relatively well defined area which is predominantly hypo to anechoic. Internal echoes are seen with good posterior enhancement suggestive of a probable benign cyst. A fine-needle biopsy was reported as benign. The patient requested thermal imaging before making a decision whether to have surgery. Thermography showed heat over the mass and abnormal vascularity. Surgical excision confirmed an infiltrating ductal carcinoma (T2NoMo).

Whilst much remains to internationally standardise thermographic technology and protocol, 10 years of breast thermal imaging at the primary health-care level have confirmed clinical usefulness with a unique ability to monitor breast health. It warrants wider support.

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Author response

New Zealand Guidelines Group (NZGG) was an independent, government-funded body with no conflict or vested interest in any type of test or intervention, and was funded only to investigate the science surrounding the use of thermography as a screening tool, a diagnostic tool and as an adjunct tool to mammography.

Dr Godfrey criticises the “narrow silo” of studies and claims that this review ‘eliminated most of the thermography literature’. There appears to be a misunderstanding about what constitutes a systematic review. There are many health care agencies conducting systematic reviews internationally and generally, there is consensus that a systematic reviews seeks to collate all evidence that fits pre-specified eligibility criteria in order to address a specific research question and to minimise bias by using explicit, systematic methods. To this end, the types of studies required to prove the effectiveness of thermograph as a tool to screen, or to diagnose breast cancer should measure thermography against a reference standard, and any review of such studies should be as scientifically rigorous as other systematic reviews of effectiveness, not less or more. The inclusion criteria for this systematic review including the types of patients, interventions, comparisons and outcomes are clearly explained, as are the types of studies eligible for inclusion.

Determining effectiveness of a test or intervention requires careful appraisal of individual studies in order that the results of any analysis are reliable, valid and of high enough quality to make decisions about health care. All of the studies included in this review had methodological weaknesses; the studies that were not included fell outside the inclusion criteria, most often because their design did not permit

diagnostic accuracy data to be calculated. This systematic review has undergone extensive peer review by several stakeholder groups including the National Screening Advisory Committee, Cancer Control New Zealand, and the Australian Population Health Development Principal Committee. To this end, we are confident that we have not missed relevant studies nor included inappropriate studies, presented erroneous data, or misrepresented the data.

The historical data outlined by Dr Godfrey includes results from studies using methods of thermography that are now obsolete. Currently, the most common method is digital infrared thermography and this systematic review specifically excluded studies conducted prior to 1984 when the thermography methods used today did not yet exist. We feel it is reasonable to have excluded studies using different technology conducted more than 30 years ago.

Many of the studies Dr Godfrey cites relate to the use of thermography as a cancer risk prediction tool (i.e. its relative risk, odds or survival benefit) which is a separate issue to that of the accuracy of thermography as a screening or diagnostic test. Thermographic changes in isolation are highly unlikely to provide an accurate picture of the risk of breast cancer in an individual patients; it may be one of several risk factors, all of which should be taken into account. Over the past two decades, several risk prediction models have been developed to assess the risk of breast cancer in both populations, and in individuals. Current models are based on combinations of risk factors, and in general their outputs include a breast cancer risk estimate over a specified time.

There are several factors known to place women at higher risk of developing future breast cancer; the presence of substantial family history of breast cancer is considered to be one of the most important factors; early menarche or late menopause, use of the combined contraceptive pill, mammographic breast tissue density, lobular carcinoma in situ, atypical ductal or lobular hyperplasia have proven to have some of the strongest links to future breast cancer. It might well be that results from thermography can be considered a risk factor, but as yet there does not appear to be any evidence that thermography has been considered together with other known risk factors in a risk prediction model.

Dr Godfrey suggests that the thermography scanner he imported has FDA approval; while this may well be the case, this statement appears out of context. FDA approval relates to the safety of a device in that it will not cause undue harm to patients, not that it is a reliable tool as part of screening or diagnosing breast cancer. In 2011 the FDA published safety information on its website[1] and made this available in a report to consumers[2] outlining its views on the scientific and clinical validity of thermography for breast cancer screening and diagnosis. They reported that: "*The FDA is not aware of any valid scientific data to show that thermographic devices, when used on their own, are an effective screening tool for any medical condition including the early detection of breast cancer or other breast disease. The FDA is concerned that women will believe these misleading claims about thermography and not receive needed mammograms*."

Data on the effectiveness of thermography as a tool to screen patients, or to detect breast cancer is yet to meet the required scientific standard. We would suggest that there is a lack of understanding of the scientific paradigm of evidence based medicine.

We encourage those that operate thermography clinics to invest in good quality studies that would prove their tool effective and safe; there is no lack of literature available which lays out the criteria for such quality scientific investigation.

Anita Fitzgerald and Jessica Berentson-Shaw

References:

1. Food and Drug Administration (FDA). Thermographic imaging systems for breast cancer screening: FDA Safety Communication, 2011.
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