Chapter 8 – Diagnostic Imaging and Other Testing

Contents

Avoid Routine Mammograms if You are Under 50

BCA Screening Policy - 2010

Cochrane Review on Mammography Lancet 10-2001

Diagnostic Mammogram Accuracy and Radiologist Training

Mammogram new regulations

Mammograms may cause breast cancer

Mammograms' Value in Cancer Fight at Issue

New BCA Screening Guidelines 2009

New Mammogram Guidelines Issued 2010

Radiation and Medical Imaging

Radiation Risks comparing Mammograms with Breast Specific Gamma Imaging

Study Questions Safety of Mammograms for Young Women at High Risk of Cancer

What You Should Know About Mammograms

MRI

Breast MRI By Mayo Clinic staff

Highlights Regarding Imaging - San Antonia Breast Conference Fall 2008

MRI - Breast Study

What is High - Field MRI?

Ultrasound

Breast ultrasound tomography

For Dense Breasts, Ultrasound Increases Cancer Detection Rate

NASA Might Help Examine Your Breasts - False reports on Mammograms and MRI

Ultrasound Technology at EPIC IMAGING

Breast Cancer Risk estimates increased with repeated Prior CT and Nuclear Imaging

Comprehensive Breast Imaging - Epic Imaging

Mammography-Thermography-Ultrasound -- What's the Difference

A Review of Breast Thermography

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Note: The following is not a comprehensive review of the literature. Over 30 years of research compiling over 800 studies in the index-medicus exist. What follows is a pertinent sample review of the research concerning the clinical application of diagnostic infrared imaging (thermography) for use in breast cancer screening. All the citations are taken from the index-medicus peer-reviewed research literature or medical textbooks. The authors are either PhD's with their doctorate in a representative field, or physicians primarily in the specialties of oncology, radiology, gynecology, and internal medicine.

The following list is a summary of the informational text that follows:

- In 1982, the FDA approved breast thermography as an adjunctive diagnostic breast cancer screening procedure.

Breast thermography has undergone extensive research since the late 1950's.

- Over 800 peer-reviewed studies on breast thermography exist in the index-medicus literature.

- In this database, well over 300,000 women have been included as study participants.

- The numbers of participants in many studies are very large -- 10K, 37K, 60K, 85K…

- Some of these studies have followed patients up to 12 years.

- Strict standardized interpretation protocols have been established for over 15 years.

- Breast thermography has an average sensitivity and specificity of 90%.

- An abnormal thermogram is 10 times more significant as a future risk indicator for breast cancer than a first order family history of the disease.

- A persistent abnormal thermogram caries with it a 22x higher risk of future breast cancer.

- An abnormal infrared image is the single most important marker of high risk for developing breast cancer.

- Breast thermography has the ability to detect the first signs that a cancer may be forming up to 10 years before any other procedure can detect it.

- Extensive clinical trials have shown that breast thermography significantly augments the long-term survival rates of its recipients by as much as 61%.

- When used as part of a multimodal approach (clinical examination + mammography + thermography) 95% of early stage cancers will be detected.

Introduction

The first recorded use of thermobiological diagnostics can be found in the writings of Hippocrates around 480 B.C.[1]. A mud slurry spread over the patient was observed for areas that would dry first and was thought to indicate underlying organ pathology. Since this time, continued research and clinical observations proved that certain temperatures related to the human body were indeed indicative of normal and abnormal physiologic processes. In the 1950's, military research into infrared monitoring systems for night time troop movements ushered in a new era in thermal diagnostics. The first use of diagnostic thermography came in 1957 when R. Lawson discovered

that the skin temperature over a cancer in the breast was higher than that of normal tissue[2].

The Department of Health Education and Welfare released a position paper in 1972 in which the director, Thomas Tiernery, wrote, “The medical consultants indicate that thermography, in its present state of development, is beyond the experimental state as a diagnostic procedure in the following 4 areas: 1) Pathology of the female breast. 2).....”. On January 29, 1982, the Food and Drug Administration published its approval and classification of thermography as an adjunctive diagnostic screening procedure for the detection of breast cancer. Since the late 1970's, numerous medical centers and independent clinics have used thermography for a variety of diagnostic purposes.

Fundamentals of Infrared Imaging

Physics – All objects with a temperature above absolute zero (-273 K) emit infrared radiation from their surface. The Stefan-Boltzmann Law defines the relation between radiated energy and temperature by stating that the total radiation emitted by an object is directly proportional to the object's area and emissivity and the fourth power of its absolute temperature. Since the emissivity of human skin is extremely high (within 1% of that of a black body), measurements of infrared radiation emitted by the skin can be converted directly into accurate temperature values.

Equipment Considerations – Infrared rays are found in the electromagnetic spectrum within the wavelengths of 0.75 micron - 1mm. Human skin emits infrared radiation mainly in the 2 - 20 micron wavelength range, with an average peak at 9-10 microns[3]. State-of-the-art infrared radiation detection systems utilize ultra-sensitive infrared cameras and sophisticated computers to detect, analyze, and produce high-resolution diagnostic images of these infrared emissions. The problems encountered with first generation infrared camera systems such as improper detector sensitivity (low-band), thermal drift, calibration, analog interface, etc. have been solved for almost two decades.

Laboratory Considerations – Thermographic examinations must be performed in a controlled environment. The primary reason for this is the nature of human physiology. Changes from a different external (non-clinical controlled room) environment, clothing, etc. produce thermal artifacts. Refraining from sun exposure, stimulation or treatment of the breasts, and cosmetics and lotions before the exam, along with 15 minutes of nude acclimation in a florescent lit, draft and sunlight-free, temperature and humidity-controlled room maintained between 18-22 degree C, and kept to within 1 degree C of change during the examination, is necessary to produce a physiologically neutral image free from artifact.

Correlation Between Pathology and Infrared Imaging

The empirical evidence that underlying breast cancer alters regional skin surface temperatures was investigated early on. In 1963, Lawson and Chughtai, two McGill University surgeons, published an elegant intra-operative study demonstrating that the increase in regional skin surface temperature associated with breast cancer was related to venous convection[4]. This early quantitative experiment added credence to previous research suggesting that infrared findings were related to both increased vascular flow and increased metabolism.

Infrared imaging of the breast may have critical prognostic significance since it may correlate with a variety of pathologic prognostic features such as tumor size, tumor grade, lymph node status and markers of tumor growth[5]. The pathologic basis for these infrared findings, however, is uncertain. One possibility is increased blood flow due to vascular proliferation (assessed by quantifying the microvascular density (MVD)) as a result of tumor associated angiogenesis. Although in one study[6], the MVD did not correlate with abnormal infrared findings. However, the imaging method used in that study consisted of contact plate technology (liquid crystal thermography (LCT)), which is not capable of modern computerized infrared analysis. Consequently, LCT does not possess the discrimination and digital processing necessary to begin to correlate histological and discrete vascular changes[7].

In 1993, Head and Elliott reported that improved images from second generation infrared systems allowed more objective and quantitative analysis[5], and indicated that growth-rate related prognostic indicators were strongly associated with the infrared image interpretation.

In a 1994 detailed review of the potential of infrared imaging[8], Anbar suggested, using an elegant biochemical and immunological cascade, that the previous empirical observation that small tumors were capable of producing notable infrared changes could be due to enhanced perfusion over a substantial area of the breast surface via regional tumor induced nitric oxide vasodilatation. Nitric oxide is a molecule with potent vasodilating properties. It is synthesized by nitric oxide synthase (NOS), found both as a constitutive form of nitric oxide synthase (c-NOS), especially in endothelial cells, and as an inducible form of nitric oxide synthase (i-NOS), especially in macrophages[9]. NOS has been demonstrated in breast carcinoma[10] using tissue immunohistochemistry, and is associated with a high tumor grade. There have been, however, no previous studies correlating tissue NOS levels with infrared imaging. Given the correlation between infrared imaging and tumor grade, as well as NOS levels and tumor grade, it is possible that infrared findings may correlate with tumor NOS content. Future studies are planned to investigate these possible associations.

The concept of angiogenesis, as an integral part of early breast cancer, was emphasized in 1996 by Guido and Schnitt. Their observations suggested that it is an early event in the development of breast cancer and may occur before tumor cells acquire the ability to invade the surrounding stroma and even before there is morphologic evidence of an in-situ carcinoma[11]. Anti-angiogenesis therapy is now one of the most promising therapeutic strategies and has been found to be pivotal in the new paradigm for consideration of breast cancer development and treatment[12]. In 1996, in his highly reviewed textbook entitled Atlas of Mammography – New Early Signs in Breast Cancer, Gamagami studied angiogenesis by infrared imaging and reported that hypervascularity and hyperthermia could be shown in 86% of non-palpable breast cancers. He also noted that in 15% of these cases infrared imaging helped to detect cancers that were not visible on mammography[13].

The underlying principle by which thermography (infrared imaging) detects pre-cancerous growths and cancerous tumors surrounds the well documented recruitment of existing vascularity and neoangiogenesis which is necessary to maintain the increased metabolism of cellular growth and multiplication. The biomedical engineering evidence of thermography's value, both in model in-vitro and clinically in-vivo studies of various tissue growths, normal and neoplastic, has been established[14-20].

The Role of Infrared Imaging in the Detection of Cancer

In order to evaluate the value of thermography, two viewpoints must be considered: first, the sensitivity of thermograms taken preoperatively in patients with known breast carcinoma, and second, the incidence of normal and abnormal thermograms in asymptomatic populations (specificity) and the presence or absence of carcinoma in each of these groups.

In 1965, Gershon-Cohen, a radiologist and researcher from the Albert Einstein Medical Center, introduced infrared imaging to the United States[21]. Using a Barnes thermograph, he reported on 4,000 cases with a sensitivity of 94% and a false-positive rate of 6%. This data was included in a review of the then current status of infrared imaging published in 1968 in CA - A Cancer Journal for Physicians[22].

In prospective studies, Hoffman first reported on thermography in a gynecologic practice. He detected 23 carcinomas in 1,924 patients (a detection rate of 12.5 per 1,000), with an 8.4% false-negative (91.6% sensitivity) and a 7.4% false-positive (92.6% specificity) rate[23].

Stark and Way screened 4,621 asymptomatic women, 35% of whom were under 35 years of age, and detected 24 cancers (detection rate of 7.6 per 1,000), with a sensitivity and specificity of 98.3% and 93.5% respectively[24].

In a mobile unit examination of rural Wisconsin, Hobbins screened 37,506 women using thermography. He reported the detection of 5.7

cancers per 1,000 women screened with a 12% false-negative and 14% false-positive rate. His findings also corroborated with others that thermography is the sole early initial signal in 10% of breast cancers[25-26].

Reporting his Radiology division's experience with 10,000 thermographic studies done concomitantly with mammography over a 3 year period, Isard reiterated a number of important concepts including the remarkable thermal and vascular stability of the infrared image from year to year in the otherwise healthy patient and the importance of recognizing any significant change[27]. In his experience, combining these modalities increased the sensitivity rate of detection by approximately 10%; thus, underlining the complementarity of these procedures since each one did not always suspect the same lesion. It was Isard's conclusion that, had there been a preliminary selection of his group of 4,393 asymptomatic patients by infrared imaging, mammographic examination would have been restricted to the 1,028 patients with abnormal infrared imaging, or 23% of this cohort. This would have resulted in a cancer detection rate of 24.1 per 1000 combined infrared and mammographic examinations as contrasted to the expected 7 per 1000 by mammographic screening alone. He concluded that since infrared imaging is an innocuous examination, it could be utilized to focus attention upon asymptomatic women who should be examined more intensely. Isard emphasized that, like mammography and other breast imaging techniques, infrared imaging does not diagnose cancer, but merely indicates the presence of an abnormality.

Spitalier and associates screened 61,000 women using thermography over a 10 year period. The false-negative and positive rate was found to be 11% (89% sensitivity and specificity). 91% of the nonpalpable cancers (T0 rating) were detected by thermography. Of all the patients with cancer, thermography alone was the first alarm in 60% of the cases. The authors also noted that “in patients having no clinical or radiographic suspicion of malignancy, a persistently abnormal breast thermogram represents the highest known risk factor for the future development of breast cancer”[28].

Two small-scale studies by Moskowitz (150 patients)[29] and Treatt (515 patients)[30] reported on the sensitivity and reliability of infrared

imaging. Both used unknown “experts” to review the images of breast cancer patients. While Moskowitz excluded unreadable images, data from Threatt's study indicated that less than 30% of the images produced were considered good, the rest being substandard. Both of these studies produced poor results; however, this could be expected from the fact alone that both used such a small patient base. However, the greatest error in these studies is found in the methods used to analyze the images. The type of image analysis consisted of the sole use of abnormal vascular pattern recognition. At the time these studies were performed, the most recognized method of infrared image analysis used a combination of abnormal vascular patterns with a quantitative analysis of temperature variations across the breasts. Consequently, the data obtained from these studies is highly questionable. Their findings were also inconsistent with numerous previous large-scale multi-center trials. The authors suggested that for infrared imaging to be truly effective as a screening tool, there needed to be a more objective means of interpretation and proposed that this would be facilitated by computerized evaluation. This statement is interesting considering that the use of recognized quantitative and qualitative reading protocols (including computer analysis) was available at the time.

In a unique study comprising 39,802 women screened over a 3 year period, Haberman and associates used thermography and physical examination to determine if mammography was recommended. They reported an 85% sensitivity and 70% specificity for thermography. Haberman cautioned that the findings of thermographic specificity could not be extrapolated from this study as it was well documented that long term observation (8-10 years or more) is necessary to determine a true false-positive rate. The authors noted that 30% of the cancers found would not have been detected if it were not for thermography[31].

Gros and Gautherie reported on 85,000 patients screened with a resultant 90% sensitivity and 88% specificity. In order to investigate a method of increasing the sensitivity of the test, 10,834 patients were examined with the addition of a cold-challenge (two types: fan and ice water) in order to elicit an autonomic response. This form of dynamic thermography decreased the false-positive rate to 3.5% (96.5% sensitivity)[32-35].

In a large scale multi-center review of nearly 70,000 women screened, Jones reported a false-negative and false-positive rate of 13% (87% sensitivity) and 15% (85% sensitivity) respectively for thermography[36].

In a study performed in 1986, Usuki reported on the relation of thermographic findings in breast cancer diagnosis. He noted an 88% sensitivity for thermography in the detection of breast cancers[37].

In a study comparing clinical examination, mammography, and thermography in the diagnosis of breast cancer, three groups of patients were used: 4,716 patients with confirmed carcinoma, 3,305 patients with histologically diagnosed benign breast disease, and 8,757 general patients (16,778 total participants). This paper also compared clinical examination and mammography to other well known studies in the literature including the NCI-sponsored Breast Cancer Detection Demonstration Projects. In this study, clinical examination had an average sensitivity of 75% in detecting all tumors and 50% in cancers less than 2 cm in size. This rate is exceptionally good when compared to many other studies at between 35-66% sensitivity. Mammography was found to have an average 80% sensitivity and 73% specificity. Thermography had an average sensitivity of 88% (85% in tumors less than 1 cm in size) and a specificity of 85%. An abnormal thermogram was found to have a 94% predictive value. From the findings in this study, the authors suggested that "none of the techniques available for screening for breast carcinoma and evaluating patients with breast related symptoms is sufficiently accurate to be used alone. For the best results, a multimodal approach should be used"[38].

In a series of 4,000 confirmed breast cancers, Thomassin and associates observed 130 sub-clinical carcinomas ranging in diameter of 3-5 mm. Both mammography and thermography were used alone and in combination. Of the 130 cancers, 10% were detected by mammography only, 50% by thermography alone, and 40% by both techniques. Thus, there was a thermal alarm in 90% of the patients and the only sign in 50% of the cases[39].

In a study by Gautherie and associates, the effectiveness of thermography in terms of survival benefit was discussed. The authors analyzed the survival rates of 106 patients in whom the diagnosis of breast cancer was established as a result of the follow-up of thermographic abnormalities found on the initial examination when the breasts were apparently healthy (negative physical and mammographic findings). The control group consisted of 372 breast cancer patients. The patients in both groups were subjected to identical treatment and followed for 5 years. A 61% increase in survival was noted in the patients who were followed-up due to initial thermographic abnormalities. The authors summarized the study by stating that "the findings clearly establish that the early identification of women at high risk of breast cancer based on the objective thermal assessment of breast health results in a dramatic survival benefit"[40-41].

In a simple review of over 15 studies from 1967–1998, breast thermography has showed an average sensitivity and specificity of 90%. With continued technological advances in infrared imaging in the past decade, some studies are showing even higher sensitivity and specificity values. However, until further large scale studies are performed, these findings remain in question.

Breast Cancer Detection and Demonstration Projects

The Breast Cancer Detection and Demonstration Project (BCDDP) is the most frequently quoted reason for the decreased use of infrared imaging. The BCDDP was a large-scale study performed from 1973 through 1979 which collected data from many centers around the United States. Three methods of breast cancer detection were studied: physical examination, mammography, and infrared imaging (breast thermography).

Inflated Expectations – Just before the onset of the BCDDP, two important papers appeared in the literature. In 1972, Gerald D. Dodd of the University of Texas Department of Diagnostic Radiology presented an update on infrared imaging in breast cancer diagnosis at the 7th National Cancer Conference sponsored by the National Cancer

Society and the National Cancer Institute[42]. In his presentation, he suggested that infrared imaging would be best employed as a screening agent for mammography. He proposed that in any general survey of the female population age 40 and over, 15 to 20% of these subjects would have positive infrared imaging and would require mammograms. Of these, approximately 5% would be recommended for biopsy. He concluded that infrared imaging would serve to eliminate 80 to 85% of the potential mammograms. Dodd also reiterated that the procedure was not competitive with mammography and, reporting the Texas Medical School's experience with infrared imaging, noted that it was capable of detecting approximately 85% of all breast cancers. Dodd's ideas would later help to fuel the premise and attitudes incorporated into the BCDDP. Three years later, J.D. Wallace presented to another Cancer Conference, sponsored by the American College of Radiology, the American Cancer Society and the Cancer Control Program of the National Cancer Institute, an update on infrared imaging of the breast[43]. The author's analysis suggested that the incidence of breast cancer detection per 1000 patients screened could increase from 2.72 when using mammography to 19 when using infrared imaging. He then underlined that infrared imaging poses no radiation burden on the patient, requires no physical contact and, being an innocuous technique, could concentrate the sought population by a significant factor selecting those patients that required further investigation. He concluded that, "the resulting infrared image contains only a small amount of information as compared to the mammogram, so that the reading of the infrared image is a substantially simpler task".

Faulty Premise – Unfortunately, this rather simplistic and cavalier attitude toward the generation and interpretation of infrared imaging was prevalent when it was hastily added and then prematurely dismissed from the BCDDP which was just getting underway. Exaggerated expectations led to the ill-founded premise that infrared imaging might replace mammography rather than complement it. A detailed review of the Report of the Working Group of the BCDDP, published in 1979, is essential to understand the subsequent evolution of infrared imaging[44]. The work scope of this project was issued by the NCI on the 26th of March 1973 with six objectives, the second being to determine if a negative infrared image was sufficient to preclude the use of clinical examination and mammography in the

detection of breast cancer. The Working Group, reporting on results of the first four years of this project, gave a short history regarding infrared imaging in breast cancer detection. They wrote that as of the sixties, there was intense interest in determining the suitability of infrared imaging for large-scale applications, and mass screening was one possibility. The need for technological improvement was recognized and the authors stated that efforts had been made to refine the technique. One of the important objectives behind these efforts had been to achieve a sufficiently high sensitivity and specificity for infrared imaging under screening conditions to make it useful as a pre-screening device in selecting patients for referral for mammographic examination. It was thought that if successful, this technology would result in a relatively small proportion of women having mammography (a technique that had caused concern at that time because of the carcinogenic effects of radiation). The Working Group indicated that the sensitivity and specificity of infrared imaging readings, with clinical data emanating from inter-institutional studies, were close to the corresponding results for physical examination and mammography. They noted that these three modalities selected different sub-groups of breast cancers, and for this reason further evaluation of infrared imaging as a screening device in a controlled clinical trial was recommended.

Poor Study Design – While this report describes in detail the importance of quality control of mammography, the entire protocol for infrared imaging was summarized in one paragraph and simply indicated that infrared imaging was conducted by a BCDDP trained technician. The detailed extensive results from this report, consisting of over 50 tables, included only one that referred to infrared imaging showing that it had detected only 41% of the breast cancers during the first screening while the residual were either normal or unknown. There is no breakdown as far as these two latter groups were concerned. Since 28% of the first screening and 32% of the second screening were picked up by mammography alone, infrared imaging was dropped from any further evaluation and consideration. The report stated that it was impossible to determine whether abnormal infrared imaging could be predictive of interval cancers (cancers developing between screenings) since they did not collect this data. By the same token, the Working Group was unable to conclude, with their limited experience, whether the findings were related to the then available

technology of infrared imaging or with its application. They did, however, conclude that the decision to dismiss infrared imaging should not be taken as a determination of the future of this technique, rather that the procedure continued to be of interest because it does not entail the risk of radiation exposure. In the Working Group's final recommendation, they state that "infrared imaging does not appear to be suitable as a substitute for mammography for routine screening in the BCDDP." The report admitted that several individual programs of the BCDDP had results that were more favorable than what was reported for the BCDDP as a whole. They encouraged investment in the development and testing of infrared imaging under carefully controlled study conditions and suggested that high priority be given to these studies. They noted that a few suitable sites appeared to be available within the BCDDP participants and proposed that developmental studies should be solicited from sites with sufficient experience.

Untrained Personnel and Protocol Violations – JoAnn Haberman, who was a participant in this project[45], provided further insight into the relatively simplistic regard assigned to infrared imaging during this program. The author reiterated that expertise in mammography was an absolute requirement for the awarding of a contract to establish a Screening Center. However, the situation was just the opposite with regard to infrared imaging – no experience was required at all. When the 27 demonstration project centers opened their doors, only 5 had any pre-existing expertise in infrared imaging. Of the remaining screening centers, there was no experience at all in this technology. Finally, more than 18 months after the project had begun, the NCI established centers where radiologists and their technicians could obtain sufficient training in infrared imaging. Unfortunately, only 11 of the demonstration project directors considered this training of sufficient importance to send their technologists to learn proper infrared technique. The imaging sites also disregarded environmental controls. Many of the project sites were mobile imaging vans which had poor heating and cooling capabilities and often kept their doors open in the front and rear to permit an easy flow of patients. This, combined with a lack of pre-imaging patient acclimation, lead to unreadable images.

In summary, with regard to thermography, the BCDDP was plagued with problems and seriously flawed in four critical areas: 1) Completely untrained technicians were used to perform the scans, 2) The study used radiologists who had no experience or knowledge in reading infrared images, 3) Proper laboratory environmental controls were completely ignored. In fact, many of the research sites were mobile trailers with extreme variations in internal temperatures, 4) No standardized reading protocol had yet been established for infrared imaging. The BCDDP was also initiated with an incorrect premise that thermography might replace mammography. From a purely scientific point, an anatomical imaging procedure (mammography) cannot be replaced by a physiological one. Last of all, and of considerable concern, was the reading of the images. It wasn't until the early 1980's that established and standardized reading protocols were introduced. Considering these facts, the BCDDP could not have properly evaluated infrared imaging. With the advent of known laboratory environmental controls, established reading protocols, and state-of-the-art infrared technology, a poorly performed 20-year-old study cannot be used to determine the appropriateness of thermography.

Thermography as a Risk Indicator

As early as 1976, at the Third International Symposium on Detection and Prevention of Cancer in New York, thermography was established by consensus as the highest risk marker for the possibility of the presence of an undetected breast cancer. It had also been shown to predict such a subsequent occurrence[46-48]. The Wisconsin Breast Cancer Detection Foundation presented a summary of its findings in this area, which has remained undisputed[49]. This, combined with other reports, has confirmed that thermography is the highest risk indicator for the future development of breast cancer and is 10 times as significant as a first order family history of the disease[50].

In a study of 10,000 women screened, Gautherie found that, when applied to asymptomatic women, thermography was very useful in assessing the risk of cancer by dividing patients into low- and high-risk categories. This was based on an objective evaluation of each patient's

thermograms using an improved reading protocol that incorporated 20 thermopathological factors[51].

From a patient base of 58,000 women screened with thermography, Gros and associates followed 1,527 patients with initially healthy breasts and abnormal thermograms for 12 years. Of this group, 40% developed malignancies within 5 years. The study concluded that "an abnormal thermogram is the single most important marker of high risk for the future development of breast cancer"[35].

Spitalier and associates followed 1,416 patients with isolated abnormal breast thermograms. It was found that a persistently abnormal thermogram, as an isolated phenomenon, is associated with an actuarial breast cancer risk of 26% at 5 years. Within this study, 165 patients with non-palpable cancers were observed. In 53% of these patients, thermography was the only test which was positive at the time of initial evaluation. It was concluded that: 1) A persistently abnormal thermogram, even in the absence of any other sign of malignancy, is associated with a high risk of developing cancer, 2) This isolated abnormal also carries with it a high risk of developing interval cancer, and as such the patient should be examined more frequently than the customary 12 months, 3) Most patients diagnosed as having minimal breast cancer have abnormal thermograms as the first warning sign[52-53].

Current Status of Detection

Current first-line breast cancer detection strategy still depends essentially on clinical examination and mammography. The limitations of the former, with its reported sensitivity rate often below 65%[54] is well-recognized, and even the proposed value of self-breast examination is now being contested[55]. While mammography is accepted as the most reliable and cost-effective imaging modality, its contribution continues to be challenged with persistent false-negative rates ranging up to 30% [56-57]; with decreasing sensitivity in patients on estrogen replacement therapy[58]. In addition, there is recent data suggesting that denser and less informative mammography images are precisely those associated with an

increased cancer risk[59]. Echoing some of the shortcomings of the BCDDP concerning their study design and infrared imaging, Moskowitz indicated that mammography is also not a procedure to be performed by the untutored[60].

With the current emphasis on earlier detection, there is now renewed interest in the parallel development of complimentary imaging techniques that can also exploit the precocious metabolic, immunological and vascular changes associated with early tumor growth. While promising, techniques such as scintimammography[61], doppler ultrasound[62], and MRI[63], are associated with a number of disadvantages that include exam duration, limited accessibility, need of intravenous access, patient discomfort, restricted imaging area, difficult interpretation and limited availability of the technology. Like ultrasound, they are more suited to use as second-line options to pursue the already abnormal clinical or mammographic evaluation. While practical, this step-wise approach currently results in the non-recognition, and thus delayed utilization of second-line technology in approximately 10% of established breast cancers[60]. This is consistent with study published by Keyserlingk et al[64].

Because of thermography's unique ability to image the thermovascular aspects of the breast, extremely early warning signals (from 8-10 years before any other detection method) have been observed in long-term studies. Consequently, thermography is the earliest known indicator for the future development of breast cancer. It is for this reason that an abnormal infrared image is the single most important marker of high risk for developing breast cancer. Thus, thermography has a significant place as one of the major front-line methods of breast cancer detection.

Conclusion

The large patient populations and long survey periods in many of the above clinical studies yields a high significance to the various statistical data obtained. This is especially true for the contribution of thermography to early cancer diagnosis, as an invaluable marker of high-risk populations, and therapeutic decision making (a contribution

that has been established and justified by the unequivocal relationship between heat production and tumor doubling time).

Currently available high-resolution digital infrared imaging (Thermography) technology benefits greatly from enhanced image production, standardized image interpretation protocols, computerized comparison and storage, and sophisticated image enhancement and analysis. Over 30 years of research and 800 peer-reviewed studies encompassing well over 300,000 women participants has demonstrated thermography's abilities in the early detection of breast cancer. Ongoing research into the thermal characteristics of breast pathologies will continue to investigate the relationships between neoangiogenesis, chemical mediators, and the neoplastic process.

It is unfortunate, but many physicians still hesitate to consider thermography as a useful tool in clinical practice in spite of the considerable research database, continued improvements in both thermographic technology and image analysis, and continued efforts on the part of the thermographic societies. This attitude may be due to the fact that the physical and biological bases of thermography are not familiar to most physicians. The other methods of cancer investigations refer directly to topics of medical teaching. For instance, radiography and ultrasonography refer to anatomy. Thermography, however, is based on thermodynamics and thermokinetics, which are unfamiliar to most physicians, though man is experiencing heat production and exchange in every situation he undergoes or creates.

Considering the contribution that thermography has demonstrated thus far in the field of early cancer detection, all possibilities should be considered for promoting further technical, biological, and clinical research in this procedure.

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Beyond Mammography

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OVERVIEW

The most devastating loss of life from breast cancer occurs between the ages of 30 to 50. Fortunately, women today have more options available to them to help in the detection of breast cancer than in past decades. Unfortunately, education and awareness of these options and their effectiveness in detecting breast cancer at different stages in life are woefully deficient.

The first part of this in-depth article explores the latest findings on the effectiveness and shortcomings of various detection methods used by the mainstream medical community, including mammography, clinical breast exams, and to a lesser extent, magnetic resonance imaging (MRIs) and PET scans.

The second part of this article goes beyond mammography, exploring a highly advanced but much maligned detection tool for breast cancer — breast thermography. Breast thermography, which involves using a heat-sensing scanner to detect variations in the temperature of breast tissue, has been around since the 1960s. However, early infrared scanners were not very sensitive and were insufficiently tested before being put into clinical practice, resulting in misdiagnosed cases.

Modern-day breast thermography boasts vastly improved technology and more extensive scientific clinical research. In fact, the article references data from major peer review journals and research on more than 300,000 women who have been tested using the technology. Combined with the successes in detecting breast cancer with greater accuracy than other methods, the technology is slowly gaining ground among more progressive practitioners.

“Beyond Mammography” concludes that breast thermography needs to be embraced more widely by the medical community and awareness increased among women. Not only has it demonstrated a higher degree of success in identifying women with breast cancer under the age of 55 in comparison to other technologies, but it is also an effective adjunct to clinical breast exams and mammography for women over 55. Finally, it provides a non-invasive and safe detection method, and if introduced at age 25, provides a benchmark that future scans can be compared with for even greater detection accuracy.

TABLE OF CONTENTS

PART I

PART II

Introduction

The most devastating loss of life from breast cancer impacts women between the ages of 30 and 50. For women between the ages of 40 and 44, breast cancer is the leading cause of death, according to the American Cancer Society. Yet the November 10, 2003 issue of the AMA journal, *American Medical News,* reports little evidence documenting that mammography saves lives from breast cancer for premenopausal women, which are many of the women who fall into these age ranges. (1)

Good evidence supports mammography as a valuable breast cancer screening tool for women in their late 50s and 60s, but reveals room for substantial improvement. For women over the age of 70, accumulated data documents limited value in doing mammograms since they do not significantly extend life. (2, 9, 10)

Obviously, as a detection tool, mammography has a valued place in clinical practice; however, other technologies are proving to be more effective in breast cancer detection and should become part of mainstream clinical practice in order to save more lives.

A Closer Look:

The Prevalence, Fear and Risk Factors of Breast Cancer

According to the American Cancer Society (ACS), breast cancer is the leading cause of death in women between the ages of 40 and 44. Although breast cancer has only 10 percent the morbidity and mortality of coronary heart disease, it is generally more feared. (3)

ACS statistics further document that every year in the United States there are approximately 200,000 new cases of breast cancer and more than 40,000 deaths. Not included in this number are more than 47,000 new cases of carcinoma in situ breast cancer, which is better known as DCIS (ductal carcinoma in situ) or LCIS (lobular carcinoma in situ) and is a very early form of breast cancer.

A Closer Look, continued…

DCIS and LCIS are very mild cancerous lesions that only become malignant in about 2 percent of cases. For this reason many physicians do not consider DCIS and LCIS true cancers.

The risk of breast cancer at age 25 is less than one in 19,000 whereas by age 35 it is one in 217. (4) Yet, the statistic people are most familiar with is that one in eight women will eventually develop breast cancer. It is important to appreciate that this number is a cumulative risk that only applies to women who have reached the age of 90.

The hereditary breast cancer genes, referred to as BRCA 1 and 2 genes, are known to be associated with both breast and ovarian cancers, but only account for 5 to 10 percent of all breast cancer. Newer, less well-known factors are estimated to account for another 10 percent of all breast cancers. In at least 70 percent of cases, however, the cause of breast cancer is yet unknown. (5)

Generally Accepted Risk Factors

The risk for breast cancer is increased if you:

- ✓ Had your first period before age 12
- ✓ Went through menopause after age 50
- ✓ Had your first child after age 30 or never were pregnant
- ✓ Were on hormone replacement therapy or birth control pills
- ✓ Consume one or more alcoholic drinks per day
- ✓ Have a family history of breast cancer
- ✓ Are found to have inherited the breast cancer genes
- ✓ Are postmenopausal and gained weight (not so for premenopausal women)
- ✓ Have elevated levels of insulin as seen with syndrome X or type 2 diabetes, which are conditions associated with central obesity and increased levels of insulin-like growth factor-1 (6)
- ✓ Are sedentary

Popular myths regarding what causes breast cancer include antiperspirants, wearing a wire bra, and having had an abortion.

Mainstream Breast Cancer Screening Technologies

The gold standard study that assesses breast cancer detection technologies stems from the "Breast Cancer Detection Demonstration Project: Five year summary report." (7) This study reviewed 283,000 women between the ages of 35 and 74 who had undergone mammography and clinical breast examinations. Over a five-year period 4,400 women were found to have developed breast cancer. So, the purpose of the study was to see how well clinical breast exams and mammography worked in identifying women with breast cancer.

The BCDDP study documented that overall, clinical breast exams discovered only 60 percent of women who actually had breast cancer. When these women had tumors that were less than 1 centimeter, only 47 percent were identified. However, detection rates were 66 percent for tumors between one and two centimeters in size, and were 79 percent of tumors bigger than 2 centimeters. Clearly, clinical breast exams are important, but overall they miss nearly 40 percent of cancers.

Results from the widely accepted BCDDP study documented that the overall ability of mammograms to detect cancer was only 70 percent.

Mammography and Women Under 50

Mammography has been the state-of-the-art screening test for several decades. However, considerable controversy remains regarding its value, particularly in women under the age of 50. (1, 8-10) Results from the widely accepted BCDDP study documented that the overall ability of mammograms to detect cancer was only 70 percent. This means that 30 percent of mammograms found to be negative for potentially cancerous lesions are actually positive.

False Positive Rate High

The false positive rate of mammograms—those patients without cancer but with a positive finding on testing—turned out to be another problem. Only one biopsy in six was found to be positive for cancer when done on

Only one biopsy in six was found to be positive for cancer when done on the basis of a positive mammogram or breast exam.

the basis of a positive mammogram or breast examination. **The combined false positive rate was determined to be as high as 89 percent.** Identifying and performing biopsies on these clinically insignificant lesions represents over diagnosis and over treatment. Further, the physical and psychological stress associated with mammogram findings is not a small concern nor are the additional costs.

Too Many Mammograms Performed?

Recent data from the University of Washington and Harvard University reveals that over a period of a single decade, one out of every two women will have a false positive result as the result of mammography, and of those, nearly 20 percent will undergo an unnecessary breast biopsy. (9) Contrary to what many health-related agencies advise, recent findings seem to demonstrate that too many rather than too few mammograms are performed every year in the United States. Further, estimates show that for every $100 spent on the cost of mammograms, $33 goes to the unproductive and unnecessary expense of false positive results.

Mammograms for Women Over the Age of 70

A recent article from Duke University Medical Center reports that women over 70 are over-screened for both breast and cervical cancers. (10) The authors estimated the cost in the year 2000 for women over the age of 70 for the unnecessary mammograms they received was approximately $460 million. The article went on to point out that clinical guidelines for women over the age of 70 are ambiguous and based on almost no clinical research.

Mammography and Younger Women

For younger women, mammography is more likely to miss breast cancers that are rapidly growing, especially in women with dense breast tissue who are at a significantly increased risk for developing breast cancer. (15)

At least 10 percent of breast cancers cannot be identified by mammography, even when they are palpable. (8)

Other Mainstream Technologies

Advances in technology now allow digitally enhanced mammograms to be taken alone or after injecting intravenous contrast, but they have not been proven to be significantly more sensitive than regular mammograms, and they have the added risk of the invasiveness of an injection that can cause other problems. Further, they come with a substantial increase in cost and still expose the patient to radiation. (11)

Similarly, MRIs with and without contrast are a step forward, but they involve similar risks and are even more costly. While their sensitivity is near 90 percent, their accuracy (specificity) in identifying cancer as opposed to some other benign finding is no better than mammograms. (12)

PET scans are useful in identifying metastatic lesions but have an overall sensitivity similar to mammography. Further, for breast tumors less than one centimeter, only 25 percent of breast cancers are identifiable using this technology. (13) The most useful application of PET scans are in discriminating between viable tumor, fibrotic scar, and necrosis. Radiologists do not recommend PET scanning as a screening tool in asymptomatic women for breast cancer. (14)

For women under the age of 40, no accurate or cost effective technology exists in mainstream medical practice that identifies lesions likely to be breast cancer with reasonable sensitivity and specificity. Given that breast cancer is the leading cause of death between the ages of 40 and 44, it is obvious that a pressing need exists for another test to identify these cancers when they are just starting to develop and still small enough to be cured.

Most breast cancers do not become palpable until they are greater than one centimeter in size—by that time 25 percent have already metastasized. Because most lethal breast cancers take approximately 15 years from their beginning to the time of death, women need reliable testing that starts when the cancer is initially forming—in their mid-twenties.

Even though there is reliable technology existing today that is available, there is limited awareness and insufficient education that has resulted in its being greatly underused in clinical practice.

The History of Breast Thermography

Breast thermography has been available in clinical practice since the 1960s. Initially, physicians were very excited when they learned that breast cancers emit more infrared heat than normal healthy tissues, and that they could be detected using infrared scanners. However, this technology was brought into practice prematurely—before clinical trials were completed, and before sufficient information about other health conditions that also emitted large amounts of infrared light were understood.

Unfortunately, this resulted in many women having breast surgeries that did not have breast cancer. Eventually, the high rate of unneeded surgeries led to the rejection of infrared breast imaging in the United States, with the entire technology being sidelined by mainstream medical practice for several decades.

Since the 1970s, however, clinical research has continued, especially in Canada and France where this technology is considered more mainstream. More than 800 research papers have been published on the subject of breast thermography, and a research databank on more than 300,000 women who have been tested with infrared breast imaging now exists.

In addition, major advances in infrared imaging technology have been achieved that improve the sensitivity to 0.05 degrees centigrade, which makes identifying breast cancer much easier and more reliable. The combination of improved technology and scientific clinical research is sparking the return of breast thermography into clinical practice today.

How Breast Thermograms Work

Breast thermography measures differences in infrared heat emission from normal breast tissue, benign breast abnormalities—such as fibrocystic disease, cysts, infections and benign tumors—and from breast cancers. It does this with a high degree of sensitivity and accuracy. Breast thermography is a non-invasive measurement of the *physiology* of breast tissue. This technology is not meant to replace mammography or other diagnostic tests presently used in clinical practice that measure *anatomical abnormalities* in breast tissue. While breast cancer can only be diagnosed by tissue biopsy, breast thermography safely eliminates the need for most unnecessary biopsies as well as their associated high cost and emotional suffering, and it does so years sooner than any other test in modern medicine.

Modern infrared scanners have a thermal sensitivity of 0.05 degrees Centigrade. Because tumor tissue does not have an intact sympathetic nervous system, it cannot regulate heat loss. When the breast is cooled with small fans in a room kept at 68 degrees Fahrenheit, blood vessels of normal tissue respond by constricting to conserve heat while tumor tissue remains hot. Thus, tumors emit more heat than their surrounding tissues and are usually easily detected by heat-sensing infrared scanners.

Over time, cancerous tissues stay hot or become even hotter—they do not cool down. In sharp contrast, however, other possible conditions such as fibrocystic breasts, infections, and other benign disorders cool down as they resolve.

Women should have breast thermography performed beginning at age 25.

Breast thermograms have highly specific thermal patterns in each individual woman. They provide a unique "thermal signature" that remains constant over years unless there is a change in an underlying condition. Thus, over time, it is possible to differentiate between cancers and benign conditions. Based on this ability to more accurately detect cancers over time, it becomes important to have a benchmark early on in a woman's life. For this reason, women should have breast thermography performed beginning at age 25.

Thermograms are graded with a system much like pap smears with grades 1-5. Th1 and Th2 are normal, Th3 is moderately abnormal, and Th4 and Th5 are severely abnormal and require careful follow-up because many of them are caused by cancer. Of significance, one recent study documented that women with Th1 and Th2 scores can be reassured with a 99 percent level of confidence that they do not have breast cancer. (16)

Clinical Research Supporting Breast Thermography

At least five important studies published between 1980 and 2003 document that breast thermal imaging is a major advancement in identifying breast cancers not only with greater sensitivity and specificity, but also *years* earlier than with any other scientifically tested medical technology.

These scientific studies include:

- ***Cancer*, 1980**, Volume 56, 45-51. (17) Fifty eight thousand patients with breast complaints were examined between 1965 and 1977. Twelve hundred and forty five patients with abnormal Th3 mammotherms had normal breasts by mammography, ultrasound, physical exam, and biopsy. Thirty-eight percent of women with

normal breasts and 44 percent of those with mastopathy developed biopsy proven breast cancer within five years. Ninety percent of patients with Th4 or 5 had diagnosis of cancer made on their first visit.

- ***Biomedical Thermology,* 1982**, 279-301, Alan Liss, Inc, NY. Michel Gautherie, MD, followed 10,834 women over 2 to 10 years by clinical examination, mammography and thermography. (15) The study followed 387 people with normal breast examinations and mammograms but Th3 thermographic scores for an average of less than three years. In those without symptoms, 33 percent developed cancer. In those with cystic mastitis, cancer developed in 41 percent. These were predominately women between 30 to 45 years of age where breast cancer is the leading cause of death.

- ***Thermology,* 1986**, Volume 1, 170-73. (18) The effectiveness of mammography, clinical palpation, and thermography were compared in the detection of breast cancer. Thermography had the best reliability, but the best results were found when all three were used together.

- ***The Breast Journal***, Volume 4, 1998, 245-51. (19) Keyserlingk et al documented 85 percent sensitivity in diagnosing breast cancer using clinical examination and mammography together. This increased to 98 percent when breast thermography was added.

- ***American Journal of Radiology***, January 2003, 263-69. (16) The journal reported that thermography has 99 percent sensitivity in identifying breast cancer with single examinations and limited views. Thus, a negative thermogram (Th1 or Th2) in this setting is powerful evidence that cancer is *not* present.

Important Highlights from Breast Thermography Studies

- Advances in infrared technology combined with data on 300,000 women with mammotherms document that breast thermography is highly sensitive and accurate. Today, this means that more than 95 percent of breast cancers can be identified, and that this is done with 90 percent accuracy. In women under the age of 50, where there is the most devastating loss of life from breast cancer, mammography, MRIs and PET scans cannot come close to matching the combined sensitivity and specificity (accuracy) of breast thermography.
- Breast thermography involves no radiation exposure or breast compression, is easy to do, is done in a private setting, and is affordable.
- The FDA approved breast thermography for breast cancer risk assessment in 1982.
- It is important to begin breast cancer screening long before age 40. It should begin at age 25 in order to identify young women who are already developing breast cancer since it takes approximately 15 years for a breast cancer to form and lead to death. Further, young women with dense breast tissue are the most difficult to evaluate using breast palpation, mammography, and ultrasound examinations, yet their significantly higher risk of developing breast cancer can be accurately detected with breast thermography.
- Mainstream procedures *are not* approved for breast cancer screening in women under age 40—it is widely known and accepted that they miss too many cancers and lead to too many false positive findings that result in far too many needless breast biopsies.

The FDA approved breast thermography for breast cancer risk assessment in 1982.

Conclusion

There is an abundance of scientific evidence supporting that breast thermography is the most sensitive and accurate way to identify women with breast cancer, especially in women under the age of 55, where it causes the most devastating loss of life. For women over 55,

breast thermography is an important adjunct to clinical breast examination and mammography, as this combination has been documented to increase identification of breast cancers to 98 percent.

Because of its low cost and high degree of sensitivity and accuracy, all women who want to be screened for breast cancer should begin having breast thermograms beginning at age 25. Clearly, there are situations that warrant the use of other modalities such as mammography, ultrasound, MRI, PET scanning, nipple aspirations, or biopsy, and these valuable tools should continue to be used in clinical practice along with breast thermography.

Many new technologies are on the horizon that may become mainstream in the near future. With the advent of highly sophisticated genetic technology, new proteins are constantly being discovered that offer promise as markers of early breast cancer. (20) Recently published reports also suggest that MRI technology may be blended with spectrophotometric measurements that could diagnose breast cancer without even doing a biopsy. (21)

The practice of medicine, just like everything in life, is in constant evolution—there is no guarantee that what is in the mainstream today will be here tomorrow. Yet, the advancement of all fields of endeavor often moves slowly and cautiously, sometimes at the expense of human life. We must remain open and alert as new, exciting, and safe strategies emerge, especially in situations where there is such a pressing need for new approaches.

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Breast Thermal Imaging, The Paradigm Shift

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Summary

Infrared thermal imaging of the breast, a non-invasive adjunctive diagnostic methodology has become all but non-existent in the United States. This is in large part due to extensive debate concerning thermography in the trial courts, related to spinal injury cases and also due to the model or basis used for breast thermal imaging. This paper attempts to identify possible factors which will bring thermal breast imaging back into serious mainstream consideration as a valid adjunct to overall breast pathology diagnosis.

Key Words
Breast thermal imaging, protocol, technology, quantification, paradigm shift, prevention, risk assessment.

Introduction

For purposes of this paper, I define the word "paradigm" to mean "model". The paradigm, or model for breast thermal imaging must change.

The initial use of thermography was for breast cancer screening and diagnosis. This was error. Thermography as a test of physiology is not capable of, and will never be capable of detecting breast cancer.

Anatomical testing such as mammography can also not detect breast cancer. This is a paradox. Both procedures, thermography and mammography, demonstrate abnormalities indicating the possibility of the presence of cancer, as well as a host of other breast conditions. These clinical findings require differential diagnosis.

ONLY laboratory confirmation of abnormal cell morphology can make the correct diagnosis of cancer.

Thermography's role in breast cancer and other breast disorders is one of early detection and monitoring of aberrant (abnormal) physiology and the establishment of risk factors for the development or existence of cancer. This is breast thermography's only role at the current time in history.

After large scale clinical trial under appropriate protocols and further development of the procedure, equipment, protocol and certification it is hoped that certain thermal "markers" may become more generally accepted and pathognomonic of various breast disorders, including types and location of cancer.

Appropriate Training

Since thermography is a non-invasive (no radiation) procedure there is no specific legislation or regulatory act under which thermography can be scrutinized in the United States. Early thermographic pioneers created entrepreneurial training and certification programs for both physicians and technicians.

These programs cultivated a host of new course instructors and a variety of organizations and certifications became available.

Some courses offered thermographic certification to people with no medical background or formal medical education. For example, injured workers in California could under vocational rehabilitation laws to become certified as thermographic technicians and open their own labs.

These individuals needed an interpreting physician, so they found doctors who were willing to review and "read" the examinations performed, although few of those physicians themselves had training or certification in the field of thermography.

To avoid a deluge of poor quality and inadequate thermographic study as well as faulty interpretation of the studies, university based training programs must be established. With the electronic super highway in existence, a global network can be aimed at creating such standards and uniformity of study, worldwide.

Appropriate Equipment

There are essentially two types of thermographic equipment utilized in medical practice.

One is LCT (liquid crystal thermography). These are essentially latex plates embedded with liquid crystals which react to surface heat of the body by giving off visible color. The mix of crystals used in the detector determines the detectors ability to differentiate heat ranges.

The other is Electronic Thermography also known as telethermography. The latter are camera\computer based systems which are highly accurate and function in real time with no contact to the subjects skin.

Many manufacturers modified thermographic equipment utilized for night vision or military applications. Some of these detectors were not

of adequate quality to read heat patterns emitted from human skin. For example, a system with a sensitivity above 0.5 degrees C, did not provide consistent quantification (numeric measurement).

Systems which sensitivity of 1.0 degrees centigrade provide for errors ranging between 0.1 and 1.9 degrees. With pathology found at the .4 to 1.0 C range, it is obvious that such equipment is not appropriate for utilization, but none the less, these inappropriate systems were heavily utilized in the 70's and 80's for this purpose.

Early electronic thermographic systems utilized detectors made from indium antimonide which had a spectral range of 2-5 millimicrons. As heat patterns detectable from breast tissue fall into the 8-13 millimicron range the 2-5 millimicron detectors were not adequate and the more expensive mercury cadmium telluride detectors should have been used(1). These detectors were much more costly to the average clinician or research facility and so they were not used. (Focal plane array cameras in the modern era are aiding in the correction of this divergence.

Unaware physicians, who desired to use thermography in their practices purchased the less expensive systems and thus the basis for many of the false positive findings reported in the literature. Had they used the appropriate systems with the correct optical wave band, these false positives would have been eliminated or significantly reduced.

Many of the manufacturers of computer based systems designed software that caused the images to look fantastic, but these images were displaying information that was not necessarily complete and thus, the unwary physician found inconsistency in his studies as well as a high false positive rate which would not have occurred had the appropriate systems been utilized in breast cancer screening.

As with any medical device the appropriate technology, performed according to a consistent and established protocol by board certified individuals will result in more accurate studies and satisfactory scientific yields.

Regulation

Though medicine as a whole cries out for less governmental control, the lack of regulation within the field of thermography is a significant problem. For example, in the United States, medical, chiropractic and podiatric licensing boards have adopted position statements regarding clinical utility of thermography and some have "accepted" various protocols for implementation, but that is all.

However, anyone can own and operate thermographic equipment. Only a licensed health care providers with portal of entry status, (MD, DC, DPM, etc.) can interpret or render a diagnostic opinion of the examination.

In addition, this also relates to the ability to bill an insurance carrier and receive payment for services. Thus entrepreneurs with no formal medical training often submitted studies to insurance companies which were of very poor quality. This resulted in not only denial of payment, but a doubt was rightfully cast on the legitimacy and quality of thermographic studies as they were being performed by inadequate personnel.

With this lack of regulation, a great many poorly performed studies found their way into the medical literature and the court system. (see personal injury model below).

Proper Protocol

A major factor related to the inconsistency of published works in the thermographic imaging field is the various protocols under which the procedures is performed. Although not difficult, the protocol of the examination, a with x-ray or any other diagnostic device, is essential to accurate and reliable outcome.

Some examples of thermographic protocols would be :

Factors Affecting Examination

the ambient room temperature at which the examination is performed

the length of time allowed for patient equilibration to the ambient temperature

the type of equipment utilized

the type of floor covering

the presence or absence of windows which can alter room temperature

the type of heating or air conditioning for thermal regulation of the room.

the usage of lotions, deodorants and cosmetics on the skin

the ingestion of vasodilator and vasoconstrictor substances (ie:caffeine)

the medications taken by the patient

While the scope of this paper can not devote a great deal of space to protocol, it is important to note that most non-thermographic clinicians that the author has had opportunity to oppose in the legal system, have had no idea that such protocol exists or is important.

When I taught the diplomate course for thermography in California, physicians were asked to submit thermographic studies as part of their completion requirements. The vast majority of unacceptable studies (which incidentally, were used for diagnosis of patients in these clinicians practices) were found to contain errors created simply by poor protocol which would have been very easy and inexpensive to correct. For example, performing the procedure on tile flooring which by its cold temperature, caused abnormal sympathetic heating responses in the subject under evaluation. A carpeted floor is required.

Protocol is everything. Without an internationally accepted protocol, no comparison of accuracy, double blinded study, or evaluation of the technology and its effectiveness can be made. With the wide ranging opinion of thermographers and pseudo-thermographers concerning appropriate protocol, it is no wonder that many studies performed worldwide do not correlate, while other studies performed to a stringent protocol are so very consistent.

Anecdotal vs Scientific Evidence

It is very important to differentiate scientific fact from anecdotal evidence. For purposes of this paper I define anecdotal to mean a myth or a fable not supported by fact, but accepted because of a common belief or usage.

Many physicians and investigative journalists use anecdotal data to support their point of view. An example of this is the often published article in a medical journal that uses 20-30 references by other authors who all have just rewritten an original thesis or premise in order to get published without contributing any new data.

Now the materia medica has a number of consistent articles or studies which appear to be powerful when used as an argument for or against a given procedure or point of view. In reality, anecdotal evidence is disastrous when not recognized.

Thermal imaging is pure science. While prone to misinterpretation by "untrained" clinicians, its diagnostic accuracy and yield are unparalleled. With respect to breast thermal imaging, a great number of studies by researchers in different parts of the world, utilizing different technology have still demonstrated the usefulness and clinical utility of the procedure. (when utilized appropriately).

In the United States, William Hobbins, MD(2) demonstrated in a sample of 37,050 patients, a yield of 56 cancers per 1,000 abnormal thermograms as compared to the 5.6 per 1,000 in the BCDDP studies utilizing mammography. In France, Gauthrie et al(3) utilizing thermography determined 73% correct diagnosis in 486 breast cancer patients.

In worldwide retrospective studies, thermograms were positive in a minimum of 71% to a maximum of 93% in patients with breast cancer as reported by Nyirjesy(4).

There are literally thousands of pages of discussion in print regarding the benefits of thermography as it relates to breast cancer. The interesting observation to this author is the wide variety of protocols and equipment utilized and yet a tremendously high statistical correlation of accuracy prevails. Think of what might happen if the technology and training were more standardized.

Comparison of Thermal Imaging to Other Diagnostic Procedures

Comparing anatomic (mammography) to physiologic (thermography) is a great irony and source of confusion in medicine. Many radiologists I have spoken to fear that their investment in mammographic equipment will be wasted because they view thermography as competitive with mammography or that stereo-tactic biopsy is better than thermography.

This is a classic example of the lack of training and anecdotal arguments I have previously described. Mammography is anatomical. So are other beneficial procedures such as ultrasound, diaphenoscopy and CT scanning.

Thermography is a test of physiology (function), and not of anatomy. One can not compare apples to oranges. The procedures are most definitely correlative and complimentary and not competitive. The view that thermography is competitive is error, and one of the most significant detractors from its effective utilization today.

When used adjunctively with other laboratory and outcome assessment tools, the best possible evaluation of breast health is made.

Radiologists need to understand the tremendous potential of thermography to detect the physiologic manifestation of disease that

so often predate the anatomical analysis of the condition. In my first paper on this subject(5) I point out the danger in "over reading" thermograms and state that we should utilize the data obtained from thermal imaging from a "screening" standpoint only, not from a diagnostic one. (1987)

This "complimentary" nature of thermal imaging is of unparalleled significance to this issue.

Quantification

Technology, especially in light of the desk top PC and the Pentium processor, has at last reached a stage of development and cost effectiveness that makes the availability of dynamic quantitative and reliable thermography a definitive reality.

In the past, the quantitative (or numbers) measurement of actual spot temperatures was difficult. Many thermographer s' used liquid crystal imaging (much like the temperature strips we use on our children's foreheads). While bright, colorful and reliable images could be obtained, no precise measurement could be made. This is called qualitative imaging (quality of image).

While the quality of a properly performed thermogram can provide immediate thermal imaging information to the unaided eye, (excluding the estimated 15% of the population who are color blind), errors can be made in the interpretation by assuming that a color change is significant when in fact it may not be.

(authors note: due to the email capabilities of this type of correspondence, the original text and illustration presented below have been modified to meet the standards available for download)

Qualitative thermography uses color or gray scale images for comparison of left to right, as in the right nipple as compared to the left, or the full breast, right compared to left. With qualitative imaging, a color scale is presented as a crude marker for comparison to the patients actual temperatures. It was assumed that a color change indicated a pathology as illustrated below. This was based on a ten

color scale, 1 degree centigrade between colors. So as represented in the diagram, a shift from yellow to orange was assumed to be a 1 degree centigrade increase in heat, left compared to right.

Sample Color Scale Representation .1 degree increments

Pink	Red	Orange	Yellow	Olive	Lime	Dk Blue	Blue	Lavender	Black
31.0*	30.0*	29.0*	28*	27*	26*	25*	24*	23*	22*

```
X          X          X-X =  1.0 degree centigrade difference
Y                  Y  Y-Y =  1.9 degree centigrade difference
        Z  Z          Z-Z =  0.1 degree centigrade difference
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* degrees centigrade

So, if the right breast were orange on the qualitative image, and the left breast were red, a pathology was assumed to exist as a 1 degree centigrade increase in heat had occurred thus shifting the color scale.

WRONG! Please notice that the beginning of each color block has a temperature selected. They increase in 1 degree centigrade increments. Also notice that there is a "0" in the tenths position. This means the system is measuring unit values of 1/10th degree centigrade. Because the color "scale" is assigning only one color to a block of temperature, all temperatures falling within that "block" are assigned by the computer, the same color.

Therefore, a difference as little as .1 degree centigrade or as much as 1.9 degrees centigrade could shift the color assignment. Obviously a .1 degree centigrade shift is minimal and non diagnostic. A 1.9 degree centigrade shift is quite severe and indicative of pathology. Both however, would assign with these outdated systems, the same relative color shift and thus the reason for misdiagnosis and the reporting of the so-called false positives.

In my thermography lecture series, I devote one hour with graphic slides explaining this phenomenon, which is so easily corrected once the "concept" is grasped

I have now designed software that differentially measures the actual spot temperatures in the contralateral tissues so that this error can no longer occur, yet many clinicians still utilize, and rely upon the outdated and dangerous qualitative imaging techniques.

Conclusion

I would like to restate, that thermography of the human breast is not a stand alone tool as some have suggested in the screening and diagnosis of breast cancer. It is adjunctive. We can not ignore thermographys' tremendous role as an early risk indicator or as a monitor for treatment.

When a thermogram is positive, a closer look at the patient's diet, exposure to environmental toxins and pollution and lifestyle is in order. Clinical blood work in addition to mammography is essential.

When mammography and blood work are negative or equivocal, thermographic monitoring on a quarterly to semi-annual basis should be performed in those patients with suspicious thermograms.

In this way changes in tumor angiogenesis can be evaluated and other procedures can be ordered to aid in the earliest possible diagnosis. The procedure is non-ionizing and safe and there is no reason to simply "wait and see" any longer.

It is here that the paradigm needs to shift. We can no longer accept the "wait and see" attitude just because a mammogram is negative. Perhaps some day with a more universal and a-political approach, thermal imaging markers can be even further classified into more effective and even pathognomonic categories. This will require a team approach, worldwide.

Until that time, one thing is certain. In the presence of cancer or not, an abnormal thermogram is indicative of abnormal physiology, and this can not be ignored any longer.

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Breast Thermography- A Responsible Second Look

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Breast cancer and other breast diseases have become a tremendous issue in women's health today, particularly in advanced industrialized nations. Also note that approximately 1,000 men get breast cancer yearly.

A procedure which has gone largely unnoticed is Breast Thermography, also known as Breast Thermal Imaging. Breast thermography promises the opportunity of earlier detection of breast disease than has been possible with breast self examination, physician palpation, or mammography.

The medical community investigated breast thermography quite extensively during the late 1970's and early 1980's. The FDA approved the procedure as an adjunctive tool in breast cancer screening, and many physicians, concerned about the radiation exposure of mammography, began to promote thermography as a replacement for mammography. This was error.

Basics of Thermal Imaging

Thermography is a non invasive test. This means that it sends nothing into your body. In fact, there is no contact with the body of any kind, no radiation and the procedure is painless.

Utilizing very sophisticated infra-red cameras and desk top computers, thermal imaging technicians simply capture a photograph of the breasts. An infra-red photograph, or heat picture. The data is stored in

a computer and then can either be printed on high resolution color printers, or sent electronically to a physician with a similar computer for analysis.

The physician, such as a radiologist or thermal imaging specialist, then compares the heat patterns in the left breast to the right breast. Any difference in heat, or any specific blood vessel patterns in one breast that do not appear in another indicate a physiologic abnormality. This may be pathological (a disease) or it might indicate an anatomical variant. When a thermogram is positive, the job of differential diagnosis begins.

This is all that thermal imaging, or thermography provides. A physiologic marker that some abnormality is present in the breast. Nothing more and nothing less. This is however, an extremely valuable and important finding, but it has historically been the interpretation of these findings that has been the problem, and is now the subject of the "responsible second look".

Competition Paradox with Mammography

Scientists and health care researchers have been looking for many decades at tools that can identify breast cancer reliably and quickly. It takes years for a tumor to grow, and the earliest possible indication of abnormality is needed to allow for the earliest possible treatment and intervention.

Thermography was viewed as a possible early diagnostic tool for cancer. The reason I stated that this was error, is quite obvious, but almost totally overlooked by the clinicians and researchers of the day.

Thermography is a test of PHYSIOLOGY. It does not look at anatomy or structure, and it only reads the infra-red heat radiating from the surface of the body.

Mammography, on the other hand, is a test of ANATOMY. It looks at structure. When a tumor has grown to a size that is large enough, and dense enough to block an x-ray beam, it produces an image on the x-

ray or mammographic plate, that can be detected by a trained radiologist. A fine needle biopsy is then generally performed to identify the type of tissue in the mass, to determine if atypical or cancerous cells are present.

We now come to an important point. Neither thermography nor mammography can diagnose breast cancer. They are both diagnostic tests which reveal different aspects of the disease process and allow for further exploration.

The problem has been, that a number of studies were done on patients who had an established diagnosis of breast cancer. These studies were done with thermal imaging, wherein the patient having known breast cancer acted as their own controls.

In other words, the patients cancerous breast was compared thermographically to the patients healthy breast. In nearly every case the cancerous breasts were hotter and had specific patterns of heat mimicking the appearance of blood vessels that suggested 1) cancerous tumors were hotter than surrounding tissue and 2) blood vessels in the vicinity of the tumor were engorged with blood and this produced hotterthermal images than the normal vessels in the opposite breast.

This made complete sense, until the research proceeded to look at younger, and younger women.. It was at this time thermography was viewed as a failure. In a local newspaper article in my home town paper covering my clinic, the caption read "Thermal Imaging...Useful tool or dinosaur in breast cancer detection".

Here is the problem. Early stage tumors have not grown large enough or dense (thick) enough to be seen by current mammography. When the thermogram picks up the heat from the tumor, a mammogram is performed and often the mass is not detected.

The result of the thermogram is then considered a "False Positive". The more patients of younger age screened with the so-called false positive, the more suspicion was placed on thermography.

Eventually lobbying efforts at the AMA's House of Delegates and at Medicare, brought about the removal of thermographic coverage by insurance companies, and the demise of thermography in large measure. This is most unfortunate.

Thermography was viewed as a competitive tool to mammography, a role for which it was never intended. This is a known fact in the community of board certified clinical thermographers. Thermography is complimentary to mammography and an adjunctive tool in the war on breast cancer. We must learn to accept the information these tools bring to us, and use the information to the best management of the patient. You and me.

The Correct Role for Thermal Imaging

This is where the correct utilization of thermographic imaging will demonstrate it's ability. In the correct model, thermography of the human breast can make a profound and positive impact on breast cancer and other breast disease. Here's the correct model.

Thermography is a risk marker for breast pathology. This paper is written for the general public and I am not going to burden the reader with a large base of complex studies that have been published demonstrating the clinical utility and reliability of the procedure. Suffice it to say it is overwhelming.

My purpose is to identify the role of thermography. It is actually quite a simple one.

In performing this procedure, which is non-invasive and non-compressive, we can establish a baseline in women as young as 18. Yearly thermographic evaluations as part of a routine annual physical can be performed inexpensively and quickly.

As soon a suspicious (positive) breast thermal examination is performed, the appropriate follow-up diagnostic and clinical testing can be ordered. This would includemammography and other imaging tests,

clinical laboratory procedures, nutritional and lifestyle evaluation and training in breast self examination.

With this protocol, cancer will be detected at its earliest possible occurrence, It has been estimated my a number of my colleagues that thermography is correct 8-10 years before mammography can detect a mass.

This is both exciting and frustrating for the clinician and the patient. It is exciting as it gives us the opportunity to intervene long before cancer can grab hold of the body. Cancer is opportunistic. We must find it, or the suspicious signs of its' presence long before the intervention stage has passed.

On the other hand, it is frightening to uneducated clinicians and patients, and poses quite a dilemma for those rooted in the "wait and see" attitude. It is very difficult to sit in front of a patient and tell them that you have a positive finding with a procedure that suggest the possibility of a terrible disease, and then have no other tools available to confirm or deny the tests correctness.

This is not thermography's failure. Indeed this is where the scientific and research community has failed thermal imaging.

If one can grasp the simple concept that thermography is detecting the fever of a breast pathology, whether it is cancer, fibrocystic disease, an infection or a vascular disease, then one can plan accordingly. One can lay out a careful clinical program to further diagnose and or MONITOR the patient until other standard testing becomes positive, thus allowing for the earliest possible treatment.

Two other positive benefits of breast thermal imaging have also been proposed by the author at scientific symposia. As a non-invasive low cost procedure, thermography can be made available to two distinct subpopulations:

1. Patients who are economically deprived and can not afford the cost of mammography.

2. Patients who are afraid of mammography due to fear of x-ray or breast compression, and thus do not get their recommended mammogram.

The Paradigm Shift

It is my position that the role of thermography is vastly different than it originally was determined to be. We must begin to look at this tool for what it really is. A highly accurate, high yield thermometer, much like the one every physician uses daily to determine the presence of fever.

Numerous studies have been published in the United States, England and France demonstrating that patients in the false positive thermographic group I mentioned earlier, those patients with positive thermograms and negative mammograms who were told the thermography was wrong, were determined by long term follow-up to have developed breast cancer in exactly the location thermography had demonstrated its positive finding 5-10 years earlier.

Thermography's only error is that it is too right ~ too early. It is our job as scientists, physicians and concerned patients, to identify the appropriate protocols once a thermogram is positive. It is in this capacity that the paradigm must shift.

We have a wonderful and exciting opportunity to at last change the incidence of this horrible disease, by screening younger women utilizing high resolution thermal imaging technology and then placing those women with positive findings into the appropriate lifestyle modification and treatment model which may be able to prevent or minimize not only cancer, but all breast disease.

This is our task.

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Cancer risk assessment with a second generation infrared imaging system

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ABSTRACT

Infrared imaging of the breasts for breast cancer risk assessment with a second generation Amber indium antimonide focal plane staring array system was found to produce images superior to a first generation Inframetrics scanning mercury cadmium telluride system. The second generation system had greater thermal sensitivity, more elements in the image and greater dynamic range, which resulted in a greater ability to demonstrate asymmetric heat patterns in the breasts of women being screened for breast cancer. Chi-square analysis for independence of the results from 220 patients with both the scanning and focal plane infrared imaging systems demonstrated that the results from the two systems were strongly associated with each other (p=.0001). However, the improved image from the second generation focal plane infrared imaging system allowed more objective and quantitative visual analysis, compared to the very subjective qualitative results from the first generation infrared imaging system. The improved image also resulted in an increase in the sensitivity for asymmetric heat patterns with the second generation focal plane system and yielded an increase in the percentage of patients with an abnormal asymmetric infrared image of the breasts from 32.7% with the scanning system to 50.5% with the focal plane system. The greater sensitivity and resolution of the digitized images from the second generation infrared imaging system has also allowed computer assisted image analysis of both breasts, breast quadrants and hot spots to produce quantitative measurements (mean, standard deviation, median, minimum and maximum temperatures) of asymmetric infrared abnormalities.

Keywords: thermography, infrared imaging, breast cancer, focal plane array, risk assessment

1. INTRODUCTION

Early studies of infrared imaging of the breast concentrated on its ability to detect and diagnose breast cancer. Mammography and infrared imaging, commonly called thermography in medicine, were compared for detection and diagnostic ability in the United States during the Breast Cancer Detection and Demonstration Projects between 1973 and 1981, but infrared imaging was discontinued after only a few years. Collection of infrared images of the breast was discontinued because of the poor quality of the infrared images being collected. The poor quality of the images was a result of the lack of standardization of instrumentation, the lack of trained technical personnel to maintain high quality infrared imaging, and the lack of trained radiologists to interpret the infrared images. Unfortunately the collection of infrared image was abandoned before enough data could be collected to be analyzed for significance in terms of detection and diagnosis. Further no risk assessment or prognostic significance information for infrared imaging was generated from the Breast Cancer Detection and Demonstration Projects.

Beginning in the 1980s studies supporting the use of infrared imaging in breast cancer risk assessment[1,2,3] began to be published. Gautherie and Gros[1] in a study of 58,000 patients found 784 patients with normal physical, mammographic and ultrasound findings who had abnormal infrared images of the breasts. Of these 784 patients 298 (38%) were diagnosed with breast cancer within 4 years, and this was the first compelling evidence that asymmetric infrared abnormalities of the breasts is a high risk marker for breast cancer. Stark[2] followed with a second study in 1985 which demonstrated that 23% (346 of the 1499 women with abnormal infrared images of the breast, while screening a total of 11,249 women) of the women with abnormal infrared images of the breast were diagnosed with cancer within the next ten years. This study further showed that women with abnormal infrared images of their breasts had a higher incidence of breast cancer (23%) than nulliparitous women (8.1%) or women with a family history of breast cancer (8.6% with either

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one or two first degree relatives). Although women with breast biopsies containing extensive hyperplasia and atypia had a 30% to 50% incidence of breast cancer in this study[2] there were only 34 women who had previous breast biopsies, and this is too small a number of woman at risk to allow major changes in incidence through prevention or intervention.

Although several studies have been reported supporting the application of infrared imaging for risk assessment in breast cancer, there still remained an unacceptably high false positive rate (women with an asymmetric infrared abnormality and a normal mammogram) of about 25% for infrared imaging of the breasts. This high false positive rate was due to the low quality of the first generation infrared imaging technology and the very subjective qualitative visual analysis of the results. We believe that the application of second generation infrared imaging systems, with greater sensitivity, improved resolution and the ability to do sophisticated real time computer assisted image analysis of the digitized images of breast heat patterns, should yield standard, reproducible qualitative and quantitative results, that will be applicable to risk assessment, detection, diagnosis and prognosis of breast cancer. Thus, the present study was undertaken to determine if improvements in infrared technology that have been incorporated into the second generation focal plane staring array Amber infrared imaging system can improve the images used for risk assessment in breast cancer.

2. MATERIALS AND METHODS

We recorded 3 breast views (right lateral, left lateral and frontal views) of 220 patients with the Amber focal plane staring array infrared imaging system at the Elliott Mastology Center. The 3 images were digitized and stored on computer hard disk during the study period. We independently analyzed the same 220 patients with the Inframetrics scanning infrared imaging system (right lateral, left lateral and frontal views) using hard copy photographic images (color frontal view and the three black and white views comparable to the Amber digitized images) of the patients that were being screened with mammography and routinely undergoing infrared imaging of their breasts during the study.

The first methodological decision we made, concerning infrared data analysis, was to try to quantitate the asymmetric abnormalities that were present in the Amber images (Table 1). Previously, with the Inframetrics system, we called

TABLE 1
SCORING OF RESULTS FORM THE INFRAMETRICS AND AMBER SYSTEMS

ABNORMALITY	INFRAMETRICS SYSTEM SCORE	AMBER SYSTEM SCORE
ASYMMETRIC SMALL FOCAL HOT SPOT	YES OR NO	0, 1
ASYMMETRIC LARGE FOCAL HOT SPOT	YES OR NO	0, 2
ASYMMETRIC GLOBAL HEAT	YES OR NO	0, 3
ASYMMETRIC VASCULAR HEAT	YES OR NO	0, 1, 2, 3
ASYMMETRIC AREOLAR HEAT	YES OR NO	0, 1
ASYMMETRIC EDGE HEAT	YES OR NO	0, 1

breast infrared images abnormal if any of the six asymmetric abnormalities were definitely present. Inframetrics images that only had a borderline infrared abnormality were called slightly abnormal (3 levels of results: normal, slightly abnormal, abnormal). For the Amber data we created a quantitative index by adding together the individual scores (Table 1) for the six possible asymmetric abnormalities (small hot spot, large hot spot, global heat, vascular heat, areolar heat and edge heat). The Amber Index could therefore range from 0 to 8 but the highest Amber Index that we computed was five.

3. RESULTS

Table 2 presents a comparison of the features of the Amber and Inframetrics imaging systems. The Amber system produced a much better image because of the focal plane staring array that contained far greater elements, and increase in dynamic range from 8 to 12 bits/element and an increase in thermal sensitivity from 100mK to 25mK. In addition the Amber image was outputed in a digital format that lends itself to image analysis.

TABLE 2
COMPARISON OF FEATURES BETWEEN THE INFRAMETRICS AND AMBER SYSTEMS

INFRAMETRICS SYSTEM	AMBER SYSTEM
First Generation	Second Generation
Scanning Mercury Cadmium Telluride Detector	Indium Antimonide Focal Plane Array
Liquid Nitrogen Cooler	Stirling Cycle Cooler
175 Elements/Line @Line Rate: 7866Hz RS-170/NTSC	256 x 256 Elements - Staring Array
Dynamic Ratings: 8 Bits/Element	Dynamic Range: 12 Bits/Element
Thermal Sensitivity: 100mK@30°C	Thermal Sensitivity: 25 mK@30°C
Spectral, Range: 8-12 Microns	Spectral Range: 3-5 Microns
External Calibration	Internal Calibration
Video Output: Analog	Video Output: Either Digital or Analog

The first comparison (Table 3) we made on the normal and high risk patients being screened for breast cancer was to

TABLE 3
COMPARISON OF INFRARED RESULTS WITH THE INFRAMETRICS AND AMBER SYSTEMS

AMBER SYSTEM	INFRAMETRICS SYSTEM		
AMBER INDEX	NORMAL	SLIGHTLY ABNORMAL	ABNORMAL
0	87/220 (39.5%)	12/220 (5.5%)	10/220 (4.5%)
1	23/220 (10.5%)	5/220 (2.3%)	4/220 (1.8%)
2	22/220 (10.0%)	16/220 (7.3%)	10/220 (4.5%)
3	10/220 (4.5%)	1/220 (0.5%)	4/220 (1.8%)
4	5/220 (2.3%)	0/220 (0.0%)	6/220 (2.7%)
5	1/220 (0.5%)	1/220 (0.5%)	3/220 (1.4%)

p=.0001, chi-square analysis for independence

determine if the results from the second generation Amber infrared imaging system differed from the results from the Inframetrics system. Chi-square analysis for independence showed that the two methods produced results that were not independent and therefore were strongly associated (p=.0001). The most interesting result was that there appeared to be an increase in the sensitivity for picking up asymmetric heat patterns with the Amber system, as 50.5% (111 of 220 patients without breast cancer) had abnormal infrared imaging, whereas only 32.7% (72 of 220 patients) had asymmetric heat patterns with the Inframetrics system. Analysis of the six asymmetric abnormalities individually (Table 4) showed

TABLE 4
DISTRIBUTION OF ABNORMALITIES FOR INFRAMETRICS AND AMBER INFRARED IMAGING SYSTEMS

ABNORMALITY	INFRAMETRICS SYSTEM	AMBER SYSTEM
ASYMMETRIC SMALL FOCAL HOT SPOT	41/218 (18.8%)	28/220 (12.7%)
ASYMMETRIC LARGE FOCAL HOT SPOT	3/218 (1.4%)	35/220 (15.9%)
ASYMMETRIC GLOBAL HEAT	6/218 (2.8%)	2/220 (0.9%) p=.1434
ASYMMETRIC VASCULAR HEAT	43/218 (19.7%)	70/220 (31.8%) p=.0054
ASYMMETRIC AREOLAR HEAT	6/218 (2.8%)	14/220 (6.4%)
ASYMMETRIC EDGE HEAT	1/218 (0.5%)	0/220 (0.0%)

that most of the increase in sensitivity could not be attributed to the small and insignificant (p=.1434) increase in small hot spots, large hot spots and global heat from 22.9% (50 of 218 patients) with the Inframetrics system to 29.5% (65 of 220 patients) with the Amber system. However there was a significant increase (p=.0054) in vascular asymmetry from 19.7% (43 of 218 patients) with the Inframetrics scanning system to 31.8% (70 of 220 patients) with the Amber focal plane system.

Two known risk factors (family history of breast cancer and previous breast biopsy) were compared to the infrared imaging results from the Inframetrics scanning and Amber focal plane systems. Neither of these risk factors were found to correlate with the infrared imaging results and therefore infrared imaging results were found to be an independent risk factor in breast cancer. Women being screened for breast cancer, who come from a family with a history of breast cancer, are at 2- to 5-fold increased risk of developing breast cancer, if one or more first degree female relatives (mother, sister or daughter) have had breast cancer. In this study women were divided into two risk categories by either the presence or absence of a family history of breast cancer and compared by group to the results of their breast infrared imaging. When patients' results from infrared imaging, either levels determined by analysis of Inframetrics infrared imaging (Table 5) or the Amber Index (Table 6), were compared to patients' family history of breast cancer, it was found that there was no relationship between having a family history of breast cancer and having an abnormal asymmetric infrared pattern of the breasts. So it seems that an abnormal infrared image is a high risk marker for breast cancer that is independent of family history of breast cancer.

TABLE 5
INFRAMETRICS SYSTEM RESULTS BY FAMILY HISTORY OF BREAST CANCER

INFRAMETRICS SYSTEM	RISK ASSESSMENT	
	NORMAL (NO FAMILY HISTORY)	HIGH (FAMILY HISTORY)
NORMAL	80/213 (37.6%)	64/213 (30.0%)
SLIGHTLY ABNORMAL	21/213 (9.9%)	12/213 (5.6%)
ABNORMAL	17/213 (8.0%)	19/213 (8.9%)

p=.3903, chi-square analysis for independence

TABLE 6
AMBER SYSTEM RESULTS BY FAMILY HISTORY OF BREAST CANCER

AMBER SYSTEM	RISK ASSESSMENT	
AMBER INDEX	NORMAL (NO FAMILY HISTORY)	HIGH (FAMILY HISTORY)
NORMAL (0)	57/213 (26.8%)	49/213 (23.0%)
SLIGHTLY ABNORMAL (1,2)	45/213 (21.1%)	32/213 (15.0%)
ABNORMAL (>2)	16/213 (7.5%)	14/213 (6.6%)

p=.7971, chi-square analysis for independence

The second risk factor that we looked at was previous breast biopsy. It has been clearly shown in studies done by other investigators that patients who have had one or more previous breast biopsies are at increased risk of being diagnosed with breast cancer. This increased risk of developing breast cancer, that has been associated with having had a previous breast biopsy, is probably due to the ability of mammography to detect not only invasive cancerous lesions but also noninvasive cancerous lesions and benign lesions (such as atypical hyperplasia and microcalcifications) that put woman at increased risk of developing breast cancer. In other words, mammographic abnormalities, that lead to open surgical biopsy, are highly associated with invasive carcinomas and further are often caused by precursors of invasive carcinoma that put woman at increased risk of developing breast cancer. These abnormalities that are present in mammograms are probably also the cause of abnormal infrared images in breast cancer screening and at diagnosis of breast cancer. The Inframetrics analysis (Table 7) showed that there was a trend (p=.0747, chi-square analysis for independence) towards patients with abnormal infrared images of the breast having breast biopsies. This trend was not confirmed (p=.3582, Table 8) when the infrared images were digitized and saved with the Amber infrared system and the Amber Index compared to the history of breast biopsy.

Digitization of the higher quality infrared Amber images allowed quantitation of infrared abnormalities by computer assisted image analysis. The location of cancer in the breast is not random and each quadrant of the breast has been shown to have its own rate of occurrence with the upper outer quadrant containing the greatest proportion of tumors. Therefore, we devised a computer analysis method that would quadrant the breast by a defined reproducible method. In all the digital images a line is drawn from the chin to the nipple, then a second line is drawn to the lowest contour of the breast, and finally a third and forth line are drawn horizontally to the left and right margins of the breast (Figure 1). The

same is done for both the right and left breast and we determine the mean, standard deviation, median, minimum and maximum temperatures for each quadrant of the breast. Then these quantitative measurements were compared between the left and right breast to quantitate asymmetric infrared abnormalities.

TABLE 7
INFRAMETRICS SYSTEM RESULTS BY HISTORY OF PREVIOUS BREAST BIOPSY

INFRAMETRICS SYSTEM	RISK ASSESSMENT	
	NORMAL (NO PREVIOUS BIOPSY)	HIGH (PREVIOUS BIOPSY)
NORMAL	116/212 (54.7%)	28/212 (13.2%)
SLIGHTLY ABNORMAL	24/212 (11.3%)	9/212 (4.2%)
ABNORMAL	22/212 (10.4%)	13/212 (6.1%)

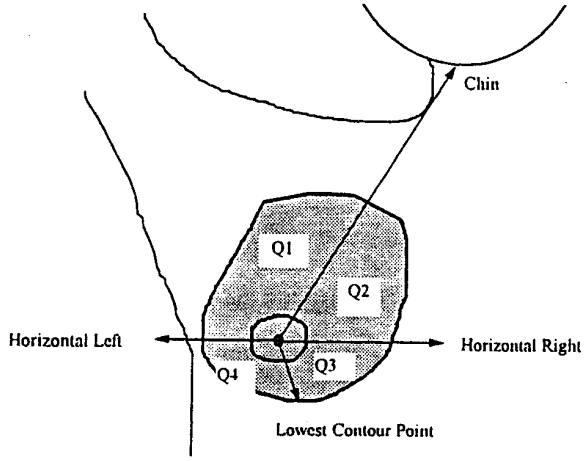
p=.0747, chi-square analysis for independence

TABLE 8
AMBER SYSTEM RESULTS BY HISTORY OF PREVIOUS BIOPSY

AMBER SYSTEM	RISK ASSESSMENT	
AMBER INDEX	NORMAL (NO PREVIOUS BIOPSY)	HIGH (PREVIOUS BIOPSY)
NORMAL (0)	84/212 (39.6%)	22/212 (10.4%)
SLIGHTLY ABNORMAL (1,2)	58/212 (27.4%)	18/212 (8.5%)
ABNORMAL (>2)	20/212 (9.4%)	10/212 (4.7%)

p=.3582 chi-square analysis for independence

FIGURE 1
GUIDELINES FOR BREAST QUADRANTS



4. DISCUSSION

Infrared imaging of the breast for breast cancer risk assessment with a second generation focal plane staring array system was found to produce images superior to a first generation scanning system. The second generation system had greater thermal sensitivity, more elements in the image and a greater dynamic range, which resulted in a greater ability to demonstrate asymmetric heat patterns in the breasts of women being screened for breast cancer. Comparison of the infrared images from the two systems showed that the 12 bit Amber image was better than the 8 bit Inframetrics image, but the digitized images that were stored on the hard drive were not as good in either case as the analog output from either system. The 16 bit capacity of the Amber system will probably be needed in order for the quality of the recalled digitized image to reach that of the analog output, and for image analysis to reach its full potential. However we did conclude that the second generation Amber infrared images both analog and digital are better for medical applications than the first generation Inframetrics Images.

The improved imaging of the second generation infrared system increased the proportion of women with abnormal breast infrared images in a group of women being screened for breast cancer, and also allowed more objective and quantitative visual analysis, compared to the very subjective qualitative results of the first generation infrared system. Eventually we hope to demonstrate that the application of a simple index (the summation of a semiquantitation of asymmetric hot spots, global heat, vascularity, areolar heat and edge heat) and an appropriate cut-off level can decrease the high false positive rate to an acceptable level. This will require us to determine what types, levels or combination of types and levels of asymmetric abnormalities are most predictive of risk of developing breast cancer. The Amber Index seems to be more suited to this purpose, than the 3 levels of results from the Inframetrics system, because there are many levels (0 to 8 levels) with the Amber Index and we actually had 6 levels of the Amber Index. In this study 50% (111 of 220) of the patients were found to have some infrared abnormality of the breasts, when an Amber Index of zero was considered normal, but if an index of one is considered to be such a small abnormality that a patient's risk of developing breast cancer is not significantly increased, then approximately 36% (79 of 220) of the patients being screened for breast cancer would be categorized as high risk individuals. If an amber index of two is considered insignificant then 14% (31 of 220) of the patients being screened for breast cancer would have sufficiently abnormal infrared images to be at increased risk of developing breast cancer. We feel that 14% would be approximately the proportion of patients in our study group that would be at increased risk of developing breast cancer and therefore an index greater than two would put a patient at increased risk of developing breast cancer. However, a clinical follow-up study will be needed to determine how well we have delineated the women at high risk of developing breast cancer. From Table 3 it can also be seen that the patients, who are determined to be at increased risk of developing breast cancer, are different with the two systems, as 16 patients who have completely normal breast infrared images with the Inframetrics system had abnormal images (Amber Index greater than 2) with the Amber system and 24 other patients with normal Amber images (Amber Index less than or equal to 2) were abnormal with the Inframetrics system. Thus 18% (40 of 220) of the patients had significantly different infrared imaging results with the two systems and we are presently doing clinical follow-up studies to determine if the Amber Index is a better predictor of risk of developing breast cancer than the previous results with the Inframetrics system.

In the past the major shortcoming of infrared imaging of the breast has been its high false positive rate which is typically between 1/4 and 1/3 of women being screened for breast cancer. This seemingly high false positive rate is partly due to mammographers calling all abnormal infrared images of the breast false positives in woman with normal mammograms, instead of being considered at high risk of developing breast cancer -- mammographers have not accepted that an abnormal infrared image is an early predictor of breast cancer. Even though women with an abnormal infrared image of their breasts is very prevalent in the screening population and this would therefore require many high risk women to be followed at shorter intervals with mammography and clinical breast exam, the fact that approximately 25% of the women with abnormal infrared images will develop breast cancer warrants its inclusion in all breast cancer screening programs. We also believe that further improvements in infrared imaging systems and analysis, such as the Amber Index, will eventually allow the clinician to better define infrared abnormalities of the breast that translate into increased risk of breast cancer and therefore decrease the high false positive rate of infrared imaging of the breast.

Patients found to have abnormal infrared images during screening for breast cancer have previously been shown to be at higher risk of developing breast cancer[1,2,3]. This study has clearly shown that the presence of an abnormal infrared image in patients being screened by mammography for breast cancer is a high risk marker independent of the commonly used high risk markers of family history and previous breast biopsy. The improvement in risk assessment that could be

achieved by integrating infrared image analysis with family history and previous breast biopsy results could have significant impact on the selection of patients for breast cancer prevention studies. For example, in hormonal intervention studies with the antiestrogen tamoxifen the addition of infrared imaging results to the other parameters presently used to select patients for these hormonal therapy prevention study might define a group of women at high enough risk of developing breast cancer to warrant the extension of hormonal therapy intervention from only postmenopausal women to both premenopausal and postmenopausal women. This extension to premenopausal women would be possible because of an increase in the therapeutic index of the hormone prevention therapy, caused by decreasing the number of women treated (higher risk women being treated) and therefore increasing the proportion of women that benefit from the hormonal therapy, while the side effects and toxicities remain the same.

The greater sensitivity and resolution of the digitized images of the second generation infrared system has allowed image analysis of total breasts, breast quadrants and hot spots to produce mean, standard deviation, median, minimum and maximum temperatures. This will allow future analysis to be both quantitative and objective as opposed to the subjective qualitative analysis that has been the standard in the past for infrared imaging of the breasts.

In conclusion we believe that infrared imaging of the breast should be an integral part of any breast cancer screening program due to its value as an independent risk factor for breast cancer and its value as a prognostic indicator[4]. The use of improved second generation focal plane staring array infrared technology for breast cancer detection, diagnosis and as a high risk and prognostic indicator should lead to both earlier detection of breast cancer, thus increasing the overall survival of breast cancer patients, and aid in determining which node negative breast cancer patients should receive adjuvant chemotherapy. Continued development of objective computer assisted analysis methods of infrared images of the breast, that compare quantitative thermal parameters of the right and left breasts, will eventually eliminate the problems inherent in the presently used subjective qualitative analysis methods. Accomplishment of these goals should significant decrease the morbidity, mortality and overall cost of therapy for breast cancer patients.

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Effectiveness of a noninvasive digital infrared thermal imaging system in the detection of breast cancer

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KEYWORDS:
Digital infrared thermal imaging;
Breast cancer;
Diagnosis;
Thermography

Abstract

BACKGROUND: Digital infrared thermal imaging (DITI) has resurfaced in this era of modernized computer technology. Its role in the detection of breast cancer is evaluated.

METHODS: In this prospective clinical trial, 92 patients for whom a breast biopsy was recommended based on prior mammogram or ultrasound underwent DITI. Three scores were generated: an overall risk score in the screening mode, a clinical score based on patient information, and a third assessment by artificial neural network.

RESULTS: Sixty of 94 biopsies were malignant and 34 were benign. DITI identified 58 of 60 malignancies, with 97% sensitivity, 44% specificity, and 82% negative predictive value depending on the mode used. Compared to an overall risk score of 0, a score of 3 or greater was significantly more likely to be associated with malignancy (30% vs 90%, $P < .03$).

CONCLUSION: DITI is a valuable adjunct to mammography and ultrasound, especially in women with dense breast parenchyma.

Digital infrared thermal imaging (DITI) is a noninvasive, non-contact system of recording body temperature by measuring infrared radiation emitted by the body surface. This technology was originally designed for US military use in night vision but also has many applications in medicine. Its use in the field of medical oncology lies in the fact that tumors generally have an increase in blood supply and angiogenesis, as well as an increased metabolic rate, which in turn translates into increased temperature gradients compared to surrounding normal tissue.[1] Detecting these infrared "hotspots" and gradients can thereby help to identify and diagnose malignancy.

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Infrared thermography has been in use in medical diagnostics since the 1960s, and in 1982 was approved by the US Food and Drug Administration (FDA) as an adjunctive tool for the diagnosis of breast cancer. Its applicability, however, was limited by the temperature resolution capability of earlier imaging technology, the bulky equipment necessary to perform procedures, and the general lack of computer analytical tools. Since then, major advances have been made in infrared thermal imaging technology, with digitalized high-resolution imaging and sophisticated artificial intelligence-based neural network image analysis. In the past, equipment for measuring infrared emission was only capable of resolving temperature variation from .5 to 1°C; some machinery required liquid nitrogen, and some even needed patient contact—a much more primitive technology requiring a special liquid crystal film to be placed on the patients' breasts so as to detect temperature. The digital

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infrared thermography cameras of today are capable of sensing changes in temperature at .08°C or better and do not require any patient contact. Now, DITI has the capability of making significant impact in medicine.[2]

In this study we assess the effectiveness of a DITI system, the Sentinel BreastScan (SBS; Infrared Sciences Corp., Bohemia, NY USA), in detecting breast pathology in a group of patients with suspicious findings on either mammography or ultrasound that all underwent biopsy in a prospective, double-blinded trial.

Methods

Ninety-two women for whom a breast biopsy had been recommended on the basis of a previously suspicious mammogram or ultrasound were included in this 2-year study conducted at New York Presbyterian Hospital–Cornell. Informed consent was obtained from all patients and approval was obtained from our Institutional Review Board. Patients who were morbidly obese, had a bra size greater than DD, or had prior contralateral mastectomy were excluded due to technical limitations.

The examination was performed with the patient disrobed from the waist up and positioned in a dedicated equipment suite with a chair equipped with lateral-view side mirrors, an integral air cooler, and a digital infrared camera. The digital camera was an uncooled focal plane array type with an image size of 320 x 240 pixels, sensitivity to .08°C, and an operating spectral (wavelength) range of 7–12 μm.

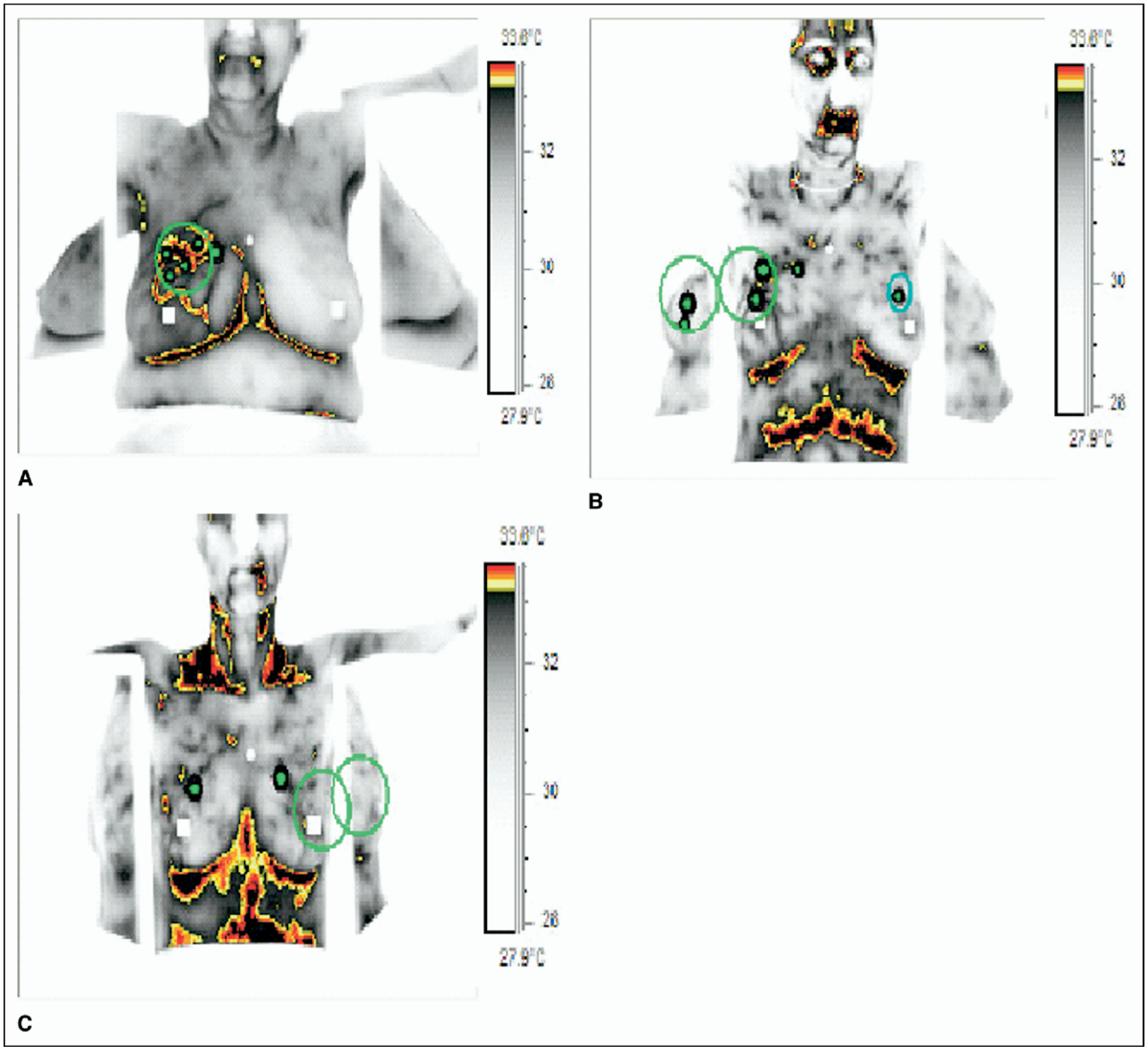

Figure 1 Digital infrared thermal imaging scans. Green circles represent areas of clinical suspicion from prior imaging. (A) pPatient with infiltrating ductal carcinoma in right breast at 12 o'clock, risk score of 4. (B) Patient with ductal carcinoma in situ in right breast at 10 o'clock, risk score of 1. (C) Patient with fibrocystic disease, risk score of 0.

The examination took approximately 4 minutes per patient, where a dynamic series containing more than 100 temperature images was gathered during the administration of a cold stress (cool air directed at the breasts). The software extracted specific thermal parameters, performed asymmetry analysis between each breast, and focused on areas of the breasts that showed the greatest difference in temperature when compared with surrounding tissue. The program then produced a color-coded, processed image of the breasts showing suspicious foci, as well as results of all measured thermal breast parameters (Figure 1).

Each patient underwent 3 modes of analysis to generate 3 different scores. An overall risk score was tabulated in the blinded screening mode, giving a score of 0 (minimal risk) to 7 (very high risk). Any score greater than 0 was considered a positive (suspicious) finding. In the clinical mode, the location of the lesion under question based on prior imaging was assessed to generate a positive or negative clinical assessment. Finally, a third score was generated using an artificial neural network (ANN) evaluation to also give a positive or negative finding.

Statistical analysis was performed using Fischer exact test with $P < .05$ considered significant.

Results

The study consisted of 94 biopsies in 92 female patients with an average age of 51 years (range 23–85). Of the 94 breast lesions, 60 were malignant (including 2 with lobular carcinoma *in situ*, since these tumors are considered stage 0) and 34 were benign on biopsy. As seen in Table 1, the majority of malignancies were infiltrating ductal carcinoma (IFDC). The median size of invasive tumors was 1.4 cm, with a range of .5–14 cm. Of 60 malignancies identified on biopsy, the SBS identified 58 correctly on both the screening mode and using ANN, and 54 of 60 using the clinical mode. Sensitivity and specificity for each of the modes of the SBS are given in Table 2. The negative predictive value for the SBS in this set of patients was 66.7% in the screening mode, 71.4% in the clinical mode, and 81.8% using ANN. All 4 ductal carcinoma *in situ* lesions were identified using the SBS system.

Table 1 Significant pathologic findings for 94 lesion biopsies

Pathology	N	% of cases
Malignant	58	62%
DCIS	4	4%
IFDC	43	46%
IFLC	5	5%
Other malignant	6	6%
LCIS*	2	2%
Benign	34	36%

DCIS = ductal carcinoma in situ; IFDC = infiltrating ductal carcinoma; LCIS = lobular carcinoma in situ.

*LCIS is included with malignancies as this is tumor-node-metastasis (TNM) stage 0.

Table 2 Sensitivity and specificity of three modes of the Sentinel BreastScan

	Screening mode	Clinical mode	Neural network
Sensitivity	96.7%	90.0%	96.7%
Specificity	11.8%	44.1%	26.5%

Compared to an overall risk score of 0, a score of 3 or greater in the screening mode was significantly more likely to be associated with a cancer diagnosis (30% vs 90%, $P < .03$). Fifty-two of 59 patients with malignancy had surgically staged disease, either stage 0 (n = 6), stage I (n = 25), stage IIa (n = 14), or stage IIb (n = 7). There was a nonsignificant trend towards higher average risk scores for patients with malignancy at later stages of disease (Figure 2).

Conclusion

In this prospective clinical trial of 92 women undergoing DITI with suspicious breast lesions identified on prior mammogram or ultrasound, we have shown that the SBS can detect breast pathology with sensitivity up to 97% and a negative predictive value of 82%. DITI is painless, noninvasive, does not emit harmful radiation, has no patient risk, provides immediate results, and is relatively inexpensive. Compared to magnetic resonance imaging (MRI)—an adjunctive diagnostic tool for breast malignancy gaining more popularity—DITI is considerably more affordable to both patient and provider. MRI may cost $2,000 to the patient for

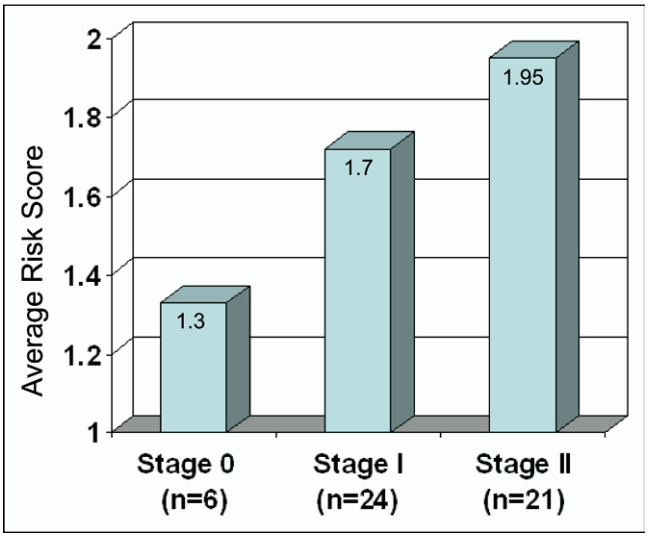

Figure 2 Correlation of stage of breast cancer with average risk score.

each examination and $2 million to own the equipment, while DITI costs less than $200 for each exam and approximately $25,000 to own the equipment.

The ability of DITI to detect tumors relies on the assumption that tumors have different biology from surrounding normal tissue. One study found a correlation between microvessel density of breast malignancies and thermographic hot spots, thus providing a mechanistic explanation for the use of DITI in cancer diagnosis.[3] However, DITI is limited by the fact that thermal recordings are only a physiologic measure and therefore must be used as an adjunct to another test such as mammography or ultrasound. Infection or inflammation of breast parenchyma, for example, can also alter temperature recordings and lead to false positive findings. In addition, morbidly obese women and breast size greater than DD preclude accurate recording of temperature from the inferior aspect (undersurface) of the breasts, so these patients may not be ideal candidates for DITI. DITI is not currently recommended or approved as a substitute for screening mammography, and correlation of findings on DITI should be made with alternative imaging techniques.

One of the first studies to document the value of infrared thermography in the identification of breast cancer was by Gautherie and Gros in 1980.[4] They reviewed thermograms performed on thousands of patients and found that patients with a "Thermogram stage Th IV or V" had a 90% chance of having cancer at time of study, and, more interestingly, 38% of 1,245 patients with Thermogram stage Th III (suspicious but not conclusive) developed cancer within 1–4 years of follow-up. Other studies have since shown correlations of infrared thermography recordings with large breast tumor size, high grade, lymph node metastasis, and tumor vascularity.[5,6] This is similar to our study where we showed a trend of higher risk scores correlating with higher stage of disease.

While previous thermography studies were limited by equipment, resolution, and sensitivity capabilities, the more sophisticated imaging and analytical tools available today make it is possible to use DITI and artificial neural networks to detect malignancy with up to 100% sensitivity.[7] The low specificity of DITI in this particular pilot study is largely due to our select patient population, all with suspicious findings on prior radiologic examination. A separate population with nonsuspicious breast pathology will be needed to accurately assess the true specificity of DITI. Ultimately, evaluating a screening population with DITI will give clinicians and patients more information so as to determine who will necessitate a biopsy and who can be followed clinically in cases where mammography or ultrasound is inconclusive.

Patients who could potentially stand to benefit from this technology are those whose diagnosis of breast cancer can be difficult, including younger women, men, patients with dense breasts, or patients with surgically altered breasts (implants, breast reduction; provided nipples are intact for orientation and asymmetry analysis). Future studies using DITI for these individual groups can help to asses this potential.

In conclusion, we have shown that a modernized DITI system can be a useful adjunctive test in detecting breast cancer with 97% sensitivity in this prospective clinical trial of 92 patients.

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Correlation of dynamic infrared imaging with radiologic and pathologic response for patients treated with primary systemic therapy for locally advanced breast cancer.

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Background: Assessment of response to therapy for locally advanced breast cancer include: serial assessments of physical exam, radiologic imaging, or repeated biopsies. Expense, subjective assessment, and patient risk make these methods impractical. Dynamic infrared imaging (DIRI) utilizes a quantum well infrared photon (QWIP) sensor with software to analyze the emission patterns over time. DIRI can detect biological temperature gradients with sensitivity of 0.009ºC. Tumor-induced local tissue nitric oxide production can increase local capillary blood flow. Anti-tumor therapies have been shown to result in decreased peri-tumoral capillary blood flow. These changes in temperature, detected by serial DIRI imaging, may provide a low cost, non-invasive, easily reproducible objective tool for real-time clinical assessment. **Methods:** In this prospective pilot study, we are evaluating patients with locally advanced breast cancer using serial DIRI. Primary endpoints include: sensitivity, specificity, PPV, and NPV of DIRI in comparison to pathologic response, concordance of DIRI to physical exam, and concordance of DIRI to standard radiographic evaluation at initial diagnosis and prior to surgery. DIRI results are reported as quantification of changes in the 0.2Hz modulation of temperature over the breast during the course of treatment and measurement of area of average temperature in a region of interest compared between breasts. One hundred patients will be enrolled in this trial. **Results:** Sixteen patients have been enrolled. Six have proceeded to surgery. All but one patient exhibited evidence of tumor response by physical exam. These findings correlated with response when comparing initial to pre-surgical MRI. In all responding patients, DIRI results revealed a decrease in the number of regions over the breast in which the 0.2Hz frequency dominated. Similarly, DIRI evaluation according to area of average temperature in the region of interest compared between breasts was concordant in patients with response to therapy. **Conclusions:** Assessment of response by physical exam, MRI, and DIRI were consistent. Preliminary data reveals that serial DIRI imaging can be an effective adjunctive tool.

A version of the article in the Journal Oncology

Oncology News International

(September 1997 Volume 6 Number 9)

Infrared Imaging as a Useful Adjunct to Mammography

MONTREAL— A group of Canadian physicians hope to spark renewed interest in the use of infrared breast imaging as a complement to mammography.

This technology lost favor some 20 years ago, but with new ultra-sensitive high-resolution digital infrared devices, efficacy is much improved, and the Canadian researchers believe that infrared exams could prove a simpler and less expensive complement to mammography than some of the other newer Imaging methods.

Researchers from the Ville Marie Breast Center examined infrared imaging in 100 women with non invasive stage I and II breast cancer. In this study, the 85% sensitivity rate of mammography alone was increased to 95% when infrared imaging was added, John R. Keyserlingk, MD, a surgical oncologist at Ville Marie, said in his presentation of the findings at the recent American Society of Clinical Oncology annual meeting.

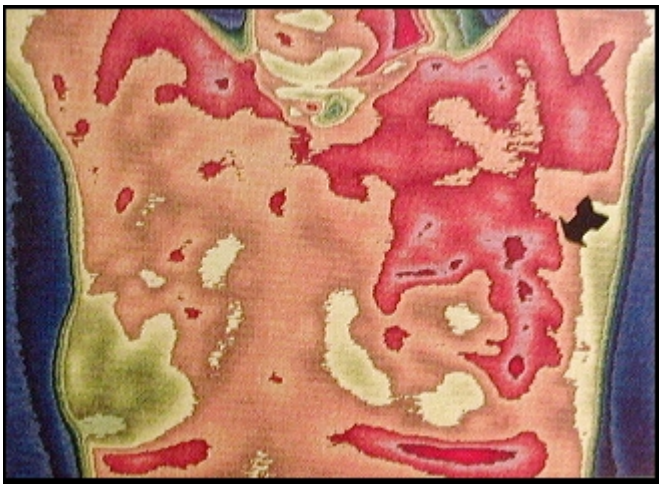
In this 38 year-old woman with a lump in the upper mid part of the left breast, mammography showed bilaterally dense fibroglandular tissue, more prominent on the left side. Infrared imaging (above) shows an asymmetrical vascular pattern over the left breast. Histopathology revealed a 2-cm infiltrating ductal carcinoma of the left breast.

Mammography and ultrasound depend primarily on structural distinction and anatomical variation of the tumor from the surrounding breast tissue, Dr Keyserlingk said, Infrared imaging detects minute temperature variations related to vascular flow and can demonstrate abnormal vascular patterns associated with the initiation and progression of tumors.

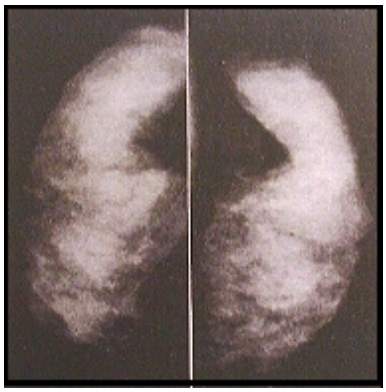
The new generation of diagnostic infrared technology, Dr. Keyserlingk said, owes much to a decade of military research and development. "In July 1995, we installed a fully integrated high-resolution infrared station," he told ONCOLOGY NEWS INTERNATIONAL. The software allows high - precision pixel temperature measurements.

In their study, Dr. Keyserlingk and his colleagues, Paul Ahlgren, MD, a medical oncologist, and Edward Yu, MD, a radiation oncologist, reviewed 100 successive patients referred to the Ville Marie Breast Center between August 1995 and December 1996 who were subsequently found to have histologically proven noninvasive ductal carcinoma in situ (four patients) or stage I or II invasive breast cancer (96 patients).

All patients had undergone preoperative clinical examination, mammography, and infrared imaging.



The infrared image from the same patient (see mammography below) shows a marked asymmetrical area of increased vascularity in the left breast (arrow). Histopathology revealed a 3-cm infiltrating ductal carcinoma of the left breast with 11 positive axillary nodes.



In this 39-year-old woman with a lump in the left breast, mammography (craniocaudal view) shows bilaterally dense fibroglandular tissue, more prominent on the left side.

Clinical examination alone was positive in 61% of the study patients. Mammography was highly suspicious in 66% of patients, with an additional 19% having contributory but nonspecific (intermediate) mammography findings. Infrared imaging was considered abnormal in 83% of patients.

Of the 39 patients with negative clinical examinations, 31 had at least one major abnormal infrared sign, and infrared was the major indication of a potential abnormality in 15 of these patients who also had a negative or intermediate mammogram.

The 15 patients with a noncontributory mammogram were an average of five years younger than the overall group (mean age, 48 years versus 53 years). Among these patients, 10 had an abnormal infrared image, and in six of these women, who also had negative clinical exams, infrared was the main indicator of a possible abnormality.

"This suggests that when done concomitantly with mammography, infrared imaging can add valuable information, particularly in those patients with nonspecific clinical and mammographic findings," Dr. Keyserlingk said.

The mean size of tumors undetected by mammography was 1.66 cm versus 1.28 cm for infrared imaging, suggesting that infrared detection is related more to vascular and metabolic changes than strictly to tumor size.

Finally, for comparison the researchers evaluated a series of 100 patients who had benign breast histology at open biopsy. Of these, 19% had an abnormal preoperative infrared study, while 30% had an abnormal mammogram, suggesting sufficient specificity as an adjuvant modality.

Dr. Keyserlingk noted that infrared imaging generally takes less than 10 minutes to perform. At the Ville Marie Breast Center, he said, patients are asked to avoid alcohol, coffee, smoking, exercise, deodorants, and lotions three hours before their infrared test.

The imaging room is maintained at between 18° and 20° C. The patient sits disrobed, hands supported over her head for a five-minute equilibration period. Imaging is then performed, consisting of four views - one anterior, one undersurface, and two lateral -which are taken, interpreted, and stored on laser disks in a process that takes only two minutes

Major abnormal findings on infrared range from significant vascular asymmetry to vascular "anarchy," consisting of unusual vessels that form clusters, loops and abnormal branching. Focal increases in temperature from 1° to 3° C may be significant when compared with temperatures at the contralateral site.

Dr Keyserlingk and his colleagues hope that their finding's will stimulate interest in infrared imaging and ultimately lead to carefully controlled multi-center trials of the technique.

Time to Reassess Value of Breast Imaging?

Infra-red thermography and breast cancer doubling time

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SUMMARY. **In 100 cancers 2 to 11 serial mammographies were performed before final diagnoses. The average number per tumour was 2,8 with a range of 2 - 11, the retrospective observation time was 2 month to 11 years, the observed doubling times ranged between 44 and 1.369 days, the geometric mean of the doubling time is 202 days with 95% - confidence limits of 179 and 227 days. The distribution of frequency of tumour diameters, volume doubling times and age of patient were log-normal. The theoretically calculated time span of growth from a first tumour cell to a 10 mm tumour (30 doubling times) takes about 16 years, from a tumour size of 2 mm to 10 mm it would take about 4 years on the average (7 doubling times). No significant correlations between doubling times, metastasizing rate and histological differentiation could be found. The shorter doubling time occurred, more often thermographic pathological signs where evident. Rapidly growing tumours with doubling times of less than 150 days were thermographically suspicious in 70%, but moderate and slowly growing tumours (doubling times of more than 150 days) in 41% only.**

Key words: thermography, mammography, tumour volume doubling time, breast cancer.

On the assumption that malignant growth is starting within one single cell or small cell cluster the number of volume doubling necessary for one given size of a tumor can be calculated (Schwartz, 1961). With known volume doubling time growth rates and - assuming constant volume doubling ,times - life spans of tumors are projectable. Information on growth rates of malignant tumour is important in many respects, especially however in view of the problems related to mass-screening for early cancer detection.

In regard to mammary carcinoma according to Spratt jr. (1977) the most important factor for prognosis and success of therapy is probably the individual growth of each tumour. Gros (1976, 1977) and Amalric (1977) showed that there are some connections between thermographic alterations and prognosis for mammary carcinoma: the more significant the alterations in thermography the less the 5-years-surviving chance.

In this paper information on the growth rate of carcinoma of the breast is given on the basis of 276 mammographies in 100 mammary carcinomas with observation times of 0,2 - 11 years. In 32 of these cases the thermographic observation are compared with the speed of growth and the metastasizing rate.

PATIENTS AND MATERIAL

In 21000 women 70% of which were asymptomatic, 582 cancers were found. In 100 cancers, 4 of which were secondary tumours in the same breast, several mammographies were performed before final treatment.

In 53 of these cases therapy was carried through in our Institute, whereas about half of the preceeding mammographies had been made at other institutes. The other 47 were X-rayed at 16 various institutes and therapeutic centers.

The average number of mammographies per tumour was 2.S with a range of 2-l 1. The average observation time was 46 months with a range of 2 months to 11 years (Table I, Table II). Serial mammographies were done in this population due to delay of the final diagnosis to refusal of treatment and to other reasons.

METHODS

Measurement of tumour diameter

Each mammography with tumour specific density (tumour nucleus shadow) was identi-

Tab. I. **Patients and material.**

Patients screened, total	21000
Breast cancers with serial mammographies	100
Number of contributing Hospitals/Institutions	17
Number of serial mammographies, total	276
Range of series per case	2-l 1
Average number of series	3
Range of observation times	0,2-l 1 years
Margin of error in doubling times (in cases with tumour diameter of 20-30 mm)	11,3%

fied and its diameter was measured in three planes perpendicular to each other.

Calculation of tumour volume doubling times

The doubling time, i.e. the time needed by the tumour to double in volume (Tv) was calculated on the basis of the the tumour diameters » and the time intervall between two measurements according to Schwartz (1961) using this equation:

$$T_v = \frac{t_2 - t_1}{\log_2 V_2 - \log_2 V_1}$$

t = time (days) v = volume (mm^3)

The inaccuracy in measurement increased the smaller the tumour becomes: when the inaccuracy in measurement is + 0,75 mm, the margin of error was 11,3% in tumours of between 20 and 30 mm (Wolff, 1967).

Construction of growth curves by geometric approximation

Individual growth curves were plotted for all tumours, using the individual observations.

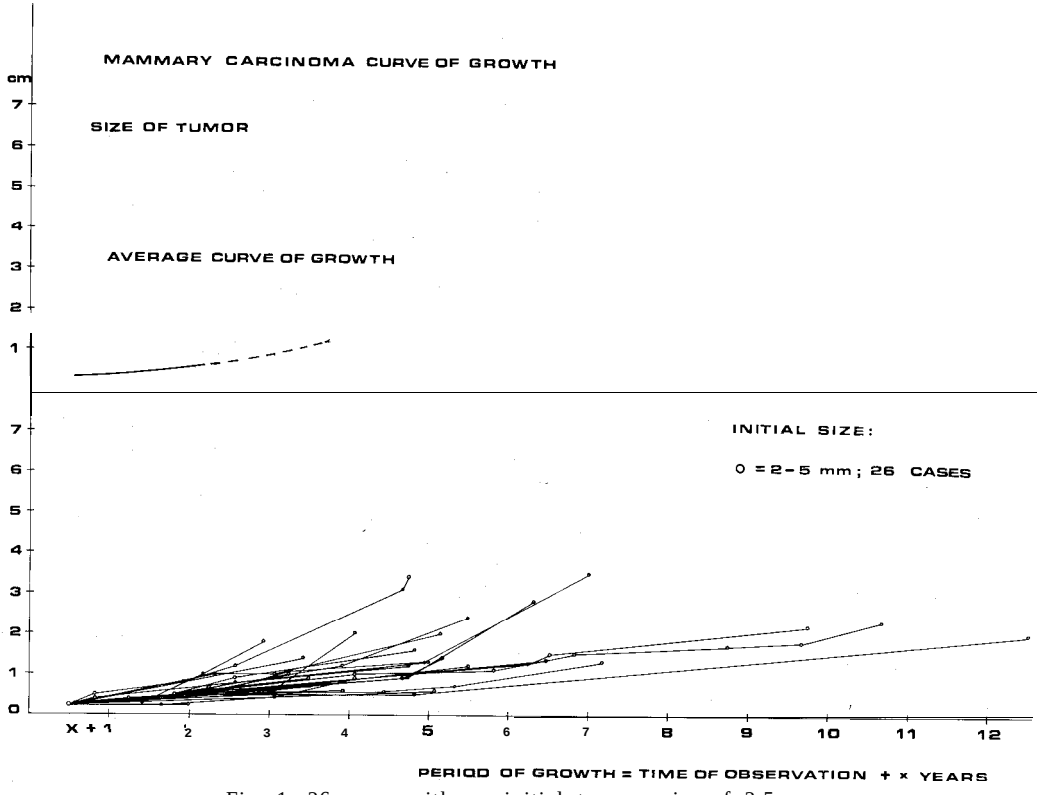

Fig. 1. 26 cases with an initial tumour size of 2-5 mm.

The main problem consists in the fact that the position of the individual initial tumour diameters is not defined on the overall time axis (x-axis).

For the construction of an average growth curve by geometrical approximation all individual curves with initial tumour diameter of 2 mm (9 cases) started at the O-point of the time axis. An average growth curve was empirically established and the next group with initial diameters of 3-5 mm (17 cases) were started on the average growth curve of the smaller tumours (Fig. 1). The same method was used to plot initial tumour diameters of the other cases between 6-30 mm (27 cases) on the average growth curve of the forgoing smaller tumours. The final composite overall growth curves is based here on 163 single tumour measurements in 53 cases and ranges between an initial size of 2 mm and a final size of 60 mm (Fig. 2).

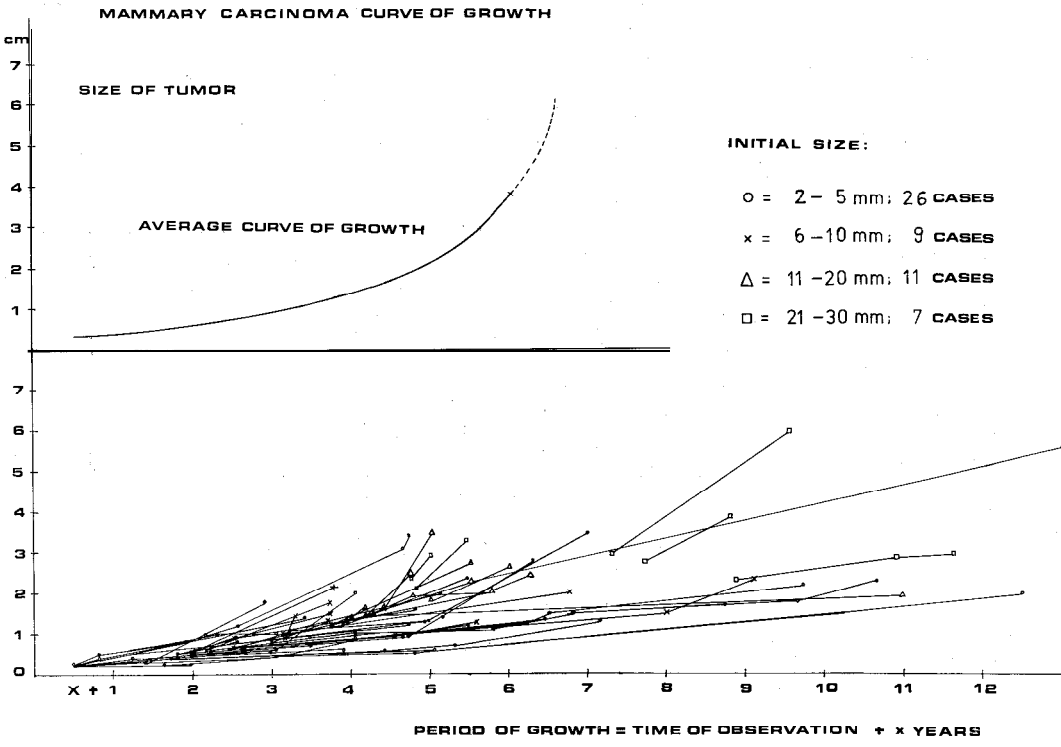

Fig. 2. 53 cases, individual and average curves of growth, geometrical approximation.

Biometrical evaluation of data

The model of the Gompertz-function frequently used is not applicable for the growth phase of the mammary carcinomas observed here. The knowledge of tumour diameter gained through mammography originates only from one part of the very short time period M shown in Fig. 6 of the whole assumed tumour life. However, this extremely small region gives too little information for estimating the parameters of the Gompertz-function.

The growth in the time period M (Fig. 6) may be fitted by an exponential growth model (logarithmic transformation)

$$\log Y = \log A + x \log B$$

The volume doubling time Tv with the upper and lower confidence limits is being estimated with the linear regression

$$Y_1 = a + b\,x_i + e_i \qquad (i = 1,2, \ldots, n)$$

Symbols:

n = number of measurements, i.e. mammographies per patient
Y_i = log, of the volume V_i in mm^3
x_i = time in days
b = regression coefficient
a = additive constant
e_i = error terms, i.e. the deviation of observation Y_i of the estimated values $y_i = a + b X_i$, $e = y_i - y_i$
s_b = standard deviation of b
significance level, in this study we used = 0,05

The parameters a and b are estimated by the least square method so that the sume of squares of the residuals

$$\sum_{1=i}^{n} \cdot e_1^2$$

is minimized.

For the estimation of b and s_b the equation is:

$$b = \frac{S_{xy}}{Sx} \text{ and } S_b = \sqrt{\frac{S_y}{Sx} \cdot \frac{1 - r^2}{n - 2}}$$

Thermographic examination

Thermographic examination with Bofors-Camera MARK 2 was performed as follows:

After cooling for 10 minutes the patient is sitting with raised arms. One frontal and two left and right oblique views are taken in order to have the lateral skin well drawn.

6 parameters or pathological signs are considered which are:

1. « Hot spot » of more than 0,8 °C
2. << Whole breast hyperthermia >) of more than 0,8 °C
3. Correspondence in projection of clinics-, roentgenography and thermography
4. Asymmetrical hypervascularization
5. Difference in thermographic types A, B, C, D, E from right to left
6. Edge sign positive

4 outstanding pathological signs were considered as ((malignancy sign P according to Amalric et al. (1976):

1. <(Hot spot >> of more than 1,5 “C
2. Total breast hyperthermia of more than 1,5 °C
3. « Anarchic hypervascularization »
4. « Extended positive edge sign »

RESULTS

Individual volume doubling times

Doubling times between 44 and 1869 days (Table II) were observed, in 9 cases - not registered in the table - even a standstill of growth was observed for some time.

Variability of doubling times within individual tumours

The variability of observed doubling times within one and the same tumour is striking. Thus one case (No. 33) showed a doubling time of 63 days, just before a T, of 384 days and later on one of 174 days.

In semilogarithmic presentation of the geometrically constructed average growth curve (of 53 cases) this curve shows a deflection to the time-axis (Fig. 3). This means, that with increasing size and age of the tumour there is an increase of volume doubling time also. But a certain selection of slower tumours with increasing observation times cannot be excluded. This deceleration of growth with increasing size and age of the tumour as shown in the semilogarithmical presentation, could follow a special exponential function known as power-function (Archambeau, 1971).

Following the geometrically constructed average growth curve (Figs. 2 and 3) it would take on the average 6 years of growth from a tumour of 2 mm in size to 10 mm in size (7 doubling times).

Rapid, slow and moderate growth

It seems reasonable to distinguish subjectively in speed of growth (Table III). Very rapid growing tumours with T_v, of less than 100 days we saw in 13%, fast growing tumours with T,. of less than 150 days in 30%, moderate growing tumours (T, = 151-300 days) in 46%, and slow growing tumours (T_v>300 days) in 24%.

Growth rate and histological diagnosis

In the 100 cases no correlations of histological diagnosis to speed of growth could be found.

Biometrical evaluations of data:

Fig. 4 indicates the frequency distribution of measurements in Table II. The distribution

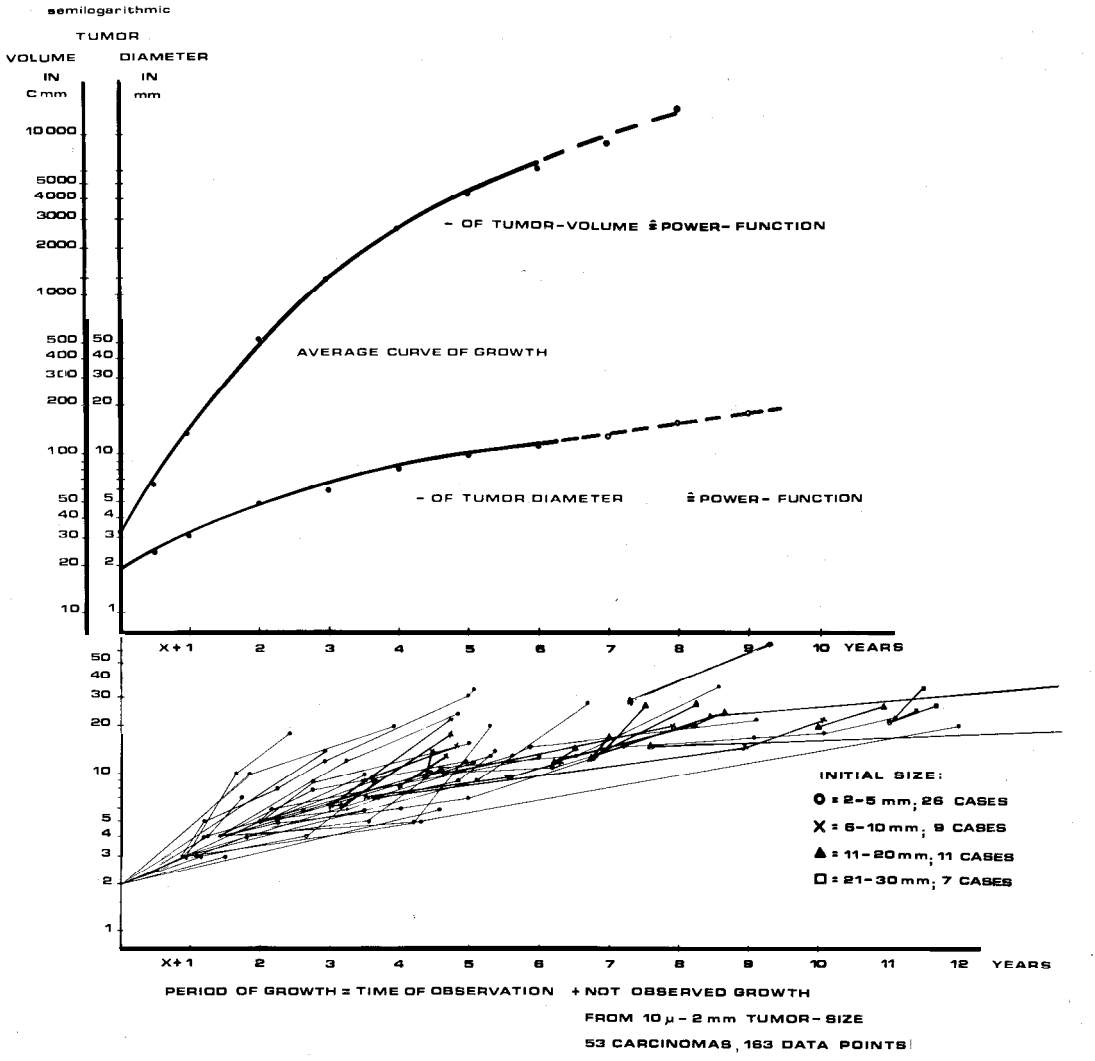

Fig. 3. Mammary carcinoma curve of growth.

of the tumour diameter (Fig. 4 A) the tumour volume (Fig. 4 B) and the volume doubling time (Fig. 4 D) show a positive skewness, their logarithms do not differ significantly from normal distribution.

The distribution of ages (Fig. 4 C) do not differ significantly from normal distribution (skewness and excess were examined).

95% of the observed volume doubling times lies between 65 and 627 days. Beyond these limits lie the 4 cases No. 8 and No. 55 with 62 und 44 days as well as No. 40 and 95 with 693 and 675 days. The cases No. 41 and 46 with extreme slow growing tumours (T_v = 1869 and 1092 days) were not considered.

Since the volume doubling time has a log-normal distribution the geometrical mean was calculated, because taking the arithmetical mean, the relatively small number of cases with slowly growing tumours would contribute too much. After retransformation the geometric mean is 202 days. Its 95% confidence limits are 179 and 227 days.

Tab. II. Basic data of 100 mammary-carcinomas at diagnosis: age at diagnosis, turnour size volume doubling time Tv: (geometric mean), stage (TNM), histological findings in axillary limph nodes.

case No	age in years at diagnosis	diameter mm	volume cm³	doubling time, Tv: days (geometr. mean)	stage (TNM)	axill. lymphnodes Met
1	53	34	20.508	169	2	—
2	54	20	4.147	200	1	
3	56	13	1.048	284	1	+
4	52	34	21.020	66	2	+
5	65	18	2.875	90	1	
6	44	25	8.454	87	2	+
7	48	32	17.538	104	2	+
8	58	29	12.299	62	2	?
9	61	14	1.539	106	1	?
10	58	18	2.969	88	1	
11	50	24	6.912	166	2	?
12	46	7	.205	119	1	+
13	77	13	1.123	297	1	—
14	65	12	.980	265	1	
15	47	14	1.290	129	1	
16	47	16	2.279	217	1	+
17	68	22	5.253	114	2	—
18	43	13	1.239	107	1	+
19	68	18	3.204	120	1	
20	50	15	1.869	180	1	—
21	66	28	11.817	164	2	+
22	64	15	1.696	172	1	
23	48	10	.565	180	1	?
24	52	10	.467	185	1	
25	42	19	3.854	249	1	—
26	79	6	.110	359	1	
27	54	12	.980	293	1	?
28	55	15	1.736	270	1	—
29	54	28	11.817	237	2	+
30	60	20	4.147	564	1	—
31	48	3	.019	252	1	+
32	61	9	.377	188	1	+
33	46	6	.110	426	1	—
34	69	23	6.624	521	2	+
35	69	35	22.981	262	2	+
36	67	13	1.123	377	1	+
37	60	22	5.529	504	2	+
38	33	12	.968	463	1	+
39	70	20	4.398	411	2	
40	51	51	70.284	693	3	-
41	55	20	4.377	1869	2	
42	40	26	9.529	270	2	—
43	66	18	2.875	277	1	+
44	49	26	8.836	277	2	+
45	68	60	114.040	272	3	
46	43	30	13.651	1092	2	+
47	46	13	1.225	383	1	—
48	43	9	.424	305	1	+
49	45	39	31.611	261	2	?
50	46	25	8.063	293	2	
51	63	24	7.540	235	2	+
52	76	22	5.564	357	2	?
53	44	18	3.204	277	1	+
54	65	27	10.249	82	2	+
55	41	31	16.069	44	2	—
56	63	6	.110	102	1	—
57	55	50	66.235	83	3	—
58	46	15	1.838	151	1	—
59	52	13	1.225	150	1	—
60	43	16	2.069	105	1	—
61	64	9	.377	96	1	—
62	51	60	114.040	178	3	+
63	46	12	.980	102	1	—
64	47	20	4.377	126	2	—
65	77	27	9.896	147	2	—
66	45	40	33.929	157	2	—
67	55	17	2.403	144	1	—
68	49	21	5.184	67	2	—
69	45	50	63.827	97	2	+
70	66	15	1.869	83	1	+
71	64	11	.691	108	1	+
72	40	41	36.838	196	2	—
73	70	13	1.239	239	1	—
74	51	26	9.189	197	2	—
75	50	5	.079	209	1	—
76	54	6	.132	322	1	—
77	62	9	.424	87	1	—
78	47	11	.760	153	1	+
79	57	28	11.479	299	2	—
80	61	11	.622	308	1	—
81	51	44	43.354	187	2	—
82	63	12	.980	204	1	—
83	47	11	.760	142	1	—
84	62	12	.898	232	1	+
85	65	8	.302	145	1	—
86	52	10	.576	239	1	—
87	72	19	3.760	190	1	—
88	56	12	.824	254	1	—
89	63	19	3.552	350	1	+
90	43	11	.691	522	1	—
91	47	17	2.413	284	1	—
92	48	8	.264	345	1	—
93	58	22	5.529	236	2	+
94	70	28	11.905	409	2	—
95	22	50	64.507	675	2	—
96	44	10	.576	561	1	—
97	71	23	6.359	297	2	—
98	68	6	.110	326	1	—
99	67	15	1.847	358	1	—
100	43	16	2.111	251	1	—

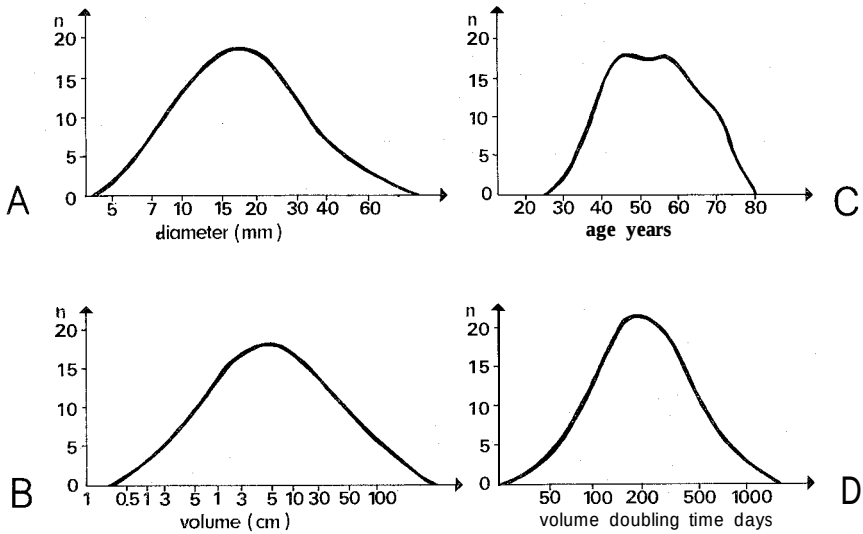

Fig. 4. Frequency distribution in: (A) tumour diameter, (B) tumour volume, (C) age of patient, (D) volume doubling time.

Tab. III. **Rapid, moderate and slow growing tumours.**

Speed of growth		*Frequency*	
		No.:	*%*
very rapid:	TV 5 100 days	13	13%
rapid:	TV 5 150 days	30	30%
moderate:	TV 150-300 days	46	46%
slow:	TV > 300 days	24	24%
		100	100%

Discussion of 12 cases with 5 and more mammographies per case

Fig. 5 contains these 12 cases. All cases show exponential growth in this relatively short phase of growth. The solid straight corresponds to the estimator

$$I', = a + bx_i$$

The deviation parallel to the ordinates of the observed volumen y_i (=points) from the estimated value y_i corresponds with the previous mentioned residuals e_i. The fitness of the observation y_i and the estimation y_i is the previous mentioned r^2, - it is good in all cases, except case No. 13, 25 and 28.

Growth rate and thermographic findings:

In 32 carcinoma cases the more conspicious then were shown by thermography the shorter their volume doubling time (Table IV). The 8 pathological thermographic signs occured more frequently the faster the growth rate of individual tumours, see Table V.

The left « column » shows rapid growing tumours with a relative frequent occurrence of pathological signs in thermography.

The right « column » shows the slower growing tumours, where thermographic signs were not so frequent.

The fast growing tumours with doubling times of less than 150 days were « suspicious » in 70% (7/10), « in need of control » in 10% (1/10) and G unsuspicious >> in 20% (2/10), (Table IV).

The medium-fast and slow growing tumours together were << suspicious >> in only 41% (9/22), « need of control » in 27% (6/22) and « unsuspicious » in 32% (7/22).

These differences, however, were not significant statistically.

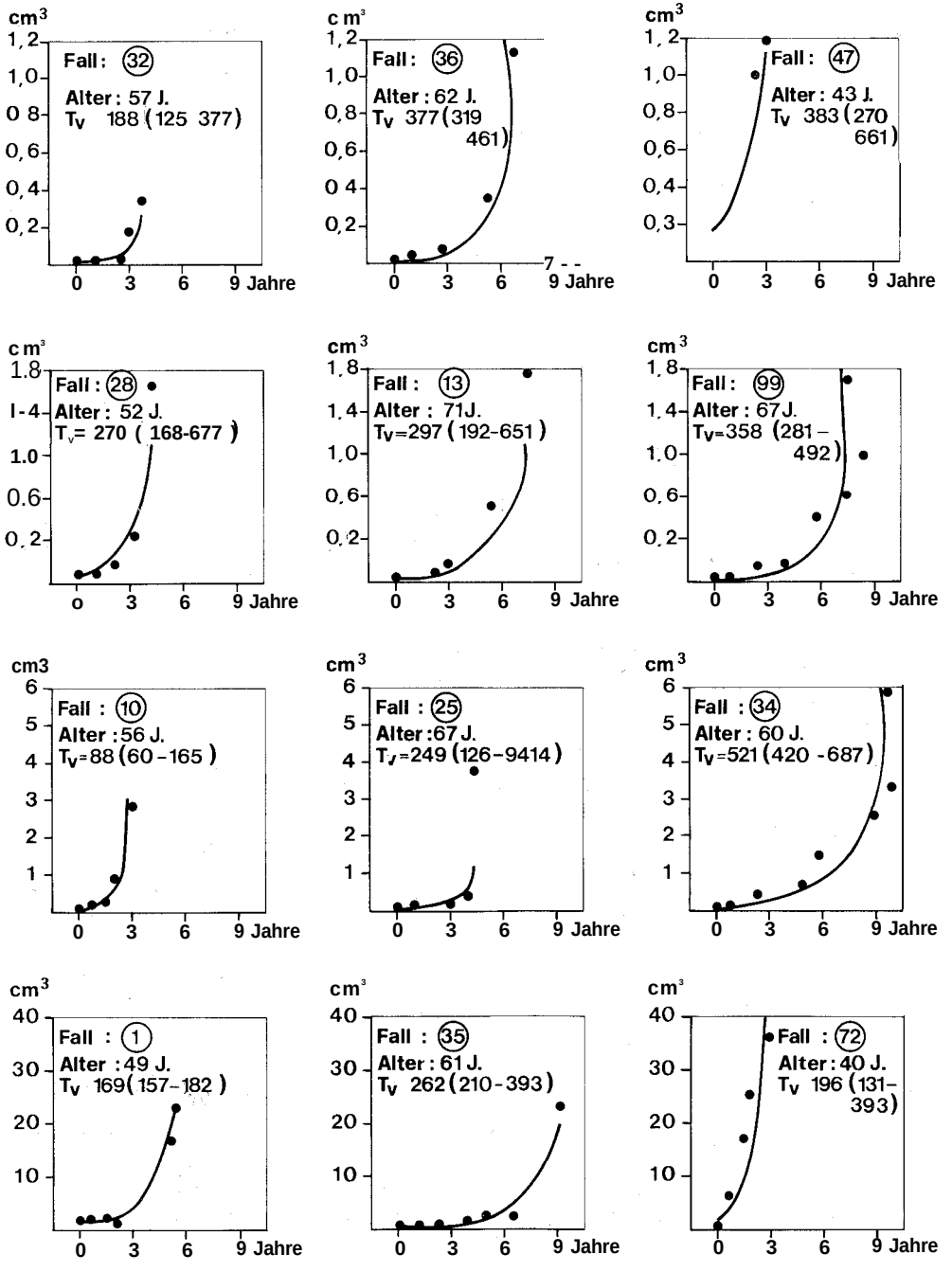

Fig. 5. Growth curves in 12 cases with 5 and more mammographies per case.

Tab. IV. **Thermographic diagnosis depending on growth rate; 32 cases of mammary carcinomas.**

Growth rate *Volume doubling time* *Tv per days*	*Thermographic diagnoses*		
	suspicious	*need of control*	*unsuspicious*
rapid growth: T_v < 150 days N = 10	7 = 70%	1 = 10%	2 = 20%
medium/slow growth: T_v more than > 150 days N = 22	9 = 41%	6 = 27%	7 = 32%

Tab. V. **Pathological and thermographic signs and speed of growth in 32 cases of mammary carcinomas.**

Pathological signs	*N = 10 rapid growth Tv < 150 days*	N = 22 *slow and* moderate *growth Tv > 150 days*
1. « hot spot » dt > 0,8 °C	90%	68%
2. correspondence: clinics-roentgenography - thermography	70%	41%
3. « hot spot » dt > 1,5 °C	70%	50%
4. type C	60%	45%
5. difference in type A-E	60%	45%
6. dt > 0,8 °C total breast hyperthermia	50%	27%
7. hypervascularization	80%	45%
8. edge sign	50%	27%

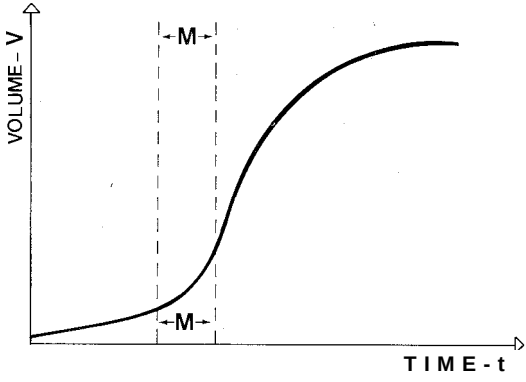

Fig. 6. Gompertz-function, a model for describing tumour growth

$$V = k_0 \times \exp. \left[\frac{k_1}{k_2} \times \left(1 - \exp. \left(- k_2 t \right) \right) \right]$$

k_0 = size at beginning
k_1 = « accelerating factor »
k_2 = « inhibiting factor »
M = time interval in which tumour measurements in mammographies were performed

Growth rate and lymph node metastases

In 32 cases the rate of axillary lymph node metastases was higher on average, the faster the tumor grew. This, however, was not significant statistically due to the small number of cases.

DISCUSSION

The construction of an average growth curve:

Geometrical approximation of all individual curves results in a curve which follows a special exponential function which corresponds to a « power-function ». This means that in semilogarithmic presentation (Fig. 3) the speed of further growth decreases with increasing age and size of tumours. On the other hand the biometrical evaluation of 12 cases with 5 and more mammographies per case demonstrates that all (within the relatively short phase of

growth we observed), show exponential growth. This short phase of observed growth also gives too little information for estimating the parameters of the « Gompertz » - function (a frequently used model for describing tumour growth Fig. 6).

The observed doubling time showed a positive log-normal distribution with a range between 44 and 1869 days. The geometric mean of the volume doubling time is 202 days. Its 95% - confidence limits are 179 and 227 days. The variability of observed doubling times within one tumor may be significant (see case No.: 33), the 12 cases with 4 and more doubling times per case, however, showed exponential growth when observation time was long enough.

Discouting failures in measurement, a certain selection of slower growing tumours during increased observation times cannot be excluded.

These results correspond with observations of Gershon-Cohen (1963) who found doubling times varying between 23 and 209 days in 18 cases.

A log-normal distribution of frequency in the doubling times was described by Kusama (1972) and Spratt (1977). Kusama found that the doubling times observed in patients under 30 years of age were shorter than those observed in patients older than 60 years. We - as well as Philippe and Le Gall (1968) and Kusama (1972) -- could only assume a connection between doubling time and rate of metastasizing into the axillary nodes but not maintained definitely.

In 12 cases with 4 or more individual doubling times the growth curves corresponded with exponential functions.

Where the average curve of growth was gained by geometrical approximation (see Figs. l-3) this corresponded to a power-function as theoretically discussed by Archambeau (1970).

Possibly this average growth curve also corresponds to a Gompertz-function, a fact, that can be established as << mathematically reliable » only when the growth of tumours will be observed in cases where the weight is considerable.

At the present time only speculation can be made with regard to the behaviour of tumour growth or even the cause of its behaviour. It seems that the effective growth of breast cancer is the net result of the predisposing cell dividing rate and also of growth inhibiting factors. The importance of these factors will probably increase the bigger the tumour becomes.

1. There may be an immunological destruction of the cells on the tumour surface.
2. It can be suggested that the bigger a tumor becomes, the more the cells are destroyed by increasing hypoxia.

Few observations are to be found in literature with regard to growth rate of mammary cancer and thermographic parameters. We showed that shorter doubling times took place more often when thermographic pathological signs were observed. Rapidly growing tumours were more often thermographically suspicious (70%) than average or even slowly growing tumours (41%). Conforming with our observation Amalric and Spitalier (1977) and Gros (1977) proposed that prognosis will be worse as the frequency of thermographic pathological signs increas. We also arrived at this result with very rapidly growing tumours with doubling times of less than 100 days in 13% (13/100) of our observed patients. These results again confirmed the observations of Spitalier (1977) who - on the basis of clinical and thermographical parameters - gave a very bad prognosis in 11% of cases.

The growth speed of metastases in mammary cancer is on average more rapid than that of the primary tumour (Kusama, 1972, Philippe and Le Gall, 1968, Lee, 1972, Spratt, 1977), especially when the epithelial surface is interrupted (Cutler, 1970).

As proof for the growth speed we examined the new thoracic wall metastases in cases with positive axillary lymph nodes (bad prognosis!), i.e. in cases where no irradiation of the thoratic wall had been performed, with the following results (N = 510): After 1 year: 4,7%, after 3 years: 8,5%, after 5 years: 14,7% thoracic wall metastases.

Practical problems should include:

1. The rate of very fast growing breast cancers with doubling times of less than 100 days (13%), the geometric mean of all observed doubling times being 202 days.
2. When (theoretically), more than 16 years

pass before a first tumour cell of 10, grows to a 10 mm tumour (30 doubling times). The time span then between a tumour size of 2 mm and a size of 10 mm is about 4 years on the average (7 doubling times).

Therefore the time interval between two mammographies in screening should be 1,5 years, when the x-ray is easily interpreted.

3. Therapeutic results should only be judged after 10 years when primary spread tumour cells even in a slowly growing tumour have had enough time to grow to a detectable size.
4. The more pathological signs shown by thermography the faster the speed of the growth will be.

Thus pathological findings in thermography are related to prognosis and therapeutical judgements.

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http://infraredbreasthealth.com/researchabstracts.htm.html

http://www.breastthermography.com/infrared_imaging_review.htm

http://www.iact-org.org/patients/breastthermography/what-is-breast-therm.html

Assess Risk for Breast Cancer with Estronex!

Source: http://www.estronex.com/

Metametrix is proud to support **Breast Cancer Awareness** month and participate in helping to identify risks associated with this epidemic cancer as well as other estrogen-sensitive cancers using the Estronex Profile.

According to the American Cancer Society, an estimated 207,090 new cases of invasive breast cancer are expected to occur among women in the United States during 2010. The Estronex Profile can help reduce your risk of becoming a statistic by measuring six key estrogen metabolites, including "good" and "bad" estrogens. The ratio of these "good to bad estrogens" is determined from a single urine specimen.

Did you know?

According to the CDC, breast cancer is the second most common cause of death in women. This year, an estimated 192,370 new cases of invasive breast cancer are expected to occur in women. Men need to be vigilant, too, as 1,910 new cases will occur in men.

With the Estronex Profile, you can determine if you have signs of long-term risk of estrogen-sensitive cancers, whether breast, uterine, cervical, or prostate.

Assess your risk

The Estronex Profile measures important estrogen metabolites with *one simple urine collection*. How your body metabolizes and eliminates certain estrogens plays an important role in determining risk levels.

Learn more about estrogens and the risk ratio.

Change your ratio

Studies have shown that the 2:16 (good to bad estrogen) ratio, which helps determine risk, is modifiable!

Estronex Profile - Urine

Assess Risk for Estrogen Sensitive Cancers

The Estronex Profile measures six important estrogen metabolites and their ratios to help women, and even men, assess whether he or she is at risk of developing estrogen sensitive cancers.

Estrogen sensitive cancers include uterine, ovarian, cervical, prostate, and even head and neck cancers. According to the American Cancer Society, an estimated 192,370 new cases of invasive breast cancer are expected to occur among women in the US during 2009; about 1,910 new cases are expected in men. Avoid chances of becoming a statistic and assess estrogen levels and decrease risk with the Estronex Profile.

The Estronex Profile measures six important estrogen metabolites, and ratios, including:

The "Good" Estrogen

- **2-hydroxyestrone (2-OHE1)** - high levels of 2-OHE1 are ideal to reduce cancer growth.
- **2-hydroxyestradiol (2-OHE2)** - shown to exhibit anti-carcinogenic effects.
- **2-methoxyestrone (2-OMeE1)** - OMeE1 has shown to have anticancer effects and is ideal in high levels.
- **4-methoxyestrone (4-OMeE1)** - as a non-cancerous metabolite, OMeE1 generally does not require treatment at high levels in the body.

The "Bad" Estrogen

- **4-hydroxyestrone (4-OHE1)** - considered a "bad" estrogen, 4-OHE1 levels should be low, as high levels may react negatively with damaged DNA.
- **16-α-hydroxyestrone (16α-OHE1)** - also considered a "bad" estrogen, 16α-OHE1 in high levels may encourage tumor development.

The Ratios

- **2-OHE:16α-OHE1 (2:16 ratio)** - 2:16 ratios less than 2.0 indicate increasing long-term risk for breast, cervical, and other estrogen sensitive cancers. Importantly, nutritional interventions can help raise Estronex 2:16 ratios and decrease long-term risk. Studies also indicate that this risk is modifiable!
- **2-OHE1:2-OMeE1** - a high level of 2-OHE1:2-OMeE1 may also indicate imbalanced estrogen metabolism and low activity in the COMT gene. Evaluation of methylation activity is recommended.

Advantages of the Estronex Profile:

- An easy-to-collect first-morning urine specimen; no blood draw is necessary!
- Cost-effective method to assess estrogen metabolism allowing clinicians to retest often to monitor therapy in patients.
- Easy to incorporate into a breast cancer prevention program.
- Ideal for men to evaluate risk of breast and prostate cancer.

Additional Profiles to Consider:

- Bone Resorption Assay - add to the Estronex Profile at a small incremental cost to assess osteoporosis risk.
- Women's Health Profile - helps assess risk factors associated with genetics, biochemical imbalances, and environmental influences for women of all ages.
- Organix Dysbiosis Profile - assess dysbiosis levels affecting estrogen in the body.
- Allergix Food Antibody Profile - assesses food allergies to identify if bad bacteria is forming in the gut deconjugating estrogen in a woman's body.
- Fatty Acids Profile - evaluate levels of anti-inflammatory fatty acids to help further assess risk.

For more information, visit www.estronex.com

Source: http://www.sciencedaily.com/releases/2012/10/121001191539.htm

A Simple Blood Test Could Be Used to Detect Breast Cancer; New Clinical Study Launched

Oct. 2, 2012 — A simple blood test could one day be a more accurate way to test for the early signs of breast cancer than using mammograms to spot a lump, say researchers today (Tuesday), as Breast Cancer Awareness Month gets underway.

They also hope the blood test could improve treatment by detecting whether breast cancer patients are likely to relapse and what drugs their particular type of tumour will respond to.

This pioneering new clinical study -- funded by Cancer Research UK in collaboration with the University of Leicester and Imperial College London -- is about to start in the UK's largest breast screening clinic at Charing Cross Hospital, London.

Researchers will take blood samples from women attending the breast screening clinic and compare the DNA in the blood of women who are diagnosed with breast cancer with those that do not have cancer to see what DNA markers are consistent.

Dr Jacqui Shaw, principal investigator from the University of Leicester, said: "This exciting research means we could one day have a blood test that detects the very early signs of cancer meaning women could have an annual blood test rather than breast screening. This would remove any worry and anxiety for women who are called for further investigations after a mammogram only to find they don't have cancer.

"As things stand we aren't able to monitor breast cancer patients after they've had surgery and treatment -- which is like treating diabetes but not measuring blood sugar levels. The new blood test could change that."

Professor Charles Coombes, co-investigator and Cancer Research UK's breast cancer expert from Imperial College, said: "This type of translational science is extremely promising and the international scientific community is collaborating on its development. When a woman has breast cancer we can tell by the DNA in their blood. But what we're trying to find out in our study is how early the signs of breast cancer show up in a blood test. So by looking at blood samples of women who have breast cancer diagnosed through screening we can see if the cancer is already showing in their blood.

"Our research team is only looking at breast cancer but there are a number of other projects that are looking at using a blood test to detect other cancers such as bowel and lung."

Kate Law, director of clinical research at Cancer Research UK, said: "We really do hope that in the not too distant future a simple blood test for breast cancer, which could not only detect cancer but help with treatment options, will become standard practice on the NHS.

"Cancer Research UK has invested over a million pounds into this project as this fascinating area of science could prove to be a huge step forward in the way certain types of cancer are diagnosed and treated."

Story Source:

Karmanos Researchers Successfully Freeze, Eradicate Breast Cancer Cells Using Cryotherapy

Wednesday, March 17, 2010

Link: http://www.karmanos.org/News/cryotherapy-breast-cancer

Peter J. Littrup, M.D.
Vice-Chair for Radiology Research, Director of Interventional Radiology at the Barbara Ann Karmanos Cancer Institute
Professor of Radiology, Urology and Radiation Oncology, Wayne State University School of Medicine.

A team of doctors from the Barbara Ann Karmanos Cancer Institute and Wayne State University's School of Medicine recently presented research findings that hold the promise of a potential new treatment method for breast cancer patients.

The study is entitled, "Cryotherapy for a Spectrum of Breast Cancer: US and CT-guidance," and was presented at the Society of Interventional Radiology's 35th Annual Scientific Meeting in Tampa, Fla. It details how researchers successfully froze breast cancer in patients who refused surgery. The women also did not need surgery to ensure the tumors were destroyed.

"Minimally-invasive cryotherapy opens the door for a potential new treatment for breast cancer and needs to be further tested," said Peter J. Littrup, M.D., vice chair for Radiology Research, director of Interventional Radiology at the Barbara Ann Karmanos Cancer Institute and professor of Radiology, Urology and Radiation Oncology at Wayne State. "When used for local control and/or potential cure of breast cancer, it provided safe and effective breast conservation with minimal discomfort for a group of women who refused invasive surgery or had a local recurrence and needed additional management.

"This is the first reported study of successfully freezing breast cancer without having to undergo surgery afterward to prove that it was completely treated."

In the 13-patient study, researchers used several needle-like cryoprobes that were evenly spaced and inserted through the skin to deliver extremely cold gas directly to the tumor to freeze it. This technique has been used for many years by surgeons in the operating room.

In the last few years, however, the needles have become small enough to be used by interventional radiologists through a small nick in the skin, without the need for an operation. The “ice ball” that is created around the needle grows in size and destroys the frozen tumor cells.

Biopsies were done at the margins of the cryotherapy site immediately after the procedure. Follow-up inspections at those cryotherapy sites showed no cancer present. No localized treatment recurrences were seen for up to five years in the study; no significant complications were noted; and women were pleased with the cosmetic outcomes, noted Dr. Littrup.

Major benefits of cryotherapy are its superb visualization of the ice treatment zone during the procedure, its low pain profile in an outpatient setting and its excellent healing with minimal scar, according to Dr. Littrup. Breast imaging has significantly advanced by accurate improvements in breast magnetic resonance imaging (MRI), allowing for excellent treatment planning of tumor size and extent within the breast, as well as showing zones of destruction thoroughly covering the tumor after cryotherapy.

This potential treatment method holds widespread promise for the nearly 200,000 women who are diagnosed with breast cancer annually in the United States. For these women, as well as the thousands of men diagnosed each year, breast cancer treatments can be highly effective but often require invasive treatment options such as surgery and chemotherapy.

Surgery offers the best chance for a cure. Until long-term data is available, interventional treatments -- such as cryotherapy, thermal ablation and laser therapy -- are reserved for women who cannot have -- or have refused surgery.

Cryotechnology promises to be more MR-compatible, Dr. Littrup said, and would also allow accurate targeting of more difficult-to-see breast tumors. More importantly, larger studies in multiple centers needs to be done, following these basic cryobiology principles of sufficient lethal temperatures generated by multiple cryoprobes spaced evenly throughout a breast cancer region.

“With recent developments of powerful new cryotechnology, multiple directions for breast cryotherapy can be pursued, including translating the current, somewhat challenging, procedure done with ultrasound and/or CT guidance to a more consistent and reproducible MR-guided approach,” said Dr. Littrup.

The study was authored by Dr. Littrup, M.D.; Monica D’Agostini, an undergraduate student who volunteered with the Department of Radiology at Karmanos Cancer Institute; Barbara Adam, cryotherapy staff nurse at Karmanos Cancer Institute; and David Bouwman, M.D., emeritus director of Karmanos’ Alexander J. Walt Breast Center and professor of surgery at Wayne State University School of Medicine; along with Bassel Jallad, M.D., and Priti Chandiwala-Mody, D.O., residents at Wayne State University’s School of Medicine.

Cryoablation or Breast Cryosurgery on the horizon for Breast Cancer Treatment

Link: http://www.karmanos.org/cancer-care/information/treatment-options/Cryoablation

Cryoablation

Cryoablation, also referred to as cryotherapy, is a minimally invasive procedure that uses extremely cold temperatures to destroy diseased tissue. In certain clinical situations, it can be preferred over other techniques and has a faster recovery time.

What is Cryotherapy?

Cryotherapy, also called cryosurgery, cryoablation or targeted cryoablation therapy, refers to the application of extreme cold to destroy diseased tissue, including cancer cells. Cryotherapy can be used to destroy skin tumors, precancerous skin moles, nodules, skin tags or unsightly freckles.

With the improvement of imaging techniques and the development of devices to better control extreme temperatures, Karmanos Cancer Center physicians use cryotherapy as a treatment for patients with the following conditions:

- Prostate cancer
- Liver tumors (usually spread from other organs)
- Cervical cancer
- Benign & malignant breast tumors (cryotherapy to treat malignant breast tumors is still considered experimental)

How does it work?

For external masses, liquid nitrogen is applied directly with a cotton swab or spray device. For internal tumors, cryotherapy is carried out by using a cryoprobe, a thin wand-like device with a handle or trigger or a series of small needles, attached via tubing to a source of nitrogen or argon, which super-cools the probe tip.

The cryoprobe is placed in the proper position using imaging guidance, and as internal tissue is being frozen, the physician avoids damaging healthy tissue by viewing the movement of the probe on ultrasound, computed tomography (CT) or magnetic resonance (MRI) images transmitted to a monitor similar to a television screen.

Once the cells are destroyed, components of the immune system clear out the dead tissue. Patients undergoing cryosurgery usually experience minor-to-moderate localized pain and

redness, which can be alleviated by aspirin or ibuprofen and application of topical steroid cream. Blisters may form, but these usually scab over and peel away.

What are the benefits vs. risks?

Cryosurgery is a minimally invasive procedure, and can be preferred to more traditional kinds of surgery because of its minimal pain, scarring, and cost; however, as with any medical treatment, there are risks involved, primarily that of damage to nearby healthy tissue and the potential for not freezing the entire tumor. Damage to nerve tissue is of particular concern.

Karmanos Cryotherapy Specialists

Peter Littrup, M.D.

Michael Cher, M.D. (prostate)

Karmanos Cancer Center
4100 John R
Detroit, MI 48201

Life-saving blood test ’spots breast cancer early’ and saves hundreds of lives

Submitted by Drew Kaplan on April 6, 2010

A simple blood test that can detect early signs of breast cancer in women could save the lives of hundreds of patients a year, scientists believe.
The test can spot tumours much earlier than traditional scans – meaning action can be taken to stop the cancer before it spreads.
The test – which is already available privately – could be in regular use on the Health Service within five years. The test can pick up a cancer the size of a small seed before a woman has developed any symptoms.

The blood test can spot tumours much earlier than traditional scans
Normal screening checks using X-rays detect a tumour only once it is three of four times bigger, by which time it may have started to spread beyond the breast.
More than 45,000 people are diagnosed with breast cancer in the UK every year.

The test, developed by Norwegian company Diagenic ASA, indicates a tumour is present by looking for raised levels of chemical ‘ markers’ for cancer in blood.
It has been proven to be 75 per cent effective at detecting early cancer in a number of small trials published in the journal Breast Cancer Research.
In younger women, mammography can miss a quarter of cases, and its developers hope the blood test can pick up some of these.
The Diagenic BCtect test is being evaluated by the National Institute for Health and Clinical Excellence, and a trial involving 6,000 women at high risk of developing breast cancer is to start next year.
It is currently available at a private Harley Street clinic for £499. Dr James Mackay, an oncologist and researcher at University College London, said: ‘This test will be particularly useful for younger women who are at risk of developing breast cancer.
‘They tend to have denser breast material which mammograms cannot easily penetrate.
‘What we are suggesting is that they have a mammogram and combine it with this test so that there is a greater chance of detection.’
Women who are found to have cancer by the test will be offered an MRI scan so the tumour can be located, biopsied and, if necessary, removed.
Experts say there have not been enough trials to be sure the test works as well as its makers believe.
But if bigger trials are successful and the test is adopted by the NHS, it would be carried out every three years – the same period as for mammograms at the moment.
Dr Mackay said he would advise women at high risk of breast cancer to have the test, which is available at the London Breast Clinic, once a year.
Professor Kefah Mokbel, a consultant breast surgeon at London’s St George’s Hospital, said: ‘We need more trials before this can be taken on by the NHS but it is an interesting development.
‘The results so far are interesting and it would be an extremely useful advance which could be combined with a mammogram to find tumours at an early stage.’

Dr Fiona MacNeil, a breast surgeon at London's Marsden Hospital, said: 'The initial research studies show some promise but the usefulness of the test needs to be established by more detailed trials.'

http://www.dailymail.co.uk/health/article-1263614/Life-saving-blood-test-spots-breast-cancer-early-saves-hundreds-lives.html

Policy on Genetic Testing for Breast Cancer Susceptibility

Breast Cancer Action (BCA) is a nonprofit grassroots organization of people who are willing to take the actions necessary to end the breast cancer epidemic, as well as people who have been diagnosed with breast cancer and their supporters. Our mission is to serve as a catalyst for the prevention and cure of breast cancer by working toward three major goals:

1. To make breast cancer a national priority through education and advocacy.
2. To promote and refocus research into the causes, treatment, cure, and prevention of breast cancer.
3. To empower both women and men so they can participate fully in decisions relating to breast cancer.

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The discovery in 1994 of a breast-ovarian cancer susceptibility gene, known as BRCA1[1], led quickly to the development of tests for the presence of gene alterations potentially associated with breast cancer. At the same time, additional discoveries related to BRCA1, such as the discovery that a mutation known as 185delAG may be present in 1 percent of Jews of Ashkenazi descent, led to calls for large, population-based screening studies related to the gene.[2]

The existence of and pressure for genetic tests, and the likelihood that they will be commercially available for clinical use in the very near future,[3] raises critical issues for people affected by breast cancer, their families, and society at large. In an informal survey that BCA conducted of its members at the close of 1995, 206 (67.1 percent) of 307 respondents indicated that they would undergo genetic testing if it were available. Of the total respondents, well over 50 percent believed that multiple issues, including insurance coverage for the cost of the tests,[4] effective options to prevent the development of the disease,[5] availability of counseling for those taking the test,[6] confidentiality of test results,[7] and availability of insurance coverage for those found to have a genetic alteration,[8] needed to be resolved before testing became generally available. Those considering being tested for BRCA1 (or any other breast cancer genes) are entitled to be fully informed about the implications of the tests before they agree to undergo them.

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Medical Issues

The BRCA1 gene is present in everyone. When it functions normally, it is thought to suppress the growth of cancerous cells in the breast.[9] However, certain alterations or mutations of the gene may create an increased susceptibility for breast and/or ovarian cancer. As of January 1996, more than 100 mutations of the BRCA1 gene had been identified by researchers.[10] The implications of these discoveries are not yet known: Do they increase the risk of breast cancer, or are they simply associated with an increased risk? Are some of these mutations unrelated to increased risk

of breast cancer? Equally important, it is not known whether all breast cancers are related in some way to BRCA1.[11] Also unknown is whether and to what extent the genetic mutations that have been identified as associated with breast cancer are inherited, as distinct from resulting from environmental or developmental factors.

Most commercial enterprises that currently market genetic tests do so without gaining clearance from the Food and Drug Administration.[12] Those contemplating being tested for BRCA1 mutations must be told whether the test to be used has been approved by the FDA, and that without such approval, there is no assurance that the laboratory tests will be performed properly.

Women (and men) contemplating genetic testing are entitled to know other important uncertainties associated with the test results. They are entitled to know that a positive test result does not mean that they will get breast cancer, and that a negative test does not mean that they will not develop the disease. A woman with no BRCA1 mutations still faces a 1 in 8 chance of developing breast cancer in her lifetime.

There is currently no known effective method for preventing breast cancer, even in those known to have a genetic mutation that predisposes them to developing the disease. Prophylactic mastectomy does not prevent breast cancer, since breast tissue remains even after this drastic surgery.

Nor is there any clearly appropriate medical care for people known to have a genetic predisposition to breast cancer. Women with a BRCA1 mutation associated with an increased risk for breast cancer are more likely to develop the disease at an early age, but regular mammography has not been shown to be effective in reducing breast cancer mortality in women under 50.[13] There are no effective means for truly early detection of breast cancer, and the availability of genetic testing serves only to highlight the need for more research in this area.

People contemplating genetic testing must be informed of these facts before they agree to be tested.

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Psychological Impacts

Little research exists on the psychological impact of being told that your genetic makeup renders you susceptible to a life-threatening illness. The knowledge that you carry a gene that may predispose you (and your children) to cancer cannot be given back, and may have devastating emotional consequences. Those contemplating genetic testing for breast cancer, the most common cancer in women, must have access to education and counseling that will help them evaluate and cope with the impact of the test and its results. Testing conducted without access to adequate education and counseling, both before and after the test, should not be permitted.

Genetic testing has implications not only for the person being tested, but also for that person's relatives, including children of all ages. These implications must be fully explained to and

explored with anyone contemplating testing before a test is conducted, and the affected relatives must have an opportunity to receive education and counseling as well.

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Insurance and Job Discrimination Issues

Genetic testing for a possible predisposition to breast cancer raises issues of confidentiality and insurance/employment discrimination. Anyone contemplating being tested for BRCA1 mutations must be fully informed about these issues before the test is administered.

While some states have laws that guarantee privacy protection of genetic information,[14] neither the federal government nor the vast majority of states provides such guarantees. Therefore, anyone contemplating having a genetic test done who wishes to know the outcome must be told whether and to what extent the information will be available to third parties.

Lack of confidentiality of test results raises the real possibility that a person who tests positive for a BRCA1 or other genetic mutation will be denied health, life, or disability insurance, or will be charged a higher premium for such insurance. Representatives of the health insurance industry have made it clear that they consider genetic susceptibility information to be a vital part of the underwriting process.[15] Without legislation that prevents discrimination based on genetic information,[16] anyone tested for a genetic predisposition to breast cancer must be informed that she or he may be denied or lose health insurance coverage, as well as life insurance and disability insurance coverage. Even in states where legislation prohibits discrimination by insurance companies based on genetic information, people whose insurance coverage derives from self-insured employers must be told that the state legislative protections in place may not apply to them.

Nonconfidential genetic testing also raises the possibility of discrimination in employment based on a positive test for a breast cancer susceptibility genetic mutation. While current law prohibits discrimination in employment based on a perceived disability,[17] that law does not apply to all employers, and has not been interpreted by any court as yet to prohibit discrimination based on susceptibility test results.[18]

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Summary

The array and number of unresolved issues related to genetic testing for susceptibility to breast cancer make compelling the need for written informed consent prior to such testing or to the release of the results of such testing to third parties. No one should be tested without access to education and counseling concerning all benefits and risks of genetic susceptibility testing, both before the test is administered and on an ongoing basis after the results are known. Legislative measures are needed to protect those who choose to be tested against discrimination by insurance companies and employers. Breast Cancer Action believes that all of these guarantees are

important to all who are considering being tested for genetic susceptibility to breast cancer, and that they must be in place before testing for breast cancer susceptibility genes takes place, whether in a research or clinical setting.[19]

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[1] Futreal PA, Liu Q, Shattuck-Eidens, D. et al. "A Strong candidate for the breast and ovarian cancer susceptibility gene BRCA1." *Science* 1994; 266:66-71.

[2] "BRCA1 — Lots of Mutations, Lots of Dilemmas," editorial, *New England Journal of Medicine*, Jan. 18, 1996, p. 188.

[3] See "BRCA1 Genetic Susceptibility for Breast and Ovarian Cancer: A Reference for Healthcare Professionals in Anticipation of BRCA1 Genetic Susceptibility Testing," Myriad Genetics Laboratories, Inc., January 1996.

[4] 183 respondents (62.5%).

[5] 214 respondents (69.7%).

[6] 209 respondents (67.8%)

[7] 216 respondents (70.4%)

[8] 249 respondents (81.1%)

[9] See "Breast Cancer Research Advance: Same Gene, Depending on Mutation, Can Fight or Cause Tumors," *San Francisco Chronicle*, March 1, 1996.

[10] "BRCA1 — Lots of Mutations, Lots of Dilemmas," editorial, *New England Journal of Medicine*, supra, p. 186.

[11] "BRCA1 — Lots of Mutations, Lots of Dilemmas," editorial, *New England Journal of Medicine*, supra, p. 187.

[12] "The Hazards of Genetic Testing," *Harvard Women's Health Watch*, January 1996.

[13] Women who carry a BRCA1 mutation may be advised to have frequent screening mammograms to facilitate "early detection." Women who carry both the BRCA1 mutation and a mutated ataxia-telangiectasia (ATM) gene, however, may increase their risk of developing breast cancer by having frequent mammograms. Ataxia-telangiectasia is a rare recessive genetic disorder whose victims usually die in their teens or early 20s. Women carriers of the ATM gene who do not have the disease have up to a fivefold increased risk of breast cancer, as compared to the "normal" population. Concerns have been raised that ATM gene carriers are more sensitive to radiation exposures and therefore at higher risk of radiation-induced cancer. ("Gene Found for Fatal Childhood Disease, Ataxia Telangiectasia," NIH News, June 22, 1995.) For women who

have a mutated BRCA1 gene and the ATM gene, frequent radiation in the form of mammograms may cause breast cancer rather than guarantee "early" diagnosis.

[14] See, e.g. California Health & Safety Code, § 1374.7; Colorado Title 10, Art. 3, Part II, § 10-3-1104.7; Florida, FL ST: 760.40.

[15] "BRCA1 Mutation Finding Draws Attention to Potential Perils of Genetic Testing," *The Cancer Letter*, Vol. 21, No. 38, October 6, 1995. At least one major health insurance company is already denying coverage to individuals who have a family history of breast cancer and "fibrocystic breast disease," a nonexistent "disease" that is actually a number of noncancerous (or precancerous) conditions that affects the vast majority of women at some point in their lives. Love, S., *Dr. Susan Love's Breast Book*, Chapter 6 (2d Edition, Addison-Wesley 1995.

[16] See, e.g. California Insurance Code, §§ 10123.3, 10140, 10148, 10149, 10149.1, 11512.95; Colorado Title 10, Art. 3, Part II, § 10-3-1104.7; Minnesota S.F. No. 259; New Hampshire NH ST: Chapter 141-H; Ohio OH ST: §§ 1742.42, 1742.43, 3901.49, 3901.491, 3901.50, 3901.501.

[17] Americans with Disabilities Act of 1990, 101 US Code §933.

[18] The Equal Employment Opportunity Commission has interpreted the ADA as making such discrimination unlawful, but the EEOC's interpretations do not have the force of law.

[19] Breast Cancer Action acknowledges the outstanding work of the Massachusetts Breast Cancer Coalition on the issues related to genetic testing for the BRCA1 gene, reflected in the coalition's position paper "What You Need to Know Before Considering Genetic Testing for Heritable Breast Cancer."

Saliva Test For Breast Cancer, Study

Main Category: Breast Cancer
Also Included In: Dentistry; Medical Devices / Diagnostics; Cancer / Oncology
Article Date: 11 Jan 2008 - 8:00 PDT

US scientists have found human saliva carries markers of breast cancer and have opened the door to the possibility that one day your doctor, or even your dentist, could do a simple saliva test for the disease.

The discovery is reported in a paper published in the 10th January issue of the journal *Cancer Investigation* and was the work of researchers at the The University of Texas Health Science Center at Houston.

The paper describes how the appearance of breast cancer changes the mix of proteins secreted by the salivary glands. A person with breast cancer secretes a different profile of proteins compared to a person without, claim the researchers.

Professor of diagnostic sciences at The University of Texas Health Science Center Dental Branch, Dr Charles Streckfus, who is an expert on human saliva and molecular epidemiology, led the study. When addressing the question of who could administer a saliva test for cancer, he said:

"Why not the dentist?"

"Most folks, especially women and children, visit the dental office way more often than they ever see the physician. Saliva is a non-invasive, quicker way for detection," explained Streckfus.

The researchers compared the saliva from three pooled samples, each taken from 10 patients. One sample was from patients who had benign breast tumours, another from patients who had malignant breast tumours (ductal carcinoma in situ, DCIS), and the third was a control sample from healthy patients with neither condition.

The researchers looked for differential expressions of proteins in the samples using isotope tagging. They compared the two tumour groups to the healthy control groups.

Streckfus and colleagues found about 130 proteins altogether. 49 of them were differently expressed between the healthy control pool and the two tumour pools.

They also found unique proteins for a benign type of tumour called fibroadenoma, the most common type of benign breast tumour. This is a unique finding, said Streckfus, "as it targets both the benign and malignant tumor, which could potentially reduce the number of false positives and false negatives associated with current cancer diagnostics".

Streckfus and colleagues concluded that:

"The study suggests that saliva is a fluid suffused with solubilized by-products of oncogenic expression and that these proteins may be modulated secondary to DCIS. Additionally, there may be salivary protein profiles that are unique to both DCIS and fibroadenoma tumors."

The research is now being applied to a technology called "lab on a chip", which basically opens up the possibility that one day, a dental practice or other health care facility, will be able to carry out a diagnostic test that detects the presence of cancer before the tumour forms.

President of the University of Texas (UT) Health Science Center at Houston, Dr James T. Willerson said:

"The unique collaborative opportunities at the UT Health Science Center at Houston, the University of Texas M.D. Anderson Cancer Center and the Texas Medical Center fostered this study and made these remarkable findings possible."

"A major strength of UT-Houston is putting together outstanding scientists in an environment of collaboration and cooperation," added Willerson, who also said how proud he was of this latest research by Streckfus and his team.

Co-researcher William P.Dubinsky said saliva could be the key to many medical secrets:

"Saliva is a complex mixture of proteins. We go through a process that compares different samples by chemically labeling them in such a way that we can not only identify the protein, but determine how much of it is in each sample," explained Dubinsky.

"This allows us to compare the levels of 150-200 different proteins in cancerous versus non-cancerous specimens to identify possible markers for disease," he added.

According to the Susan G. Komen for the Cure Foundation, an estimated 10 million women worldwide will die from breast cancer in the next 25 years if no cure is found, emphasizing the urgency and importance of early detection.

Screening for breast cancer currently involves use of ultrasound, mammograms, biopsies, and blood tests. The researchers in this study hope that one day that list will include salivary diagnostics.

Dean of the UT Dental Branch at Houston, Dr Catherine M. Flaitz said that:

"Dentistry has entered an exciting new era. On every front, our researchers are exploring links between oral health and the overall health of patients, often with astonishing findings. We're working to bring those discoveries out of the lab and into the real world of dentists' and physicians' offices."

"Breast Cancer Related Proteins Are Present in Saliva and Are Modulated Secondary to Ductal Carcinoma In Situ of the Breast."

Charles F. Streckfus; Otilia Mayorga-Wark; Daniel Arreola; Cynthia Edwards; Lenora Bigler; William P. Dubinsky.

DOI: 10.1080/07357900701783883
Cancer Investigation Published online on 10 January 2008.

Sources: journal abstract, University of Texas at Houston press release.

Written by: Catharine Paddock

The New England Journal of Medicine

Original Article

Effect of Screening Mammography on Breast-Cancer Mortality in Norway

Mette Kalager, M.D., Marvin Zelen, Ph.D., Frøydis Langmark, M.D., and Hans-Olov Adami, M.D., Ph.D.

N Engl J Med 2010; 363:1203-1210September 23, 2010

Background

A challenge in quantifying the effect of screening mammography on breast-cancer mortality is to provide valid comparison groups. The use of historical control subjects does not take into account chronologic trends associated with advances in breast-cancer awareness and treatment.

Methods

The Norwegian breast-cancer screening program was started in 1996 and expanded geographically during the subsequent 9 years. Women between the ages of 50 and 69 years were offered screening mammography every 2 years. We compared the incidence-based rates of death from breast cancer in four groups: two groups of women who from 1996 through 2005 were living in counties with screening (screening group) or without screening (nonscreening group); and two historical-comparison groups that from 1986 through 1995 mirrored the current groups.

Results

We analyzed data from 40,075 women with breast cancer. The rate of death was reduced by 7.2 deaths per 100,000 person-years in the screening group as compared with the historical screening group (rate ratio, 0.72; 95% confidence interval [CI], 0.63 to 0.81) and by 4.8 deaths per 100,000 person-years in the nonscreening group as compared with the historical nonscreening group (rate ratio, 0.82; 95% CI, 0.71 to 0.93; P<0.001 for

both comparisons), for a relative reduction in mortality of 10% in the screening group (P=0.13). Thus, the difference in the reduction in mortality between the current and historical groups that could be attributed to screening alone was 2.4 deaths per 100,000 person-years, or a third of the total reduction of 7.2 deaths.

Conclusions

The availability of screening mammography was associated with a reduction in the rate of death from breast cancer, but the screening itself accounted for only about a third of the total reduction. (Funded by the Cancer Registry of Norway and the Research Council of Norway.)

Source Information

From the Cancer Registry of Norway, Oslo (M.K., F.L., H.-O.A.); the Departments of Epidemiology (M.K., H.-O.A.) and Biostatistics (M.Z.), Harvard School of Public Health; and the Dana–Farber Cancer Institute and Harvard Medical School (M.Z., H.-O.A.) — all in Boston; and the Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm (H.-O.A.).

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Study finds mammograms offer modest benefit

Associated Press

By ALICIA CHANG, AP Science Writer Alicia Chang, Ap Science Writer –
2 hrs 35 mins ago

LOS ANGELES – Mammograms don't help women over 50 as much as has been believed, new research suggests.

Only a third of the reduced risk of death credited to breast cancer screening is actually deserved — the rest is due to better treatment and greater awareness of the disease, a large study in Norway found.

The research, published in Thursday's New England Journal of Medicine, is the latest to show that the benefits of mammography are limited.

"It's not the great lifesaver that people think it is. It's not a magic bullet," said Georgetown University researcher Dr. Jeanne Mandelblatt who was not involved in the study.

Mandelblatt headed six teams that helped shape the new mammogram guidelines issued last year by an influential government task force. The U.S. Preventive Services Task Force concluded that women at average risk for breast cancer don't need mammograms in their 40s and should get one just every two years starting at 50.

The World Health Organization estimates that mammograms reduce the breast cancer death rate by 25 percent in women over 50. Other groups put the figure at 15 to 23 percent.

The latest study found that while mammograms cut the risk of dying, the benefit was disappointingly low. Women who were screened had a 10 percent lower risk of death from breast cancer, but only a third of that reduction was due to screening itself.

Some 2,500 women would have to be regularly screened over 10 years to save one life from breast cancer, Dr. H. Gilbert Welch of Dartmouth Medical School noted in an accompanying editorial.

In the study, scientists were able to tease out the benefits of mammography by studying Norway's breast cancer screening program, which began as a pilot in 1996 and later expanded to the entire country. As part of the national screening program, teams of doctors were set up in every county to treat any breast cancer cases that did occur, whether they were found by mammograms or other ways.

Some 40,000 women with breast cancer were included in the study. Women ages 50 through 69 were offered screening every two years.

Researchers compared the breast cancer death rate in four groups: a screening group of women living in areas where mammograms were offered; a non-screening group in regions that did not have screening; and two comparison groups of women from the decade before the screening program began, from the same counties as the women in the other two groups.

This allowed researchers to separate the effects of mammography from other factors that may have an impact on survival such as improved treatment and increased awareness.

Among women in the screening group, the breast cancer death rate declined by 7.2 deaths per 100,000 people compared with women in the decade before the screening program started. The death rate in the non-screening group fell by 4.8 deaths per 100,000 people compared with its historical counterpart.

That means that mammography reduced mortality by only 2.4 deaths per 100,000 people — a third of the total risk of death.

A second part of the study bore this out: Women over 70, who weren't eligible for screening, had an 8 percent lower risk of dying from breast cancer compared to the previous decade, pointing to the benefit of better care.

The study was funded by the Cancer Registry of Norway and the Research Council of Norway. It was led by Dr. Mette Kalager of Oslo University Hospital with collaboration from Harvard University and the Dana-Farber Cancer Institute.

More than 1 million women worldwide are diagnosed with breast cancer each year and more than 500,000 die from it. In the United States last year, there were an estimated 194,280 new cases and 40,610 deaths from the disease.

The American Cancer Society has long advocated that women get annual breast cancer screenings starting at 40.

The small benefit of mammograms in the latest study may be because the women weren't followed long enough, suggested Otis Brawley, the cancer society's chief medical officer, in a statement.

"The total body of the science supports the fact that regular mammography is an important part of a woman's preventive health care," Brawley said. "Following the American Cancer Society's guidelines for the early detection of breast cancer improves the chances that breast cancer can be diagnosed at an early stage and treated successfully."

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Online:

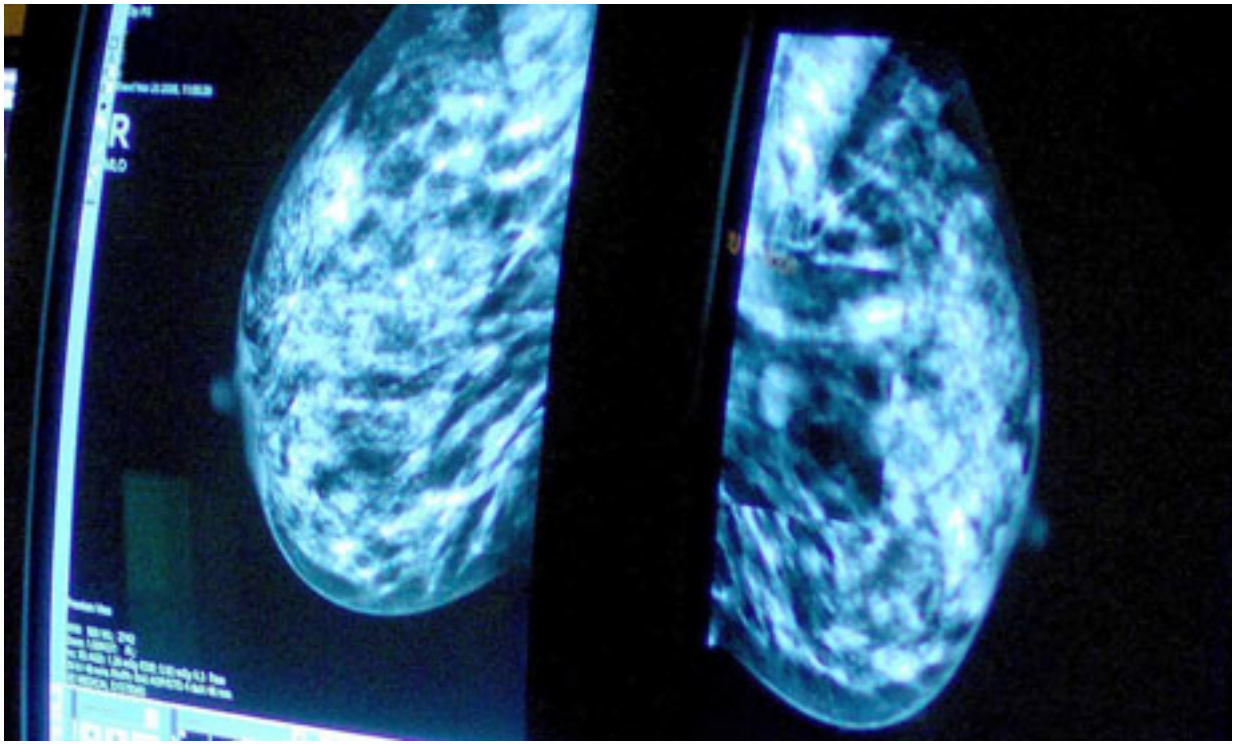
Journal: http://www.nejm.org

Breast cancer screening cannot be justified, says researcher

Book argues harm outweighs small number of lives saved, and accuses mammography supporters of misconduct

Sarah Boseley, health editor

The Guardian, Monday 23 January 2012



Women in the UK are called for breast screening every three years from the age of 50. Photograph: Rui Vieira/PA

Breast cancer screening can no longer be justified, because the harm to many women from needless diagnosis and damaging treatment outweighs the small number of lives saved, according to a book that accuses many in the scientific establishment of misconduct in their efforts to bury the evidence of critics and keep mammography alive.

Peter Gøtzsche, director of the independent Nordic Cochrane Collaboration, has spent more than 10 years investigating and analysing data from the trials of breast screening that were run, mostly in Sweden, before countries such as the UK introduced their national programmes.

Mammography screening: truth, lies and controversy, from Radcliffe Publishing, spells out the findings of the Nordic Cochrane group for laywomen, rather than for scientists.

The data, Gøtzsche has maintained for more than a decade, does not support mass screening as a preventive measure. Screening does not cut breast cancer deaths by 30%, it saves probably one life for every 2,000 women who go for a mammogram. But it harms 10 others. Cancerous cells that will go away again or never progress to disease in the woman's lifetime are excised with surgery and sometimes (six times in 10) she will lose a breast. Treatment with radiotherapy and drugs, as well as the surgery itself, all have a heavy mental and physical cost.

"I believe the time has come to realise that breast cancer screening programmes can no longer be justified," Gøtzsche said. "I recommend women to do nothing apart from attending a doctor if they notice anything themselves."

The book is published as a UK review of the evidence for breast cancer screening, triggered by the Nordic Cochrane group's publications in scientific journals, gets under way. In October, the cancer tsar Sir Mike Richards promised an independent investigation of the data. It will be chaired by Sir Michael Marmot and will include some eminent statisticians, none of whom have been involved in the breast screening controversy before.

Richards has promised to act on its findings. "Should the independent review conclude that the balance of harms outweighs the benefits of breast screening, I will have no hesitation in referring the findings to the UK national screening committee and then ministers," he wrote at the time.

Women in the UK are called for breast screening every three years from the age of 50, and the age range is being extended to encompass all from 47 to 73. The NHS screening programme has consistently disputed the Nordic Cochrane Collaboration's work.

In July last year, in response to a paper that showed no difference in death rates between similar pairs of countries that had introduced or not introduced screening, Professor Julietta Patnick, director of the NHS cancer screening programmes, said: "We can't comment on screening programmes in other countries but here in England we do know that the best evidence available shows that women aged 50-69 who are regularly screened are less likely to die from breast cancer." She cited an estimate from the International Agency for Research on Cancer (IARC) of the World Health Organisation which said mortality was reduced by 35% through screening — a figure Gøtzsche disputes in his book.

Gøtzsche's book tells of personal attacks on him and on other researchers by the pro-screening lobby, some of whom had financial interests in the continuation of screening programmes, he alleges.

He compares screening advocates to religious believers and argues that their hostile attitudes are harmful to scientific progress. A lot of false evidence has been put forward to claim that the screening effect was large, he writes. Those who tried to expose the errors came under personal attack, as if they were blasphemers.

"I cannot help wonder why many people shrug their shoulders when they learn of scientific misconduct and why many scientists don't care that they deceive their readers repeatedly and betray the confidence society has bestowed on them, whether for a political gain, for fame, for money, for getting research funding or for any other reason. People may keep on being dishonest, may get away with it and may publish in the same journals time and again, to the hurrahs of like-minded people who are often editors of the same journals," he writes.

Some of the screening trials were biased or badly done, the book says, for instance by deciding on the cause of death of a woman after researchers knew whether she had been screened for breast cancer or not. The best trials, it says, failed to prove that lives were saved by screening.

Gøtzsche's group also found that one in three cancers detected by screening was misdiagnosed.

Breast cancer deaths have gone down, he says, but better treatment and better-aware women, who go to the doctor as soon as they find a lump, are responsible. Half of all breast cancers are found between screenings, he says.

Gøtzsche and his group have been highly critical of the leaflet sent to women by the NHS screening programme, which, they say, inflates the benefits and discounts the harms. He says he is hopeful that something good will come of the review.

Klim McPherson, professor of public health epidemiology at Oxford University, has been a critic of the information given to women by the NHS and is also hopeful. He gives credit to Gøtzsche for his assiduous work over many years to get to the truth. "His Cochrane reviews of breast cancer screening are of extremely high quality and not to be lightly dismissed," he said.

Gøtzsche says his work is focused on helping women understand the risks and benefits of screening. In the book, he says one of the leaders of the Swedish trials claimed mammography was the best thing that had happened for women during the last 3,000 years and added: "There are still people who don't like mammography. Presumably they don't like women."

Gøtzsche sees it differently. "People who like women, and women themselves, should no longer accept the pervasive misinformation they have consistently been exposed to," he writes. "The collective denial and misrepresentation of facts about overdiagnosis and the little benefit there is of screening, if any, coupled with the disregard of the principles for informed consent and national laws, may be the biggest ethical scandal ever in healthcare.

"Hundreds of millions of women have been seduced into attending screening without knowing it could harm them. This violation of their human rights is the main reason we have done so much research on mammography screening and also why I have written this book."

http://www.guardian.co.uk/science/2012/jan/23/breast-cancer-screening-not-justified

Avoid Routine Mammograms if You are Under 50

Posted By Dr. Mercola | December 05 2009 | 34,710 views

According to updated guidelines set forth by the U.S. Preventive Services Task Force, women in their 40's should not get routine mammograms for early detection of breast cancer.

The group's previous recommendation was for routine screenings every year or two for women age 40 and older. They now recommend that before having a mammogram, women ages 40 to 49 should talk to their doctors about the risks and benefits of the test, and then decide if they want to be screened.

While roughly 15 percent of women in their 40's detect breast cancer through mammography, many other women experience false positives, anxiety, and unnecessary biopsies as a result of the test, according to data.

The Obama administration distanced itself from the new standards, saying government insurance programs would continue to cover routine mammograms for women starting at age 40.

Sources:

- CNN November 16, 2009
- New York Times November 18, 2009

Dr. Mercola's Comments:

A new recommendation from the U.S. Preventive Services Task Force is stirring up controversy in the conventional medical community, where the long-held advice was for women to get a mammogram every year or two after age 40.

Now the Task Force has revised their recommendation, saying that women in their 40s should not get routine mammograms.

The new advice is a small step in the right direction, but many are up in arms, fearing a decrease in mammograms will put women's lives at risk from breast cancer, or that insurance companies will stop covering the procedure until a woman reaches age 50.

What is being completely overlooked by the majority of media outlets, however, is the reason WHY the Task Force decided to trim their mammogram recommendation. The prior advice was given in 2002, before a host of new research came out showing the problems of overdiagnosis, including false positives.

Back in 2001, around the time that U.S. health officials widened the use of mammograms to included women over 40 (previously it was only women over 50), a Danish study published in The Lancet revealed some startling data.

The study concluded that previous research showing a benefit was flawed and that *widespread mammogram screening is unjustified*.

That mammograms are still recommended *at all* speaks volumes about the state of modern medicine.

Decades ago in 1974, the National Cancer Institute (NCI) was warned by professor Malcolm C. Pike at the University of Southern California School of Medicine that a number of specialists had concluded "giving a women under age 50 a mammogram on a routine basis is close to unethical."

Why is Routine Mammography "Unethical"?

For starters mammograms expose your body to radiation that can be 1,000 times greater than that from a chest x-ray, which poses risks of cancer. Mammography also compresses your breasts tightly, and often painfully, which could lead to a lethal spread of cancerous cells, should they exist.

Dr. Samuel Epstein, one of the top cancer experts, stated:

"The premenopausal breast is highly sensitive to radiation, each 1 rad exposure increasing breast cancer risk by about 1 percent, with a cumulative 10 percent increased risk for each breast over a decade's screening."

Dr. Epstein, M.D., professor emeritus of Environmental and Occupational Medicine at the University of Illinois School of Public Health, and chairman of the Cancer Prevention Coalition, has been speaking out about the risks of mammography since at least 1992. As for how these misguided mammography guidelines came about, Epstein says:

"They were conscious, chosen, politically expedient acts by a small group of people for the sake of their own power, prestige and financial gain, resulting in suffering and death for millions of women. They fit the classification of "crimes against humanity.""

Not surprisingly, as often happens when anyone dares speak out against those in power, both the American Cancer Society and NCI called Dr. Epstein's findings "unethical and invalid."

But this didn't stop others from speaking out as well.

- In July 1995, The Lancet again wrote about mammograms, saying "The benefit is marginal, the harm caused is substantial, and the costs incurred are enormous ..."

- Dr. Charles B. Simone, a former clinical associate in immunology and pharmacology at the National Cancer Institute, said, "Mammograms increase the risk for developing breast cancer and raise the risk of spreading or metastasizing an existing growth."
- "The high sensitivity of the breast, especially in young women, to radiation-induced cancer was known by 1970. Nevertheless, the establishment then screened some 300,000 women with Xray dosages so high as to increase breast cancer risk by up to 20 percent in women aged 40 to 50 who were mammogramed annually," wrote Dr. Epstein.

Mammograms Often Give False Positives

Aside from the radiation risks, mammograms carry a first-time false positive rate of up to 6 percent. False positives can lead to expensive repeat screenings and can sometimes result in unnecessary invasive procedures including biopsies and surgeries.

Just thinking you may have breast cancer, when you really do not, focuses your mind on fear and disease, and is actually enough to trigger an illness in your body. So a false positive on a mammogram, or an unnecessary biopsy, can really be damaging.

Not to mention that women have unnecessarily undergone mastectomies, radiation and chemotherapy after receiving false positives on a mammogram.

What about Breast Self-Exams?

The revised U.S. Preventive Services Task Force recommendations also discourage doctors from teaching breast self-examination (BSE).

BSEs have long been recommended as a simple way for women to keep track of anything unusual in their breasts. However, studies have found that such exams do not reduce breast cancer death rates, and actually increase the rate of unnecessary biopsies.

So the problem with breast self-exams is that it typically forces women into a conventional, and potentially dangerous, diagnostic model, as if you do find something unusual, you will typically be brought in for a mammogram.

A Safer Breast Screening Option

Most physicians continue to recommend mammograms for fear of being sued by a woman who develops breast cancer after he did not advise her to get one. But I encourage you to think for yourself and consider safer, more effective alternatives to mammograms.

The option for breast screening that I most highly recommend is called thermographic breast screening.

Thermographic screening is brilliantly simple. It measures the radiation of infrared heat from your body and translates this information into anatomical images. Your normal blood circulation is under the control of your autonomic nervous system, which governs your body functions.

Thermography uses no mechanical pressure or ionizing radiation, and can detect signs of breast cancer as much as 10 years earlier than either mammography or a physical exam!

Whereas mammography cannot detect a tumor until after it has been growing for years and reaches a certain size, thermography is able to detect the possibility of breast cancer much earlier.

It can even detect the potential for cancer before any tumors have formed because it can image the early stages of angiogenesis -- the formation of a direct supply of blood to cancer cells, which is a necessary step before they can grow into tumors of size.

More men's lives could also be spared from the disease as mammography is not frequently used

Top Breast Cancer Prevention Tips

Women have a one in eight chance of developing breast cancer during their lifetime. In fact, breast cancer is the most common cancer among women -- except for skin cancers -- and the second leading cause of cancer death in women, exceeded only by lung cancer.

The American Cancer Society estimates that over 192,000 new cases of the disease will be diagnosed in women in 2009, and over 40,000 will die from it.

While screening tools can help you to *detect* breast cancer, they obviously do nothing to help *prevent* the disease, and this latter strategy is the best one for avoiding cancer.

Researchers estimate that about 40 percent of U.S. breast cancer cases, or about 70,000 cases every year, could be prevented by making lifestyle changes.

A healthy diet, physical exercise, optimized vitamin D levels and an effective way to manage your emotional health are the cornerstones of just about any cancer prevention program.

It's also important to make sure you're getting sufficient amounts of animal-based omega-3 fats such as krill oil.

Two studies from 2002 offer explanations for how omega-3 fats can protect against breast cancer. BRCA1 (breast cancer gene 1) and BRCA2 (breast cancer gene 2) are two tumor suppressor genes that, when functioning normally, help repair DNA damage (a process that also prevents tumor development).

Earlier research had discovered that women who carry mutated versions of these two genes are at higher risk of developing both breast and ovarian cancer than women who do not have these genetic mutations. Currently, women with BRCA1 mutations account for about 5 percent of all breast cancer cases. Omega-3 and omega-6 fats have been found to influence these two genes.

Omega-3 fats tend to reduce cancer cell growth while highly processed and toxic omega-6 fats have been found to cause cancer growth.

Three additional steps that can lower your breast cancer risk as well include:

- Not drinking alcohol, or limiting your drinks to one a day for women
- Breastfeeding exclusively for up to six months
- Watching out for excessive iron levels. This is actually very common once women stop menstruating. The extra iron actually works as a powerful oxidant, increasing free radicals and raising your risk of cancer.

All you need to do is measure your ferritin level and if it is above 80, donate blood, which will reduce the amount of iron that you have and thereby lower your cancer risk.

Related Links:

» Stop! Read This BEFORE You Get that Mammogram…

» Why Mammography is NOT an Effective Breast Cancer Screen

» Major Confusion on How to Do Breast Checks

BREAST CANCER ACTION RECOMMENDATIONS AND POLICY STATEMENT: BREAST CANCER SCREENING AND EARLY DETECTION

Breast Cancer Action (BCA) believes women need access to unbiased information in order to make informed choices about the detection of breast cancer. To fill this need, BCA developed the following recommendations and policy statement on breast cancer screening. Following the presentation of BCA's recommendations, the *BCA Policy on Breast Cancer Screening and "Early Detection"* includes information on the following topics:

Breast Cancer Action's Screening Recommendations

The recommendations that follow are for women who are *not* at elevated risk of breast cancer. Excluded from these recommendations are women with inherited genetic risk for or family history of the disease, women with a history of chest radiation treatment, and African American women. The first two these groups were specifically excluded from the 2009 U.S. Preventive Services Task Force (USPSTF) Guidelines. The complex risks facing African American women were, however, not acknowledged although many of the studies on which the new guidelines were based did include them. Because we believe these issues to be critically important, the BCA policy includes more information specifically on African American women. The specific needs of other women of color are not addressed in this policy because it is unclear at this time to what extent their needs are the same or different from those of African American or white women.

There is still a great deal we do not know about risk for breast cancer, and people need to consider their own circumstances as they review these recommendations.

BCA recommends women *not* at elevated risk for breast cancer participate in **mammography screening** for breast cancer as follows:

- Beginning at menopause (one year following cessation of menstruation)
- Every other year until age 75
- After 75, at intervals that take into consideration their other health conditions

BCA recommends that women *not* at elevated risk for breast cancer have a **clinical breast exam (CBE)** ideally annually or at least once every three years. Women should begin having CBE when they begin receiving care from a women's health provider but at least by age 21. CBE can be performed by anyone who has been formally trained to do it. The provider does not need to be a doctor.

BCA recommends that women **know their bodies** but how to go about this is entirely up to them. Even if a woman is getting regular CBE, and/or mammograms at the appropriate times, a familiarity with her own body may be her best approach, since a third of all breast cancers are found by women themselves. Any changes should, of course, be reported to a health care provider and pursued according to the wishes of the individual.

The rationale and support for this policy is explained in the accompanying Policy on Breast Cancer Screening and "Early Detection." This policy advances the overarching goals of Breast Cancer Action. BCA recognizes that dealing with breast cancer detection requires us to look beyond mammography. Focusing on mammography is not enough. Accordingly, we work to: 1) promote better tools for detecting breast cancer that are not radiation based; 2) support research to effectively distinguish between types of breast cancer; and 3) make sure that everyone has access to the best tools and care available. This is part of BCA's work to put patients first.

Policy on Breast Cancer Screening and "Early Detection"

This policy updates the prior Breast Cancer Action policy of October, 2006.

Defining Breast Cancer Screening

Breast cancer screening refers to the testing of otherwise healthy women with no symptoms of breast cancer. Screening is different from diagnostic interventions that follow the identification of something that might be breast cancer such as a lump or a finding on mammogram. Screening is performed because there are some breast cancers for which earlier detection and treatment reduce the risk of dying from the disease. However, not all cancers that are detected early need to be treated and not all cancer deaths can be prevented even if the cancer is discovered and treated early. It is also important to understand that no form of screening prevents breast cancer from occurring.

There are currently three commonly utilized methods for breast cancer screening: mammography (both digital and film), breast exam conducted by a licensed health care provider (called clinical breast exam), and breast examination conducted by a woman herself (formally called breast self exam, which BCA refers to as "know your body"). Each of these methods is useful in some women and not in others, and none is fool proof.

As with all health care interventions, breast cancer screening techniques have risks and benefits associated with their use. Breast Cancer Action therefore recommends that women be given complete, understandable information and are encouraged to make individual choices about screening based on their own values and their own evaluation of the benefits and risks involved. No two women should be expected to make the same decision but all women should have access to the same information to inform their decisions. What should not determine women's decisions about breast cancer screening is the type of health insurance coverage they do or do not have.

The Biological Complexity of Breast Cancer and Its Impact on Early Detection

Many breast cancer awareness and education campaigns focus on the idea that "early detection is the best protection." They also carry the assurance that "breast cancer found early is almost 100% curable." But the promotion of screening in this manner obscures the actual value of "early" detection. The fact that 98% of women diagnosed at a localized stage are alive five years after diagnosis does not mean that they have been cured of breast cancer.(7) The disease can and does recur at any time, though the likelihood of recurrence is highest in the first two years after treatment, and declines over time. Being cancer-free for five years following diagnosis is accurately considered a cure for some cancers, but not for breast cancer.

Many campaigns urging women to get screened are based on the premise that breast cancer found early can always be effectively treated. This is the justification for starting regular screening as early as possible. According to this argument, the earlier we detect the disease the more likely we are to stop it from becoming a serious threat. But the complex biology of breast cancer means that women diagnosed "early" with breast cancer fall into one of three groups.(8)

- One group has very aggressive disease that, no matter how small it is when it is found, cannot be effectively treated with the therapies that are currently available. This kind of cancer will likely spread (metastasize) beyond the breast to other life-sustaining organs. There is currently no cure for metastatic breast cancer, which tragically means that many of these women will die prematurely of breast cancer. One way to think of this kind of breast cancer is that it's like a bird that flies away before it can be caught.

- Another group has a type of either non-aggressive invasive disease or a type of DCIS (ductal carcinoma in situ) that will never become life-threatening. This kind of breast cancer is like a turtle that just stays put most of the time.

- The third group has a type of breast cancer that responds to currently available treatments. This kind of breast cancer is like a bear that is not threatening until it awakes from hibernation. Finding breast cancer earlier does increase the likelihood that treatment will work for these women.

We do not know how many women historically have fallen into each of these three groups. And, while these divisions and the treatments currently available mean that "early detection" only matters for women in the third group, for the most part we still cannot tell women which group they belong to *at the time of diagnosis*. The result is that we mistreat or over-treat many women diagnosed with breast cancer. Women in the first group are likely to be mistreated—made sick by the treatments they receive, reducing the quality of their lives

without extending their lives. Women in the second group will be over-treated, undergoing chemotherapy and radiation that they do not need or from which they do not benefit. These treatments are significant and often have an impact on women's overall health and well-being.

It is the inability of the currently available methods of screening to identify those most likely to benefit from treatment—and the consequential risks of this uncertainty—that makes it essential **to examine the three methods** currently used or recommended for breast cancer detection in the United States.

Benefits and Harms of Screening

The benefits of breast cancer screening are enormous for women who are diagnosed early with the kind of breast cancer that responds positively to available treatments. The benefits include a reduced likelihood of dying of breast cancer. Screening for breast cancer by any method also involves risks.

- False positive results. A false positive means that the screening test indicates a possible cancer, but, on further investigation, there is no health problem. In these circumstances, women undergo additional diagnostic tests to rule out the presence of cancer. While the finding that they don't have breast cancer is of course a relief, during the work-up process women experience stress and emotional strain, as well as exposure to radiation, which may contribute to increasing their risk of breast cancer later. The contribution of radiation to breast cancer risk is discussed later in this document.(9) A work up may also trigger additional biopsies, which, for reasons not yet understood, may also increase the risk of breast cancer later.

  The research that contributed to the U.S. Preventive Services Task Force recommendations discussed below found that the rate of false positives from mammography screening is related to the age at which mammography is performed as well as to how many mammograms a woman has had.(13) For example, the cumulative risk for false positives is between 29% and 49% after ten annual screenings starting at age 50 and up to 56% for women starting between ages 40 and 49.(14)

- False negative results: A false negative means that the screening test does not indicate the presence of cancer, when there is, in fact, cancer present. Not only do false negative results give patients an inappropriate sense of security, they may also result in a late diagnosis that increases the risk of dying from the cancer that is present for those women whose cancers can be effectively treated.

- Overtreatment**:** Overtreatment is a growing concern in the breast cancer arena. Because mammograms find many kinds of cancer that are "turtle" like in their behavior, there are increasing numbers of people being treated for breast cancers that will never be life-threatening. This overtreatment, including surgery, radiation, and drugs, can negatively affect the health of the treated person.

Mammography

Historical Context of Approaches to Mammography Screening

Since the early 1980s, the United States' public campaign to control breast cancer has focused largely on efforts that promote mammography screening. Mammography is routinely referred

to as "prevention for breast cancer" although it does not prevent the disease but rather detects the condition, reducing the likelihood that some women will die from it. In recent years, mammography screening has been the subject of considerable debate within the health care community, particularly with respect to its use among premenopausal women, and, increasingly, with respect to its optimal use as a screening tool for women of any age.

The most highly debated aspect of mammography surrounds the recommendation that all women begin having annual mammograms after age 40. While debate regarding the scientific basis for this recommendation has existed for over two decades, political and advocacy forces have ensured that the women aged 40 to 49 hear only one side of the issue: the message encouraging routine screening.

Access to mammography for women from traditionally underserved populations, particularly African American women, has been a focus of significant advocacy and outreach efforts over the last two decades. In many ways, women have gained access to the larger health care system through the door of mammography. Thus, the revised guidelines may come as a blow to communities that have historically struggled for access to mammograms and health care in general. While higher screening rates with mammography in these populations have not led to the anticipated significant decline in mortality, mammography has been an important community empowerment tool. In light of the new guidelines, renewed advocacy efforts in traditionally underserved and African American communities must take into consideration these complex histories. Attention must be paid to promoting replacement activities to support these communities and to strategize ways to work for equitable health care access when mammography is not the focus.

United States Preventive Services Task Force Guidelines

In late 2009, the U.S. Preventive Services Task Force (USPSTF) revised its 2002 breast cancer screening recommendations, downgrading the recommendation of mammography for women age 40 to 49 from a "B" to a "C" rating.(10) (See box below for more information on this rating scheme.) The USPSTF is a government-appointed independent body charged with reviewing the science of preventive health care interventions. Their job is to assess the balance between risks and benefits and to make recommendations to health care providers about preventive health care interventions. The USPSTF does not evaluate or consider the financial costs of these interventions.

The USPSTF does not recommend that everyone in the 40 to 49 age range be routinely encouraged to have a mammogram. Instead, every woman in this age group should consider the risks and benefits of screening as they apply *to her* (her particular circumstances, temperament, tolerance for uncertainty, feelings about cancer treatment, and/or medical and family history). The USPSTF also does not categorically reject screening for women in their 40s. Instead, it legitimizes the decision to delay it until age 50. In other words, it provides scientific support for an alternative choice.

The second change proposed by the USPSTF involves the frequency of routine mammography for post-menopausal women. The Task Force now recommends that post-menopausal women undergo mammography every other year rather than annually. The rationale for this change is that there is no improved reduction in mortality from annual (as compared to biennial) mammography, but there are additional risks associated with increased frequency of mammography. This is a "B" recommendation for women aged 50 to 74.

Why 50?

Age 50 is used as a surrogate for menopause. The average age at which women stop menstruating in the U.S. is 51.(11) Following menopause, breast tissue often becomes less dense, making it is easier to see meaningful changes on mammograms. Women who start menopause earlier may want to consider starting mammography earlier.

In addition, the USPSTF concluded that there was insufficient evidence to assess the additional benefits and harms of screening for women over 75. As women over 75 may have a more complicated health status, BCA recommends that decisions about mammography include an assessment of other ongoing health conditions.

These recommendations do not apply universally to all women. The USPSTF explicitly excludes women with a prior history of chest radiation (for an earlier cancer or for any other condition, see discussion below for more information) and women with a family history of breast cancer and/or known genetic mutations.

Chest Radiation

An estimated 50,000 to 55,000 women in the United States have been treated with moderate to high dose chest radiation for pediatric or young adult cancer. These women are at clinically significantly increased risk for breast cancer and breast cancer mortality after cure of their primary cancer. Breast cancer risk is greatest among women treated with high-dose mantle radiation for Hodgkin lymphoma, but it is also elevated among women who received moderate-dose chest radiation.(1) One research team has estimated that among women aged 35 to 39, mammography itself in this group of women induces 82 cases of cancer for every million women screened.(5)

Nor does the USPSTF have any advice to offer African American women who may be susceptible to more life-threatening forms of breast cancer before age 40 (see “African American Women: The Limbo of Not Enough Information,” p. 11).

The USPSTF has updated its definitions of the grades it assigns to recommendations and now includes "suggestions for practice" associated with each grade. The USPSTF has also defined levels of certainty regarding net benefit. These definitions apply to USPSTF recommendations voted on after May 2007.

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Risks and Benefits from Mammography Screening

Based on the best available data, screening mammography has led to a 15% relative risk reduction in mortality from breast cancer.(10) However what this means to women on an individual level is best understood as the reduction in absolute risk (see *discussion below on Absolute v. Relative Risk).*

Absolute v. Relative Risk

Figuring out the benefits and risks for any medical intervention is often confusing, and that certainly is the case with mammography screening. Both benefits and harms vary by age at the time of screening, as well as by family and medical history, race, previous experience with mammography, proficiency of the screening technicians and radiologists who interpret the results, and the reliability of the equipment, not to mention other unknown factors.

The USPSTF's review of the literature describes what is known about the effects of mammography screening for healthy women without known increased risk of breast cancer. To understand their work, it's helpful to know the statistical meaning of absolute risk and relative risk.

A group of researchers at the University of California, San Francisco, who train advocates to critically appraise biomedical research, uses a good example to explain the difference.(3) If you went to Las Vegas with $50, and you came home with $100, you could say:

1. You won $50 (the absolute increase in dollars),
2. You doubled your money (% change in dollars, a relative increase).

WOW! You doubled your money!

If you went to Las Vegas with $500, and you came home with $550, you could say:

1. You won $50 (the absolute increase in dollars), or
2. You increased your money by 10% (% change in dollars, a relative increase).

At least you didn't lose money.

Proponents of various medical interventions sometime use both relative risk *and* absolute risk to describe benefits or harms to either maximize the seeming benefits or to minimize the apparent harms.

For example, best research estimates of the benefits of screening mammography every one to two years for women age 40 to 49 are a 15% relative reduction in breast cancer mortality (after 14 years of follow-up). That is, you have a 15% smaller chance of dying from breast cancer if your tumor was found by mammography rather than in some other way. This is a way of expressing the relative risk of dying from breast cancer in pre-menopausal women.

Wow! A 15% smaller risk of dying!

But very few women without symptoms, thankfully, are found to have breast cancer in their early 40s. And even fewer, thankfully again, die from the disease.

The five year breast cancer risk for a 40 year old woman with no known risk factors is 0.4% (that is, forty women out of 10,000 this age would develop breast cancer over five years). The five-year survival rate for women 45 years old and younger is 81%.(6)

This means that approximately 8 of the 40 women diagnosed with disease (or 8 out of 10,000 screened) would die within five years. A 15% reduction in that number is slightly over one (1.2). In other words screening 10,000 healthy women for five years would result in about one less death. This is an expression of screening mammography's benefits in terms of absolute risk of mortality.

Or: A little more than one life saved in 10,000 women screened.

Human life is very, very precious, and some would understandably argue that having 10,000 healthy women undergo mammography annually for five years would be worth the saving of a single life. However, we know that screening's harms in this age group include a high percentage of false-positive results, increased radiation to the chest (a known cause of breast cancer), false reassurance, and the ill effects and expense of treatment of lesions that would not threaten a person's life.

Mammograms use low-dose X-rays to examine the breast. X-rays are ionizing radiation, a known carcinogen which has a cumulative effect on the body. The greater the radiation exposure/dosage over a lifetime, the greater the risk of radiation-induced cancer.(4) This risk is highest in tissue in which cells are rapidly changing, such as the breast tissue of adolescent females (12) or potentially women in menopausal transition (no research has yet examined this question).

Radiation Exposure Facts

- All sources of radiation affect us the same way, whether from natural sources (radon, cosmic rays) or man-made (from occupational and medical exposures or consumer products).
- Americans were exposed to more than seven times as much ionizing radiation from medical procedures in 2006 than they were in the 1980s. Medical exposures have more than tripled and now account for almost half the total annual exposure to radiation in the United States.(2)
- No regulatory agency has ever set a limit on an individual's annual exposure to medical radiation although even the very small doses of radiation from screening mammography can exceed an individual's average annual exposure from all other sources combined.
- A typical radiation dose associated with a course of radiotherapy is about 10,000 times the mammogram dose.(4)

Because mammography is less accurate in finding cancers in premenopausal breasts, clinical Breast Exam may be a more useful screening tool in younger women. (See Clinical Breast Exam section below on page 10 for a discussion of the limitations of existing data on CBE.)

Film vs. Digital Mammography

Over the last few years digital mammography has begun to replace film mammography. The driving force behind this change is increased efficiency (the images can be easily shared electronically). But the newer technology is significantly more expensive than film mammography. Early evidence regarding digital mammography suggests that, on the whole, it is no more accurate than film mammography and that the probability of false-positive results is similar for the two techniques.(10) One study, however, has found that digital mammography was better at detecting lesions in women who were younger than fifty years or premenopausal, or who had dense breast tissue.(16)

Breast Cancer Action's Recommendation

Given the available information, BCA recommends that women *not* at elevated risk for breast cancer participate in mammography screening at menopause (one year following cessation of menstruation), continue thereafter every other year until age 75, and after 75, at intervals that take into consideration other health concerns.

Clinical Breast Exam

Clinical breast exams (CBE) are done by licensed health care professionals who periodically examine a woman's breasts for any palpable masses (masses that can be felt). There is wide variation in the training health care providers receive in CBE and an equal amount of variation in how well they are performed in clinical practice.(17, 18) The data are inadequate to determine whether routine performance of a CBE results in reduced mortality from breast cancer.(19) Reflecting the lack of sufficient evidence, the USPSTF did not make a recommendation related to CBE. Several large clinical trials are ongoing internationally (20, 21) and new evidence will continue to inform recommendations related to this screening method. What evidence there is suggests that a quality CBE cannot be performed quickly or without sufficient training.

Women should understand the limitations of CBE and not assume that a lack of a finding means that they do not have breast cancer. Conversely a positive finding on CBE may not be cancer and a false positive result may lead to unnecessary and potentially harmful interventions. Women relying on CBE as a means of breast cancer screening should know that not all breast exams are the same and are highly dependent on the skill of the clinician performing the exam. Different people conducting CBE will find different things, and not all people trained to do CBE are trained in the same way.

Breast Cancer Action's Recommendation

Recognizing the limitations of current knowledge, BCA recommends that women obtain CBE ideally annually or at least every three years from a health care provider trained to do the exam.

Breast Self Exam

For years, advocates and clinicians have told stories of the many women who found their own breast cancers. In response, research began to study whether women could be taught techniques that would increase the likelihood of self identification and reduce the risk of dying of breast cancer. This formalized process became known as breast self examination or BSE. Clinicians and health educators routinely encouraged women to perform BSEs on a monthly basis. But the procedure was not without its critics who argued that the recommendation to perform BSEs, while not a mandate, had the effect of alienating women from their own bodies.(22)

Researchers have been unable to demonstrate any survival benefit that BSEs offer over other forms of routine screening. Two large randomized clinical trials in Russia and China found that the harms from having clinicians teach women to perform BSE outweighed the benefits.(23, 24) Critics of these studies argue that the availability of different intervention options for women in the United States make the findings from these trials inapplicable in the U.S. context. The USPSTF, nevertheless, recommends against clinicians teaching women how to perform BSE.(10)

Breast Cancer Action's Recommendation

Rather than focus on a standardized monthly form of self examination, BCA recommends that women know their bodies, and be aware of their breasts (size, shape, feel), examining themselves for changes on a periodic basis, using whatever technique and interval makes them comfortable. Many women will continue to find changes in their breast that are meaningful. Women need to know, however, that not all lumps are cancer and that finding a lump may lead to the same unnecessary interventions that follow a positive result on a mammogram or CBE, namely additional mammograms and biopsies that may, in the long run, increase their risk of cancer. BCA, however, believes that familiarity with one's body, including one's breasts, is an important part of overall health.

African American Women: The Limbo of Not Enough Information

African American women are at higher risk of dying from breast cancer than white women, even though they have an overall lower incidence of the disease. The available data suggest that African American women are more likely to be diagnosed with breast cancer before they reach the age of 40 and to die from the disease at a rate that is approximately 37% higher than the death rate for Caucasian women.(7) In addition, there are substantial differences in tumor characteristics across racial/ethnic groups in the United States, though aggressive tumor characteristics are not unique to any particular ethnic or racial group.(25) The reasons for these differences are not fully understood but include differential environmental exposures, increased stress, and discrimination as well as numerous other structural inequalities.(26) Initially thought to be the result of lower breast screening rates among African American women, the differences in mortality have not declined despite high rates of mammography in many African American communities.

The USPSTF did not, however, address the situation confronted by African American women, or an aspect of ethnic or racial inequities in its analysis of mammography. More recent research looking at women under 40 suggests that African American women undergoing screening are more likely than their white counterparts to be recalled for additional workup and to receive both false positive *and* true positive results (that is, both false alarms and diagnoses of breast cancer).(27)

Mammography is also a tool that is less accurate in finding cancers in dense breast tissue. Consequently, it is less effective at diagnosing breast cancer in women under 50, who are more likely to have dense breast tissue. Thus the risks from mammography are greater and the benefits significantly lower for premenopausal women. For this reason, it is important that pre-menopausal African American women have information about all screening methods, and access to the most useful interventions – including CBE and Know Your Body at the appropriate ages. Admittedly, these options do not offer a satisfactory solution. Taken together, these options expose both the weakness of a "one size fits all" approach that fails to address the needs of those who may be at greater risk of dying from the disease, as well as the limitations of our screening methods.

Premenopausal Women

Mammography is less useful in women prior to menopause because premenopausal women tend to have dense breasts. Mammography has difficulty distinguishing tumors, which are also dense, from the normal tissue in women with dense breasts. Evidence does not yet exist for

the value of CBE in reducing the risk of breast cancer mortality for this group. And while knowing one's body may help identify changes, there is no evidence to date that such findings reduce one's chance of dying of cancer. As such, premenopausal women concerned about the risk of breast cancer have limited choices. Women in this category may benefit from the use of other technologies used in the breast cancer field but which have yet to be studied as screening tools. These include interventions such as thermography, ultrasound, and magnetic resonance imaging (MRI). Ultrasound has been studied in conjunction with mammography in women at elevated risks for breast cancer and found to be useful for women with dense breasts. In conjunction with mammography, more cases of breast cancer are found using ultrasound, but false positives also significantly increase (28). Ultrasound has not yet been studied as a screening tool.

Readers of this policy may wish to explore what is known, and not yet known about these options (see separate BCA policy on screening technologies, currently being updated). Women deciding to use these tools should be aware that they suffer from the same limitations as existing tools: false positives necessitating additional procedures, over treatment resulting from identifying cancers that do not need treatment, mistreatment of people whose cancers cannot be effectively treated, and false negative results.

Making Sense of the Recommendation to "Talk with Your Doctor"

Because of the controversy surrounding breast cancer screening, many organizations—including the USPSTF—encourage patients to "talk to your doctor." This approach is insufficient to help women make informed choices. Physicians as well as other health care providers may be concerned about liability resulting from their failure to recommend screening. Additionally, many health care providers may not be aware of the most recent science related to breast cancer screening, or they may have entrenched attitudes of their own about the risks and benefits of screening. Still others may have a financial interest in promoting screening services for women—many practices own their screening and/or diagnostic equipment. For all these reasons, BCA encourages women to learn about the benefits and risks of breast cancer screening and to be sure that they are making a personal decision whether or not to undergo screening. The most important aspect of the discussion with a health care provider is that the individual woman should feel that her decision is respected and supported.

Talking to your doctor

The following questions may help a woman initiate a conversation about breast cancer screening with her health care provider.

- ✓ I am interested in your opinion but I am going to make my own decisions. Can you work with me?
- ✓ How do you evaluate my personal risk for breast cancer and what do you consider in evaluating that risk?
- ✓ Do you recommend I get a mammogram? Why?
- ✓ At what age do you recommend that all women get a mammogram?
- ✓ What do you see as the risks and benefits of a mammogram for me at my age?
- ✓ What alternatives might be available to me if I don't want to get a mammogram?

BCA Recommendations Explained

For women with no family history of breast cancer, no prior history of significant chest radiation, and who do not have an elevated risk for breast cancer, BCA recommends initiating screening mammography at the time of menopause (for most women this will be at age 50) and having a mammogram every other year until age 75. Women who are younger than age 50 and particularly concerned about breast cancer may wish to consider earlier mammography but should be aware of the higher risks of false positives, the reality that mammography is less effective in pre-menopausal women, and the risks of radiation from both screening and unnecessary treatment. These women may want to consider other forms of breast cancer screening including quality clinical breast exam. Regardless of the age of initiation, mammography is best performed every other year, rather than every year, unless there is a clinical reason for more frequent mammography.

BCA believes that all women should receive a clinical breast exam from a qualified provider in the course of their regular women's health care, preferably annually but at least once every three years.

Finally, women should be encouraged to know the size, shape and feel of their breasts. In all cases, women who identify an abnormality should seek care as soon possible and be sure that they are followed until they believe the issue has been satisfactorily resolved.

Summary

BCA believes that once a woman is fully informed about the pros and cons of each breast cancer screening method, she should make her own decision about whether or not to make use of the tool. Informed consent, in this case, presents women with difficult choices. Those who choose to have screening mammograms should have ready access to the best available technology, with the expense covered by their health insurance provider, whether private or public. Similarly, women who choose to have CBE should have access to properly trained clinicians with appropriately allotted time to complete a thorough exam.

Women should be informed that mammograms—whether film or digital—as well as CBEs and self examination do not always detect breast cancer— thereby yielding "false negative" results (when a detection method fails to find a breast cancer that is present). Conversely, mammography, CBE, and self examination yield false positive results which lead to additional interventions and occasionally unnecessary and harmful treatments. The tools can also detect cancers that can be treated and thus reduce a woman's risk of dying from the disease. How women make decisions about the balance between risks and benefits is based on individual values and preferences.

The care a woman receives, however, should not be based on the type of insurance or financial resources to which a woman has or does not have access. Breast Cancer Action believes all women should have access to the same choices about breast cancer screening (please see our policy on universal access to care).

BCA believes that attention and resources should be focused on improving screening methods for both younger and older women, understanding and addressing the experiences of populations with unequal distribution of disease, developing better treatments for the kinds of breast cancer that we are currently unable to treat effectively, and developing techniques for distinguishing, at the time of diagnosis, between those cancers that require—and respond to—treatment and those that do not.

Breast Cancer Action is a national grassroots organization whose mission is to carry the voices of people affected by breast cancer to inspire and compel the changes necessary to end the breast cancer epidemic. We recognize that fundamental social changes are necessary to accomplish our mission, and we are dedicated to organizing people to work toward those changes. As a matter of policy, BCA does not accept funding from any company that is profiting from or contributing to cancer, including pharmaceutical and other health care corporations.

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Cochrane review on screening for breast cancer with mammography

Ole Olsen, Peter C Gøtzsche

In 2000, we reported that there is no reliable evidence that screening for breast cancer reduces mortality. As we discuss here, a Cochrane review has now confirmed and strengthened our previous findings. The review also shows that breast-cancer mortality is a misleading outcome measure. Finally, we use data supplemental to those in the Cochrane review to show that screening leads to more aggressive treatment.

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We previously assessed the results of the seven randomised trials of screening mammography, and concluded that screening is unjustified because there is no reliable evidence that it reduces mortality.[1] We reassessed this finding in a Cochrane review[2] in which we paid close attention to the standard dimensions of methodological quality of trials: the randomisation method, baseline comparability, exclusions after randomisation, and unbiased assessment of outcome (see protocol for the Cochrane review [issue 3, 2001, Cochrane Library]). Additionally, we noted whether early introduction of screening in the control group had occurred. Details of the trial assessments are presented in our review.[2] On the basis of these assessments, we classified the quality of the available trial data into four groups: high, medium, poor, and flawed.

We found that the results confirmed and strengthened our original conclusion. No trial data were of high quality, two were of medium quality (Malmö and Canada), three were of poor quality (Two-County, Stockholm, and Göteborg), and two were flawed (New York and Edinburgh). The review provided evidence that assessment of cause of death is unreliable and biased in favour of screening. Even when endpoint committees masked to group assignment were used, uncertain causes of death were significantly more commonly ascribed to breast cancer than to other causes in the control group. The credibility of this finding is supported by another meta-analysis, which showed that radiotherapy reduces local recurrence by two-thirds.[3] Treatment of early cancers by tumourectomy and radiotherapy might increase the likelihood that deaths among screen-detected breast cancer cases will be misclassified as deaths from other causes,[3] particularly other cancers.[2] We noted that the two trials with medium-quality data failed to find an effect of screening on deaths ascribed to any cancer, including breast cancer (relative risk 1·02 [95% CI 0·95-1·10]). The estimate for the trials with poor-quality data was similar (1·00 [0·91-1·10]). Furthermore, the greater use of radiotherapy in screened women than in controls[1] is expected to increase overall mortality because of cardiovascular adverse effects.[3] These deaths were not counted as deaths related to screening in the trials we assessed.

The main outcome measure in the screening trials was breast-cancer mortality. This choice seems rational, since larger trials would be needed to show an effect on overall mortality. However, we showed that the assumption that a demonstrated effect on breast-cancer mortality can be translated into a reduction in overall mortality rests on

suppositions that are not correct.[2] The only reliable mortality estimates are therefore those for overall mortality. The relative risk of overall mortality was 1·00 (0·96-1·05) in the two trials of highest methodological quality (figure).[2] The Swedish trialists have recently reported an updated mortality estimate for the four Swedish trials:[4] this estimate was also 1·00 (0·98-1·02) after adjustment for imbalances in age that had occurred despite attempts at randomisation.[1,2] Thus, although the trials were underpowered for all-cause mortality, the reliable evidence does not indicate any survival benefit of mass screening for breast cancer.

In our previous paper,[1] we divided the trials into two groups on the basis of methodological quality. We reported that the effect estimate for breast cancer mortality in the two best trials was significantly different from that for the five poor-quality trials, which is a sign that something is wrong. In our latest review, we therefore omitted the trials from New York and Edinburgh from the analysis of the poor-quality trials, since they are flawed.[2] However, there was still a significant difference between the two estimates for breast-cancer mortality. The two best trials failed to find an effect of screening on deaths ascribed to breast cancer (relative risk 0·97 [0·82-1·14) after 13 years, whereas the three remaining trials with poor-quality data found a marked effect (0·68 [0·58-0·78]; p=0·001 for the difference between the two effect estimates). Given the strong heterogeneity, results from the different quality groups should not be combined.

The largest effects on breast-cancer mortality were reported in trials that had long intervals between screenings (Two-County trial), that invited many women to only two or three screenings (Two-County and Stockholm trials), that started systematic screening of the control group after 3-5 years (Two-County trial, Göteborg trial, and Stockholm trial) and that had poor equipment for mammography (New York trial). This surprising situation suggests that differences in reported effects between the trials are related to the methodological quality of the trials and not to the quality of the mammograms or the screening programmes.[2]

We have also confirmed, with additional data (see www.thelancet.com), which the editors of the Cochrane Breast Cancer Group have elected to defer from publication until further editorial review has been completed, our earlier finding[1] that screening leads to more aggressive treatment, increasing the number of mastectomies by about 20% and the number of mastectomies and tumourectomies by about 30%. The greater use of surgery was not merely an initial phenomenon caused by the tumours detected at the prevalence screen, but seemed to persist. The increased mastectomy rate in the trials might be higher than in current practice, since there has been a general policy change towards fewer mastectomies. However, screening identifies some slow-growing tumours that would never have developed into cancer in the women's remaining lifetimes, as well as cell changes that are histologically cancer but biologically benign. Furthermore, carcinoma in situ does not always develop into invasive cancer, but since these early lesions are often diffuse, women are sometimes treated by bilateral mastectomy. Therefore, the increase in surgery rates could also be an underestimate, since reoperations and operations in the contralateral breast seemed not to have been included. Furthermore, "better" diagnostic methods--eg, better mammograms--could

lead to additional overtreatment because of detection of even more early or questionable lesions. Quality assurance programmes could possibly reduce the surgical activity to some degree, but the problem cannot be avoided.

Our earlier report[1] has been criticised,[5,6] especially for its emphasis on imbalances in baseline variables. However, the main reason for the ongoing controversy is probably that our opponents keep referring to the criticisms of our paper without referring to our reply.[7] Furthermore, they seem to have ignored this sentence in our paper: "Our analyses focused on age as a marker for imbalance as this was the only baseline information we had available for the Swedish trials".[1] We have not postulated that the baseline imbalances per se caused the inflated effect, but we used the imbalances as markers of poor trial methodology[7]--an approach that led us to new important information about the trials.[2] Contrary to what the critics assert,[6] the fact that that there was no age imbalance in the two best trials was confirmed in the correspondence that followed our *Lancet* paper, and we believe that all relevant criticism has now been addressed in our review.[2]

We have provided detailed evidence on the mammography screening trials, and hope that women, clinicians, and policy-makers will consider these findings carefully when they decide whether or not to attend or support screening programmes. Any hope or claim that screening mammography with more modern technologies than applied in these trials will reduce mortality without causing too much harm will have to be tested in large, well-conducted randomised trials with all-cause mortality as the primary outcome.
This study was funded by the Danish Institute for Health Technology Assessment.

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Diagnostic Mammograms: Interpretation Is in the Eye of the Beholder

Sensitivity and false-positive rates varied among radiologists' interpretations of diagnostic mammograms.

Radiologists' interpretations of screening mammograms are known to vary widely. In a National Cancer Institute–funded study, investigators assessed the performance of 123 radiologists in their interpretations of more than 35,000 diagnostic mammograms in women with signs or symptoms of breast cancer. Mammograms were considered positive if they were suspicious or highly suggestive of cancer or if they prompted recommendation for biopsy or surgical consultation. Women were considered to have breast cancer if invasive carcinoma or ductal carcinoma in situ was diagnosed within 1 year of the diagnostic mammogram. Sensitivity was defined as the percentage of positive examinations among women with a breast cancer diagnosis. The false-positive rate was defined as the percentage of positive examinations among women without a breast cancer diagnosis.

Approximately three quarters of the radiologists (mean age, 49; range, 34–70) had been interpreting mammograms for at least 10 years. Only 6% were based at academic centers; 3% had fellowship training in breast imaging. For most (87%), less than 40% of their time was devoted to breast imaging. The median sensitivity of diagnostic mammography was 79%, and the median false-positive rate was 4.3%. Sensitivity varied substantially even among radiologists with similar false-positive rates. Radiologists at academic centers had higher interpretive sensitivity (88% vs. 76%) and higher false-positive rates (7.8% vs. 4.2%) than did other radiologists.

Comment: The prevalence of breast cancer is 10-fold higher in women undergoing diagnostic mammography than in women undergoing screening breast imaging. Accordingly, the variability in radiologists' interpretations of diagnostic mammograms is worrisome. Although high sensitivity expedites breast cancer diagnosis, the rate of false-positive interpretations (which generate invasive procedures and anxiety) tends to increase with sensitivity. Therefore, achieving optimal accuracy — high sensitivity without excessive false-positives — is critical in interpreting diagnostic mammograms. General radiologists read most of the mammograms in the U.S., yet breast imaging constitutes a relatively small part of their practices. These results point to the variability among radiologists; from here, we must determine how best to improve accuracy in the interpretation of diagnostic mammograms.

— ***Andrew M. Kaunitz, MD***

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Mammogram new regulations

Does Mammography Screening Save Lives? Let's Talk About It

By Barbara A. Brenner, Executive Director

Debates about who should have screening mammograms -- those given to women with no breast symptoms --and when are not new to longtime followers of BCA's work. Our position has long been clear: women who are pre-menopausal should not have regular screening mammograms, and everyone should know the benefits and risks of all screening methods (mammograms, breast self-exam, clinical breast exam) and make the best decisions for themselves.

Interestingly, emerging science and revised recommendations on screening are now confirming what BCA has long said about these matters. One of the leading health policy organizations- the US Prevention Services Task Force (USPSTF)– has issued new screening recommendations for women who are asymptomatic and who are not at elevated risk of breast cancer.

In addition to calling for an end to routine mammography screening for women 40 to 49, the USPSTF is also encouraging a shift away from annual mammograms for post-menopausal women, and toward biannual (every two year) screening. This recommendation is consistent with the practice in most other countries with screening programs, and those countries have no worse outcomes in terms of breast cancer mortality than the U.S.

But as we know from long experience of bucking the trends in breast cancer policy that many people will be upset and/or confused by these new recommendations.

Some people will be upset because their breast cancer was found on a mammogram that would not have happened under the new guidelines. Some people will be confused because they don't understand what the downsides could possibly be to the early detection of breast cancer.

It's very difficult for people to ignore their personal situations in thinking about what should happen as a matter of policy. But emerging science tells us that we need to try to do that if we're going to get to the best place in terms of both reducing deaths from breast cancer and minimizing the harms that occur when we do mammography screening

One thing to keep in mind is that mammograms are a medical intervention, and, like all medical interventions, they have benefits and risks. The benefits have to do with finding some cancers early enough to effectively treat them so that fewer women die of breast cancer. The risks are these:

* False negative results (mammogram reads as clear, but there is breast cancer present)

* False positive results (mammogram shows a problem, but biopsy reveals that the problem is not cancer). False positive results result in unnecessary biopsies, increased anxiety and stress, and physical scarring

* Cumulative exposure to radiation. (Radiation is one of the few known causes of breast cancer. All radiation exposures accumulate in the body. Our bodies do not eliminate these exposures.

* Diagnosis and treatment of cancers that are not life threatening at the time of diagnosis and will never become life threatening if untreated.

These risks can and should be balanced against the benefit of finding breast cancer early enough to effectively treat the disease and reduce the number of women who die of breast cancer.

What is not well understood is that “early detection” doesn’t really mean what we’ve been lead to believe, which is that finding breast cancer early is the key to survival. It’s not that simple.

BCA’s current screening policy explains the limits of breast cancer “early detection.” Briefly, the complex biology of breast cancer means that women diagnosed with “early” breast cancer fall into one of three groups, related to the biology of cancer:

1. They have a type of breast cancer that responds to currently available treatments
2. They have a type of breast cancer that is not and will never become life-threatening
3. They have very aggressive disease that cannot be effectively treated with currently available therapies

While we don’t know how big these groups are, we do know that the only people who actually benefit from early detection are those in the first group. Its these women whose lives can be saved by early detection, if they get the appropriate treatment in a timely manner. These are the women who need screening.

We have suffered from oversimplification of the breast cancer early detection message for far too long. The new recommendations on screening may help us move to a more nuanced understanding of breast cancer, and ultimately for a better place for all of us.

So, don’t throw up your hands. Contact BCA if you have questions and make the best decision for yourself.

Mammograms cause breast cancer (and other cancer facts you probably never knew)

Monday, August 15, 2005 by: Dawn Prate, citizen journalist

Breast cancer is the leading cause of death among American women between the ages of 44 and 55. Dr. Gofinan, in his book, *Preventing Breast Cancer*, cites this startling statistic along with an in-depth look at mammographic screening, an early-detection practice that agencies like the American Cancer Society recommend to women of all age groups. According to most health experts, catching a tumor in its early stages increases a woman's chances of survival by at least 17 percent.

The most common method for early detection is mammography. A mammogram is an X-ray picture of your breast that can reveal tumor growths otherwise undetectable in a physical exam. Like all x-rays, mammograms use doses of ionizing radiation to create this image. Radiologists then analyze the image for any abnormal growths. Despite continuous improvements and innovations, mammography has garnered a sizable opposition in the medical community because of an error rate that is still high and the amount of harmful radiation used in the procedure.

Effectiveness of Mammography

Is mammography an effective tool for detecting tumors? Some critics say no. In a Swedish study of 60,000 women, 70 percent of the mammographically detected tumors weren't tumors at all. These "false positives" aren't just financial and emotional strains, they may also lead to many unnecessary and invasive biopsies. In fact, **70 to 80 percent of all positive mammograms do not, upon biopsy, show any presence of cancer**.

At the same time, mammograms also have a high rate of missed tumors, or "false negatives." Dr. Samuel S. Epstein, in his book, *The Politics Of Cancer*, claims that in women ages 40 to 49, one in four instances of cancer is missed at each mammography. The National Cancer Institute (NCI) puts the false negative rate even higher at 40 percent among women ages 40-49. National Institutes of Health spokespeople also admit that mammograms miss 10 percent of malignant tumors in women over 50. Researchers have found that breast tissue is denser among younger women, making it difficult to detect tumors. For this reason, false negatives are twice as likely to occur in premenopausal mammograms.

Radiation Risks

Many critics of mammography cite the hazardous health effects of radiation. In 1976, the controversy over radiation and mammography reached a saturation point. At that time mammographic technology delivered five to 10 rads (radiation-absorbed doses) per screening, as compared to 1 rad in current screening methods. In women between the ages of 35 and 50, each

rad of exposure increased the risk of breast cancer by one percent, according to Dr. Frank Rauscher, then-director of the NCI.

According to Russell L. Blaylock, MD, one estimate is that annual radiological breast exams increase the risk of breast cancer by two percent a year. So over 10 years the risk will have increased 20 percent. In the 1960s and 70s, women, even those who received 10 screenings a year, were never told the risk they faced from exposure. In the midst of the 1976 radiation debate, Kodak, a major manufacturer of mammography film, took out full-page ads in scientific journals entitled *About breast cancer and X-rays: A hopeful message from industry on a sober topic*.

Despite better technology and decreased doses of radiation, scientists still claim mammography is a substantial risk. Dr. John W. Gofman, an authority on the health effects of ionizing radiation, estimates that 75 percent of breast cancer could be prevented by avoiding or minimizing exposure to the ionizing radiation. This includes mammography, x-rays and other medical and dental sources.

Since mammographic screening was introduced, the incidence of a form of breast cancer called ductal carcinoma in situ (DCIS) has increased by 328 percent. Two hundred percent of this increase is allegedly due to mammography. In addition to harmful radiation, mammography may also help spread existing cancer cells due to the considerable pressure placed on the woman's breast during the procedure. According to some health practitioners, this compression could cause existing cancer cells to metastasize from the breast tissue.

Cancer research has also found a gene, called oncogene AC, that is extremely sensitive to even small doses of radiation. A significant percentage of women in the United States have this gene, which could increase their risk of mammography-induced cancer. They estimate that 10,000 A-T carriers will die of breast cancer this year due to mammography.

The risk of radiation is apparently higher among younger women. The NCI released evidence that, among women under 35, **mammography could cause 75 cases of breast cancer for every 15 it identifies**. Another Canadian study found a 52 percent increase in breast cancer mortality in young women given annual mammograms. Dr. Samuel Epstein also claims that pregnant women exposed to radiation could endanger their fetus. He advises against mammography during pregnancy because "the future risks of leukemia to your unborn child, not to mention birth defects, are just not worth it." Similarly, studies reveal that children exposed to radiation are more likely to develop breast cancer as adults.

Navigating the Statistics

While the number of *deaths* caused by breast cancer has decreased, the *incidence* of breast cancer is still rising. Since 1940, the incidence of breast cancer has risen by one to two percent every year. Between 1973 and 1991, the incidence of breast cancer in females over 65 rose nearly 40 percent in the United States.

Some researchers attribute this increase to better detection technologies; i.e., as the number of women screened for breast cancer rises, so does the number of reported cases. Other analysts say

the correlation between mammographic screening and increases in breast cancer is much more ominous, suggesting radiation exposure is responsible for the growing number of cases. While the matter is still being debated, Professor Sandra Steingraber offers ways to navigate these statistics. According to Steingraber, the rise in breast cancer predates the introduction of mammograms as a common diagnostic tool. In addition, the groups of women in whom breast cancer incidence is ascending most swiftly – blacks and the elderly – are also least likely to get regular mammograms.

The majority of health experts agree that the risk of breast cancer for women under 35 is not high enough to warrant the risk of radiation exposure. Similarly, the risk of breast cancer to women over 55 justifies the risk of mammograms. The statistics about mammography and women between the ages of 40 and 55 are the most contentious. A 1992 Canadian National Breast Cancer Study showed that mammography had no positive effect on mortality for women between the ages of 40 and 50. In fact, the study seemed to suggest that women in that age group are more likely to die of breast cancer when screened regularly.

Burton Goldberg, in his book, *Alternative Medicine*, recommends that women under 50 avoid screening mammograms, although the American Cancer Society encourages mammograms every two years for women ages 40 to 49. Trying to settle this debate, a 1997 consensus panel appointed by the NIH ruled that there was no evidence that mammograms for this age group save lives; they may even do more harm than good. The panel advises women to weigh the risks with their doctors and decide for themselves.

New Screening Technologies

While screening is an important step in fighting breast cancer, many researchers are looking for alternatives to mammography. Burton Goldberg totes the safety and accuracy of new thermography technologies. Able to detect cancers at a minute physical stage of development, thermography does not use x-rays, nor is there any compression of the breast. Also important, new thermography technologies do not lose effectiveness with dense breast tissue, decreasing the chances of false-negative results.

Some doctors are now offering digital mammograms. Digital mammography is a mammography system in which x-ray film is replaced by solid-state detectors that convert x-rays into electric signals. Though radiation is still used, digital mammography requires a much smaller dose. The electrical signals are used to produce images that can be electronically manipulated; a physician can zoom in, magnify and optimize different parts of breast tissue without having to take an additional image.

The experts speak on mammograms and breast cancer:

Regular mammography of younger women increases their cancer risks. Analysis of controlled trials over the last decade has shown consistent increases in breast cancer mortality within a few years of commencing screening. This confirms evidence of the high sensitivity of the premenopausal breast, and on cumulative carcinogenic effects of radiation.
The Politics Of Cancer by Samuel S Epstein MD, page 539

In his book, "Preventing Breast Cancer," Dr. Gofinan says that breast cancer is the leading cause of death among American women between the ages of forty-four and fifty-five. Because breast tissue is highly radiation-sensitive, mammograms can cause cancer. The danger can be heightened by a woman's genetic makeup, preexisting benign breast disease, artificial menopause, obesity, and hormonal imbalance.
Death By Medicine by Gary Null PhD, page 23

"The risk of radiation-induced breast cancer has long been a concern to mammographers and has driven the efforts to minimize radiation dose per examination," the panel explained. "Radiation can cause breast cancer in women, and the risk is proportional to dose. The younger the woman at the time of exposure, the greater her lifetime risk for breast cancer.
Under The Influence Modern Medicine by Terry A Rondberg DC, page 122

Furthermore, there is clear evidence that the breast, particularly in premenopausal women, is highly sensitive to radiation, with estimates of increased risk of breast cancer of up to 1% for every rad (radiation absorbed dose) unit of X-ray exposure. This projects up to a 20% increased cancer risk for a woman who, in the 1970s, received 10 annual mammograms of an average two rads each. In spite of this, up to 40% of women over 40 have had mammograms since the mid-1960s, some annually and some with exposures of 5 to 10 rads in a single screening from older, high-dose equipment.
The Politics Of Cancer by Samuel S Epstein MD, page 537

No less questionable—or controversial—has been the use of X rays to detect breast cancer: mammography. The American Cancer Society initially promoted the procedure as a safe and simple way to detect breast tumors early and thus allow women to undergo mastectomies before their cancers had metastasized.
The Cancer Industry by Ralph W Moss, page 23

The American Cancer Society, together with the American College of Radiologists, has insisted on pursuing largescale mammography screening programs for breast cancer, including its use in younger women, even though the NCI and other experts are now agreed that these are likely to cause more cancers than could possibly be detected.
The Politics Of Cancer by Samuel S Epstein MD, page 291

A number of "cancer societies" argued, saying the tests — which cost between $50-200 each - - are a necessity for all women over 40, despite the fact that radiation from yearly mammograms during ages 40-49 has been estimated to cause one additional breast cancer death per 10,000 women.
Under The Influence Modern Medicine by Terry A Rondberg DC, page 21

Mammograms Add to Cancer Risk—mammography exposes the breast to damaging ionizing radiation. John W. Gofman, M.D., Ph.D., an authority on the health effects of ionizing radiation, spent 30 years studying the effects of low-dose radiation on humans. He estimates that 75% of breast cancer could be prevented by avoiding or minimizing exposure to the ionizing radiation from mammography, X rays, and other medical sources. Other research has shown that, since mammographic screening was introduced in 1983, the incidence of a form of breast cancer called

ductal carcinoma in situ (DCIS), which represents 12% of all breast cancer cases, has increased by 328%, and 200% of this increase is due to the use of mammography.69 In addition to exposing a woman to harmful radiation, the mammography procedure may help spread an existing mass of cancer cells. During a mammogram, considerable pressure must be placed on the woman's breast, as the breast is squeezed between two flat plastic surfaces. According to some health practitioners, this compression could cause existing cancer cells to metastasize from the breast tissue.
Alternative Medicine by Burton Goldberg, page 588

In fact the benefits of annual screening to women age 40 to 50, who are now being aggressively recruited, are at best controversial. In this age group, one in four cancers is missed at each mammography. Over a decade of pre-menopausal screening, as many as three in 10 women will be mistakenly diagnosed with breast cancer. Moreover, international studies have shown that routine premenopausal mammography is associated with increased breast cancer death rates at older ages. Factors involved include: the high sensitivity of the premenopausal breast to the cumulative carcinogenic effects of mammographic X-radiation; the still higher sensitivity to radiation of women who carry the A-T gene; and the danger that forceful and often painful compression of the breast during mammography may rupture small blood vessels and encourage distant spread of undetected cancers.
The Politics Of Cancer by Samuel S Epstein MD, page 540

Since a mammogram is basically an x-ray (radiation) of the breast, I do not recommend mammograms to my patients for two reasons: 1) Few radiologists are able to read mammogams correctly, therefore limiting their effectiveness. Even the man who developed this technique stated on national television that only about six radiologists in the United States could read them correctly. 2) In addition, each time the breasts are exposed to an x-ray, the risk of breast cancer increases by 2 percent.
The Hope of Living Cancer Free by Francisco Contreras MD, page 104

Mammography itself is radiation: an X-ray picture of the breast to detect a potential tumor. Each woman must weigh for herself the risks and benefits of mammography. As with most carcinogens, there is a latency period or delay between the time of irradiation and the occurrence of breast cancer. This delay can vary up to decades for different people. Response to radiation is especially dramatic in children. Women who received X-rays of the breast area as children have shown increased rates of breast cancer as adults. The first increase is reflected in women younger than thirty-five, who have early onset breast cancer. But for this exposed group, flourishing breast cancer rates continue for another forty years or longer.
Eat To Beat Cancer by J Robert Hatherill, page 132

The use of women as guinea pigs is familiar. There is revealing consistency between the tamoxifen trial and the 1970s trial by the NCI and American Cancer Society involving high-dose mammography of some 300,000 women. Not only is there little evidence of effectiveness of mammography in premeno-pausal women, despite NCI's assurances no warnings were given of the known high risks of breast cancer from the excessive X-ray doses then used. There has been no investigation of the incidence of breast cancer in these high-risk women. Of related concern is the NCI's continuing insistence on premeno-pausal mammography, in spite of contrary warnings

by the American College of Physicians and the Canadian Breast Cancer Task Force and in spite of persisting questions about hazards even at current low-dose exposures. These problems are compounded by the NCI's failure to explore safe alternatives, especially transillumination with infrared light scanning.
The Politics Of Cancer by Samuel S Epstein MD, page 544

High Rate of False Positives—mammography's high rate of false-positive test results wastes money and creates unnecessary emotional trauma. A Swedish study of 60,000 women, aged 40-64, who were screened for breast cancer revealed that of the 726 actually referred to oncologists for treatment, 70% were found to be cancer free. According to The Lancet, of the 5% of mammograms that suggest further testing, up to 93% are false positives. The Lancet report further noted that because the great majority of positive screenings are false positives, these inaccurate results lead to many unnecessary biopsies and other invasive surgical procedures. In fact, 70% to 80% of all positive mammograms do not, on biopsy, show any presence of cancer.71 According to some estimates, 90% of these "callbacks" result from unclear readings due to dense overlying breast tissue.72
Alternative Medicine by Burton Goldberg, page 588

"Radiation-related breast cancers occur at least 10 years after exposure," continued the panel. "Radiation from yearly mammograms during ages 40-49 has been estimated to cause one additional breast cancer death per 10,000 women."
Under The Influence Modern Medicine by Terry A Rondberg DC, page 122

According to the National Cancer Institute, there is a high rate of missed tumors in women ages 40-49 which results in 40% false negative test results. Breast tissue in younger women is denser, which makes it more difficult to detect tumours, so tumours grow more quickly in younger women, and tumours may develop between screenings. Because there is no reduction in mortality from breast cancer as a direct result of early mammogram, it is recommended that women under fifty avoid screening mammograms although the American Cancer Society still recommends a mammogram every two years for women age 40-49. Dr. Love states, "We know that mammography works and will be a lifesaving tool for at least 30%."
Treating Cancer With Herbs by Michael Tierra ND, page 467

Equivocal mammogram results lead to unnecessary surgery, and the accuracy rate of mammograms is poor. According to the National Cancer Institute (NCI), in women ages 40-49, there is a high rate of "missed tumors," resulting in 40% false-negative mammogram results. Breast tissue in younger women is denser, which makes it more difficult to detect tumors, and tumors grow more quickly in younger women, so cancer may develop between screenings.
Alternative Medicine by Burton Goldberg, page 973

Even worse, spokespeople for the National Institutes of Health (NIH) admit that mammograms miss 25 percent of malignant tumors in women in their 40s (and 10 percent in older women). In fact, one Australian study found that more than half of the breast cancers in younger women are not detectable by mammograms.
Underground Cures by Health Sciences Institute, page 42

Whatever you may be told, refuse routine mammograms to detect early breast cancer, especially if you are premenopausal. The X-rays may actually increase your chances of getting cancer. If you are older, and there are strong reasons to suspect that you may have breast cancer, the risks may be worthwhile. Very few circumstances, if any, should persuade you to have X-rays taken if you are pregnant. The future risks of leukaemia to your unborn child, not to mention birth defects, are just not worth it.
The Politics Of Cancer by Samuel S Epstein MD, page 305

Other medical research has shown that the incidence of a form of breast cancer known as ductal carcinoma in situ (DCIS), which accounts for 12% of all breast cancer cases, increased by 328% — and 200% of this increase is due to the use of mammography!
Under The Influence Modern Medicine by Terry A Rondberg DC, page 123

As the controversy heated up in 1976, it was revealed that the hundreds of thousands of women enrolled in the program were never told the risk they faced from the procedure (ibid.). Young women faced the greatest danger. In the thirty-five- to fifty-year-old age group, each mammogram increased the subject's chance of contracting breast cancer by 1 percent, according to Dr. Frank Rauscher, then director of the National Cancer Institute (New York Times, August 23, 1976).
The Cancer Industry by Ralph W Moss, page 24

Because there is no reduction in mortality from breast cancer as a direct result of early mammograms, it is recommended that women under 50 avoid screening mammograms, although the American Cancer Society is still recommending a mammogram every two years for women ages 40-49. The NCI recommends that, after age 35, women perform monthly breast self-exams. For women over 50, many doctors still advocate mammograms. However, breast self-exams and safer, more accurate technologies such as thermography should be strongly considered as options to mammography.
Alternative Medicine by Burton Goldberg, page 973

In the midst of the debate, Kodak took out full-page ads in scientific journals entitled "About breast cancer and X-rays: A hopeful message from industry on a sober topic" (see Science, July 2, 1976). Kodak is a major manufacturer of mammography film.
The Cancer Industry by Ralph W Moss, page 24

The largest and most credible study ever done to evaluate the impact of routine mammography on survival has concluded that routine mammograms do significantly reduce deaths from breast cancer. Scientists in the United States, Sweden, Britain, and Taiwan compared the number of deaths from breast cancer diagnosed in the 20 years before mammogram screening became available with the number in the 20 years after its introduction. The research was based on the histories and treatment of 210,000 Swedish women ages 20 to 69. The researchers found that death from breast cancer dropped 44 percent in women who had routine mammography. Among those who refused mammograms during this time period there was only a 16 percent reduction in death from this disease (presumably the decrease was due to better treatment of the malignancy).
Dr Isadore Rosenfeld's Breakthrough Health By Isadore Rosenfeld MD, page 47

In 1993—seventeen years after the first pilot study—the biochemist Mary Wolff and her colleagues conducted the first carefully designed, major study on this issue. They analyzed DDE and PCB levels in the stored blood specimens of 14,290 New York City women who had attended a mammography screening clinic. Within six months, fifty-eight of these women were diagnosed with breast cancer. Wolff matched each of these fifty-eight women to control subjects—women without cancer but of the same age, same menstrual status, and so on—who had also visited the clinic. The blood samples of the women with breast cancer were then compared to their cancer-free counterparts.
Living Downstream by Sandra Steingraber PhD, page 12

One reason may be that mammograms actually increase mortality. In fact numerous studies to date have shown that among the under-50s, more women die from breast cancer among screened groups than among those not given mammograms. The results of the Canadian National Breast Cancer Screening Trial published in 1993, after a screen of 50,000 women between 40-49, showed that more tumors were detected in the screened group, but not only were no lives saved but 36 percent more women died from
The Cancer Handbook by Lynne McTaggart, page 57

One Canadian study found a 52 percent increase in breast cancer mortality in young women given annual mammograms, a procedure whose stated purpose is to prevent cancer. Despite evidence of the link between cancer and radiation exposure to women from mammography, the American Cancer Society has promoted the practice without reservation. Five radiologists have served as ACS presidents.53
When Healing Becomes A Crime by Kenny Ausubel, page 233

Premenopausal women carrying the A-T gene, about 1.5 percent of women, are more radiation sensitive and at higher cancer risk from mammography. It has been estimated that up to 10,000 breast cancer cases each year are due to mammography of A-T carriers.
The Politics Of Cancer by Samuel S Epstein MD, page 539

A study reported that mammography combined with physical exams found 3,500 cancers, 42 percent of which could not be detected by physical exam. However, 31 percent of the tumors were noninfiltrating cancer. Since the course of breast cancer is long, the time difference in cancer detected through mammography may not be a benefit in terms of survival.
Woman's Encyclopedia Of Natural Healing by Dr Gary Null, page 86

The American College of Obstetricians and Gynecologists also has called for more mammograms among women over 50. However, constant screening still can miss breast cancer. mammograms are at their poorest in detecting breast cancer when the woman is under 50.
The Cancer Handbook by Lynne McTaggart, page 53

Despite its shortcomings, every woman between the ages of fifty and sixty-nine should have one every year. I also recommend them annually for women over seventy, even though early detection isn't as important for the slow-growing form of breast cancer they tend to get. One mammogram should probably be taken at age forty to establish a baseline, but how often women should have them after that is debatable. Some authorities favor annual screening. Others feel

there's not enough evidence to support screening at all before fifty. Still others believe that every two years is sufficient. I lean toward having individual women and their doctors go over the pros and cons and make their own decisions. Finally, a mammogram is appropriate at any age if a lump has been detected.

The Longevity Code By Zorba Paster MD, page 234 For breast cancer, thermography offers a very early warning system, often able to pinpoint a cancer process five years before it would be detectable by mammography. Most breast tumors have been growing slowly for up to 20 years before they are found by typical diagnostic techniques. Thermography can detect cancers when they are at a minute physical stage of development, when it is still relatively easy to halt and reverse the progression of the cancer. No rays of any kind enter the patient's body; there is no pain or compressing of the breasts as in a mammogram. While mammography tends to lose effectiveness with dense breast tissue, thermography is not dependent upon tissue densities.
Alternative Medicine by Burton Goldberg, page 587

The Breast Cancer Screening Mistake Millions Make…

Posted By Dr. Mercola | October 15 2010 | 33,023 views

new study reported in the *New England Journal of Medicine* suggests that increased awareness and improved treatments rather than mammograms are the main force in reducing the breast cancer death rate.

The study, medical experts say, is the first to assess the benefit of mammography in the context of the modern era of breast cancer treatment.

While it is unlikely to settle the debate over mammograms — and experts continue to disagree about the value of the test — it indicates that improved treatments with hormonal therapy and other targeted drugs may have, in a way, washed out most of mammography's benefits by making it less important to find cancers when they are too small to feel.

As stated by the *New York Times*:

"In the new study, mammograms, combined with modern treatment, reduced the death rate by 10 percent, but the study data indicated that the effect of mammograms alone could be as low as 2 percent or even zero.

A 10 percent reduction would mean that if 1,000 50-year-old women were screened over a decade, 996 women rather than 995.6 would not die from the cancer — an effect so tiny it may have occurred by chance."

Sources:

- New York Times September 23, 2010
- New England Journal of Medicine September 23, 2010; 363(13):1203-10

Dr. Mercola's Comments:

Mammograms are often touted as a "life-saving" form of cancer screening, responsible for reducing breast cancer death rates by 15-25 percent. But this reported benefit is based on outdated studies done *decades* ago …

The *New England Journal of Medicine* is one of the most prestigious medical journals and it has now published the first *recent* study to look at the effectiveness of mammograms in years, and their findings are a far cry from what most public health officials and physicians would have you believe.

A Close to ZERO Percent Benefit …

In the latest study, researchers analyzed data from over 40,000 Norwegian women with breast cancer and found that those who had mammograms and were treated by special breast cancer medical teams had a 10 percent lower breast cancer death rate than women who had neither.

However, they also found that women over the age of 70 who were treated by the special teams had an 8 percent lower death risk from breast cancer, even though they had not received mammograms.

What this suggests, and what Dr. H. Gilbert Welch wrote in an accompanying editorial, is that mammograms may have only reduced the cancer death rate by 2 percent -- an amount so small it may as well be zero.

So the fact remains that there is no solid evidence that mammograms save lives. Past research has also demonstrated that adding an annual mammogram to a careful physical examination of the breasts does not improve breast cancer survival rates over getting the examination alone.

Now, if mammograms were completely safe and capable of reducing your cancer death risk even a small amount, you might be able to make an argument for their use. But mammograms are not only ineffective … they're unsafe as well.

The Dangers of Mammography: Ionizing Radiation

The first problem with mammograms is that they use ionizing radiation at a relatively high dose, which in and of itself can contribute to the development of breast cancer. Mammograms expose your body to radiation that can be *1,000 times greater* than that from a chest x-ray, which we know poses a cancer risk.

Mammography also compresses your breasts tightly, which could lead to a dangerous spread of cancerous cells, should they exist. Dr. Charles B. Simone, a former clinical associate in immunology and pharmacology at the National Cancer Institute, said:

"Mammograms increase the risk for developing breast cancer and raise the risk of spreading or metastasizing an existing growth."

Dr. Samuel Epstein, one of the top cancer experts, similarly stated:

"The premenopausal breast is highly sensitive to radiation, each 1 rad exposure increasing breast cancer risk by about 1 percent, with a cumulative 10 percent increased risk for each breast over a decade's screening."

False Positives are Alarmingly Common

The second glaring problem with mammography is its unacceptably high rate of false positives.

If a mammogram detects an abnormal spot in a woman's breast, the next step is typically a biopsy. This involves taking a small amount of tissue from the breast, which is then looked at by a pathologist under a microscope to determine if cancer is present.

The problem is that early stage cancer like ductal carcinoma in situ, or D.C.I.S., can be very hard to diagnose, and pathologists have a wide range of experience and expertise. There are no diagnostic standards for D.C.I.S., and there are no requirements that the pathologists doing the readings have specialized expertise.

Dr. Shahla Masood, the head of pathology at the University of Florida College of Medicine in Jacksonville, told the *New York Times*:

"There are studies that show that diagnosing these borderline breast lesions occasionally comes down to the flip of a coin."

Of course, upon receiving a breast cancer diagnosis, most women are afraid and even frantic to do whatever it takes to fight and remove the cancer. In the conventional medical arena, typically this means full or partial mastectomy, drugs and radiation.

Imagine going through surgery, having one or both of your breasts removed along with receiving debilitating radiation treatments and toxic drugs, only to later be told that you never had cancer.

This scenario happens more often than you might think, and you can read about several women's terrifying ordeals with false breast cancer diagnoses here.

How Often do Mammograms Lead to False Positive Diagnoses?

Estimates suggest that 17 percent of D.C.I.S. cases found through needle biopsy (often the next step after a mammogram detects a mass) are misdiagnosed. *The New York Times* also reported on several other concerning findings about the frequency of misdiagnosis:

- A 2006 study by Susan G. Komen for the Cure estimated that in 90,000 cases when women were diagnosed with D.C.I.S. or invasive breast cancer, they either did not have the disease or they got incorrect treatment due to a pathologist error.
- A 2002 study at Northwestern University Medical Center found that nearly 8 percent of 340 breast cancer cases " had errors serious enough to change plans for surgery."
- Dr. Lagios, a pathologist at St. Mary's Medical Center in San Francisco, reviewed nearly 600 breast cases in 2007 and 2008 and found discrepancies in 141 of them.

Mammograms also carry a first-time false positive rate of up to 6 percent. False positives can lead to unnecessary emotional stress and expensive repeat screenings, exposing you to even more radiation. Plus, as discussed earlier, they can sometimes result in unnecessary invasive procedures including biopsies, unnecessary surgery, radiation, chemotherapy and more.

The BEST Way to Lower Your Risk of Breast Cancer

Mammograms will not *prevent you* from getting breast cancer, and the latest study shows they offer very little benefit in improving your chances of survival if you do have it. So the best strategy, which I encourage all women to embark upon today, is not to simply get your yearly mammogram and hope for the best -- it's to make lifestyle changes that will significantly cut your cancer risks in the first place.

Researchers estimate that about 40 percent of U.S. breast cancer cases, or about 70,000 cases every year, could be prevented by making lifestyle changes.

A healthy diet, regular physical exercise, and an effective way to manage your emotional health are the cornerstones of just about any cancer prevention program, including breast cancer, but you will also want to make sure your vitamin D levels are optimized.

Vitamin D, a steroid hormone that influences virtually every cell in your body, is easily one of nature's most potent cancer fighters.

According to one landmark study, some 600,000 cases of breast and colorectal cancers could be prevented each year if vitamin D levels among populations worldwide were increased. And that's just counting the death toll for two types of cancer (it actually works against at least 16 different types)!

So please do watch my one-hour free lecture on vitamin D to find out what your optimal vitamin D levels should be … and how to get them there. This is one of the most important steps you can take to protect yourself from cancer.

There's also research showing that by simply supplementing your diet with animal-based omega-3 fats like krill oil you may reduce your breast cancer risk by 32 percent, so this is another strategy I suggest you embrace.

What about Screening?

Effective cancer screening methods are important, but mammography is simply NOT a safe or effective cancer screen. Instead, I strongly advise you to consider the safer and more effective alternative of thermographic breast screening, especially if you are younger and have not already been diagnosed with, or undergone treatment for, breast cancer.

By measuring the radiation of infrared heat from your body, thermographic screening can detect signs of breast cancer as much as 10 years earlier than either mammography or a physical exam -- all without any ionizing radiation or mechanical pressure.

Its ability to detect the possibility of breast cancer, before any tumors have formed, is because it can provide a picture of the early stages of angiogenesis -- the formation of a direct supply of blood to cancer cells, which is a necessary step before they can grow into tumors of size.

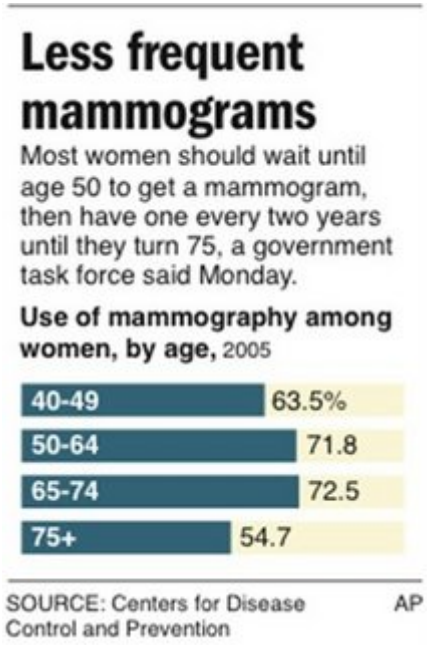
I recently discussed this mechanism in another article. In it, Dr. Li presents compelling evidence that by including more anti-angiogenetic foods in your diet, you may be able to effectively starve cancer and prevent tumors from ever forming since they must have sufficient blood supply to thrive, just like all other cells.

Were you to undergo a thermographic screening and discover that angiogenesis is taking place, meaning that tiny blood vessels have begun sprouting to an area to feed cancer cells, you now have YEARS at your disposal to effectively "cure yourself" (although by conventional standards you're not yet ill) by implementing lifesaving lifestyle changes.

This would logically include increased amounts of anti-angiogenetic foods such as red grapes, berries, turmeric and broccoli, just to name a few. For more information, I recommend watching Dr. Li's video.

New advice: Skip mammograms in 40s, start at 50

Associated Press



AP – HOLD FOR RELEASE UNTIL 5 p.m. EST; graphic shows the use of mammography among women 40 and older by age

By STEPHANIE NANO and MARILYNN MARCHIONE, Associated Press Writers Stephanie Nano And Marilynn Marchione, Associated Press Writers – 31 mins ago

NEW YORK – Most women don't need a mammogram in their 40s and should get one every two years starting at 50, a government task force said Monday. It's a major reversal that conflicts with the American Cancer Society's long-standing position.

Also, the task force said breast self-exams do no good and women shouldn't be taught to do them.

For most of the past two decades, the cancer society has been recommending annual mammograms beginning at 40.

But the government panel of doctors and scientists concluded that getting screened for breast cancer so early and so often leads to too many false alarms and unneeded biopsies without substantially improving women's odds of survival.

"The benefits are less and the harms are greater when screening starts in the 40s," said Dr. Diana Petitti, vice chair of the panel.

The new guidelines were issued by the U.S. Preventive Services Task Force, whose stance influences coverage of screening tests by Medicare and many insurance companies.

But Susan Pisano, a spokeswoman for America's Health Insurance Plans, an industry group, said insurance coverage isn't likely to change because of the new guidelines. No changes are planned in Medicare coverage either, said Dori Salcido, spokeswoman for the Health and Human Services department.

Experts expect the task force revisions to be hotly debated, and to cause confusion for women and their doctors.

"Our concern is that as a result of that confusion, women may elect not to get screened at all. And that, to me, would be a serious problem," said Dr. Len Lichtenfeld, the cancer society's deputy chief medical officer.

The guidelines are for the general population, not those at high risk of breast cancer because of family history or gene mutations that would justify having mammograms sooner or more often.

The new advice says:

_Most women in their 40s should not routinely get mammograms.

_Women 50 to 74 should get a mammogram every other year until they turn 75, after which the risks and benefits are unknown. (The task force's previous guidelines had no upper limit and called for exams every year or two.)

_The value of breast exams by doctors is unknown. And breast self-exams are of no value.

Medical groups such as the cancer society have been backing off promoting breast self-exams in recent years because of scant evidence of their effectiveness. Decades ago, the practice was so heavily promoted that organizations distributed cards that could be hung in the shower demonstrating the circular motion women should use to feel for lumps in their breasts.

The guidelines and research supporting them were released Monday and are being published in Tuesday's issue of the Annals of Internal Medicine.

The new advice was sharply challenged by the cancer society.

"This is one screening test I recommend unequivocally, and would recommend to any woman 40 and over," the society's chief medical officer, Dr. Otis Brawley, said in a statement.

The task force advice is based on its conclusion that screening 1,300 women in their 50s to save one life is worth it, but that screening 1,900 women in their 40s to save a life is not, Brawley wrote.

That stance "is essentially telling women that mammography at age 40 to 49 saves lives, just not enough of them," he said. The cancer society feels the benefits outweigh the harms for women in both groups.

International guidelines also call for screening to start at age 50; the World Health Organization recommends the test every two years, Britain says every three years.

Breast cancer is the most common cancer and the second leading cause of cancer deaths in American women. More than 192,000 new cases and 40,000 deaths from the disease are expected in the U.S. this year.

Mammograms can find cancer early, and two-thirds of women over 40 report having had the test in the previous two years. But how much they cut the risk of dying of the disease, and at what cost in terms of unneeded biopsies, expense and worry, have been debated.

In most women, tumors are slow-growing, and that likelihood increases with age. So there is little risk by extending the time between mammograms, some researchers say. Even for the minority of women with aggressive, fast-growing tumors, annual screening will make little difference in survival odds.

The new guidelines balance these risks and benefits, scientists say.

The probability of dying of breast cancer after age 40 is 3 percent, they calculate. Getting a mammogram every other year from ages 50 to 69 lowers that risk by about 16 percent.

"It's an average of five lives saved per thousand women screened," said Georgetown University researcher Dr. Jeanne Mandelblatt.

Starting at age 40 would prevent one additional death but also lead to 470 false alarms for every 1,000 women screened. Continuing mammograms through age 79 prevents three additional deaths but raises the number of women treated for breast cancers that would not threaten their lives.

"You save more lives because breast cancer is more common, but you diagnose tumors in women who were destined to die of something else. The overdiagnosis increases in older women," Mandelblatt said.

She led six teams around the world who used federal data on cancer and mammography to develop mathematical models of what would happen if women were screened at different ages and time intervals. Their conclusions helped shape the new guidelines.

Several medical groups say they are sticking to their guidelines that call for routine screening starting at 40.

"Screening isn't perfect. But it's the best thing we have. And it works," said Dr. Carol Lee, a spokeswoman for the American College of Radiology. She suggested that cutting health care costs may have played a role in the decision, but Petitti said the task force does not consider cost or insurance in its review.

The American College of Obstetricians and Gynecologists also has qualms. The organization's Dr. Hal Lawrence said there is still significant benefit to women in their 40s, adding: "We think that women deserve that benefit."

But Dr. Amy Abernethy of the Duke Comprehensive Cancer Center agreed with the task force's changes.

"Overall, I think it really took courage for them to do this," she said. "It does ask us as doctors to change what we do and how we communicate with patients. That's no small undertaking."

Abernethy, who is 41, said she got her first mammogram the day after her 40th birthday, even though she wasn't convinced it was needed. Now she doesn't plan to have another mammogram until she is 50.

Barbara Brenner, executive director of the San Francisco-based Breast Cancer Action, said the group was "thrilled" with the revisions. The advocacy group doesn't support screening before menopause, and will be changing its suggested interval from yearly to every two years, she said.

Mammograms, like all medical interventions, have risks and benefits, she said.

"Women are entitled to know what they are and to make their best decisions," she said. "These guidelines will help that conversation."

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Medical Writer Marilynn Marchione reported from Milwaukee.

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On the Net:

Government advice: http://www.ahrq.gov/clinic/uspstf/uspsbrca.htm

New Mammogram Guidelines Issued ... Again

Breast cancer screening just got more confusing today, as two medical organizations announced annual mammograms should begin at age 40, and earlier for high-risk women. The recommendations contradict a recent advisory for less frequent screenings beginning at age 50, not 40.

The recommendations for less frequent mammograms, released in November, came from the U.S. Preventive Services Task Force, with panel experts saying they were responding to data showing routine mammograms starting at age 40 rarely saved lives and more often resulted in misdiagnoses that just fueled anxiety and debilitating treatment.

This new advice, which is published in the January issue of the Journal of the American College of Radiology, comes from the Society of Breast Imaging (SBI) and the American College of Radiology (ACR). And these groups suggest just the opposite - that the screening does save lives.

"The significant decrease in breast cancer mortality, which amounts to nearly 30 percent since 1990, is a major medical success and is due largely to earlier detection of breast cancer through mammography screening," said lead study author Dr. Carol H. Lee, a radiologist at Memorial Sloan-Kettering Cancer Center. "For women with the highest risk of developing breast cancer, screening technologies in addition to mammography have been adopted," said Lee, who is the chair of ACR's Breast Imaging Commission.

What's a woman to do? Regarding how women should follow the task force recommendations from November, Dr. Carl D'Orsi, director of Emory University's Breast Imaging Center, said, "As a bottom line, they should be ignored." D'Orsi was a member of the team that came out with today's recommendations.

Dr. Ned Calonge, chairman of the U.S. Preventive Services Task Force, had not responded to a request for an interview as of this writing.

Screening science

D'Orsi and his colleagues reviewed the results of several randomized trials in Europe and North America, which included nearly 500,000 women in total. The review of these studies showed a 26 percent reduction in breast cancer mortality.

"This is scientifically driven with data, unlike what the task force did," D'Orsi said.

While today's recommendations are consistent with those put out by other groups, including the American Cancer Society, the new ones include other imaging techniques in addition to mammography.

Here are some of the highlights:

- The average patient should begin annual mammograms at age 40, and high-risk patients should begin by age 30 but not before 25. A woman with certain mutations to the BRCA1 or BRCA2 genes would be considered a high-risk individual.
- Annual MRI (magnetic resonance imaging) starting by age 30 is recommended for carriers of deleterious BRCA mutations. Women who are considered to have at least a 20 percent lifetime risk for breast cancer based on family history should get annual mammograms and annual MRI starting at age 30 (not before age 25), or 10 years before the age of the youngest affected relative, whichever is later.
- Ultrasound, in addition to mammography, can be considered for high-risk women and those with dense breast tissue. While ultrasound isn't as sensitive as MRI to detecting breast cancer, D'Orsi said some women can't get an MRI due to their weight (those over 300 pounds) and other factors.

Comparing recommendations

The U.S. Preventive Services Task Force, an independent government agency made up of 16 primary care physicians and public health specialists, in November recommended breast cancer screening every other year for women aged 50 to 74. They argued against routine screening before this age.

That was counter to their own guidelines from 2002, D'Orsi said.

"All of a sudden, with no new data - ignoring the fact that there are seven trials that demonstrate a drop in breast cancer mortality with use of mammography versus no mammography, plus that breast cancer mortality has dropped 30 percent - they come out with a recommendation that no screening be done at age 40 to 49," D'Orsi told LiveScience.

He added, "Basically they said nothing is good. Just wait until it breaks through your skin and we'll take care of it. That's what we did in 1940."

In fact, the task force did note a 15-percent reduction in mortality among those ages 40 to 49 who are screened," D'Orsi and colleagues wrote in their research paper. But they stated the harms outweigh the benefits. These harms include: anxiety over false positive results, the screening itself, need for additional testing or biopsy, and the possibility of overdiagnosis and overtreatment.

Why start screening at age 50? Essentially, years ago scientists began grouping women under and over age 50 into separate groups. And so when the age groups get compared, there are far fewer incidences of breast cancer in the younger group than in those 50 and older.

"Of course there's more breast cancer there, because it's age dependent," D'Orsi said. "That doesn't mean you don't screen. As a matter of fact those cancers [in the younger age group] are biologically more significant and may have a greater impact on life expectancy."

Radiation and Medical Imaging

What is radiation?

Radiation is best described as energy moving through space, and it can take many forms, including visible light, x-rays, gamma-rays, microwaves, and radio waves. Radiologists use low dose radiation in the form of x-rays to create images of different parts of your body. High doses of radiation can also be used to treat certain types of cancer.

Where does radiation come from?

Radiation is all around us. The two main sources of ionizing radiation are from natural background radiation and medical exposure (CT scans and x-rays). Natural background radiation comes from the Sun (cosmic radiation), the Earth (mostly Radon gas), and from naturally radioactive substances in our body. Natural background radiation exposure accounts for an average of 3.1 mSv/yr with variations depending on where you live. The average radiation exposure to individuals in the US is 6.2 mSv/yr which includes natural background and medical imaging.

What are x-rays?

X-rays are a type of radiation used in medical imaging much like a camera uses visible light to create an image. X-rays pass through the body and create an image on film based on how many x-rays get absorbed and how many pass through. These films are commonly referred to as "x-rays," but x-rays are actually the type of radiation that is used to produce the image. Studies that use x-rays include plain films, fluoroscopy, and computed tomography (CT scans).

Understanding Risk

It is important to realize that in a properly performed individual exam, the potential health benefits almost always outweigh the potential risks of radiation exposure. Great effort has been made throughout the medical community to ensure patient safety while providing quality diagnostic images. However, there is data to suggest that high doses of radiation increase your future risk of cancer. The data is compiled from high dose exposures including survivors of atomic bombs and radiation spills. There is no proof that the low doses of radiation used with common x-rays or CT scans cause cancer, but we know enough to use this technology carefully and only when needed.

Typical Radiation Doses

Exam	Dose (mSv)
Dental x-rays	0.01
Airline Flight	0.02
Mammogram	0.04
Chest x-ray	0.10
Natural Background	3.1 / year
Average US Exposure	6.2 / year
Chest CT	7.0
Abdominal CT	8.0

Quick Tips

- Benefits of study usually outweigh potential risks.
- Don't get any study you don't need.
- Keep a history of your studies to avoid unnecessary repeat exams.

X-RAY RISK

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Provided by www.XrayRisk.com. Visit online to learn more and to access our risk calculator.

Radiation, Risks Are Focus of Breast Screening Studies

Journal Radiology Published: August 24, 2010

By RONI CARYN RABIN

When Dr. Deborah Rhodes orders a diagnostic test that involves radiation, she consults a chart in her office that lists the amount of radiation exposure from each test. She considers the patient's total past exposure, and then carefully weighs the risks and benefits of each test and any alternative approaches she can take.

Two new studies appearing in Tuesday's issue of the journal Radiology suggest more physicians should take this approach. One study found that certain nuclear-based breast imaging exams that involve injecting radioactive material into patients expose women to far higher doses of radiation than regular mammography, increasing their risk of cancer in vulnerable organs beyond the breast, like the kidneys, bladder or ovaries.

Over all, the United States population's annual radiation dose from medical procedures increased sevenfold between 1980 and 2006, a second paper reports.

"I'm a radiation phobe — I'll come right out and say this," said Dr. Rhodes, an internist at the Mayo Clinic who is doing research to develop screening technologies that require less radiation exposure to the patient. "I'm constantly monitoring radiation doses in my patients."

Unfortunately, she said, "this is something that isn't well understood, not just by the public — but by physicians who order the tests."

R. Edward Hendrick, a physicist who has studied breast imaging for almost 30 years, said he was motivated to quantify the radiation exposure from nuclear breast imaging technologies in a published paper because of similar concerns.

"I would go to the international breast meeting and the big radiology meetings, and nobody had a clue what the doses and risks were," Dr. Hendrick said. "They're treating all the tests as if they have the same radiation dose and risk as mammography, and the truth is they have a much, much higher risk. The point of the paper was to say that not all the breast imaging procedures have comparable risks and doses."

Dr. Hendrick, a clinical professor of radiology at the University Colorado-Denver School of Medicine in Aurora, Colo., is a consultant to G.E. Healthcare regarding digital breast tomosynthesis, another breast imaging technique, and is on the medical advisory boards of Koning and Bracco, which make other imaging technologies.

The nuclear technologies **breast-specific gamma imaging (B.S.G.I.) and positron emission mammography (P.E.M.)** are meant to be used as complements or adjuncts to mammography and ultrasound, once there is concern about a cancerous lesion, and not for routine screening. These technologies are also more useful in women who have very dense breast tissue, when mammography often does not provide clear images.

But a single breast-specific gamma imaging or positron emission mammography exam exposes patients to a risk of radiation-induced cancer that is comparable to the risk from an entire lifetime of yearly mammograms starting at 40, according to Dr. Hendrick's study.

While digital mammography has an average lifetime risk of inducing 1.3 fatal breast cancers per 100,000 women aged 40 at exposure, a single B.S.G.I. exam was estimated to involve a lifetime risk 20 to 30 times greater in women aged 40, and the lifetime risk of a single P.E.M. was 23 times greater.

Moreover, mammography only increases a woman's risk for breast cancer while B.S.G.I. and P.E.M. increase the risk of cancer in other organs, such as the intestines, kidneys, bladder, gallbladder, uterus, ovaries and colon, the study said.

There is also a concern that use of the imaging technologies will become more widespread and casual. "B.S.G.I. and P.E.M. are great tools for problem solving, if you have a patient with an abnormal mammogram and you're not really sure," said Dr. Rhodes. "The problem is these tests are now being considered and even being used in some cases as screening tests, and this is not appropriate."

"I'm not saying 'Don't do the test,' I'm just saying 'Don't prescribe these tests willy-nilly like you would an ultrasound exam,' " Dr. Hendrick said.

In another paper in the same issue of Radiology, William R. Hendee, a distinguished professor of radiology, radiation oncology, biophysics and bioethics at the Medical College of Wisconsin in Milwaukee, called on radiologists to spearhead a campaign to reduce overuse of imaging technologies that expose patients to radiation unnecessarily and drive up health costs in the process

Suggested proposals for curbing excessive use of imaging include developing national evidence-based appropriateness criteria for imaging, educating referring physicians and the public, curbing the physician practice of self-referral and finding ways to reduce duplicate exams.

Companies that make the two nuclear-based breast imaging exams did not argue with the assessment of radiation exposure, but said the comparison with mammography — which exposes patients to very low levels of radiation, equivalent to about two months of natural background radiation — was inappropriate because the tests are used differently.

"The comparison to mammography is a bit like comparing apples to oranges," said Doug Kieper, vice president of science and technology for Dilon Technologies Inc., which developed the B.S.G.I. technology. "This is not being used as a screening procedure for the general asymptomatic population who have no indication of disease." He added that studies were already under way to see if the same results could be obtained using lower doses of radiation.

Guillaume Bailliard, vice president for marketing for Naviscan, which makes the P.E.M. scanner, said it should never be used as a tool for routine screening. "It is true that P.E.M. provides a higher dose than mammography," he said, "but physicians balance the risk-to-benefit when making decisions."

A version of this article appeared in print on August 24, 2010, on page D5 of the New York edition.

Study Questions Safety of Mammograms for Young Women at High Risk of Cancer

By DENISE GRADY

Published: December 1, 2009 New York Times

For young women who have a high risk of breast cancer because of genetic mutations or family history, the radiation from yearly mammograms may make the risk even higher, researchers reported at a radiology conference on Monday.

The report is particularly troubling because it suggests that the very women who are told they need mammograms most may also be the most vulnerable to harm from them. Doctors routinely urge high-risk women to have mammograms earlier in life and more often than women judged to be at average risk.

Researchers caution that the new report is not conclusive, and that the issue needs more study.

High doses of radiation can increase the risk of breast cancer, especially in young women, but mammography uses a low dose. The American Cancer Society and many breast cancer experts say the benefits of screening far outweigh any theoretical risk from the radiation.

But the new findings will probably fuel the debate that was ignited by a recent article in The Journal of the American Medical Association questioning the value of breast cancer screening and a report by a government task force suggesting that most women could start having mammograms later in life and repeat them less often than had generally been recommended.

The latest findings come not from new research, but from an analysis that pooled the data from six earlier studies involving about 5,000 high-risk women in the United States and Europe, some who had breast cancer and some who did not. Their median age was 45.

Looking back at their medical histories, researchers found that those women who had had mammograms or chest X-rays (which use a lower radiation dose than mammography) were more likely to have breast cancer.

Specifically, women exposed to radiation before age 20 or women with five or more exposures were 2.5 times more likely to develop breast cancer than were women who had not been exposed. The difference was statistically significant after all the data was pooled, but only some of the individual studies had significant findings; in those that did not reach statistical significance, the results could have been due to chance.

The analysis applies only to women who, like those in the study, have a high risk of breast cancer — about 0.5 percent to 1 percent of the population.

Marijke C. Jansen-van der Weide, the first author of the study and an epidemiologist at University Medical Center Groningen in the Netherlands, presented the analysis in Chicago at a meeting of the Radiological Society of North America.

In a telephone interview, Dr. Jansen-van der Weide said it was of concern to find a doubling of risk in women whose baseline risk was already high, and she suggested that young women at high risk should avoid repeated exposure to even low-dose radiation. She said the same mutation that increased the risk of breast cancer might make the breast more susceptible to cancer caused by radiation.

“For high-risk women, it’s important to weigh the benefits and risks of mammography with their doctor and come together on a screening strategy, and to keep in mind that at a young age you can use an alternative screening technique like M.R.I.,” Dr. Jansen-van der Weide said.

Robert Smith, director of cancer screening for the American Cancer Society, questioned the analysis’ methodology and disagreed with the idea that M.R.I. could replace mammography in high-risk women. Dr. Smith said M.R.I. missed some tumors that mammography could find, and vice versa, so the best approach for high-risk women was to use the two tests together.

“It’s not as if clinicians are unaware and unconcerned about radiation risks in young women,” he said. “If mammography offered no advantage, they wouldn’t do it.”

More Articles in Health » A version of this article appeared in print on December 1, 2009, on page A16 of the New York edition.

BREAST CANCER ACTION

What You Should Know About Mammograms

Mammography is a method of examining the breasts by using low-dose x-ray. Currently it is the best screening method widely available. Annual screening mammograms—x-rays given to healthy women without any symptoms—may reduce the breast cancer death rate in women over 50. There has been much debate about use of mammograms to screen women aged 40 to 49. To make an informed decision about mammograms, women must be aware of the following facts:

Mammograms do not prevent breast cancer.

They detect cancer that already exists. Most breast cancers have been present for six to eight years by the time they appear on mammograms.[1]

Mammography is a form of ionizing radiation.

Radiation is a known cause of cancer, and the effects of small amounts may accumulate in the body. This does not mean you should never have an x-ray, but rather that you should be thoughtful of your exposure to radiation. The risk of harm from radiation is highest in tissue where cells are rapidly changing, such as the growing breast tissue of adolescent females.

The quality of mammography screening varies widely.

Quality depends on many factors including the age and maintenance of the equipment, and the expertise of the radiologist who interprets the films. For your first mammogram, do not hesitate to ask to meet with your radiologist to discuss how readable your mammogram is or isn't. Newer machines are tested to ensure they emit lower amounts of radiation. To check if a center is accredited by the American College of Radiology, call 1-800-4-CANCER.

Mammography is an imperfect test.

It misses 10% of all tumors, and 25% of tumors in women younger than 50.[2] Pre-menopausal women are more likely to have dense breast tissue, which appears white on an x-ray, as does cancer. So the false positive rate—the frequency of unnecessary biopsies—is twelve times higher among women under 50 than women over 50.[3]

Mammography has been shown to lower mortality only in women ages 50 to 65.

If every woman in this age group had an annual mammogram, the breast cancer mortality rate could be reduced for this group by as much as one third, though recent studies have cast some doubt on this estimate.

For women between 40 and 49, trials have shown no consistent effect on mortality.[4] Healthy women younger than 50 should not have mammograms as a routine matter. The risk of radiation, combined with the high incidence of both false negatives and false positives, means that routine mammography for women under 50 may well do more harm than good.

Mammograms should be part of, rather than all of, a breast cancer detection program.

Mammograms should be combined with monthly breast self-exams and annual clinical exams by trained professionals. For women under 50, the most powerful detection method may very well be their own two hands.

Notes:

1 Love, Susan M. with Karen Lindsey, Dr. Susan Love's Breast Book, 2nd Edition, p. 251. Merloyd Lawrence, 1998.

2 National Institutes of Health Consensus Development Conference Statement, Breast Cancer Screening for Women Ages 40-49, January 21-23, 1997.

3 Love, Susan M. with Karen Lindsey, Dr. Susan Love's Breast Book, 2nd Edition, p. 258, Merloyd Lawrence, 1998.

4 National Institutes of Health Consensus Development Conference Statement: Breast Cancer Screening for Women Ages 40-49, January 21-23, 1997.

BREAST CANCER ACTION

What You Should Know About Mammograms

Glossary:

Biopsy: removal of breast tissue to check for the presence of cancer cells. Mammograms alert doctors to possibly cancerous tumors. A biopsy is the only way to be sure whether or not the abnormality is cancer.

Cancer: a term for diseases in which abnormal cells divide without control.

Ionizing radiation: radiation that can change molecules when exposed to it, turning them into electrically charged particles (ions). X-rays are one form of ionizing radiation, nuclear waste also generates ionizing radiation.

Resources

California Breast Cancer Early Detection Program
(free screening for low-income women over 40)
800-511-2300

Bay Area Breast Cancer Network, San Jose
408-261-1425; www.babcn.org

Charlotte Maxwell Complementary Clinic
(free complementary therapies for low-income women with cancer)
510-601-7660; www.charlottemaxwell.org

Community Breast Health Project, Palo Alto
650-326-6686; www.med.stanford.edu/CBHP

Marin Breast Cancer Watch
415-256-9011; www.breastcancerwatch.org

National Breast and Cervical Cancer Early Detection Program
888-842-6355; www.cdc.gov/cancer/nbccedp/

The Wellness Community, Walnut Creek
925-933-0107; www.twc-bayarea.org

Women's Cancer Resource Center, Berkeley
510-548-9272; www.wcrc.org

For Free Second Opinion in the Bay Area

Regional Cancer Foundation
415-775-9956

For Legal Assistance

California Women's Law Center
1-888-774-5200; www.cwlc.org

Patient Advocate Foundation
800-532-5274; www.patientadvocacy.org

National Support/Health Groups

National Y-ME
(referrals to local support groups)
800-221-2141; www.y-me.org

National Latina Health Organization
510-534-1362

National Lymphedema Network
800-541-3259; www.lymphnet.org

National Women's Health Network
202-347-1140; www.womenshealthnetwork.org

Breast Cancer Action
55 New Montgomery Street
Suite 323
San Francisco, CA 94105

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877-278-6722
415-243-9301
415-243-3996 Fax

Email: info@bcaction.org
www.bcaction.org

Breast MRI By Mayo Clinic staff

Original Article: http://www.mayoclinic.com/health/breast-mri/MY00300

Definition

Breast MRI

Magnetic resonance imaging (MRI) of the breast — or breast MRI — is a test used to detect breast cancer and other abnormalities in the breast.

A breast MRI captures multiple pictures of your breast. Breast MRI images are combined, using a computer, to generate detailed pictures.

Breast MRI usually is performed when your doctor needs more information than a mammogram, ultrasound or clinical breast exam can provide. In certain situations, such as when a woman has a very high risk of breast cancer, breast MRI may be used along with mammograms as a screening tool for detecting breast cancer.

Why it's done

Breast MRI is most often used to screen for breast cancer in women thought to have a very high risk of the disease. Breast MRI may be used to diagnose breast diseases and conditions. Your doctor may recommend a breast MRI if:

- You've been diagnosed with breast cancer and your doctor wants to determine the extent of the cancer
- Your doctor finds a suspicious area on your mammogram
- You or your doctor can feel a mass or other lump in your breast, but it's not detectable on mammogram or ultrasound
- You have a suspected leak or rupture of a breast implant
- You're at high risk of breast cancer, defined as a lifetime risk of 20 to 25 percent or greater, as calculated by risk tools that take your family history and other factors into consideration
- You have a strong family history of breast cancer or ovarian cancer
- You have very dense breast tissue and your prior breast cancer wasn't detected on mammogram
- You have a history of precancerous breast changes — such as atypical hyperplasia or lobular carcinoma in situ — a strong family history of breast cancer and dense breast tissue

If you're unsure whether you're considered high risk, ask your doctor to help you determine your personal risk estimate. A referral to a breast clinic or breast health specialist may help you better understand your risk and your screening options.

Breast MRI is intended to be used in addition to a mammogram or another breast-imaging test — not as a replacement for a mammogram. Although it's a very sensitive test, breast MRI can still miss some breast cancers that a mammogram will detect.

Risks

A breast MRI is a safe procedure that doesn't expose you to radiation. But as with other tests, a breast MRI has risks, such as:

- **A risk of false-positive results.** A breast MRI may identify suspicious areas that, after further evaluation, turn out to be benign. These results are known as "false-positives." A false-positive result may cause unneeded anxiety if you undergo additional testing, such as a biopsy, to assess the suspicious areas.
- **A risk of reaction to the contrast dye used.** A breast MRI involves using a dye to make the images easier to interpret. This dye can cause allergic reactions and can cause serious complications for people with kidney problems.

How you prepare

To prepare for a breast MRI, your doctor may recommend that you:

- **Schedule your MRI for the beginning of your menstrual cycle.** If you're premenopausal, the MRI facility may prefer to schedule your MRI at a certain point during your menstrual cycle, around days seven to 14. Let the facility know where you are in your cycle so that optimal timing for the breast MRI can be arranged.
- **Tell your doctor about any allergies you have.** Most MRI procedures use a dye to make the images easier to interpret. The dye is usually given through a vein in your arm. Tell your doctor about any allergies to avoid complications with the dye.
- **Tell your doctor if you have kidney problems.** A dye commonly used to enhance MRI images called gadolinium can cause serious complications in people with kidney problems. Tell your doctor if you have a history of kidney problems.
- **Tell your doctor if you're pregnant.** MRI generally isn't recommended for women who are pregnant.
- **Tell your doctor if you're nursing.** If you're nursing, your doctor will likely recommend that you stop for two days after your MRI. This gives your body time to eliminate the contrast dye and minimize the risk to your baby.
- **Don't wear anything metallic during the MRI.** Metallic objects, such as necklaces, hairpins and watches, can be damaged during an MRI. Leave metallic objects at home or remove them before your MRI.
- **Tell your doctor about implanted medical devices.** If you have an implanted medical device, such as a pacemaker, defibrillator, implanted drug port or artificial joint, tell your doctor before your MRI.

What you can expect

Breast MRI

When you arrive for your appointment, a member of your health care team will give you a gown and a robe to wear. You'll receive instructions on removing clothing and jewelry. If you have trouble being in a small, confined space, tell your doctor before your breast MRI. You may be given a mild sedative.

A contrast agent (dye) may be injected through an intravenous (IV) line in your arm to enhance the appearance of tissues or blood vessels on the MRI pictures.

The MRI machine has a large, central opening. During the breast MRI, you lie facedown on a padded scanning table. Your breasts fit into a hollow depression in the table, which contains coils that detect magnetic signals from the MRI machine. The entire table then slides into the opening of the machine.

The MRI machine creates a magnetic field around you, and radio waves are directed at your body. You won't feel the magnetic field or radio waves, but you may hear loud tapping and thumping sounds coming from inside the machine. Because of this, you may be given earplugs to wear.

During the test, the technologist monitors you from another room. You can speak to the technologist through a microphone. You'll be instructed to breathe normally but to lie as still as possible.

The breast MRI appointment may take 30 minutes to one hour.

Results

Breast MRI results

A radiologist — a doctor specializing in imaging techniques — reviews the images from your breast MRI, and a member of your health care team will contact you to discuss the results of the test.

References
MY00300 July 23, 2011

See BCCA news letter from 3/30 for link to conference and slides

Imaging

There were a number of talks on breast cancer imaging, both for detection (screening) and for making a more precise diagnosis after a tumor is detected.
Ultrasound in Breast Cancer Screening

Wendie Berg, a radiologist, started from the premise that mammography is the gold standard but noted that some subgroups of women may not benefit from mammography. She thinks that women at high risk of developing breast cancer should get MRIs for screening under the American Cancer Society's guidelines. And she also maintains that women getting MRIs and mammograms don't need to do ultrasound, too.

But for women at intermediate risk, Berg finds lots of things to favor ultrasound: it's relatively inexpensive, widely available, not radiation based, and well tolerated. The ongoing trial of ultrasound for screening—ACCRIN 666—which published its first results in JAMA in May 2008, shows that ultrasound is good at finding small lesions and node-negative disease, but there are a lot of false positives, leading to unnecessary biopsies. Of course, this happens with every detection method currently in use.

Issues of technologist training and insurance reimbursement also need to be resolved. And, as is always the case whenever the discussion is about screening, Berg pointed out that ultrasound supplements but doesn't replace mammography.
MRI as a Diagnostic Tool

Monica Morrow is a surgical oncologist who heads Memorial Sloan-Kettering Cancer Center's Breast Service. Her major research interest is the application of knowledge from clinical trials to daily surgical practice, and her talk was a beautiful example of this.

MRI is used in detecting breast cancer in asymptomatic women (screening) and in providing information to improve patient outcome in women with breast cancer (diagnosis). Morrow addressed MRI's use as a diagnostic tool only. The potential benefits of MRI in diagnosis are to refine decisions about breast conservation therapy, determine the extent of the tumor, identify potential contralateral cancer, and decrease the risk of local recurrence.

In a range of studies, the total number of mastectomies is persistently double in women who have MRI. Furthermore, having MRI delays surgery for an average of three weeks. Diagnosis-related MRI studies have been retrospective and not randomized. Women who undergo MRI are on average six years younger and are selected for imaging because they are more likely to benefit, which would result in more favorable research outcomes for MRI. Even so, no advantage has been shown for such imaging.

Morrow summed up by saying that MRI finds more cancer but what is found is not clinically relevant. Neither short-term surgical outcomes nor long-term local control or contralateral cancer rates are improved with MRI. Because of this, she recommends MRI only for BRCA1 and 2 carriers, those who present with positive lymph nodes, those who are being assessed for neoadjuvant therapy, or those whose diagnosis is not resolved by physical exam, mammogram, and ultrasound.

“The routine use of MRI in cancer patients requires some evidence of clinical benefit. To date, this [evidence] does not exist.”

“The routine use of MRI in cancer patients requires some evidence of clinical benefit,” Morrow said, as she ended her lecture. “To date, this does not exist.”

Morrow’s presentation was followed by a report on the first and only prospective study of MRI, the COMICE trial, which was sponsored by the research arm of the British National Health Service. (England and Canada sponsor significant research on actual effectiveness as a means of cost containment). The results of COMICE substantiated Morrow’s perspective

In Summary

Attending SABCS, for those of us who are not medical researchers, was a major challenge, but it is important for those of us who follow the progression from ideas to treatment. Our web site includes daily accounts of events we attended, but everyone has access to slides and abstracts on the SABCS web site. We encourage you to make use of this information.

Jane Zones is a medical sociologist and a board member of Breast Cancer Action.

MRI - BREAST STUDY

Source: http://www.oregonimaging.com/breast/

Magnetic Resonance Imaging (MRI) is one of the safest and most comfortable diagnostic imaging studies available. Using a strong magnetic field, radio frequency waves and an advanced image processing computer, MRI scans produce accurate images of organs, soft tissues, bone and virtually all internal body structures without exposing the patient to ionizing radiation (X-rays). Your images are stored on a specialized computer network dedicated to medical image storage called a Picture Archival and Communications System. Also known as PACS, this system allows our radiologists to interpret your images and collaborate with your physician.

Oregon Imaging Centers offers MRI scans for all parts of the anatomy. You can review information specific to your scan by selecting from the '**study type**' menu in the left column.

Technology

(1) Philips Achieva 1.5 tesla high field MRI scanner located at the Breast & MRI Center on the RiverBend Campus in Springfield.

The Experience

During your visit, a patient advocate will show you to the changing area and can assist you if necessary. Our changing rooms offer secure lockers, but we encourage patients to leave valuables at home. Once changed, our patient advocate will guide you to the sub-waiting area where you will find a selection of magazines and newspapers. A staff member will notify you when it is time for your MRI Scan and introduce you to the MRI technologist.

The technologist is specially trained and certified by the American Registry of Radiological Technologists to take care of you during your MRI scan. A device called a coil may be placed around the area of your body we are scanning. Once you are comfortable, the technologist will move the table into the MRI. You will be able to speak to the MRI technologist over an intercom.

MRI scanners make a distinctive knocking and buzzing sound as it acquires images. These sounds are normal and may last a few minutes. Some patients request ear plugs or you may prefer to wear headphones. We have a variety of music choices you can select from or you may bring a CD and ask the technologist to play it for you. Some patients also find it comforting to wear goggles or prism glasses, which can help patients who might feel claustrophobic.

Most MRI studies require an IV injected contrast agent called gadolinium to help the radiologist visualize certain tissue or blood vessels. Some patients describe a metallic taste or tingling sensation after the injection. This is normal and usually subsides quickly.

After The Exam

- A small percentage of patients with tattooed eyeliner experience temporary skin irritation in association with the MRI.
- A sub-specialized radiologist will interpret your images and prepare a diagnostic report for your physician.
- Results are usually made available to your physician in two or three days. If outside comparison studies are required, it may take longer for your results to be made available.
- Your physician will determine how the radiologists' report can be used to develop a treatment plan and speak with you about your results.

What are we looking for?

A breast MRI is often performed for patients who have had an abnormal mammogram, a strong family history of breast cancer, discovered a palpable mass or have breast implants that interfere with receiving a standard mammogram. A bilateral MRI breast study is indicated for mastectomy patients to allow the radiologist to evaluate the lymph nodes, chest wall, residual tissue and post surgical changes.

What is High-Field MRI?

Source: Health Diagnostics

Link: http://www.healthdiagnostics.com/svc_hi_field.php

High-Field MRI means the MRI scanner uses a very strong magnet. Magnet strength is measured in Tesla units. For years, **High-Field MRIs were typically 1.5 Tesla machines, but now there are 3.0T MRIs as well.** The only way to generate these powerful magnetic field strengths is to employ superconductive technology. The drawback of this technology is that patients are required to lie down in a cylinder-like space that some find uncomfortable.

The advantages of High-Field MRI are higher picture resolution, fast scans, and the ability to visualize physiological processes. For studies where exceptionally fine anatomical detail and clarity is required, such as in imaging the brain, High-Field MRI is usually the physician's choice.

Q: What is MRI?
A: MRI stands for Magnetic Resonance Imaging. An MRI scanner allows physicians to look inside the body without using surgery, harmful dyes, or X-rays. The MRI scanner uses magnets, radio waves and computers to produce very clear pictures, or images, of the human anatomy. MRI images depict soft tissue anatomy far better than any other diagnostic imaging equipment.

Q: What is MRI used for?
A: Because MRI makes such detailed pictures of soft-tissue structures near and around bones, it is ideal for spinal and joint problems. MRI is widely used to diagnose sports-related injuries, especially those affecting the knee, shoulder, hip, elbow and wrist. MRI images allow physicians to see very small tears and injuries to ligaments and muscles.

In addition, MRI of the heart, aorta, coronary arteries and blood vessels is a quick, noninvasive tool for diagnosing coronary artery disease and heart problems. Physicians can examine the size and thickness of the chambers of the heart and determine the extent of damage caused by a heart attack or progressive heart disease.
Organs of the chest and abdomen—including the lungs, liver, kidney, spleen, pancreas and abdominal vessels—can also be examined in high detail with MRI, enabling the diagnosis and evaluation of tumors and functional disorders. MRI is growing in popularity as an alternative to traditional x-ray mammography in the early diagnosis of breast cancer. Because no radiation exposure is involved, MRI is often the preferred diagnostic tool for examination of the male and female reproductive systems, pelvis and hips and the bladder.

Q: Can anybody have an MRI? Any dangers?
A: An MRI scan can be dangerous for certain people.

- If you have a cardiac pacemaker, you should not have an MRI scan. It can be fatal. This is because there may be certain parts in the pacemaker that may be adversely affected by

the magnetic field of the MRI scanner, causing the apparatus to malfunction or cease operating. Even someone accompanying a patient must not be allowed in the MRI scanner room if he/she has a pacemaker.

- Do not have an MRI exam if you are pregnant or possibly pregnant.

- Aneurysm clips in the brain. Some aneurysm clips are MRI safe; some aren't. You must check with the surgeon who installed the clip to be sure the manufacturer has tested it and found it to be "MRI Safe."

- Other Potential Dangers:

Neurostimulators

Heart Valves

Metal Implants

Drug Infusion Device/Pump

Ear Implants

Hearing Aid (The MRI can damage it.)

Inferior Vena Cava Filter

Metal Objects in Eyes

Surgical Staples or Wires

Bone or Joint Replacements

Metal Plates, Rods, Pins or Screws

Contraceptive Diaphragms or Coils

Permanent Dentures

Penile Implants

Shrapnel

Vascular Coils and Filters

If any of the above applies to you, it might be DANGEROUS for you to have an MRI exam. Be sure to make the technologist and staff at the MRI center aware, and also tell the doctor who prescribed the MRI exam. They will be able to tell you if it is safe for you to have the MRI exam. In most cases you will be able to have the scan, but please leave that decision to the professionals.

Breast ultrasound tomography: bridging the gap to clinical practice

Neb Duric ; Peter Littrup ; Cuiping Li ; Olivier Roy ; Steven Schmidt ; Roman Janer ; Xiaoyang Cheng ; Jeffrey Goll ; Olsi Rama ; Lisa Bey-Knight ; William Greenway

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Text Size: A A A
From Conference Volume 8320

- Medical Imaging 2012: Ultrasonic Imaging, Tomography, and Therapy
- San Diego, California, USA | February 04, 2012

Abstract
References

abstract

Conventional sonography, which performs well in dense breast tissue and is comfortable and radiation-free, is not practical for screening because of its operator dependence and the time needed to scan the whole breast. While magnetic resonance imaging (MRI) can significantly improve on these limitations, it is also not practical because it has long been prohibitively expensive for routine use. There is therefore a need for an alternative breast imaging method that obviates the constraints of these standard imaging modalities. The lack of such an alternative is a barrier to dramatically impacting mortality (about 45,000 women in the US per year) and morbidity from breast cancer because, currently, there is a trade-off between the cost effectiveness of mammography and sonography on the one hand and the imaging accuracy of MRI on the other. This paper presents a progress report on our long term goal to eliminate this trade-off and thereby improve breast cancer survival rates and decrease unnecessary biopsies through the introduction of safe, cost-effective, operatorindependent sonography that can rival MRI in accuracy. The objective of the study described in this paper was to design and build an improved ultrasound tomography (UST) scanner in support of our goals. To that end, we report on a design that builds on our current research prototype. The design of the new scanner is based on a comparison of the capabilities of our existing prototype and the performance needed for clinical efficacy. The performance gap was quantified by using clinical studies to establish the

baseline performance of the research prototype, and using known MRI capabilities to establish the required performance. Simulation software was used to determine the basic operating characteristics of an improved scanner that would provide the necessary performance. Design elements focused on transducer geometry, which in turn drove the data acquisition system and the image reconstruction engine specifications. The feasibility of UST established by our earlier work and that of other groups, forms the rationale for developing a UST system that has the potential to become a practical, low-cost device for breast cancer screening and diagnosis.

Topics

Biopsy ; Breast ; Breast cancer ; Breast imaging ; Data acquisition boards ; Image restoration ; Magnetic resonance imaging ; Mammography ; Medical diagnostics ; Radiation

Citation

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For Dense Breasts, Ultrasound Increases Cancer Detection Rate

By Charles Bankhead, Staff Writer, MedPage Today
Published: May 13, 2008
Reviewed by Zalman S. Agus, MD; Emeritus Professor
University of Pennsylvania School of Medicine.

LUTHER, Md., May 13 -- For women at increased risk of breast cancer because of dense breast tissue, adding an ultrasound to mammography significantly improved detection of small, node-negative lesions, investigators here reported.

The diagnostic yield increased from 7.6 per 1,000 women screened with mammography alone to 11.8 per 1,000 women screened (*P*=0.003), Wendie A. Berg, M.D., Ph.D., of American Radiology Services and Johns Hopkins Green Spring, and colleagues reported in the May 14 issue of the *Journal of the American Medical Association*.

However, there were also more false-positive results with the ultrasound.

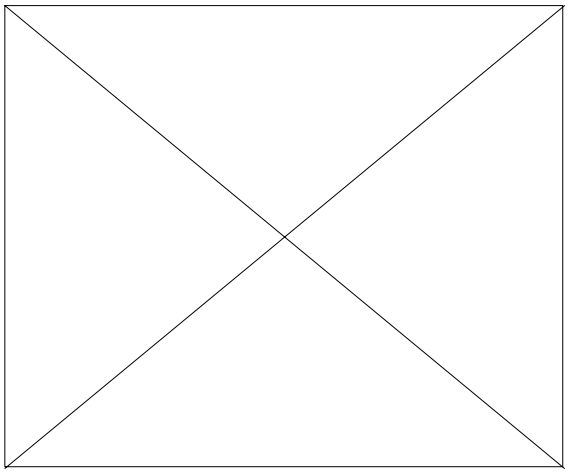
Action Points

- Explain to interested patients that this study suggests that a mammogram supplemented with ultrasound will pick up more breast cancers in women who have dense breasts.
- Note, however, that there were also more false-positive tests with ultrasound.

"Whether the risk of false-positive results with ultrasound will diminish in our study population with subsequent screening rounds, as has been seen with mammography and in small series with both ultrasound and MRI, is under evaluation," the authors said.

From the perspective of early detection of breast cancer, the "benefit of a single screening ultrasound in women at elevated risk of breast cancer is now well validated," they added.

Invasive breast cancers most often manifest as noncalcified masses that can be mammographically subtle or occult, particularly in the presence of dense breast parenchyma. More than half of women younger than 50 have heterogeneously dense or extremely dense breast tissue, as do at least a third of older women, the authors said.



In the presence of dense breast tissue, mammographic sensitivity may decrease to as low as 30%, associated with higher interval cancer rates and worse prognosis, the researchers said.

Moreover, dense breast tissue is a marker of increased breast cancer risk on the order of four- to six-fold, they continued.

Single-center studies of screening ultrasound have demonstrated that the supplemental imaging detected lesions missed by mammography and that most of the lesions were 1 cm or smaller in size. However, concern has persisted regarding the operator-dependent accuracy of the technique, lack of qualified breast ultrasonographers, and lack of standardized screening protocols.

So Dr. Berg and colleagues conducted the American College of Radiology Imaging Network (ACRIN) 6666 study, the largest trial in which mammography and ultrasound were performed and read independently, using a standardized ultrasound protocol and interpretation criteria.

In contrast to previous studies, participants were women at increased risk of breast cancer because of dense breast tissue.

Investigators at 21 sites enrolled 2,809 women with at least heterogeneously dense breast tissue in at least one quadrant. Each patient had mammography and physician-performed ultrasound in randomized order.

The primary outcomes included diagnostic yield, sensitivity, specificity, and diagnostic accuracy of mammography plus ultrasound versus mammography alone.

Additionally, investigators determined the positive predictive value of biopsy recommendations with combined imaging versus mammography by itself.

The statistical analysis included 2,637 women who had complete pathology and 12-month follow-up data. Breast imaging detected cancer in 41 breasts of 40 study participants:

- Eight were suspicious on mammography and ultrasound
- 12 on ultrasound alone
- 12 of mammography alone
- Eight (nine breasts) were not suspicious on either imaging study

The difference in diagnostic yield between mammography alone and combined imaging was 4.2 per 1,000 women screened (95% CI 1.1 to 7.2 per 1,000 women screened).

Mammography alone had a diagnostic accuracy (area under the curve) of 0.78, which increased to 0.91 with supplemental ultrasound (P=0.003).

Eleven of 12 cancers detected by ultrasound alone were invasive and had a median size of 10 mm.

The positive predictive value of biopsy recommendation after complete diagnostic workup was 22.6% for mammography (19 of 84), 8.9% for ultrasound (21 of 235), and 11.2% for combined imaging (31 of 276).

The tradeoff between increased diagnostic yield and more false-positive results is an issue best resolved by each woman, Christiane K. Kuhl, M.D., of the University of Bonn in Germany, said in an editorial.

"The number of false-positive diagnoses increased from 116 (for mammography alone) to 275 (for the combined use of mammography and

ultrasound)," Dr. Kuhl noted.

"This might be considered far too many. But this has to be weighted against the benefit of the additional cancer diagnosis yield of ultrasound. Twelve cancers, i.e., 29% of the total 41 cancers, were only detected by ultrasound," she noted.

She also pointed out that "it is well established that MRI is superior to both mammography and ultrasound. Ultrasound may be about as expensive as MRI because with modern high-frequency ultrasound probes, screening both entire breasts is a time-consuming endeavor."

"The concept of mammographic screening has been in use for more than 40 years," Dr. Kuhl added. "It may now be time to carefully reconsider. Individualized screening schemes tailored to the individual risk and to the personal preferences of a woman may be the way to consider how to screen for breast cancer."

She concluded that "whether in the long run, ultrasound or breast MRI will be more appropriate for this purpose remains to be seen."

The study was funded by the Avon Foundation and by grants from the National Cancer Institute.

Dr. Berg reported serving as a consultant to Naviscan PET Systems, MediPattern, and Siemens and has received equipment support from Siemens and a travel grant from General Electric. Dr. Kuhl reported no disclosures.

Primary source: Journal of the American Medical Association
Source reference:
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Additional source: Journal of the American Medical Association
Source reference:
Kuhl CK "The 'coming of age' of nonmammographic screening for breast cancer"*JAMA*. 2008; 299: 2203-2205.

Additional Breast Cancer Coverage

Find this article at:
http://www.medpagetoday.com/HematologyOncology/BreastCancer/tb/9433

Check the box to include the list of links referenced in the article.

NASA Might Help Examine Your Breasts

By CHRIS AYOTTE

Updated 3:30 PM EDT, Fri, Oct 15, 2010

The software NASA scientists use to determine the depths of lakes from space could be used to study women's breasts.

Bartron Medical Imaging Inc., which has a lab in New Haven, recently received clearance from the Food and Drug Administration to go to market with its MED-SEG system, a program to help doctors analyze mammograms, ultrasounds, digital x-rays and other medical imaging tests.

"The use of this computer-based technology could minimize human error when evaluating radiologic films and might allow for earlier detection of abnormalities within the tissues being imaged," Dr. Thomas Rutherford, director of gynecologic oncology at Yale University in New Haven, said in a news release.

The FDA has approved the system for trained professionals to process images, but it's not allowed for use during primary diagnosis.

Dr. Molly Brewer, a professor with the Division of Gynecologic Oncology at the University of Connecticut Health Center in Farmington, would like to do clinical trials with the system.

"One problem with mammograms is, they often give a false negative for detecting abnormalities in women's breasts," Brewer said. "Women who either have high density or a strong family history of breast cancer are often sent for MRIs, which are costly, very uncomfortable and have a high false positive rate resulting in many unnecessary biopsies."

So far, Bartron has installed the system at the University of Connecticut Health Center and might install evaluation systems at Yale-New Haven Medical Center and two other facilities.

First Published: Oct 15, 2010

Source: http://www.nbcconnecticut.com/news/health/New-Frontier-For-NASA--New-Haven-Company-Breasts-105038804.html

Ultrasound Technology at EPIC IMAGING

Link: http://www.epicimaging.com/imaging-technology-2/imaging-technology/ultrasound/

Ultrasound Technology Defined

Ultrasound is a safe, painless diagnostic procedure that uses high frequency sound waves to see specific areas within the body. The primary benefit of ultrasound is its ability to generate highly-detailed, real-time images without being invasive and without using radiation.

EPIC Imaging has one of the most comprehensive ultrasound departments in the Portland metro region with expertly trained specialists in breast, vascular, musculoskeletal (MSK), pelvic and obstetrical sonography. Ultrasound is an invaluable technology with many applications in imaging.

- In obstetrical imaging, ultrasound is used to assess fetal age, health and well-being.
- In breast imaging, ultrasound provides more detailed examination of potential abnormalities found in breast tissue during mammography. It quickly allows the radiologist to assess whether a lump is just a fluid filled cyst or a solid mass requiring biopsy.
- In vascular imaging, the advanced color flow and doppler functionality on EPIC's state-of-the-art ultrasound technology makes it ideal to evaluate major blood vessels and evaluate potential blockages to flow by plaque or clots.
- In abdominal disorders, ultrasound is used to evaluate abdominal or pelvic pain as in the case of gallstones, liver disorders or appendicitis.
- For MSK, the flexibility of ultrasound provides a real-time view of effects of movement on the structures of joints, tendons, ligaments, etc.
- In addition to these applications, ultrasound is widely used as a guidance tool during procedures like biopsies and specialized interventional pain injections.

How Ultrasound Works

Ultrasound uses the same echo-locating principles of sonar technology employed for decades by ships at sea. When sound waves are directed into the body, they produce echoing waves as they bounce against the internal fluids of the human body. The echoes are captured and reconstructed by sophisticated computer software into live images on a computer monitor.

During an ultrasound exam, the, painless high frequency sound waves are emitted and received by a small hand-held device called a transducer. The transducer is placed in close contact with the skin and a gel-like substance is used to ensure that contact is optimized. As the sound waves move through the various structures of the body, "echoes" will bounce back and be captured by the ultrasound computer attached to the transducer. These echoes will be displayed instantly as real-time images on a monitor. Depending on the type of exam the physician has requested, images will be selectively captured onto film for the radiologist to interpret.

Breast Cancer Risk Estimates Increased with Repeated Prior CT and Nuclear Imaging

PRNewswire-USNewswire

11-27-12

CHICAGO, Nov. 27, 2012 /PRNewswire-USNewswire/ -- Researchers reviewing the records of approximately 250,000 women enrolled in an integrated healthcare delivery system found that increased CT utilization between 2000 and 2010 could result in an increase in the risk of breast cancer for certain women, including younger patients and those who received repeat exams. According to the study, which was presented today at the annual meeting of the Radiological Society of North America (RSNA), nuclear medicine examinations may also contribute to increased breast cancer risk.

CT uses ionizing radiation in the form of X-rays to produce cross-sectional images of the body. In nuclear medicine imaging, a radiopharmaceutical--a compound that includes a small amount of a radioactive material--is delivered inside the body to help visualize internal organs.

"When a woman undergoes CT or nuclear medicine imaging of her chest, abdomen or spine, her breast tissue will absorb some radiation," said senior author Rebecca Smith-Bindman, M.D., professor of radiology and biomedical imaging at the University of California, San Francisco. "Breast tissue is one of the tissues in the body known to be sensitive to developing cancer as a result of radiation exposure."

The study, led by Ginger Merry, M.D., M.P.H., breast imaging fellow at Prentice Women's Hospital - Northwestern Memorial Hospital in Chicago, found that among the system's female enrollees, CT utilization increased from 99.8 CT scans per 1,000 women in 2000 to 192.4 CT scans per 1,000 women in 2010 (an annual increase of 6.8 percent). In 2010, 46 percent of those CT examinations exposed the breast to radiation. Nuclear medicine imaging decreased from 39.3 scans per 1,000 women in 2000 to 27.5 scans per 1,000 women in 2010 (a 3.5 percent annual decline); however, in 2010, 84 percent of nuclear medicine studies exposed the breast to radiation.

"Until now, the impact of this increased use of imaging on radiation exposure to breast tissue and the subsequent risk of breast cancer has not been known," Dr. Smith-Bindman said. "Our goal was to quantify imaging utilization and radiation exposure to the breast among women enrolled in an integrated healthcare delivery system and to use these data to determine the imaging-related risk of breast cancer from those studies."

The research team collected CT dose information from 1,656 patients who underwent CT examinations that exposed the breast to radiation and, using a new automated computational method, estimated the patients' effective radiation dose and the amount of radiation absorbed by the breast. The team also analyzed the radiopharmaceutical volume and associated radiation exposure used in 5,507 nuclear medicine exams that exposed the breast to radiation.

"We found that the estimated breast radiation doses from CT were highly variable across patients, with the highest doses coming from multiple-phase cardiac and chest CT examinations, where successive images of the organ being studied are captured," Dr. Smith-Bindman said.

The researchers then estimated the women's imaging-related risk of breast cancer and compared it to their underlying risk of developing breast cancer. Each woman's 10-year imaging-related risk of developing breast cancer, beginning 10 years after her exposure to imaging and based on her age at exposure, was estimated using the breast-specific radiation data and a statistical risk model. A women's underlying risk of developing breast cancer was estimated based on data collected by the National Cancer Institute-funded Breast Cancer Surveillance Consortium.

"Young women receiving several chest and or cardiac CTs had the greatest increased risk of developing breast cancer at

approximately 20 percent," said Diana Miglioretti, Ph.D., study coauthor and senior investigator at the Group Health Research Institute. "A 15-year-old girl with no risk factors for breast cancer would double her 10-year risk of developing breast cancer at 25."

To lower imaging-related risk of developing breast cancer, Dr. Smith-Bindman said imaging providers should analyze the radiation doses associated with each exam, reduce the use of multi-phase protocols and employ dose-reduction software wherever possible to minimize exposures.

"If imaging is truly indicated, then the risk of developing cancer is small and should not dissuade women from getting the test they need," she said. "On the other hand, a lot of patients are undergoing repeat chest and cardiac CT, many of which aren't necessary. Women, and particularly young women, should understand there is a small but real potential risk of breast cancer associated with cardiac and chest CT, and the risk increases with the number of scans."

Coauthors are Choonsik Lee, Ph.D., and Eric Johnson, M.S.

Note: Copies of RSNA 2012 news releases and electronic images will be available online at RSNA.org/press12 beginning Monday, Nov. 26.

RSNA is an association of more than 50,000 radiologists, radiation oncologists, medical physicists and related scientists, promoting excellence in patient care and health care delivery through education, research and technologic innovation. The Society is based in Oak Brook, Ill. (RSNA.org)

Editor's note: The data in these releases may differ from those in the published abstract and those actually presented at the meeting, as researchers continue to update their data right up until the meeting. To ensure you are using the most up-to-date information, please call the RSNA Newsroom at 1-312-949-3233.

For patient-friendly information on CT, visit RadiologyInfo.org.

AT A GLANCE

-- Increased CT utilization from 2000 to 2010 may increase the risk of

breast cancer for certain women.

-- CT uses ionizing radiation in the form of x-rays to produce

cross-sectional images of the body.

-- Women should not be dissuaded from getting necessary imaging exams.

Radiological Society of North America (RSNA)

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Comprehensive Breast Imaging

Source: Epic Imaging

Link: http://www.epicimaging.com/specialties/womens-imaging/comprehensive-breast-imaging/

Breast imaging is divided into two primary categories: screening and diagnostic. Screenings are most often conducted with mammography. However, women in certain high risk groups may have their screening conducted using ultrasound or MRI. The technology used to accomplish a diagnostic exam will depend on what information your physician needs to aid in his or her diagnosis. It is not uncommon in comprehensive breast imaging to undergo multiple exams using different technologies. Each yields unique and valuable information that together provide the most complete diagnostic picture.

If you are asked to undergo additional procedures following a screening mammogram, please try not to worry. Follow-up procedures are common and the vast majority of all breast abnormalities are NOT cancerous.

Mammography
Mammography can show changes in the breast up to two years before a patient or physician can feel them. For this reason, the American Medical Association and the American College of Radiology recommend women have annual mammograms beginning at age 40.

The mammography services at EPIC Imaging are performed with digital mammography machines, the most advanced technology available. Like standard mammography, digital mammography uses x-rays to produce images of the breast.

However, instead of capturing an image on film, within seconds digital mammography sends the image directly to a computer. Once there, we can put the power of the computer to work. If we have a concern, we can zoom in, enhance the area and examine it more closely without having to take additional pictures. Exams are twice as fast with significantly less radiation exposure.

At Epic Imaging, we have used digital mammography since September 2000, making us the most experienced center in Oregon in this remarkable technology. Because images are immediate, call-backs have been greatly reduced. By adjusting contrast levels we have been able to reveal early calcifications and very small cancers that might have been missed in the single contrast world of film. The technology is ideal for seeing through dense breast tissue and offers better visibility of the breast near the skin line and chest wall.

In 2002 the technology was improved yet again when EPIC added a computer software program known as CAD to our digitally acquired images. CAD is short for Computer Aided Diagnosis. Using advanced mathematical measurements called algorithms, CAD allows the radiologist to conduct a computerized review of digital breast images. This review enables the radiologist to confirm an interpretation or highlight a potential area of concern that may not have been initially

apparent to the eye. Research confirms CAD is helping find cancers at very early stages when treatment is most effective.

Breast Ultrasound
Breast ultrasound is a frequently used follow-up procedure for evaluating abnormalities found during mammograms or breast exams performed by your doctor. It can quickly and painlessly determine if a suspicious area is in fact a fluid filled cyst (almost always non-cancerous) or a mass of solid tissue, which may require further tests to confirm or rule out cancer.

Ultrasound uses the same echo-locating principles as sonar technology employed for decades by ships at sea. As very high frequency sound waves are directed through the breast, echoes are captured and reconstructed by a computer into live images on the computer monitor. The exam is completely non-invasive and uses no radiation.

Breast MRI
Breast MRI provides a different kind of image than either ultrasound or mammography. Like ultrasound, MRI uses no x-rays or radiation. It combines the naturally occurring force ofa magnetic field with radiowaves to produce signals that are reconstructed on a sophisticated computer. With MRI, we are able to enhance the breast tissue using a contrast agent called gadolinium. By studying the properties and appearance of the gadolinium-enhanced breast tissue and vasculatures the radiologist is able to gain insight that would not be available with other technologies.

MRI is particularly important for screening women with a family history of breast cancer or a genetic predisposition for the disease. Women with a genetic predisposition may have inherited a mutation of the BRCA1 or BRCA2 gene. Screening mammography is less effective in detecting cancer among these women, perhaps because they often contract the disease at a young age when their breast tissue is dense and not easily penetrated with mammography.

Breast MRI has proven its ability to diagnose cancers that mammography can sometimes miss, particularly DCIS (ductal carcinoma in situ). It is also being used increasingly as a screening tool for high risk women. If you know you have a genetic predisposition, you should ask your doctor if MRI is appropriate for you and consider regular screenings as early as age 25.

MRI is routinely used to evaluate women who have symptoms, like a lump, that are not explained with either mammography or ultrasound. It is also very effective for determining the extent or spread of breast cancer. For this reason, it is a valuable tool to assist with the difficult decision between a lumpectomy and a mastectomy after a cancer has been diagnosed. Finally, breast MRI is very effective in evaluating breast implants for leakage or rupture.

PET/CT Breast Imaging
PET imaging, short for Positron Emission Tomography, is a powerful tool in the fight for improved breast cancer survival rates. Unlike conventional imaging which measures the structure of a tumor, PET measures the metabolic changes that occur in cells when cancer is present. These changes occur very early on in the course of the disease, long before a tumor is formed. In addition, unlike many procedures that focus on a single area of concern, PET scans provide a

picture of the metabolic activity of the entire body. Because of this, PET imaging is frequently used to help determine the extent or spread of cancer as well as how it is responding to treatment.

At EPIC, we utilize the advanced combination PET/CT scanner. This remarkable advance combines two important technologies into a single scanner. PET shows metabolic activity. CT shows the precise form and location of an abnormality. Used in combination, PET/CT provides a full body view revealing the presence or absence of disease, how active it is, whether or not it has spread and precisely where and how large an abnormality is.

Since breast cancer typically responds quickly to chemotherapy, if it is going to respond at all, PET/CT scans provide breast cancer patients with quick confirmation of the effectiveness of treatment. This, in turn, allows the oncologist to make frequent changes in chemotherapy early in the course of treatment to achieve the most successful outcome for the patient.

Molecular Breast Imaging

Molecular Breast Imaging (MBI) is a relatively new technique to detect or evaluate breast cancers. It is particularly useful in women with dense breast tissue and when the results of other technologies are equivocal. EPIC has two MBI technologies: PEM, short for Positron Emission Mammography and BSGI, short for Breast Specific Gamma Imaging. Like PET (see previous page), PEM and BSGI measure the metabolic changes that occur in cells when cancer is present. Unlike PET, these technologies have been optimized for imaging the breast. Both produce extremely high resolution and very detailed images of breast abnormalities.

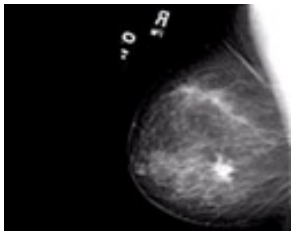
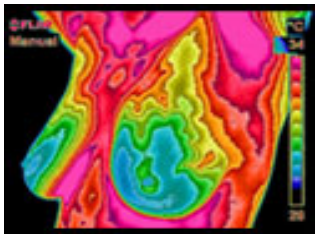
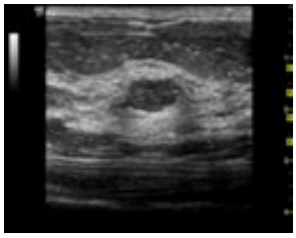
For breast cancer patients, MBI provides a valuable tool for difficult diagnostic cases and pre-surgical planning for confirmed breast cancers. It is one of our best measures to date to evaluate if a patient is a candidate for breast conserving surgery (lumpectomy) versus mastectomy. In many cases, PEM also provides the earliest possible view of the effectiveness of treatment.

Breast Biopsy

A breast biopsy is a tissue sampling technique used to confirm or rule out the presence of breast cancer. The primary benefit of biopsy is to avoid invasive, unnecessary surgeries. Various methods of obtaining the sample are currently employed at EPIC: ultrasound-guided biopsy, MRI-guided biopsy and stereotactic breast biopsy. The method employed depends upon many factors such as breast size, tissue density and the nature of the abnormality. All methods are minimally invasive alternatives to surgery. Regardless of the method used, local anesthetic is always administered to minimize any possible discomfort.

Mammography/Thermography/Ultrasound
What's The Difference?

The following graph outlines the differences between mammography, medical infrared imaging (thermography), and ultrasound. Medical infrared imaging detects surface heat as a byproduct of biochemical reactions. As such, the test adds valuable physiologic information that cannot be obtained from any other imaging procedure. Thermography is designed to be used as an adjunct (an additional test) to a woman's regular breast health care.

Mammography	**Medical Infrared Imaging**	**Ultrasound**
		
Uses X-rays to produce an image that is a shadow of dense structures. Suspicious areas need to be dense enough to be seen.	Uses infrared sensors to detect heat and increased vascularity (angiogenesis) as the byproduct of biochemical reactions. The heat is compiled into an image for computerized analysis.	High frequency sound waves are bounced off the breast tissue and collected as an echo to produce an image.
Structural imaging. Ability to locate the area of suspicious tissue.	Functional imaging. Detects physiologic changes. Cannot locate the exact area of suspicion inside the breast.	Structural imaging. Ability to locate the area of suspicious tissue.
Early detection method.	Early detection method. Used as an adjunctive imaging test.	Low spatial resolution (cannot see fine detail). Good at distinguishing solid masses from fluid filled cysts. Used as an adjunctive imaging test.
Findings increase suspicion. **Cannot diagnose cancer.**	Findings increase suspicion. **Cannot diagnose cancer.**	Findings increase suspicion. **Cannot diagnose cancer.**

A biopsy is the only test that can determine if a suspected tissue area is cancerous.		
Mammography	**Medical Infrared Imaging**	**Ultrasound**
Can detect tumors in the pre-invasive stage.	May provide the first signal that a problem is developing.	Ability to detect some cancers missed by mammography.
	A positive infrared image represents the highest known risk factor for the existence of or future development of breast cancer – 10 times more significant than any family history of the disease.	
Average 80% Sensitivity (20% of cancers missed), in women over age 50. Sensitivity drops to 60% (40% of cancers missed) in women under age 50.	Average 90% Sensitivity (10% of cancers missed) in all age groups.	Average 83% Sensitivity (17% of cancers missed) in all age groups.
Hormone use decreases sensitivity.	No known effect.	No known effect.
Large, dense, and fibrocystic breasts cause reading difficulties.	No effect.	No known effect.
In most women, the medial upper triangle, peripheral areas next to the chest wall, and the inframammary sulcus cannot be visualized.	Not applicable.	All areas visualized.
Sources: Index Medicus – ACS, NEJM, JNCI, J Breast, J Radiology, J Clin Ultrasound Index Medicus – Cancer, AJOG, Thermology Text – Atlas of Mammography: New Early Signs in Breast Cancer Text – Biomedical Thermology		