BREAST CANCER IN TOUGH ECONOMIC TIMES

DISRUPTIVE TECHNOLOGY EMERGING

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The objective of this study was to investigate the efficacy of melding three emerging technologies: Pharmacogenomics, Modified Military Digital Infrared and Halo to establish their capability in diagnosing ultra-small breast cancers as well as other cancers. Mammography, ultrasound and MRI technologies have been available for over forty years, however, there is still no uniform utilization by women, costs continue to escalate and problems persist like high false positive rates for MRI and high false negative rates for mammography.

Of the first 500 IR patients, 499 were female and 1 male. Of 550 OncoVue patients, 129 opted to undergo IR. A total of 19 were lost to follow-up. Patients who were negative on IR: 419/500 (84%). Of these, 63/419 went to biopsy because of findings of other diagnostic modalities.

Of these 61/63 with negative IR had a negative biopsy. Of two missed, one was the fault of the investigator but was included. In this series 2/500 were false negative (0.4%). The sensitivity was 96% and the specificity was 79%. In total, 46 cancers were identified including five outside the breast (e.g. 2 lung cancers). A total of 92 MRIs were done and in 71/92 patients IR and MRI agreed. Using these three modalities the smallest cancer found was a 4 mm invasive cancer.

The study demonstrated that these diagnostic techniques can dramatically lower cost and provide results at least as good as the older paradigms. Further research and a multicenter clinical trial are necessary to shift the paradigm of breast cancer diagnosis and treatment.

KEY WORDS: Pharmacogenomics, Infrared, Breast Cancer, Halo, Cryogenic Surgery

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DISRUPTIVE TECHNOLOGY EMERGING

Phillip Bretz, M.D., Richard Lynch, D.O.

A plea to introduce state-of-the-art 21st century techniques into breast cancer diagnosis.
1. INTRODUCTION

The State of California has eliminated the benefit of mammograms for women who have Medi-Cal health insurance below the age of 50. These women without many resources have very few options available to them to obtain proper lifesaving breast imaging. California’s population consists of different races and ethnic groups, some of whom have a higher rate of getting breast cancer and at a younger age that is more deadly. An example is the so-called triple negative breast cancer occurring in African-American women. With the hope of surviving this diagnosis depending on early diagnosis, withholding mammography particularly in this group arguably presents a problem. Since the rational for this restriction on mammography was mainly based on saving the state revenue at a time of austerity, the question should arise is there an alternative to be found in state-of-the-art technology that would save money and lives?

The worldwide financial debacle, together, with the call to health care reform from the administration in Washington, has led to the exploration of a new paradigm in diagnosing and treating breast cancer. Why the need to reinvent the wheel? Digital mammography, 3 D ultrasound and 3T MRI are capable of resolving very small cancers. Nonetheless these modalities in and of themselves, after 40 years of evolution, have not held the answer to defeating breast cancer. This is especially true with the release of the new mammography guidelines on November 17, 2009.

Proponents on both sides of the new guidelines can debate these issues but what is not debatable is that the current screening employed by the United States is not ideal and not able to serve every woman. Problems with current screening methods are replete in the literature but are not the subject of this paper (1-7). However, African American women presented at such an early age that one conclusion of a paper by the American College of Surgeons, May 2009 was arguably that current mammographic guidelines would need to be altered to include African American women starting at age 33.

Implementing this recommendation would mean again altering guidelines and further increase in cost and radiation in younger women. There is a need for an alternative in monitoring these women and women with dense tissue where mammography is less accurate and MRI too costly. As the density of breast tissue goes up (seen in younger women) so does the risk of breast cancer as well as false negative mammography statistics. Thus implementing the American College of Surgeons recommendations would lead us back to the same problem in these high risk younger women.

When one considers breast cancer on a global level, it has been predicted that by 2030, 70% of the all breast cancers will occur outside traditional countries (8) like the United States and occur in countries like China, India and Brazil. How China, which has around 800 million women, implements breast screening is of vital importance. It is against this backdrop that melding Pharmacogenomics, Modified Military Digital Infrared and Halo came to be.

2. MATERIALS AND METHODS

BRCA 1 & 2 genes are located on chromosomes 17 and 13 respectively and have long given physicians information about familial risk of breast cancer. While state-of-the-art when discovered, BRCA only accounts for about 10% of all breast cancers and cannot tell the attending physician when that risk will manifest. In the past five years with expanding knowledge of the human genome, newer genetic predictive tests have evolved, among them OncoVue.
2.1 ONCOVUE

It is imperative that state-of-the-art genomic knowledge is brought into each physician's lexicon. OncoVue, developed by InterGenetics, is one such test (17-30). It is a DNA saliva test that not only indicates the degree of risk of breast cancer but can demonstrate when that risk is likely to manifest within about ten years - pre, peri or postmenopausal. It does this by identifying abnormal single nucleotide polymorphisms, 'SNPs'. A clinical trial investigating steroid hormone pathway genes has identified and confirmed age-specific genetic associations with breast cancer risk for SNPs in four genes. As epigenomics has elucidated, environmental factors tend to vary with age depending on exposure. However, the penetrance of SNPs are thought to be constant throughout a person's life.

The C/C genotype of cytochrome P450 X1B2 (CYP11B2) was associated with decreased risk at younger ages (30-40) but increased risk at older ages (55-69), a so-called “flipper” gene. In an alternative finding, the CG/CG genotype of UDP glycolytransferase 1A7 (UGT1A7) was associated with increased risk at younger ages but decreased risk at older ages.

Interestingly, associations in cytochrome P450 (CYP 19) and progesterone receptor (PGR) were confined to middle age (45-54). In developing OncoVue, SNPs that influence endogenous estrogen levels or the bio availability of reactive estrogen metabolites have been associated the higher breast cancer risk. SNPs in functional regions of genes involved in steroid synthesis may differentially impact breast cancer risk depending on age and hormonal status. Genomic DNA is isolated and samples are genotyped by microbead- based, allele-specific primer extension. Precise age association may vary among individuals and thus a 10 year sliding window strategy was utilized to reduce random variations between single year differences. It was found that the homozygous C/C (OR=1.7, p=0.002) and heterozygous C/T (OR=1.5, p=0.004) genotypes were both associated with increased risk in older groups.

Individuals with the T/T genotype at the PGR locus exhibit an elevated breast cancer risk in middle age only (9). Sometimes the magnitude of breast cancer risk associated with a steroid pathway gene SNPs vary with age and the direction of risk changed either higher or lower. The sequence of events is as follows. The patient fills out an information page with personal risk data and deposits saliva in a specialized collection container. All specimens are bar coded. The specimen is returned from the lab in about 10 days. Having this heretofore, unavailable information, a personal surveillance program can be instituted using Modified Military Digital Infrared technology as well as either diagnostic modalities like mammography and Halo.

Typically for higher risk patients, infrared breast imaging is done six months after a mammogram so that twice a year the breasts are formally imaged. More frequent infrared exams are done, (since there is no ionizing radiation), as risk goes up and time to expression of the breast cancer grows shorter.

2.2 MODIFIED MILITARY DIGITAL INFRARED

The infrared employed is not the technology of the 1970s but rather modified military digital infrared coupled with immediate computer read out of results and analysis via a neural network (artificial intelligence). The U.S. Government declassified the technology in 1992. The unit is called Sentinel BreastScan developed by Infrared Sciences (10). What is infrared? Infrared is part of the electromagnetic spectrum lying between visible and microwave segments of the spectrum. An infrared imaging camera observes and measures thermal energy emitted from an object. The higher the object's temperature, the greater the IR energy emitted. The infrared camera is a non-contact device that detects infrared energy and converts it into an electronic signal that is then processed to produce a thermal image on a video monitor. It also performs temperature calculations. Recent innovations in detector technology have made its use in breast imaging much more accurate. A micro bolometer is used as a detector in infrared cameras. Emitted infrared energy from an object with wave length from 8 to 13 um strikes the detector, heating it, and thus is changing its electric resistance. This resistance change is measured and proceeds into temperature, which can be used to create an image on the video monitor.
The micro bolometer used in the FLIR A 40 is an un-cooled thermal sensor. Simply put the military uses advanced infrared technology because it works. The military's use of infrared ranges from sniper scopes to cameras on board the Predator, to visible light video tracking systems such as THEL (Tactical High Energy Laser). By using infrared as an adjunct, the imaging of the tracked target is improved under no light conditions or heavy cloud cover.

Thus the target's bearing, range and elevations can be constantly updated. This is called Range Phenomenology. Modern un-cooled detectors all use sensors that work by the change of resistance, voltage or current when heated by infrared radiation. A possible sensor assembly uses an integrated circuit that includes barium strontium titanate, bump-bonded polymide in a thermally insulated connection. The FLIR A40 detector is a focal plane array, an uncooled micro bolometer with 320,240 pixels. The neural network (artificial intelligence) is constantly updated. It currently uses a collection of infrared reports integrated with pathology reports and programmed into the computer. The military has a name for objects on the ground sensed by infrared from air: “heat signature”. So too do cancers leave a “heat signature”. This is what the neural network (artificial intelligence) is designed to learn and then becomes more accurate as experience develops. The current camera has the capability of detecting heat coming from a developing cancer of 1.5 mm. It also works independent of angiogenesis and has detected small (2 mm) clusters of evolving benign calcifications.

2.3 HALO

Halo is a relatively new diagnostic test that is melded with OncoVue and IR in an attempt to diagnose ultra-small breast cancers (31). Halo is non-toxic, low cost and works this way. Upon an abnormal infrared scan where mammography may still be negative, NAF (nipple aspirate fluid) is collected by a gently acting suction device that essentially gives us access to the cellular workings of the breast as a direct measure (like a biopsy without the biopsy). It is not ductal lavage where an individual cannula is inserted into a dilated duct and endoscopic evaluation and tissue sampling follows. Halo allows for sampling multiple ducts at one time. Milk ducts inside the breast are the sight for about 90% of breast cancer development. These ducts are normally lined by a single layer of epithelial cells. Because of various insightful factors they can undergo hyperplasia (creating multiple layers of cells) and therefore expansion within the duct and discohesiveness and desquamation follow eventually of atypical cells. These abnormal or cancerous cells are collected with the Halo device. These abnormal cells would normally not be available for examination (lying in the ducts) remaining occult potentially for years and thus delay identification of evolving tumors. To recap, the key elements are knowing the risk of a woman, when that risk is likely to manifest (information provided by OncoVue), next finding would be abnormal infrared study that alerts us to the possibility of a developing cancer. Then finding the occult cancer with Halo enables the identification of ultra-small breast cancers (2-3mm). While not the intent of this paper, the crux of this actionable capability allows for the final step and thereby changes the entire paradigm of breast cancer treatment. This final step would make possible the killing of this small cancer with a one time outpatient procedure utilizing a 3mm cryogenic probe. Whether or not adjuvant radiation would be necessary will be answered by The Condi-Waters Study. However, any traditional surgery and chemotherapy would be avoided saving disfigurement, countless lives, families and over 10 billion dollars a year. In addition, this entire setup can be made portable carrying out diagnosis and treatment in one day. This capability would be very important in a country like South Africa where mobile mammography is sent out hundreds of miles in the country to do mammograms only to learn that if an abnormality is found; generally that woman has no means of traveling to get help. This paradigm shift would resolve that problem.
3. ILLUSTRATIONS

While a detailed explanation of interpreting nuances of OncoVue and infrared is beyond the scope of this manuscript, the following five patients are put forth as a matter of reference and documentation.

Patient 1 (Figure 1) is a typical-negative infrared exam. However, in this case, IR picked up a red spot at the suprasternal notch of the manubrium where there shouldn't be any. It was a “basal cell carcinoma” and we coined the term “Ruby Sign”. It is one of five cancers outside the breast that IR was able to identify.

![Sentinel BreastScan Patient Analysis Report](image)

**Fig 1**
Patient 2 (Figure 2) is an example of just how small a heat signature can be picked up by this infrared machine. In this patient IR picked up an evolving 2mm focus of dystrophic benign calcifications in the left breast at 6 o’clock. This is indicated by the ‘threshold’ larger pink circle. Angiogenesis was not involved. Importantly, in this patient the IR report indicated this would be benign. However, with the attending mammography report indicating a BIRADS 4 (suspicious for cancer) a stereotactic core biopsy was done with a benign result.

Fig 2
Pathology report for patient 2

Patient: Female
Age: 41 Y
DOB: 12/27/1965

Date of Service: 01/26/2007 06:25 AM

Final Report


*** Tissue Final Report ***

Clinical Notes:
Preoperative Diagnosis:
  Status post 11 gauge vacuum assisted stereotactic core needle biopsy of calcification, 6:00 for posterior left breast

Procedure(s):
  Left breast 6:00

Note:
The attending pathologist whose signature appears on this report has reviewed the slides and has edited, as needed, the gross and/or microscopic portion of the report in rendering the final diagnosis.

Gross Description:
Specimen is received in formalin labeled “left”. It consists of ten cylindrical cores of fibrofatty tissue. They measure 0.1-0.5 cm in diameter and 0.3-7.2 cm in length. Stained with ink and totally submitted for microscopic examination as “1071 1-3”.

Microscopic Description:
Sections are of multiple needle biopsy cores of breast tissue. There is stromal fibrosis, a cyst formation is also present with associated calcifications. No proliferative epithelial disease is present. Certainly, there is no atypical hyperplasia or carcinoma.

Final Diagnosis:
  Left breast. Stereotactic core needle biopsy at 6:00 for calcifications:
  Fibrocystic change with associated calcification.
  No atypical hyperplasia or carcinoma.

01/27/07 08:47 LWR:cg

LWR (Electronic Signature)
Patient 3 (Figure 3) demonstrates how in this particular patient OncoVue and infrared aided in diagnosing a 4 mm invasive breast cancer. She had not had a mammogram for years. She heard about OncoVue and Infrared in the local press and came in. OncoVue indicated higher risk now and in the future and infrared was positive for the right breast. Suspicious calcifications on mammography mandated stereotactic biopsy, which did demonstrate calcifications but did not reveal a cancer. Because of the two findings raising suspicion open biopsy was performed and found a 4 mm invasive cancer, performed in essence due to the abnormal OncoVue and infrared image.

Fig 3
FINDINGS:
CLINICAL: Callback right breast density.

The tissue of the right breast is heterogeneously dense. This may lower the sensitivity of mammography.
There is an asymmetry in the right breast at 10 o'clock middle depth. This is seen in additional views.
There also is a 6 mm area of clustered calcifications in the right breast at 11 o'clock posterior depth. These are seen in additional views.
No other significant masses or calcifications are seen in the breast.

IMPRESSION: INCOMPLETE: NEEDS ADDITIONAL IMAGING EVALUATION
The asymmetry in the right breast at 10 o'clock middle depth is indeterminate. An ultrasound is recommended.
The 6 mm area of clustered calcifications in the right breast at 11 o'clock posterior depth is at an intermediate suspicion for malignancy. A stereotactic biopsy is recommended.
The findings and recommendations were discussed with the patient today.
IR report Fig 3 and pathology report

Sentinel BreastScan Patient Analysis Report

Patient Name:  DOB: 9/12/2007 1:06:14 PM
Patient ID: 11849

Differential Level Indications: High Med Low

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Sentinel BreastScan is FDA Approved

ANATOMICAL PATHOLOGY CONSULTATION

Patient:  Medical Record #: (0000)2409750
Financial #: 0733000535  Birthday: 02/26/1957
Sex: F  Age: 50
Physician(s): BRETZ, PHILLIP
Date Received: 12/03/07

ADDENDUM REPORT

Surgery Date: 12/03/07  Accession No.: S-07-09397A

This addendum is issued to correct the tumor size in the Tumor Summary. Corrected tumor size: 0.4 cm.
Patient 4 (Figure 4) demonstrates how OncoVue and infrared can work together to help in difficult clinical problems. This patient has two sisters with breast cancer. She has not done BRCA 1 & 2 because of cost and her question was “Should I remove both breasts?” This is a frequently occurring question given today’s genetic knowledge of risk. OncoVue showed her at increased risk now but more risk years from now. Infrared was negative as was mammography, ultrasound and even bilateral core biopsies (of asymmetric tissue on mammography) failed to disclose even abnormal cells.

She is on an accelerated surveillance program utilizing yearly mammography, infrared twice yearly as well as MRI as deemed necessary. In the future, she will be a candidate for active prevention using either Tamoxifen or Raloxifen. This seems a reasonable alternative against the only option of bilateral prophylactic mastectomy. This patient is engaged to be married (one of her desires) which one could argue would have been difficult, if she had chosen bilateral mastectomy.
The Age Interval Risk is based on the patient's age on the date of the test and includes her risk for the entire age interval. The OncoVue® Patient Risk percentage takes into account your patient's genetic risk and certain personal history measures to determine risk of developing breast cancer based on the patient's age on the date of the test. The Average Woman's Risk percentage reflects the average woman's probability of developing breast cancer within each age category. The OncoVue® Patient Risk Category is assigned based upon the following table:

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<td>2%-3%</td>
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<tr>
<td>Moderate</td>
<td>3%-6%</td>
<td>3%-6%</td>
<td>3%-6%</td>
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<tr>
<td>High</td>
<td>&gt;6%</td>
<td>&gt;6%</td>
<td>&gt;6%</td>
</tr>
<tr>
<td>Standard</td>
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<td>2%-3%</td>
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<td>Moderate</td>
<td>3%-6%</td>
<td>3%-6%</td>
<td>3%-6%</td>
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<tr>
<td>High</td>
<td>&gt;6%</td>
<td>&gt;6%</td>
<td>&gt;6%</td>
</tr>
</tbody>
</table>

The assignment of the patient risk category is based upon the absolute risk for the specified age interval. The OncoVue Risk Category is provided as an additional reference and does not replace the quantitatively computed absolute risk.
**Sentinel BreastScan Patient Analysis Report**

Patient Name: [Name Redacted]
Patient ID: 9027
DOB: 12/4/1959
IR Date: 2/16/2007 1:17:29 PM

Differential Level Indicators: High, Med, Low

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### Parameter Values

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<th>Evaluation</th>
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Sentinel BreastScan is FDA Approved

Fig 4
Patient 5 (figure 5) illustrates a typical cost saving case. This patient had infrared which was negative for $150.00. Her mammogram and other diagnostic tests were suspicious for cancer. She eventually had a hospital based (negative) stereotactic core biopsy after extra mammographic views and her total bill in the system was $14,361.50. There are roughly between 500,000-700,000 breast biopsies performed yearly in the United States. The cost savings here are obvious. Below are the OncoVue, mammogram, infrared report, pathology and part of the final billing statement.

Fig 5
ATTENTION:
Philip D. Bretz MD
70034 Calle Barcelona
La Quinta, CA, 92253

Phone: (760) 771-4959 Fax: 9-771-4749

Right

#26296150 - MG US BREAST(S) UNILAT OR BILAT
ULTRASOUND OF THE RIGHT BREAST: 5/19/2009

FINDINGS:

CLINICAL HISTORY: This 55-year-old-woman has a multinodular appearance to her breast tissue on mammography and extensive fibrocystic change demonstrated on previous breast MRI. A new density in the lower right breast was suggested on screening study.

FINDINGS: Real-time ultrasound of the right breast shows multiple subcentimeter cysts throughout the breast. However, at the 10 o'clock position approximately 6 cm from the nipple, there is a dominant solid mass identified which measures 1.0 x 0.8 x 1.0 cm. This mass is lobulated in shape and does not have increased blood flow on color Doppler imaging. A similar appearing solid lesion at the 6 o'clock position, 1 cm from the nipple may well correspond to the density seen on the mammogram and measures 0.5 x 0.4 x 0.3 cm. This mass is lobulated in shape and has somewhat indistinct margins.

IMPRESSION: SUSPICIOUS OF MALIGNANCY - FOLLOW-UP RECOMMENDED
Sentinel BreastScan Patient Analysis Report

Patient Name:  
DOB:  
Patient ID:  9112  
IR Date:  

Differential Level Indications:  
- High  
- Med  
- Low

![Image of Sentinel BreastScan analysis](image)

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<td>CF =</td>
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Sentinel BreastScan is FDA Approved

Fig 5
Fig 5 pathology

ANATOMICAL PATHOLOGY CONSULTATION

Patient:  
Financial#: 0914100416  
Sex: F  
Physician(s): BREITZ, PHILLIP  
Date Received: 05/26/09  
Medical Record #: (0000)1490589  
Birthday: 09/16/1953  
Age: 55

SURGICAL PATHOLOGY REPORT

Surgery Date: 05/26/09  
Accession No.: S-09-04028

GROSS DESCRIPTION

This case has two parts. Each specimen is received in a plastic container with the patient's name, date of birth, and medical record number.

Part A
Received in formalin labeled "right 10 o'clock mass" are multiple off-white/yellow tissue cores and fragments ranging from 0.3 to 2.0 cm in greatest dimension and up to 0.3 cm in diameter, which are filtered and entirely submitted in A.

Part B
Received in formalin labeled "right 6 o'clock mass" are multiple off-white/yellow tissue cores and fragments ranging from 0.1 to 0.7 cm in greatest dimension and up to 0.2 cm in diameter, which are filtered and entirely submitted in B.

MICROSCOPIC DIAGNOSIS

A. RIGHT BREAST MASS, ULTRASOUND VACUUM-ASSISTED NEEDLE CORE BIOPSY @ 10 O’CLOCK:
   FIBROADENOMA.
   NONPROLIFERATIVE FIBROCYSTIC CHANGES.
   COLUMNAR CELL CHANGE.

B. RIGHT BREAST MASS, ULTRASOUND NEEDLE CORE BIOPSY @ 6 O’CLOCK:
   PROLIFERATIVE AND NONPROLIFERATIVE FIBROCYSTIC CHANGES.
   CYST WALL.
   CHRONIC INFLAMMATION.
   DYSTROPHIC CALCIFICATIONS.
4. RESULTS

Since November of 2006, 500 infrared and 550 OncoVue patients have been studied. The first 500 patients included 129 OncoVue patients, 499 were female and 1 male. A total of 19 were lost to follow up. Of 550 OncoVue patients, 129 opted to undergo IR.

4- very high risk
32- high risk
44- moderate risk.
7- average risk
22- below average risk
12-low risk
2 very low risk
5 flippers (conferring low risk early on, then higher risk, or visa versa).

IR results (500 total patients).

In this series, 419/500 were IR negative (84%). Of those, 63/419 went on to biopsy because of findings on other diagnostic modalities. In the 54/63 who went on to biopsy, either mammography ultrasound or MRI reports “said suspicious for cancer”. A total of 61/63 had a negative biopsy were IR said no cancer. Infrared missed two cancers that were identified out of 63. One of these cases was the fault of the investigators. In that patient (one of the first) an ultrasound was done immediately prior to the IR exam and the cold gel totally blocked Infrared's capability of detecting heat from the tumor. In any case this miss is included. In this series 2/500 were false negative (0.4%). In this series the Negative Predictive Value was 99.5 %.

Sensitivity = \[
\frac{\text{# true positive (46)}}{\text{# true positives (46) + # false negatives (2)}} = 96\%
\]

SPECIFICITY = \[
\frac{\text{# true negatives (61)}}{\text{# true negatives (61) + # false positives (16)}} = 79\%
\]

In this series, 46 patients had positive IR and did have cancer (including a bilateral breast case, 2 lung cancers (heretofore undiagnosed), 2 CLL cases (Chronic Lymphocytic Leukemia) and a basal cell carcinoma of the skin).

Also, 16 had a positive IR and a negative biopsy (all these patients has a prior biopsy or lumpectomy with resultant fat necrosis, dystrophic calcifications, inflammation or fibrosis). No patient who had a positive IR had a normal biopsy. The false positive rate was 3.2%. The false negative rate for mammography in this series was 24%.

A recent paper entitled “even top docs missing cancer on mammography” showed, that of 36,000 diagnostic mammograms read by 123 radiologist 20% of all cancers were missed (2). Screening mammograms and diagnostic were included in this current study and also patients in this study presented with typically difficult diagnostic dilemmas. So, the false negative rate of 24% in this series is not surprising. A total of 92 MRIs were done on 500 IR patients (18%). If the cancer patients are excluded then 84 MRIs were done (17%). In this series IR and MRI agreed 77% of the time (71/92), IR and MRI disagreed 23% of the time (21/92). Of the 21 disagreeing cases over time IR was 100% correct in diagnosing no cancer. The MRI impression was DCIS or recurrent tumor on 12/21 (66%). MRI showed multiple targets but the impression did not include cancer in 4/21.
Of the 14 cases where the MRI report said “cancer”, 3/14 had improving MRI results on repeat exam months later and cancer was no longer mentioned. A negative biopsy was obtained in 8/14 where MRI mandated biopsy and IR said no cancer. A benign diagnostic (not biopsy) report was obtained on 2/14 later on.

In 14/14 where IR and MRI disagreed (IR implying no cancer and MRI indicating possible cancer), MRI or mammogram either improved or the biopsy was negative, MRI did not miss any cancers. In 33 patients, IR showed improving imaged results on repeat exam. These results support our hypothesis that this newly develop technology should be implemented to diagnose ultra-small breast cancers. Simultaneously, costs can be cut while improving access, saving lives and possibly obviating traditional surgery, chemotherapy and radiation.

5. COMMENT

With multiple emerging genetic tests, genomic knowledge is rapidly becoming a key step for evaluation of a myriad of diseases and conditions. A specific case in point is utilization of Tamoxifen or Raloxifene for breast cancer prevention. Each lowers a woman's risk of developing breast cancer by 50%. The question is this: What female population is afforded that choice? More specifically, familial breast cancer identified by BCRA 1 & 2 only accounts for 10% of all breast cancers. In other words, 90% of the women at risk for breast cancer are currently not afforded the opportunity to learn if they are candidates for these medications because of the lack of participating in genetic risk test like OncoVue. Consequently then any preventive impact for a lifesaving intervention for these women will have been squandered.

OncoVue has made it possible to formulate a patient specific follow up plan for true early detection of breast cancer. Abandoning mammography, ultrasound and MRIs is not the answer and is not being advocated. What is being advocated is bringing awareness of these new technologies that could hold the answer for screening, saving lives and cost reduction. In the future, employing other no-invasive modalities that identify pre-malignant diseases such as analysis of NAF (nipple aspirate fluid) via Halo (11) may be the key in optimizing OncoVue and infrareds capability in finding cancer less than 3 mm. Their melding is the key and is the subject of a future multicenter trial called The Condi-Waters Study. Finally, with the identification of five other cancers (outside the breast), it is clear that further investigation into infrared’s ability to diagnose other conditions outside the breast is in order.

6. REFERENCES


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