



DECEMBER 2003
HEALTH MEDICINE INSTITUTE

Beyond Mammography

Len Saputo, MD

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

Introduction4

SIDE BAR:

A Closer Look 4

The Prevalence, Fear and Risk Factors of Breast Cancer

Mainstream Breast Cancer Screening Technologies..... 6

Mammography and Women Under 50 6

Study Finds High False Positive..... 6

Too Many Mammograms Performed? 7

Mammograms for Women Over the Age of 70 7

Mammography and Younger Women 7

Other Mainstream Technologies 8

PART II

The History of Breast Thermography 9

How Breast Thermograms Work 10

Clinical Research Supporting Breast Thermography 11

Important Highlights from Breast Thermography Studies..... 12

Conclusion..... 13

References 14

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.

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

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.

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 mammothems 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

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

- Advances in infrared technology combined with data on 300,000 women with mammothers 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.

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.

REFERENCES

1. Elliott, V S. Mammography debate: Who should get screened and when? American Medical News, an AMA publication. Volume 10, number 42, pages 35-37, November 10, 2003. www.amednews.com.
2. Kerlikowske, K. Use of mammograms in older women questionable. JAMA. December 10, 2003.
3. Time Magazine, April 28, 2003. Cover story: The No. 1 Killer of Women.
4. SEER, National Cancer Institute: Chances of developing breast cancer at a given age.
5. de Sanjose S, et al. Prevalence of BRCA1 and BRCA2 germline mutations in young breast cancer patients: a population-based study. Int J Cancer 2003; 106 (4): 588-93.
6. Furstenberger et al. Insulin like growth factors mediate breast cancer growth and proliferation. Onkologie, 2003. Volume 26, number 3, pages 290-94.
7. Baker L. Breast cancer detection demonstration project: Five year summary report. Cancer, 1982, volume 32, pages 194-225.
8. Sickles EA. Breast masses: mammographic evaluation. Radiology 1989. Pages 173-303.
9. Fletcher, S W, and Elmore, J G. Mammographic Screening for Breast Cancer. New England Journal of Medicine. Volume 348, no. 17, pages 1672-80. April 24, 2003.
10. Ostbye, T. Elderly women over-screened for cancers with little measurable benefit. Annals of Family Practice. November/December issue, 2003.
11. Pisano, E. Digital Mammography Offers Better Breast Cancer Diagnoses. Presented at the Radiologic Society of North America annual meeting, December 2003. Research conducted at University of North Carolina School of Medicine. etpisano@med.unc.edu.
12. Freidrich M. MRI of the breast: State of the art. European Radiology, 1998. Volume 8, pages 707-725.
13. Avril N, Rose CA, Schelling M, et al. Breast imaging with positron emission tomography and fluorine-18 flourodeoxyglucose: use and limitations. Journal of Clinical Oncology, 2000. Volume 18, pages 3495-3502.
14. Avril N. Discussions in PET Imaging 2003. CMP Healthcare Media, DPI no. 621, PET and Breast Cancer.
15. Gautherie, M, Haehnel, P, Walter, J p, Keith, L. Long-Term Assessment of Breast Cancer Risk by Liquid-Crystal Thermal Imaging. Biomedical Thermology, pages 279-301. 1982 Alan R. Liss, Incl, 150 Fifth Avenue, New York, NY 10011.

-
16. Parisky, Y R, et al. Efficacy of Computerized Infrared Imaging Analysis to Evaluate Mammographically Suspicious Lesions. American Journal of Roentgenology, January 2003, 263-69.
 17. Gautherie, M, and Gros, C M. Breast Thermography and Cancer Risk Prediction. Cancer, 1980, volume 56, 45-51.
 18. Nyirjesy, M D, et al. Clinical Evaluation, Mammography and Thermography in the Diagnosis of Breast Carcinoma. Thermology, 1986, volume 1, 170-73.
 19. Keyserlingk, M D, et al. Infrared Imaging of the Breast: Initial Reappraisal Using High-Resolution Digital Technology in 100 successive cases of Stage I and II Breast Cancer. The Breast Journal, volume 4, 1998, 245-51.
 20. Zangar, R. Breast Cancer Research and Treatment. July 3, 2003.
 21. Bolan, P. In vivo quantification of choline compounds in the breast with ¹H MR spectroscopy. Magnetic Resonance in Medicine. Volume 50, Issue 6, Date: December 2003, Pages: 1134-1143.