1. BREAST SCREENING

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NO DISCLOSURES
Question #1: No correct answer

- When do you recommend patients start screening and at what interval:
  1. Annual starting at 40yo
  2. Annual starting at 50yo
  3. Biennial starting at 50yo
  4. Let the patient decide
  5. Annual starting at 40yo and then biennial at 50yo
<table>
<thead>
<tr>
<th>Society</th>
<th>Age to start</th>
<th>Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Cancer Society</td>
<td>45yo</td>
<td>Every yr 45-55yo Every 2 yrs &gt;55yo</td>
</tr>
<tr>
<td>USPTF</td>
<td>50yo</td>
<td>Every 2 yrs</td>
</tr>
<tr>
<td>American College of Radiology</td>
<td>40yo</td>
<td>Every year</td>
</tr>
<tr>
<td>American College of Obstetricians and Gynecologists</td>
<td>40yo</td>
<td>Every year</td>
</tr>
<tr>
<td>American Academy of Family Physicians</td>
<td>50yo</td>
<td>Every 2 yrs</td>
</tr>
</tbody>
</table>
Screening MGM Facts

• No trials have shown that MGM improves overall survival, only breast cancer specific mortality
• MGM increased the number of early stage cancers but has not impacted later stage cancers
• Approximately 30% of cancers are overdiagnosed

3D Tomosynthesis Mammography
Retrospective Study

• Total of 454,000 screening MGMs
• Decreases call back rates
  – Digital MGM 10.5%
  – Tomosynthesis MGM 8.9%
• Improves cancer detection rates
  – Increased from 4.2/1000 to 5.4/1000 screens
  – Invasive cancer detection 2.9 to 4.1/1000 screens
• ?? Disease specific mortality benefit
• 43% of all screening MGMs are 3D tomosynthesis

Friedwald S et al JAMA 2014; 311:2499
JAMA Intern Med 2019; 179:1292
Asymptomatic Women
40-74yo
No prior breast cancer

Digital Mammography

Tomosynthesis Mammography

Primary endpoint:
Advanced cancers:
Metastases
Node positive
>2cm
>1cm, triple negative or HER2neu +

Enrollment goal:
164, 496 women
Dense Breast Tissue

Are you DENSE?
exposing the best-kept secret

How dense are you?

- **LEVEL 1**: <25% Density
  - Fatty Breast Tissue
- **LEVEL 2**: <50% Density
  - Scattered Density
- **LEVEL 3**: >50% Density
  - Heterogeneously Dense
- **LEVEL 4**: >75% Density
  - Extremely Dense
Prevalence of Dense Breast Tissue

- 43% of US women 40-74yo have heterogenous or dense breast tissue
  - 44% of these women are 40-49yo
- Equivalent to 27 million women

Sprague BL et al, JNCI 2014; 106: 1-6
10

Regarding breast density, Illinois Law requires:
1. Must inform patients of their density
2. Must inform patients of the consequences of dense breast tissue
3. Must cover supplemental U/S for patients with dense breast tissue
4. Must provide coverage for supplemental U/S at no additional cost to the patients
5. All of the above

Question #2: correct answer 5
• Providers of mammography services
  – Are required to provide EDUCATIONAL MATERIAL to our patient population AND
  – Per amendment C-15, inform patients of the “meaning and consequences of dense breast tissue” under the guidelines of the BIRADS of the ACR
• If a routine mammogram reveals heterogeneous or dense breast tissue, insurance coverage
  – must provide for a comprehensive ultrasound screening of an entire breast or breasts, when
    determined to be medically necessary by a physician

• The required coverage for mammograms and ultrasound screenings must be provided
  – at no cost to the insured (i.e., co-pays or deductibles may not be applied) if a preferred provider is utilized.
Automated Breast U/S (ABUS)
## ABUS Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>No pts</th>
<th>Cancer detection with MGM vs ABUS</th>
<th>Recall rate MGM vs ABUS</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kelly et al-8 facilities</td>
<td>2009</td>
<td>4419 High risk</td>
<td>3.6/1000 vs 7.2/1000</td>
<td>4.2% vs 9.6%</td>
<td>90% of inv cancers &lt;2cm</td>
</tr>
<tr>
<td>Somo-Insight Trial-multictr</td>
<td>2015</td>
<td>15, 318 Dense pts</td>
<td>5.4/1000 vs 7.3/1000</td>
<td>15% vs 18%</td>
<td>93% of ca detected were invasive</td>
</tr>
</tbody>
</table>

*References*

Brem et al Radiology 2015; 274:663
Kelly et al Eur Radiology 2010;20:734
All of the following patients are candidates for annual screening breast MRI except:

1. Dense breast tissue without any other risk factors
2. Lifetime risk >20% based on family history
3. BRCA 1 and BRCA 2 gene mutation carrier
4. H/o chest wall radiation prior to 30yo
American Cancer Society guidelines:
- Women with a >=20-25% lifetime risk of developing breast cancer, including women with a family history of breast cancer
  - Defined by risk models largely dependent on family history
  - Radiation to the chest between 10-30yo
  - Gene mutation carriers
- No ABUS needed if a pt is undergoing MRI
MRI Trial

- Randomized trial of abbreviated MRI vs 3D tomosynthesis
- Eligibility criteria:
  - Category 3 or 4 breast density
  - No family history
- Primary endpoint: detection of invasive cancers
- Results pending
Downsides of MRI?

- Claustrophobia
- Long test for patients
- Long test to read for radiologists
- MRI contrast-gadolinium

www.fda.gov
Recommendations

Asymptomatic patient presents for screening

High risk: >20% lifetime risk based on risk models

- Annual 3D tomosynthesis
- Annual MRI
- Alternating every 6mos

If can’t tolerate MRI:
- Annual 3D tomosynthesis
- Annual ABUS (if dense)
- Performed concurrently

Not high risk but has dense breast tissue

- Annual 3D tomosynthesis
- Annual ABUS
- Performed concurrently

Not high risk but does not have dense breast tissue

- Annual 3D tomosynthesis
- Annual MRI
- Alternating every 6mos
Conclusions/Future Directions

• Days of annual (or biennial) MGM alone for everyone are numbered—need to move to personalized screening
• More data needed on ABUS
• Need better ways to identify those who are at high risk
Personalized Screening

Wisdom
WISDOM Study
Clinicaltrials.gov
identifier: NCT02620852

MyPeBS
Personalising Breast Screening
THANK YOU
Principles of Screening MGM

- Women should be counseled about risks and benefits, shared decision making
- Consider life expectancy <=10yrs
- No upper limit to screening MGM
- Inform about dense breast tissue, risks and benefits of supplemental screening
- No support for thermography, sestamibi scan, PET scan

www.NCCN.org/professionals
Overdiagnosis of Cancers

31% of all breast cancers are overdiagnosed

Adoption of 3D Tomosynthesis into Practice

- 2015-2017
- BCBS claims
- Overall 43% of all screening exams were 3D tomosynthesis

JAMA Intern Med 2019; 179:1292
Eligibility:

• Annual screening-
  – Premenopausal
  – Postmenopausal with other risk factors (dense, FHx, high risk lesion)

• Biennial screening
  – Postmenopausal women
## Handheld Screening U/S

<table>
<thead>
<tr>
<th>Trial</th>
<th>No</th>
<th>Cancer detection rate</th>
<th>False positives</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACRIN 6666- multicenter Year 2012</td>
<td>2309 Dense High risk</td>
<td>76./1000 to 11.8/1000</td>
<td>MGM 1:40 U/S 1:10</td>
<td>Used digital MGM</td>
</tr>
<tr>
<td>ASTOUND (3D)-5 ctrs in Italy Year 2016</td>
<td>3231 Dense</td>
<td>4.1/1000 to 7.1/1000</td>
<td>No difference in recall for any testing or biopsy</td>
<td>Used 3D MGM</td>
</tr>
</tbody>
</table>

Berg WA et al JAMA 2012; 307: 1394-4040
Tagliafico et al JCO 2016
Automated Breast Screening U/S at NorthShore

- Performed over XXX ABUS exams
- Performed for those patients with breast density:
  - Heterogenously dense
  - Dense, extremely dense
- Performed concurrent to MGM
Downsides of 3D Tomosynthesis?

- Hospital to upgrade equipment
- Learning curve for radiologists
- Increased radiation exposure?
  - Reconstructed images lessens radiation exposure
Downsides of ABUS?

- Hospital to buy new equipment
- May not be reimbursed
  - Patients
  - Hospitals
- Learning curve for radiologists
- False positives/recall rates??