President’s Column:  
A Tale of Two Countries

I recently returned from a two week trip to the Middle East. I spent a week in Israel, where I lectured for two days, plus a week in Jordan, where I did the same. The Israeli course was organized by Dr. Rachel Brem from George Washington University and the Jordanian program was organized by Dr. Michael Linver from Albuquerque, New Mexico. Both courses were extremely well run and each was well attended and appreciated by the attendees. There were, however, great differences between the breast imaging standards in both countries. My trip gave me a better perspective of how fortunate we are in developed nations to be able to practice our craft in a favorable environment.

The Israeli program consisted of a series of lectures which dealt with topics such as new imaging equipment, tailoring these modalities to the individual patient and other content, such as the new edition of BI-RADS®. It was clear that the attendees were already familiar with these topics and they welcomed the opportunity to learn more about them. The radiologists were already using good equipment in their practices and they had technologists who generated high quality images. Expert technologists from the United States offered a dedicated session for these technologists to improve their skills.

The Israeli breast screening program is run by the Israel Cancer Society. The program has been very successful since its inception. The compliance rate among eligible women is 70%! Since that the program was initiated, the mortality rate from breast cancer in Israel has decreased by 30% (similar to that in America). This is despite the national trend toward tailored management specific to the individual patient. A highlight of the week will be Condoleezza Rice’s lecture Tuesday in the Arie Crown Theater titled, “Mobilizing Human Potential.” In all, this year attendees will have approximately 3,000 scientific presentations and posters to choose from, to learn about the latest and the greatest in the field of radiology. Additionally, “France Presents” is featured at RSNA 2013, highlighting several exhibitors from France along with a number of scientific presentations.

In breast imaging, the submitted presentations include papers on digital breast tomosynthesis, quantitative imaging and magnetic resonance imaging (MRI) phenotypes, and MRI screening of intermediate risk women (including women with a personal history of breast cancer and/or cellular atypia). These presentations reveal the trend toward tailored management specific to the individual patient. A mixture of educational presentations and educational exhibits will be available, including material on quality control and imaging-pathology correlation. Residents and younger radiologists may find the exhibits to be great review opportunities. Also, clinical presentations will be available for practicing radiologists in breast MRI and related

RSNA 2013 Preview

By Stamatia Destounis MD, FACR

Before we know it, another Radiological Society of North America (RSNA) meeting will be here. For the 99th Scientific Assembly & Annual Meeting, the program theme is “The Power of Partnership.” In the ever changing field of radiology, we all are realizing more and more how important our partnerships with others can be. Dr. Sarah Donaldson, RSNA president, will open RSNA 2013 Sunday morning in the Arie Crown Theater with the president’s address on partnerships. Dr. Damian Dupuy will follow Dr. Donaldson’s lecture with the Annual Oration in Diagnostic Radiology titled “We Must Stand on the Shoulders of Giants.” A highlight of the week will be Condoleezza Rice’s lecture Tuesday in the Arie Crown Theater titled, “Mobilizing Human Potential.” In all, this year attendees will have approximately 3,000 scientific presentations and posters to choose from, to learn about the latest and the greatest in the field of radiology. Additionally, “France Presents” is featured at RSNA 2013, highlighting several exhibitors from France along with a number of scientific presentations.

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image quality was poor because the manufacturers did not provide the users with any applications training. For example there was no instruction in how to properly maintain a processor. Chemicals went unchanged for months, resulting in images with poor contrast. The technologists also lacked positioning skills. As a result, the radiologists lost faith in mammography and often performed screening ultrasound as a substitute (not the best way to provide service screening). There were no formal QC or QA programs in Jordan, and the facilities had no idea whether or not they were providing good services. Moreover, there was a cultural impediment to women undergoing mammography. Consequently patients often presented with advanced breast cancers, which were associated with poor prognoses.

The national screening program began with the support of the Jordanian royal family and the Jordanian health ministry. The royal family and the health ministry were committed to improving the quality of breast imaging and to developing a coordinated system to provide women access to screening mammography. Dr. Michael Linver and other experts went to Amman to assess the state of the Jordanian mammography services. The experts decided that they needed to start with the basics. A two day annual course was established to teach the radiologists how to analyze a mammogram for image quality and lesion characteristics. One hundred screening cases were given to the participants to reinforce the process of screening interpretation. Technologists in Jordan were also offered teaching in positioning as well as instruction in QC. The response of the registrants was overwhelmingly positive. The American College of Radiology (ACR) accreditation program served as the model for the facilities’ improved programs.

Equally important to the success of the endeavor was the ability of the teaching personnel to reach out to women across Jordan and to convince them that it was beneficial for them to undergo screening mammography. The teaching personnel also had to convince male relatives that obtaining a mammogram was more important than old cultural taboos. These women who performed this outreach function deserve much of the credit for improving the acceptance of mammography in Jordan.

Since its beginning, the Jordanian mammography course has attracted participants not only from Jordan, but also from other Middle Eastern countries including Libya, Egypt, Syria, Saudi Arabia and the United Arab Emirates. Although there is still room for improvement, the number of sites performing high quality mammography has risen dramatically, and the death rate from breast cancer has started to decrease.

When I returned home, I was still thinking about the two countries’ commitment to high quality breast screening. There was no criticism by the press about the harms of screening. No one harped on the “overdiagnosis” of ductal carcinoma in situ (DCIS). Women were not complaining about how they were being manipulated into undergoing a procedure which they might not need. The people were united in their desire to aid women and lower the death rate from breast cancer.

Here in the United States, we are fortunate to have an abundance of resources. We have access to the newest cutting-edge technologies, the best teaching, and a health system which allows women access to mammography and other modalities which are used for supplemental screening. However, our national compliance for screening mammography is a disappointing 50%. The press and our professional colleagues in other branches of medicine continue to attack the benefits our programs. The United States government is more concerned about curtailing health care costs than in saving women’s lives. Where do we go from here? Sometimes it is important to take a step back and see how other countries function. There is much we can learn by doing this.

Murray Rebner, MD, FACP
President, Society of Breast Imaging

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procedures, automated whole breast ultrasound, along with newer techniques, including optoacoustic breast imaging, and high intensity focused ultrasound.

This year’s conference will cover a range of topics, from the current controversy over breast tissue density and risk assessment to new technologies, including contrast-enhanced mammography, and nuclear and molecular imaging. Sunday afternoon will begin the discussion on current issues in breast cancer screening, including breast density based screening by Dr. Stephen Feig. A special interest session will be held on Monday which will further discuss breast density, risk assessment, communication, and approaches to supplemental imaging. This session will cover the current advocacy movement, including state and federal requirements to inform the patient of her breast density, along with the risks associated with breast density and supplemental imaging options for those patients with dense breasts. As more and more states are adopting density legislation, sessions such as these are sure to attract a lot of interest.

New technologies will be heavily represented. Dr. John Lewin will discuss contrast mammography during a breast series on Emerging Technologies in Breast Imaging. As expected, digital breast tomosynthesis will be included in many sessions. Scientific presentations on tomosynthesis will be presented in several breast imaging sessions, including Dr. Mark Helvie’s discussion on tomosynthesis research during the breast series on Emerging Technologies. Breast MRI and breast ultrasound will be discussed as well, including interactive biopsy courses with both modalities. There will be several more offerings on breast MRI, including a series on breast MRI which will include image acquisition, diffusion-weighted Imaging, and advanced techniques and spectroscopy. New research involving breast MRI will be presented during multiple breast imaging sessions, including MRI Interpretation, moderated by Dr. Elizabeth Morris and Dr. Constance Lehman on Monday and MRI Lesion Characterization on Wednesday, moderated by Dr. Christiane Kuhl MD and Dr. Janice Sung.
Editor's Note

It’s that time of year again. When I dropped my children off at school this morning, it was 36 degrees Fahrenheit outside. That’s cold anywhere – especially in Houston!

This is Thanksgiving time. Sally Herschorn contributed an important article in this issue, reminding us to be thankful for the many dedicated team members who enable us to do what we do each and every day. A successful breast imaging operation requires countless trained, patient-centered individuals in addition to the radiologists.

Right around the corner is the Radiological Society of North America (RSNA) meeting. In this issue, Toulou Destounis provides an exciting preview of the big meeting. For me, RSNA means meetings, educational sessions, navigating McCormick Place, and, best of all, seeing “old” friends.

Happy Thanksgiving to you and your family and safe travels! See you in Chicago! ☺

What Is PQRS And Why Should I Care?

By Bernadette Redd, MD

Several new Centers for Medicare and Medicaid Services (CMS)-generated health care initiatives are currently being implemented. The goal of these initiatives is to move the United States health care payment system from a volume-driven, fee-for-service model to one that rewards quality. New initiatives administered by CMS, such as meaningful use (MU) and accountable care organizations (ACOs), previously discussed in this column, are designed to further this goal. The Physician Quality Reporting System (PQRS) was also developed with the aim of improving patient outcomes through quality care. PQRS is currently the nation’s largest pay for performance (P4P) program. P4P programs are models that financially incentivize desired behaviors and outcomes in the hopes of improving care and reducing health care costs (1, 2).

PQRS provides an incentive payment to physicians for satisfactorily reporting data on specific quality measures for covered Physician Fee Schedule (PFS) services provided to Medicare Part B beneficiaries (3). CMS established PQRS, originally called the Physician Quality Reporting Initiative (PQRI), as part of the 2006 Tax Relief and Health Care Act (TRHCA). PQRI’s name changed to PQRS and it became a permanent program after the passage of the Patient Protection and Affordable Care Act (PPACA)(1).

Participation in PQRS has been voluntary since 2007. Participants receive a bonus or a financial incentive if they report on three or more quality measures for 80% of their relevant patients (2). Bonuses peaked at 2% of PQRS participants’ total Medicare reimbursement per year in 2009 and 2010. Bonuses decreased to 1% in 2011 and will be provided at a rate of 0.5% for 2012-2014 (4). Participation in the program will remain voluntary, but starting in 2015, bonuses will no longer be given; instead, penalties of 1.5 % for 2015 and 2% for 2016 and thereafter will be implemented (5). Of note, the reporting period for the 2015 penalty is 2013 (5).

It is important to understand that PQRS is a system for reporting quality measures. PQRS does not require that practice performance on the measure meet a certain standard. For example, a measure available for reporting by radiologists is titled “reminder system for mammograms” (6). The participant reports the percentage of all patients aged 40 years and older undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram (6). Participating radiologists could report that patient data is being entered into a reminder system only 25% of the time and still receive the full incentive payment, because the reporting requirement has been met - despite the fact that the quality of the delivered care as measured by this metric is low.

The realization that PQRS measures reporting, and therefore does not specifically measure quality, is a well-known criticism of the program, as is the cost of implementation. A study published by Drs. Federman and Keyhani in Health Policy in 2011 found that “relatively few physicians equated reporting under the PQRI with better quality of care, and reporting is often expensive for providers to implement” (2). Another difficulty with the program is that efforts to comply with the program’s requirements do not always prove fruitful. A study by Dr. Duszak and colleagues published in the American College of Radiology (JACR) in 2013 that looked at the national experience of radiologists with PQRS from 2007–2010 found that “only a minority of radiologists successfully qualified for financial incentives under PQRS, but that the numbers had increased each year” (1).

Given the concerns about PQRS’ limited impact on quality and low rates of incentive reimbursements for radiologists, one could be forgiven for being tempted to forfeit the bonus payments. However, the decision not to participate would need to be made with the understanding that doing so could be associated with a significant loss of CMS reimbursement over time, because PQRS will soon be tied to other CMS quality initiatives, such as value-based payment modifiers (VBM) and maintenance of certification (MOC). Dr. Silva noted in a recent article in JACR that in the not-too-distant future, avoiding VBM penalties and receiving MOC bonuses will require successful participation in the PQRS program (5). The aggregate decrease in payments due to noncompliance with these types of programs could be 4% in 2015 and 8.5% or higher by 2019 (5).

Many would agree that the relatively new CMS-sponsored quality initiative programs, which are intended to encourage the transition from fee-for-service care to quality-based care, are not perfect. Despite the frustrations associated with implementation of these health care initiatives, it is crucial for radiologists to be well informed and to remain active in the ongoing development of these programs. Radiologists in all types of practice settings need to provide specific feedback to CMS and to professional organizations such as the American College of Radiology (ACR) so that these initiatives can evolve in ways that promote high-quality imaging and patient care. ☻

References

**NAPBC Board of Trustees Meeting**

By Jay Baker, MD

The National Accreditation Program for Breast Centers (NAPBC) held its board meeting in Washington, D.C. on October 7, 2013. The NAPBC is a multidisciplinary consortium of medical organizations focused on breast cancer detection and treatment that sets minimum practice standards and accredits breast programs. The board is comprised predominantly of physicians representing each of the major specialties that constitute a high quality breast care program including breast surgeons, oncologists, radiation oncologists, pathologists, and, of course, breast imagers. Eight breast imagers are represented among the board of the NAPBC.

The board meeting opened with an update on the status of the NAPBC, which continues to grow, though at a slower pace than previously, with 510 accredited programs. An additional 227 programs have completed applications.

An interesting point of discussion turned to the question of whether accreditation by groups like NAPBC actually leads to better care for patients. This issue was brought into focus because the Center for Medicare & Medicaid Services (CMS) reversed its policy in September 2013 and ruled that Medicare patients will no longer be required to choose accredited facilities for bariatric surgery procedures. The decision was ostensibly made due to the lack of evidence that accredited facilities provided better outcomes or lower costs. The NAPBC similarly cannot point to specific data to demonstrate better outcomes for patients in accredited facilities using metrics such as reduced re-excision rates, lower biopsy rates, decreased expenses, or improved mortality rates. Board members agreed that such data will be important to confirm the value of this accreditation program to both patients and insurance companies.

The board next discussed whether and how the NAPBC should respond to important events such as “breaking news,” newly released research studies, or new guidelines affecting breast care. The event prompting this discussion was the request by the radiology representatives for the NAPBC to publicly support American College of Radiology (ACR) and Society of Breast Imaging (SBI) screening guidelines in light of research articles supporting watered down recommendations. There was broad agreement that the NAPBC needed a formal, fast response mechanism. In the interest of a quick turnaround and to minimize controversy, it was determined that any such response would be drafted and signed by the executive committee of the NAPBC rather than by the individual societies that comprise the umbrella organization.

The second half of the meeting was largely comprised of reports from the six committees made up of members of the board. For example, the education and dissemination committee reported that efforts were underway to identify an appropriate breast imaging meeting at which a workshop could be held to increase the visibility of the NAPBC among radiologists.

The standards and accreditation committee proposed an update to the breast imaging standards for NAPBC accreditation. The standard was revised to include the requirement that all breast imaging be performed at MQSA-accredited facilities, which is already required by federal law. The standard now includes the strong recommendation that breast MRI be performed at sites with ACR accreditation for breast MRI.

The next meeting of the board of the NAPBC will be held in Phoenix, Arizona in February 2014. A leadership retreat will be held just prior to that board meeting to determine the strategic direction for the NAPBC. Dr. Peter Jokich will represent the breast imagers at that retreat.

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**The Breast Diagnostic Management Team**

By Stephanie Kurita, MD

At Vanderbilt University Medical Center (VUMC), the concept of a diagnostic management team (DMT) was created in response to the ever increasing complexity of medical treatments across multiple clinical subspecialties throughout the institution. The multidisciplinary DMT is charged with improving care coordination, establishing standard operating procedures (SOPs), evaluating workflow, and defining quality metrics to improve the application and coordination of evidence-based care. The model has proven successful at VUMC within hematopathology (1), and has been adapted to the diagnosis, treatment, and management of patients with breast cancer.

Work on the breast DMT at VUMC was initiated at a design workshop in September, 2012, where representatives from all areas of the breast center partnered with administrative leaders and information technology specialists to review case scenarios designed to highlight various clinical and operational issues. At this workshop, the initial scope of the DMT was defined as the events surrounding a breast biopsy for a patient referred by a VUMC provider. These events included scheduling the biopsy, additional diagnostic testing, pathology and associated steps leading up to the first medical or surgical oncology appointment after a new diagnosis of breast cancer. It was determined that in order to improve care for these patients, systems to increase efficiency in the breast center would be required. Specifically, goals were defined as decreasing the time from biopsy recommendation to treatment, evaluating workflow, creating reflex testing in radiology and pathology, generating evidence-based SOPs, creating comprehensive reports, and designing metrics to evaluate change.

The breast DMT began bi-weekly meetings in January 2013 with multiple subgroups meeting on a more frequent basis. Representatives from surgical oncology, medical oncology, pathology, and radiology as well as systems engineers and specialists in medical informatics were included. Through teamwork, many of the established goals have already been realized. A comprehensive literature review provided the evidence to create biopsy management SOPs in both radiology and pathology. Review of the data after implementation of the SOPs allowed for targeted counseling for those radiologists who were not following the established guidelines. Ongoing accumulation of data will allow the DMT to evaluate the impact after counseling. Regarding comprehensive...
Breast Diagnostic, continued from previous page

reporting, a breast impression flow sheet in the electronic medical record (StarPanel) was created including data from both radiology and pathology reports, allowing for a continuously updated view of a patient’s radiology and pathology findings. With involvement by William Gregg’s My Health Team, informatics tools, including breast center navigator panels, are under development to provide operational support and customizable views for various providers in the breast center. Additionally, Powerscribe templates for standardized radiology reports were created for potential data extraction. Workflow analysis and evaluation of timing metrics identified a mean seven day delay in biopsy scheduling due to anticoagulation. A subsequent literature review provided evidence supporting a change in protocols, with early data suggesting at least a two day decrease in the time from a recommendation of biopsy to procedure completion.

While many of the initial goals of the breast DMT have been achieved, additional work continues. A comprehensive literature review regarding preoperative MRI in patients with breast cancer failed to provide sufficient evidence for creation of a SOP; and therefore, creation of a consensus statement regarding preoperative MRI is currently underway with representatives from surgical oncology and radiology. Additionally, discussions with third party payers in order to allow reflex testing remain in progress. There are continued efforts in workflow analysis and attempts at improved efficiency, including the creation of electronic patient forms and a potential provider notification system through the electronic medical record.

The value of multidisciplinary cancer care has been established for over four decades (2) with a perceived benefit of consistent, coordinated and cost-effective care to the patient (3). Our goal with the breast DMT is to further improve clinical outcomes and enhance evidence-based care in the most efficient way possible. We hope that the work and processes developed at VUMC through the breast DMT may provide a framework that others find useful as we strive to meet the challenges of our changing healthcare environment.

References
Dr. Etta Pisano Honored

By Syndee Winston

On October 9, 2013, the National Women’s History Museum (NWHM) honored Dr. Etta Pisano, Vice President for Medical Affairs and Dean of the College of Medicine at the Medical University of South Carolina, with the Dr. Helen Taussig Living Legacy Award for her outstanding accomplishments in medicine. The award was presented at the Museum’s annual de Pizan Honors ceremony in Washington, D.C.

More than 200 guests filled the Mead Center for American Theatre at Arena Stage to celebrate American women who have enriched the fabric of this nation through their life’s work.

Other 2013 honorees included Tony Award-winning actress and activist Phylicia Rashad (Lena Horne Living Legacy Award), and world-renowned opera singer Denyce Graves (Marian Anderson Living Legacy Award). Multi-award winning documentary filmmaker Ken Burns was honored with the Henry Blackwell Award, named for the 19th century women’s rights advocate who co-founded the American Women Suffrage Association. The award honors men who have championed, supported, encouraged and appreciated the contributions, achievements and, most importantly, the experiences of American women.

Dr. Pisano is a leader in breast cancer imaging and a co-founder of NexRay, Inc, which will commercialize a device she and her co-founders invented to create medical images (using x-rays) through diffraction enhanced imaging. This device will be most important to children and young adults, as well as young women undergoing breast cancer screening.

The NWHM created the Dr. Helen Taussig Living Legacy Award in honor of the pioneering physician considered to be the founder of pediatric cardiology. Dr. Taussig developed a surgical procedure to address “blue baby syndrome” or anoxemia -- a condition in which an infant’s heart does not circulate enough blood to the lungs. Untreated, anoxemia is often fatal. The operation, known as the Blalock-Taussig shunt, was performed on thousands of children with a mortality rate of less than five per cent. Dr. Taussig was also the first female president of the American Heart Association.

In accepting the award, Dr. Pisano reflected on the unique challenges women in science, technology, engineering, and mathematics (STEM) face. “Women in STEM find it too hard to succeed,” she noted. “I will work hard to change what’s possible for women and girls in science.”

Created in 2011, the de Pizan Honors bridge the past with the present. The awards posthumously honor three historical, game-changing women and three contemporary women who are making remarkable contributions in similar fields.

Upcoming Events & Activities

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Honorees Denyce Graves, Dr. Etta Pisano and Phylicia Rashad with NWHM President Joan Wages.
Women with Dense Breasts Should Be Screened with Ultrasound: In Favor

By Carol Lee, MD, FACR

Mammography saves lives. Despite continued attacks, there is very little doubt that this is true and mammography is the only imaging modality that has been proven to decrease mortality from breast cancer. What is also true, however, is that mammography is not perfect and can miss cancers, particularly in women with dense breasts. In the DMIST study of digital mammography, the sensitivity of mammography for detection of cancer in women with dense breasts was only 38%. Currently, 12 states have laws requiring direct patient notification of breast density and as a result, there is increasing demand for additional screening for women with dense breasts. In most cases, that additional screening is with ultrasound. We know from a number of single center studies that screening women with ultrasound results in an incremental cancer detection rate of approximately 3/1000. The multi-center ACRIN 6666 study yielded similar results [1]. The majority of the cancers detected by ultrasound only are invasive cancers, rather than DCIS. Therefore, overdiagnosis is likely less of a consideration with ultrasound-only detected cancers. In addition, most of the ultrasound screen-detected cancers are small, node negative tumors suggesting that finding these will result in better patient outcomes.

Until recently, all but one of the studies of screening ultrasound in the literature were based on physician-performed examinations. In the ACRIN 6666 study in which the studies were done by the radiologist, the mean time to acquire a study was 19 minutes. Having radiologists perform the screening examination represents a burden on personnel resources and is not feasible for most practices. Recent reports from Connecticut, however, which was the first state to require direct patient notification of breast density, were based on technologist-performed studies and also showed an incremental cancer yield of approximately 3/1000 [2]. The majority of screening ultrasound examinations can be acquired in about the same amount of time that is required to obtain a screening mamogram. Therefore, it seems that screening ultrasound performed by technologists is efficacious and is something that most practices can offer.

Some of the disadvantages of screening ultrasound that have been cited are the low positive predictive value of biopsy recommendations and the relatively high number of probably benign findings that
Ultrasound In Favor, continued from previous page

require short interval follow-up. However, ultrasound guided biopsies are easily and quickly performed and generally well tolerated. In addition, with increased experience we may better be able to identify cases that can be assessed a BIRADS 2 rather than BIRADS 3 category. For example, a recent study based on data from the ACRIN 6666 study suggests that multiple circumscribed masses seen on screening ultrasound can be assigned a BIRADS 2 assessment, similar to such findings seen on screening mammography [3].

Ultrasound is non-invasive, readily available, and relatively inexpensive and there is evidence that technologist-performed examinations are as effective in finding cancers as those done by physicians. Biopsies generated by ultrasound findings are easily performed. With increased awareness of the limitations of mammography in the presence of dense breast tissue and the proliferation of legislation mandating direct patient notification of breast density, there will be increased demand for this test. Screening ultrasound can find cancers that are occult to mammography and there is little reason not to offer this test in those women in whom we know mammography has low sensitivity. Perhaps in the not too distant future we will be able to say with confidence that, like mammography, ultrasound saves lives.

References

Ultrasound Screening for Breast Cancer? NO!

By Valerie P. Jackson, MD, FACR

For many years, ultrasound (US) has been an integral part of breast imaging, as a primary imaging method for young women and as an adjunctive technique to mammography for women over the age of 30 years. There have been many studies regarding the value of US for screening, yet its role remains controversial.

While US is a powerful diagnostic tool, there are four main reasons why it is less successful as a screening modality: 1) operator dependence; 2) cost; 3) false negatives; and 4) false positives (1). The high degree of operator dependence in breast US creates potential problems with examination quality and reproducibility. It is easy to do a quick, poor quality sonogram. It takes time and skill to perform a high quality, accurate exam and even then it can be difficult to reproduce small or subtle findings on subsequent studies. Currently, there is a shortage of breast imaging technologists and radiologists in the United States. Who will perform the US screening exams – and do them well? The ACRIN 6666 trial utilized specially trained radiologists who were breast imaging experts – they personally performed all of the sonograms using specific protocols. In personal conversations, several of the radiologists who participated in the trial complained bitterly about the time it took to perform the exams to study specifications. While the participants’ attitudes may match those of “real world” radiologists, their expertise was much greater. Therefore, it is likely that the ACRIN 6666 results reflect the best possible scenario and that generalized practice will fall far short (2).

To determine the ultimate value of screening breast US, one must consider not only the cost of the exam – equipment, operator, supplies, overhead, and interpretation – but also the cost of subsequent biopsies and follow-up tests that may ensue. The cost for a true positive exam can be justified. However, screening breast US has been shown to have a high false positive rate. In the ACRIN 6666 trial, the positive predictive value (PPV) for screening US was only 8.8% (6.7% if cyst aspirations were included in the biopsy cases). These numbers are unacceptably low for an initial screen. For subsequent (incidence) screening sonograms, 5% of women had abnormalities that led to biopsy. Only 7.4% of biopsied women were found to have cancer. We always worry about false negative exams, and studies have shown that magnetic resonance imaging (MRI) is better for the detection of breast cancer than US. Why use a suboptimal screening modality with inferior results when we can use a significantly better modality for patients who need supplemental screening (2)?

The American Cancer Society (ACS), the American College of Radiology (ACR), and the Society of Breast Imaging (SBI) currently recommend screening high risk women with mammography and MRI. US may be considered if the woman cannot have an MRI, which would be a minority of cases. To date, the published scientific study results do not justify a recommendation for screening US for the general public or instead of/in addition to MRI for very high risk women. As we work hard to reduce the cost of health care in the United States, it is important for us to utilize evidence-based criteria in order to get the maximum bang for our ever-shrinking bucks.

References
Interesting Case

By Peter Eby, MD

In 2008, a 71-year-old woman underwent a screening mammogram that was interpreted as normal (Fig. 1). She presented for a screening mammogram in 2009 (Fig. 2). How would you interpret this examination?

The 2009 exam was assessed a BI-RADS 0, and spot compression views and ultrasound were recommended for “an oval mass measuring 7 mm at 9 o'clock posteriorly.” The left side was negative.

She returned for the diagnostic examination that showed the mass on spot compression views (Fig. 3). An ultrasound was performed (Fig. 4). The final assessment incorporating all the available imaging was benign (BI-RADS 2) and summarized as: “Ultrasound demonstrates a lymph node at the site of the mammographic mass.”

In 2011, the patient was recalled from screening for enlargement of the mass in the right breast at 9 o'clock (Fig. 5). Diagnostic ultrasound revealed a mass adjacent to a lymph node at 9 o'clock (Fig. 6). Subsequent biopsy confirmed a grade 1 invasive ductal carcinoma.

This case illustrates a number of challenges and potential pitfalls in the workup of solid masses. First, some solid masses have relatively benign features such as oval shapes and smooth margins that can provide false reassurance. These features can be seen in benign entities such as cysts, fibroadenomas, and lymph nodes but they can also be seen in cancers. Do not be fooled. Get the spot compression views which can help visualize suspicious features such as indistinct margins or calcifications.

Second, in this case, the patient has stable low axillary and intramammary lymph nodes, best seen on the MLO views from 2008 and 2009 (Fig. 1b and 2b, arrows), that are very similar to the mass in question. We may be tempted to call this mass a lymph node based on proximity and similarity. However, the key difference is that this mass was not present on the 2008 examination, and lymph nodes do not appear in the breast de novo in adulthood. Do not be fooled. Inspect multiple prior examinations to establish whether a posterior mass is stable or new.

Third, correlation between mammographic and sonographic findings can be difficult. This is especially true when searching for a small mass in a large breast. In this case, a lymph node was detected at the approximate location of the mass. The radiologist concluded that the sonographic lymph node explained the mammographic mass. However, as discussed above, a new mass in a 72-year-old woman should not be a lymph node. Do not be fooled. The radiologist and/or sonographer should keep searching. If the mass cannot be found with ultrasound, then stereotactic biopsy is indicated to evaluate a new mass.

Fortunately, this was a low grade, slow-growing cancer that had not spread to the lymph nodes. The patient’s prognosis was not impacted by the delay in diagnosis. However, the results could have been different if the patient had a high grade and/or a rapidly growing tumor. High grade cancers have been described as more frequently demonstrating oval or round shapes and smooth margins, which can be mistaken for benign features [1].

References


Figure 1. The right CC (a) and MLO (b) views from the screening examination in 2008. There are two normal low axillary and intramammary lymph nodes (arrows).
Figure 2. The right CC (a) and MLO (b) views from the screening examination in 2009 show a new mass at 9 o’clock, posterior depth (arrow).

Figure 3. CC (a) and MLO (b) spot compression views from the 2009 diagnostic examination show that the mass has indistinct margins. There are no associated calcifications.

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Part I of this series presented various types of clinical research that are amenable to being performed in a private practice setting. Part II will concentrate on the steps needed to set up and perform a prospective clinical trial. A clinical trial generally provides the most reliable way to evaluate the clinical efficacy of a new technology and is generally the only way to compare two technologies that is not prone to selection bias and other limitations. Compared to other types of clinical research, however, a clinical trial is significantly more difficult to set up and run.

The first step in setting up a clinical trial in private practice is getting the buy-in of your partners and the clinics in which you work. It is an advantage if your group owns their own clinics since you are more likely to get the cooperation of the technical staff and the administration. It is also an advantage compared to academic practices, since most universities are separate entities from their affiliated hospitals.

Next, you must develop a budget for the project. The budget has to take into account all the possible costs of the research including the time spent by radiologists, technologists and other clinical personnel, as well as equipment and supplies. A research assistant will also need to be hired, either part-time or full-time. It is also important to include extra time for you to set up and administer the research. This may include participation in weekly or monthly conference calls with the study organizers and other investigators.

In addition to the direct costs noted above, the sponsor will generally pay an extra percentage for indirect costs, also called overhead. In some cases, the indirect rate is set by the trial organizers, but in other cases you may be able to negotiate this amount. An advantage of private practice is that the money paid as indirect costs does not disappear into the institution's general fund as it typically does at an academic site.

The next step in setting up the research project is to get approval from an institutional review board (IRB). Many private hospitals or hospital chains have their own IRBs, but if there is not one affiliated with your site you can use a national for-profit IRB such as Western IRB. This may be very helpful if the national IRB has already approved the process at other sites. An IRB submission requires the inclusion of multiple documents, but the IRB will guide you with the process. In a multicenter trial, the key documents, the protocol and consent form, will have been provided by the study organizers. The consent form may have to be modified to fit local requirements. While obtaining IRB approval may seem redundant for a clinical trial already up and running at other sites, an advantage of private practice is the absence of a cancer committee. At an academic site, cancer committee approval is needed in addition to IRB approval. The cancer committee looks not only at human subject safety but at overall study design and can easily delay study initiation by six months, or prevent it altogether.

Once you are ready to go, then running the trial is generally the easiest part. The key to doing clinical research is to be as compulsive as possible. The protocol must be followed to the letter, and every patient enrolled must completely meet the inclusion criteria. Every line on every form must be filled out. Both patient safety and integrity of the data are extremely important and must always trump recruitment.

**Is it Worth It?**

The most important thing to consider when planning a clinical trial is whether it is worth doing. To answer this you need to balance what you will get out of participating against the costs in terms of both time and unaccounted costs to your group. Both sides of the equation vary, depending on whether the trial is an American College of Radiology Imaging Network (ACRIN) trial, an industry-sponsored trial or research that you initiate on your own (known as an “investigator initiated” trial).

The rewards of joining an ACRIN trial include interesting interactions with your academic and non-academic peers and a chance to break up your clinical work with something different. You may also be included as an author on a paper or two, depending on how the trial organizers handle authorship and on the number of participating sites. The risk is basically that the amount of work will exceed the amount of money paid by ACRIN to run the study. The rewards of an industry-sponsored multicenter trial are similar to those of an ACRIN trial, with the added reward of getting to be the first to use a new technology. While there is less certainty of an industry trial resulting in a published paper, there may be satisfaction in knowing that the research either resulted in a useful technology getting to market or a not-so-useful one being kept out. In general, an industry trial will be better funded and more efficiently run, lessening the financial risk.

Initiating your own clinical trial has the potential to be much more rewarding than joining an existing trial, since you are necessarily studying something you greatly care about. It is also a lot more work. Unlike in multicenter trials, it is up to you to design the research and analysis, write your own protocol and prepare the consent form and other documents needed for IRB submission. Most importantly, you need to secure your own funding. This is usually the hardest part and is beyond the scope of this article.

**Summary**

Joining a clinical trial, or starting your own, can be a rewarding experience but there are no guarantees. What is guaranteed is that it will involve a lot of work -- both to get it going and to actually do the research. It is important to consider all factors before deciding whether or not to pursue a clinical trial. While academic sites have some structural advantages for performing research, there are advantages to private practice, primarily in terms of fewer bureaucratic hurdles and the absence of institutional overhead costs. ▶
Minimally Invasive Ablation for Breast Cancer Treatment

By Marilyn A. Roubidoux, MD

Screening mammography has facilitated the detection of progressively smaller, early stage breast cancers, averaging less than 15 mm in size. This has permitted the development of less invasive treatments that could be as effective as surgery and offer superior cosmetic results. Such treatment options would also be useful for elderly patients or those with multiple co-morbidities. Cryoablation of benign fibroadenomas has been approved for treatment by the United States Food and Drug Administration (FDA). Cryoablation results in the disappearance of 95% of benign lesions with generally excellent cosmetic results. This is a useful model for cryoablation of breast cancers (1, 2), as similar cosmetic results might be expected.

Minimally invasive and noninvasive techniques with thermal methods (heating or freezing) have been investigated over many years. Unifocal invasive carcinomas < 2 cm in size may be successfully destroyed, and larger tumors may be treated, using more than one probe. Cryoablation (1-3), radiofrequency ablation (RFA) (4, 5), laser ablation (LA) and microwave ablation (MWA) are percutaneous methods requiring a probe, whereas high intensity focused ultrasound (HIFU) is transcutaneous and noninvasive (i.e., no probe is necessary) (6, 7).

Ultrasound is usually used for guidance, and in some instances, magnetic resonance imaging (MRI) is employed. MRI is necessary for guiding HIFU (6). Most clinical trials have been done with cryoablation or RFA, along with post-ablation lumpectomy to measure success. Successful ablations of stage I tumors have been reported. Most recently, complete ablation rates of 98% with RFA (4) and 93% with cryoablation (3) have been achieved. Cryoablation and RFA have also been used to treat larger cancers without surgical excision, such as high stage non-resectable tumors in elderly patients and breast cancer patients refusing conventional surgery (5).

Patient tolerance is highest for cryoablation because freezing is analgesic, so that only lidocaine is necessary. Heat-based methods may require local analgesia over the pectorals major muscle, sedation and/or general anesthesia. Heat-based methods have been associated with some skin burns and substantial patient discomfort.

Except for HIFU, all methods use percutaneous probes. Accurate placement of the probes into the geometric center of the tumor is necessary. RFA limits visibility during the procedure due to increased echogenicity of the surrounding tissue, and cryoablation has some visibility limitations due to the ice ball that encompasses and obscures the targeted lesion.

Percutaneous ablation is not recommended for in situ carcinoma or invasive lobular carcinoma (5), due to limitations in accurately defining tumor extent. Higher success rates have been reported among tumors < 1.5 to 2 cm in size without extensive ductal carcinoma in situ (DCIS). Up to now, all clinical trials of ablations have excised the tumor site after ablations, to determine cell death and measure accuracy. The most recent clinical trials have used MRI pre-ablation to identify tumor occult to ultrasound, and post-ablation, to detect residual malignancy.

A study of RFA in 41 patients reported a complete ablation rate of 98% among tumors < 2 cm, with the one residual malignancy detected by MRI (4). Similarly, a 93% ablation rate was reported using cryoablation (3) among 15 patients with < 2 mm tumors, with MRI detecting one case of a 3 mm residual tumor. A large multicenter clinical trial of 100 patients with stage 1 tumors undergoing cryoablation is being performed by the American College of Surgical Oncology Group (Z1072), which will evaluate the efficacy of pre- and post-ablation MRI. Additional clinical trials are needed to measure outcomes of these promising, less invasive breast cancer treatment methods (7).

References

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The Symphony of Breast Imaging

By Sally Herschorn, MD

As the medical director of a busy academic breast imaging division, I never cease to be amazed at the complexity of the breast imaging process and the details needed to be attended to in order to have a successful practice. I want to share how fortunate I feel to be working in breast imaging as part of a team. Any job can become fairly routine; even one as challenging and interesting as breast imaging. You get the screens read, perhaps occasionally detect a likely cancer on a screening study (that makes for interesting reading). You tackle the diagnostic studies, which are often quite challenging, and you try your best to impart confidence when speaking with the patients who turn out to have negative or benign findings and compassion and hope to those with suspicious findings. You perform biopsies with efficiency, accuracy and as little pain as possible and feel good if the patient tells you it was less painful than she expected. You review results of biopsies and decide on further management. If you are at an academic facility, you do all this while trying to teach and supervise residents and engage in meaningful research.

Behind the scenes, there are a whole host of other employees making all that you do possible. This includes the technologists and the sonographers who deal with difficult patients and challenging imaging studies every day. It includes the schedulers who try to schedule the right examination at the right time for the right patient. It includes the assistants who keep us on track, organize our consults, and identify our errors in our dictated reports (yes! we often make them, especially in the era of voice recognition), find us outside reports and print out summaries from the electronic medical record when needed. It includes our digital librarian who creates worklists for us and gets us the outside films. It includes the mammography liaison who contacts screening patients who are BI-RADS’ category 0 and schedules the patients for the needed imaging studies while trying to calm their fears, and our biopsy coordinator, who schedules biopsies, explains procedures to patients, enters pathology results in the audit system, contacts patients to ask about complications following the procedures and gives the patients their pathology results. It also includes the management team needed to keep us abreast of billing and regulatory and quality issues and to keep the staff happy and motivated. Come to think of it, it really takes a village!

A few weeks ago, we had a patient call our breast center because at age 48 years, she noticed a hard, painful, purple red breast with restricted arm movement. She had tried to get an appointment with a primary care doctor but did not have one and was on a waiting list. We require an order from a physician for diagnostic imaging, so we were unable to perform an examination without her having seen a physician. The triage person at our surgical oncology center described the breast to a surgeon, who ordered diagnostic imaging (without having seen the patient) to include mammography, ultrasound and a biopsy to be performed the next day (Friday) and scheduled the patient for a surgical consultation the following Tuesday morning. Our staff had to jump through many hoops to make this complicated scheduling work, as the schedule was already full for the following day. The mammographers added on a shift, the sonographer agreed to scan through lunch, while her colleagues did her regular patients. Everyone involved was horrified at the appearance of the long neglected, obvious breast cancer, involving very large axillary lymph nodes. I reviewed the case with the surgeon, and the surgeon asked me to try to expedite the pathology (sent in late Friday afternoon) so the results would be available by the following Tuesday morning at 8 am. Pathology called the results on Monday, and the patient was able to meet the entire multidisciplinary team Tuesday morning. While this probably did not help this patient, who ultimately proved to have advanced metastatic disease, it proves how multiple people can step up to the plate and accomplish a lot for the good of patient care when needed.

We are often faced with patients who travel 3–4 hours from home for their surgical or breast imaging care and if there are unanticipated findings, we usually twist ourselves into pretzels to accommodate the additional imaging needed to avoid the patients having to make return trips. I am so fortunate to work with an incredible staff who will drop everything to care of an anxious patient, switch patient appointments to accommodate a BI-RADS’ category 5 add-on biopsy, and very often add on patients to be scanned when they are supposed to be having a lunch break.

Our direct involvement and constant interaction with our technologists, sonographers and supportive breast imaging staff, makes for a team approach that is unfortunately no longer found in diagnostic radiology. When I started in abdominal imaging some 25 years ago, we worked directly with computed tomography (CT) and plain film technologists and sonographers. We would regularly consult face to face about scans, patient protocols, provide feedback on image quality, and occasionally share some laughs about work and life. In modern all-digital, all-picture archiving and communication system (PACS) radiology, this no longer occurs. With the radiologist protocolling studies electronically in the radiology information system (RIS), reading from a worklist and occasionally providing feedback to technologists through an electronic peer review button on PACS, we have lost much of the camaraderie I used to love about radiology. This camaraderie is, thankfully, still alive and well in modern day breast imaging.

My husband is an architect and photographer by trade but loves to play guitar in a band. He has had this hobby off and on as long as I have known him. Recently, his latest band dissolved. Since he was so busy with everything else on his plate, I asked him what he really missed about being in the band. He told me it was the feeling that he had while rehearsing or performing in the band of creating something wonderful together as a group. As a solo architect and as a solo freelance sports photographer, he creates cool things, but being in a band gave him a group creative experience not available from his other endeavors.

Personally, I find I get that satisfaction of having created something with a group of colleagues every day in breast imaging, as we struggle to care for patients and each of us gives a little to accommodate a difficult situation. While the lead pianist in the orchestra or lead guitarist in the band may be very talented and accomplished, he or she would be nothing without the other orchestra players or band members. As radiologists, we are called upon to make difficult diagnoses and medical decisions on a daily basis. We should never forget the orchestra playing along with us. The orchestra’s talents and compassion for patients are so essential. Without the efforts of our associates, we would have no images to interpret. Without their efforts, we would not have patients scheduled for biopsies and examinations. Without their efforts we could not effectively teach residents and students or carry on research. It is this ability to work together and to draw strength and comfort from each other while overcoming problems together that creates the beautiful symphony that is breast imaging at its best. We should all take a moment to thank our fellow band members for their invaluable contributions. ❖
Radioactive Seed Localization

By James V. Vasek Jr., MD

Detection of small, nonpalpable breast lesions as a result of breast cancer screening and improved imaging techniques has led to a greater need for image-guided localization to assist with surgical excision (1). Small lesions are typically suitable for breast-conserving therapy and therefore require precise localization to assure complete excision with negative margins. Traditionally, wire localization (WL) has been the standard of care with the wire placed into the lesion under imaging guidance on the same day as the scheduled surgery. Although effective, potential complications can arise as a result of the wire being displaced prior to surgery or improper positioning of the wire in relation to the lesion. Having the wire protrude from the skin, scheduling conflicts, and delays on the day of surgery are other inconveniences associated with traditional WL.

Radioactive seed localization (RSL) as an alternative to WL is a relatively new technique gaining popularity throughout the breast community. RSL involves the use of a titanium capsule containing iodine-125 (I-125) to assist in the localization and subsequent excision of breast lesions, typically those that are nonpalpable. Numerous studies have shown reduced positive margin rates and reduced reoperation rates compared with standard WL (2). Radioactive seeds may also be placed up to 3-4 days prior to surgery, and the radiologist can use the best approach for accurate localization without having to consider the surgeon’s excision site. Few disadvantages exist for RSL, but include the small radiation dose to the patient and the inability for the radiologist to remove the seed if it is placed in an unsatisfactory position.

Placement of I-125 seeds can be done using either sonographic or mammographic guidance. Sterilized needles may be purchased with the seed already preloaded or the sterile seed may be placed into an 18-gauge spinal needle with the stylet removed and the needle tip dipped in sterile bone wax to seal it closed (2). The lesion is then localized and with the tip of the needle positioned in the center of the lesion, and the seed is deployed by advancing the stylet. A post-procedural mammogram is obtained to confirm seed placement and the patient is sent for surgical excision. In the operating room, a standard intraoperative gamma probe is used to identify the point of greatest radioactivity on the skin surface and then to guide the excision to the seed-containing lesion. The specimen containing the seed and the lesion may be imaged with a specimen radiograph. The seed is then removed in the pathology laboratory and transported to nuclear medicine for appropriate processing.

RSL has been shown to be a safe, accurate, and effective procedure for preoperative localization of nonpalpable breast lesions. The technique is relatively easy to learn. However, a cohesive multidisciplinary team is necessary for a successful implementation. Fewer complications, decreased re-excision rates, and less logistical restrictions may soon make RSL the method of choice for tumor resection. Fewer complications, decreased re-excision rates, and less logistical restrictions may soon make RSL the method of choice for tumor resection.

Breast Density Update

By Carl J. D’Orsi, MD, FACR

Legislation mandating that the breast density status be sent to women is actively under consideration by several states in addition to other states, including Connecticut [Connecticut Public Act 09-41, section 2, section 38a-530(c)], where legislation has been approved. Suggestions indicating the benefits of supplemental examinations in addition to screening mammography have also been included in some of the legislation. As with most complex issues, there frequently is not a “one-size-fits-all” answer.

Let us first address the issue of “dense breasts” as an independent and moderate to high risk factor for the development of breast cancer. It seems apparent that the first problem to solve for verification of density as a major independent risk factor is a reproducible, objective and simple method to measure breast density (1). Presently, breast density is almost always subjectively assessed using BI-RADS® criteria of “almost entirely fatty,” “scattered fibroglandular density,” “heterogeneously dense,” and “extremely dense.” In order to provide some guidance for these assessments, BI-RADS® provided a percentage of “glandular tissue” from < 25% for fatty to > 75% for extremely dense (2). These percentages were for visual guidance only and not meant to reflect the actual volume of glandular tissue within the breast. As a matter of fact, these percentages have been dropped from the forthcoming 5th edition of BI-RADS®.

Many of the publications describing the relative risk do so comparing the highest density category with the lowest. This is not a meaningful method of comparison, falsely elevating the risk, since about 40% of women fall into each of the two middle groups of visual breast density estimation (scattered and heterogeneously dense). A more realistic evaluation of relative risk would be to consider the risk of a given BI-RADS® assessment of density compared to the average breast density (somewhere between scattered and heterogeneously dense). If we review data accumulated via the Digital Mammographic Imaging Screening Trial (DMIST), which compared film-screen mammography to digital mammography, and define dense breasts as those falling into the BI-RADS® heterogeneously dense and extremely dense categories, then approximately 46% of women had dense breasts. If we accept this definition for density, we are then saying that 46% of the 49,528 women enrolled in DMIST were at moderate to high risk for development of breast cancer based on density alone (3).

Does a 50-year-old woman who gains 100 pounds and now has breasts that appear to be of scattered density rather than heterogeneously dense due to breast fat storage have a lower risk of breast cancer because she is now non-dense? Does her obesity as a risk factor outweigh the appearance of the now non-dense breasts? Is a 40-year-old woman with dense breasts at the same risk for breast cancer, due to density alone, as a 60-year-old woman with dense breasts? With the advent of digital mammography, there are programs that may be capable of a better estimation of actual glandular volumes. We are still far from quickly and accurately determining the true percentage of glandular versus non-glandular tissue utilizing two-dimensional (2D) or probably even three-dimensional (3D) digital techniques. There is obviously an association between breast density and the risk of malignancy. What we do not know is the magnitude of this association.

Of more immediate importance are the masking effects of density continued on next page
Breast Density Update, continued from previous page

and the addition of supplemental examinations in an effort to improve sensitivity for early breast cancer detection. Carney et al (4), using data from the National Cancer Institute's Breast Cancer Surveillance Consortium (BCSC), reviewed 463,372 mammograms linked to 2223 cases of breast cancer in an effort to determine the individual and combined effects of age, breast density and the use of hormone replacement therapy (HRT) on mammographic accuracy. Women with predominately fatty breasts had a mammographic sensitivity of 87% and a specificity of 96.9%, compared to women with extremely dense breasts, where mammographic sensitivity was 62.9% and specificity was 89.1%. Sensitivity increased with age, which is understandable, due to the involution of the fibroglandular tissue with age. The DMIST trial demonstrated that the accuracy of digital mammography was significantly higher than the accuracy of film-screen mammography for women less than 50 years of age and for those with heterogeneously or extremely dense breasts. Thus, digital technique alone does help to improve accuracy of x-ray mammography for dense breasts (3).

Can we add supplemental techniques that will further improve accuracy in women with dense breasts? The least invasive technique is breast ultrasound. The American College of Radiology Imaging Network (ACRIN) 6666 study was initiated to determine the supplemental yield of breast cancer when ultrasound was added to mammography in women at an elevated risk for breast cancer (5). Although data were not arranged according to breast density, the results are helpful. If we look at only the first screen (prevalent), the sensitivities of mammography alone and mammography plus ultrasound were 55.6 and 94.4%, respectively. The specificities were 89.1 and 74.3%, respectively. The equations used to calculate sensitivity (true positives [TP]/TP+false negatives [FN]) and specificity (true negatives [TN]/TN+false positives [FP]) clearly show that as FPs increase, specificity decreases and as FNs increase, sensitivity decreases. Analyzing the metrics from the ACRIN 6666 trial, we see an increase in sensitivity for the combination of mammography and US over mammography alone (94.4% and 55.6%, respectively) but a decrease in specificity for the combination of mammography and US compared to mammography alone (74.3% and 89.1%, respectively). Thus, while US did increase sensitivity by decreasing false negatives, it did so at the expense of a decrease in specificity due to an increase in FPs. There is no free lunch in life or for early breast cancer detection (6).

Is it worth it? This is a very difficult question to answer. As physicians, we immediately assume “of course.” However, there are many additional factors that must be considered. Cost and availability of trained sonographers and physicians to perform and/or monitor these studies are important considerations. What about magnetic resonance imaging (MRI) as a supplemental examination to mammography? A recent study by Sardanelli et al (7) compared the efficacy of clinical breast examination, mammography, ultrasound, and contrast-enhanced MRI for breast cancer detection in a high risk population involving 18 centers and 1592 screening rounds (prevalence and incidence). MRI alone was more sensitive (91%) than mammography and ultrasound (63%). Thus, considering breast cancer detection, the potential combination of mammography and MRI seems better than the combination of mammography and ultrasound.

We must also consider the financial costs and the effectiveness of these examinations, either alone or in combination. Two of the methods utilized to evaluate cost-effectiveness are cost per cancer detected (obtained by dividing the total cost of a screening program by the number of cancers detected) and cost per year of life expectancy gained (obtained by dividing the screening program costs by the expected number of years gained for the screened women. To put this into perspective, utilizing cost per life–year saved, the median cost per life-year saved with screening mammography from age 40–79 years is $18,800 and for automobile seat belts and air bags is $32,000. Even if the actual dollar amounts vary, the ratio of seat belt-air bag cost to screening mammography cost will probably not change significantly (8). The interaction of appropriately measured determinants of risk and cost of supplemental screening exams is important and clearly demonstrated by Taneja et al (9). If we examine populations with an annual cancer prevalence of 3, 2, or 1%, the incremental cost (the cost of MRI and mammography minus the cost of mammography alone) per year of life expectancy gained was $73,813, $154,045, and $315,210, respectively. Thus, we see that a realistic and accurate determination of risk is extremely important and impacts the cost effectiveness of supplemental screening examinations.

The perfect storm has developed. At present, we do not have a reliable, accurate, and simple measure of breast density. We understand that there is a risk, but the true extent of that risk is not known and may never be known. This becomes important for cost effectiveness discussions since "cost," of at least supplemental MRI, is very dependent on the risk of developing breast cancer. Although supplemental ultrasound may be a more attractive alternative to supplemental MRI, due to its noninvasive nature, greater accessibility and lower cost, it is clearly not as accurate as MRI. Does breast density alone as a risk factor justify the addition of MRI to screening mammography or, for that matter, screening ultrasound? Presently, we have a scarcity of evidence-based data and an excess of well-intentioned desire, legislation and reticence to pay for these supplemental examinations. Without standardized metrics, this discussion of breast density as a risk factor and as a reason for utilization of supplemental screening examinations will remain problematic.

References
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