What’s New in Breast Imaging

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Disclosure

• Hologic, Inc. Shareholder and research agreement.
• Volpara Solutions, Ltd. Shareholder and research agreement.
Objectives

• Be familiar with new breast imaging technologies including tomosynthesis, screening US, fast MRI, and contrast-enhanced spectral mammography (CESM).

• Describe the potential added benefit and potential negative aspects of screening women with these new modalities.

• Understand how screening may be stratified based on risk and density.
Breast Cancer mortality has declined by >30% since 1990
Mammography

Limitations
• Many false positives; recall rates 2-15%
• Mortality reduced by 15-40% (film-screen)
• Sensitivity reduced in women with dense breasts

Potential Improvements
• Improve visualization of breast structures
• Functional imaging of blood flow or cellular activity
54 yo, palpable lump left breast
Outcomes in Dense Breasts

• Cancer more often presents as a lump
  – Clinically detected in the interval between screening exams
• More often stage IIB, III
• More often multifocal, multicentric; mastectomy more frequently needed
• May result in increased risk of death (requires long-term follow up)
• Increased risk of recurrence (if no XRT)
Early Matters
stage of tumor at discovery
influences prognosis

Be informed about your breast density »

WHAT IS dense breast tissue?

Dense breast tissue is comprised of less fat and more connective tissue which appears white on a mammogram. Cancer also appears white on a mammogram thus tumors are often hidden behind the dense tissue. As a woman ages, her breasts usually become more fatty.

HOW DO I KNOW if I have dense breast tissue?

A radiologist determines the density of a woman’s breasts by examining a mammogram. Request a copy of your mammography report from your referring doctor. Make sure it is the report that is generated from the radiologist and not a form letter. Read the report carefully. Look for descriptions of your breast tissue.

WHAT DO I DO if I have dense breast tissue?

Talk to your doctor about having an ultrasound or breast MRI. Connecticut General Statute Sections 38a-603 and 38a-530 requires insurance companies to provide coverage for comprehensive ultrasound screening of an entire breast or breasts if a mammogram demonstrates heterogeneous or dense breast tissue based on the BIRADS (Breast Imaging Reporting and Data System) established by the American College of Radiology (ACR). Additional legislation requires that women in Connecticut are informed of their breast density when they receive their mammography report. To determine the laws in your state, contact your state representative or public health department. Learn More »

What’s New

THE ARE YOU DENSE “RIBBON RIDE” 8-31-13 »

TENNESSEE, HAWAII, MARYLAND, ALABAMA & NEVADA ENACT BREAST DENSITY NOTIFICATION LEGISLATION »

SANDY USES HER VOICE TO TELL HER SISTER CAROL’S STORY OF MISSED CANCER YEAR AFTER YEAR UNTIL DISCOVERED AT STAGE 4 »

WALL STREET JOURNAL »

http://areyoudense.org/
States with Density Legislation

2012

2015

http://areyoudenseadvocacy.org/
VA HB 83

- Effective July 1, 2012
- “Your mammogram demonstrates that you may have dense breast tissue, which can hide cancer or other abnormalities.”

NEWS AND EVENTS

VIRGINIA BECOMES THE 3RD STATE TO ENACT A BREAST DENSITY NOTIFICATION LAW

Virginia becomes the 3rd state in the nation to require the communication of breast density to women. Despite early opposition from the Radiological Society and the Medical Society, the advocates, with support from champion legislators, Representative Robert Orrock and Senator John Edwards, were able to succeed in ushering the bill through both chambers.

Governor McDonnell signs bill on Feb. 28, 2012 which becomes law effective July 1, 2012. Women in Virginia will be notified of their breast density and its risk factors. They will be NOW be able to fully participate in their breast health care.
“YOUR MAMMOGRAM DEMONSTRATES THAT YOU HAVE DENSE BREAST TISSUE. DENSE BREAST TISSUE IS VERY COMMON AND IS NOT ABNORMAL. HOWEVER, DENSE BREAST TISSUE CAN MAKE IT HARDER TO FIND CANCER ON A MAMMOGRAM AND MAY ALSO BE ASSOCIATED WITH AN INCREASED RISK OF BREAST CANCER.

THIS INFORMATION IS GIVEN TO YOU TO RAISE YOUR AWARENESS. USE THIS INFORMATION TO TALK TO YOUR DOCTOR ABOUT YOUR OWN RISKS FOR BREAST CANCER. AT THAT TIME, ASK YOUR DOCTOR IF MORE SCREENING TESTS MIGHT BE USEFUL BASED ON YOUR RISK.

A REPORT OF YOUR MAMMOGRAPHY RESULTS HAS BEEN SENT TO YOUR REFERRING PHYSICIAN'S OFFICE, AND YOU SHOULD CONTACT YOUR PHYSICIAN IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT THIS REPORT."
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New & Evolving Technologies

- Tomosynthesis (3D mammography)
- Screening US
- Fast MRI
- Contrast-enhanced spectral mammography
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Digital Breast Tomosynthesis

X-ray tube swings during tomo

Stationary breast platform
Breast Tomosynthesis Acquisition

- X-ray tube moves through a proscribed arc of excursion
- 15 low-dose projection images are acquired during a 5-second sweep
Reduce Recalls

• Recall reduction of 16-40%

Rafferty EA. Radiology, 2013.
Screening
Tomosynthesis

2D

3D

3D Slice
Cancers are More Apparent on Tomo
Increased Sensitivity with Tomo

• Norwegian Breast Screening Program
• 12,631 exams, Nov 2010-Dec 2011
• Cancer detection
  – 6.1/1000 mammography alone
  – 8.0/1000 mammo + tomo
  – 30% increase in cancer detection
  – 40% increase in detection of invasive cancers

Skaane P. Radiology 2013
Screening Recall
Screening

2D

3D Slice
Primary Advantages of Tomo

- Reduce summation artifact resulting in improved specificity - lower recall rate
- Improve visualization of cancers, resulting in improved sensitivity and cancer detection rate
Cost-Benefit of Tomosynthesis

- Economic model of managed health plan with 1 million women
- Digital vs. Digital + tomosynthesis
- 4,523 women avoid further testing
- Overall benefit of tomo $78.53 per woman screened. If hypothetical $50 fee for tomo, then net benefit of $28.53 per woman screened.
- Overall cost savings of $2.4 million/year

Bonafede MM et al. Clinicoecon Outcomes Res 2015
Challenges with Tomo

- Higher radiation
- Increased interpretation time
- Reimbursement
- Not likely great for extremely dense tissue
Reducing Radiation with Tomo

- 2D + 3D is double radiation dose
- Dose reduced to similar level using synthesized 2D view
- No difference in cancer detection or recall rates using synthetic 2D

Skaane, Radiology 2014
Zuley, Radiology 2014
New & Evolving Technologies

- Tomosynthesis (3D mammography)
- Screening US
- Fast MRI
- Contrast-enhanced spectral mammography
Screening US

• Bilateral whole breast US
• Radiologist or technologist performed
• Automated US commercially available
Screening US in “High” Risk Women

ACRIN 6666/Avon trial
• 2662 moderate and high-risk women had annual mammo + screening US, over 3 years
• 111 cancers (110 women)
• Additional cancers by US
  – 5.3 CA/1000 Year 1
  – 3.7 CA/1000 Y 2 & 3
• 8.9% PPV for US lesions
• Additional 14.7 CA/1000 by MR

Berg WA. JAMA 2008
Berg WA. JAMA 2012
Connecticut was first with Breast Density Legislation
Screening US in Practice

- Studies from practices in CT
- Additional 3 cancers/1000
- 5-7% will have a biopsy
- PPV for biopsy 6.5-6.7%
- 9-20% BI-RADS 3

Weigert J. *Breast J* 2012
Hooley RJ, *Radiology* 2012
New & Evolving Technologies

- Tomosynthesis (3D mammography)
- Screening US
- Fast MRI
- Contrast-enhanced spectral mammography
Current Breast MRI

- T1
- T1 FS
- Sag T1
- T2
- T1 Post X5
- Diffusion Weighted (DWI)
- CAD
Fast MRI

- **Contrast Enhanced**
  - One Pre T1, w fat sat
  - Two post contrast, w fat sat

- **Non-contrast**
  - T1, no fat sat
  - T2
  - Diffusion-weighted x 4
New & Evolving Technologies

- Tomosynthesis (3D mammography)
- Screening US
- Fast MRI
- Contrast-enhanced spectral mammography
Contrast-Enhanced Spectral Mammography (CESM)

- IV iodinated contrast injection
- Wait 2 minutes
- Obtain routine mammographic views
  - Low energy exposure (26-30 kVp)- below k edge of iodine (33 kVp)
  - High energy exposure (45-49 kVp)

Fallenberg. Eur Radiol, 2014
Woman in her 50s, right nipple retraction
CESM
Sensitivity/Specificity of CESM

- 113 women with abnormal screening mammogram underwent CESM
- 32 cancers

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
<th>ROC</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D</td>
<td>96.9% (83.7-99.6)</td>
<td>42.0% (31.1-53.5)</td>
<td>39.7% (28.8-51.5)</td>
<td>97.1% (85.0-99.5)</td>
<td>0.779 (0.707-0.851)</td>
</tr>
<tr>
<td>CESM</td>
<td>100% (89.0-100.0)</td>
<td>87.7% (78.5-93.9)</td>
<td>76.2% (60.6-87.9)</td>
<td>100% (94.9-100)</td>
<td>0.976 (0.994-0.999)</td>
</tr>
</tbody>
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Lobbes. Europ Radiol 2014
40s, palpable mass LUIQ
CESM
CESM may have Sensitivity and Specificity Similar to MRI

- 80 women with new breast cancer underwent MG, CESM, MRI
- Cancer visible in:
  - 66/80 MG
  - 80/80 CESM
  - 77/79 MRI

Fallenberg. Eur Radiol, 2014
Potential Advantages

• Functional imaging that may be similar in sensitivity and may be more specific than breast MRI
• Low cost
• Not limited by dense tissue
Potential Disadvantages

- Higher radiation - 80% higher than conventional 2D
- Reimbursement
- Allergic reactions to contrast

Jeunkens. Invest Radiol, 2014
New & Evolving Technologies

• Tomosynthesis (3D mammography)
• Screening US
• Fast MRI
• Contrast-enhanced spectral mammography
Current Breast Cancer Screening

- Women
- Age 40 (50) and older
- Add Screening MRI if very high risk (>20% lifetime risk)
Ancillary Screening in Addition to Mammography

• Based on Risk

• Based on Limitations of Mammography (e.g. dense breasts)
## Breast Cancer Risk Stratification

<table>
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<tr>
<th>Lifetime Risk</th>
<th>Associated Risk Factors</th>
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<tbody>
<tr>
<td>Average Risk</td>
<td>&lt; 15%</td>
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<tr>
<td>Moderate Risk</td>
<td>15 – 20%</td>
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<tr>
<td>High Risk</td>
<td>&gt; 20-25%</td>
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</table>

- **Average Risk**: LCIS, ADH, ALH, Prior breast cancer, Intermediate family history, Dense breast tissue.
- **Moderate Risk**: Hereditary Breast and Ovarian Cancer (HBOC) syndrome (e.g. BRCA), Other genetic mutations, Chest Radiation at a young age, Combination of risk factors.
- **High Risk**: MRI - whether dense or not, Extremely Dense: US, Heterogeneous: Tomo, US, Fatty/Scattered: Tomo.
Conclusions

• Mammography reduces breast cancer mortality by 15-40%.
• **Tomosynthesis** decreases recall rate and increases cancer detection by 30%. Overall reduction in utilization and cost.
• **Screening US** also increases cancer detection by 30%, but at the cost of low specificity. May be the current best option for ancillary screening of women with extremely dense tissue.
• **MRI** is highly sensitive but very expensive. Fast techniques may be possible for screening at lower cost.
• **Contrast-enhanced spectral mammography (CESM)** may have sensitivity similar to MRI at relatively low cost. May be best option for women with extremely dense breasts in the future.
• Recommendations regarding ancillary screening are evolving but will likely be determined by risk and breast density.