Supplemental Screening with Ultrasound

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Breast Density Legislation
1. Shortcomings of mammography has led to passage of breast density legislation in many states
2. Laws recommend women with dense breasts consider supplemental screening
3. Mandated for all women and not just high-risk
4. Type of supplemental screening not specified

State Bills on Breast Density

Whole Breast Screening Ultrasound
1. Default supplemental screening modality due to relatively low cost and wide availability
2. Supplemental cancer yield: 3-4/1000
3. Limitation of WBUS include:
   - Low PPV (8-9%)
   - High frequency of short-term follow recommendations
   - Time consuming
Screening US

Most data from studies of high-risk patients using hand-held
- Hand-held whole breast screening ultrasound
  - Physician performed
  - Technologist performed
- Automated whole breast screening (limited data)

Hand-held Screening Physician Performed US

Selected Screening Outcomes

<table>
<thead>
<tr>
<th></th>
<th>US</th>
<th>Mammo</th>
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</thead>
<tbody>
<tr>
<td>Prevalence Ca rate</td>
<td>0.3%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Biopsy rate</td>
<td>3.4%-5.2%</td>
<td>1.5%</td>
</tr>
<tr>
<td>PPV₃</td>
<td>5%-16%</td>
<td>25%-40%</td>
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<tr>
<td>Short-Intvl F/U Rate</td>
<td>5%-9%</td>
<td>1.5%</td>
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Screening US

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>CA/1000</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gordon et al, 1995</td>
<td>12,706</td>
<td>3</td>
<td>16%</td>
</tr>
<tr>
<td>Buchberger et al, 2000</td>
<td>8,103</td>
<td>4.1</td>
<td>9%</td>
</tr>
<tr>
<td>Kaplan et al, 2001</td>
<td>1,862</td>
<td>3</td>
<td>12%</td>
</tr>
<tr>
<td>Kolb et al, 2002</td>
<td>13,547</td>
<td>2.3</td>
<td>3%</td>
</tr>
<tr>
<td>Crystal et al, 2003</td>
<td>1,517</td>
<td>4.6</td>
<td>18%</td>
</tr>
<tr>
<td>ACRIN, 2008</td>
<td>2,637</td>
<td>4.2</td>
<td>9%</td>
</tr>
</tbody>
</table>

Screening US: PPV

<table>
<thead>
<tr>
<th>Study</th>
<th>Operator</th>
<th>Mean Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaplan et al, 2001</td>
<td>Technologist</td>
<td>10 min (7-20 min)</td>
</tr>
<tr>
<td>Kolb et al, 2002</td>
<td>Radiologist</td>
<td>4 min, 39 sec (2 min, 11s-11 min, 30s)</td>
</tr>
<tr>
<td>Crystal et al, 2003</td>
<td>Radiologist</td>
<td>7 min (4-15 min)</td>
</tr>
<tr>
<td>ACRIN, 2008</td>
<td>Radiologist</td>
<td>19 min (2-90 min)</td>
</tr>
</tbody>
</table>

Screening US: Time
**ACRIN 6666**

- Multicenter, randomized trial
- 2659 high risk patients
  - Personal hx: 53%
  - ≥25% Gail or Claus: 19%
  - Atypia or LCIS: 3%
  - BRCA-1 or -2: 1%
- Dense in one quadrant
- Blinded to mammographic findings

**ACRIN 6666: US**

- CA detection rate: 4/1000 (0.4%)
  - Invasive cancers—not DCIS
  - All but one node negative
- Short term f/u recommended: 9%
- Bx recommended: 9%
- PPV: 9%

**Technologist Performed Hand-held US Screening**

- Use most skilled US techs
- Document single image per quadrant and retroareolar region for negative patients

**Connecticut Screening Ultrasound Yale Experience**

- 937 women in 1 year period
- 66% low risk
- 13% intermediate risk
- 12% high risk
- 75% BIRADS 1 or 2
- 20% BIRADS 3
- 5% BIRADS 4

**Connecticut Screening Ultrasound Multi-center Experience**

- 6 radiology groups over 1 year period
- 8650 screening ultrasound exams
- 86% BIRADS 1 or 2
- 9% BIRADS 3
- 5% BIRADS 4 or 5
Connecticut Screening Ultrasound
Multi-center Experience

- 429 biopsies
- 28 cancers
- 3.2 cancers/1000
- PPV 6.5%

MSKCC Tech Based Program

- Highly selected technologists:
  - Only 3 of most experienced/skilled techs
- Representative image of each quadrant + subareolar region
- Do not take images of simple or complicated cysts

MSKCC: Tech Based Program

- If “negative”, physician does not scan
- Physician scan for any indeterminate or suspicious findings
- Goal was to maintain sensitivity, reduce BI-RADS 3 recommendations, and improve PPV

How did we do?

Results: BI-RADS 4 or 5

- Biopsy recommended in 5% (43/916)
- Biopsy performed in 39/43 suspicious lesions in 43 patients
  - 4 lesions not sampled:
    - 1 not visualized at time of biopsy
    - 3 declined biopsy and had negative follow up

Biopsy Results

<table>
<thead>
<tr>
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<th>Biopsies Performed (n=39)</th>
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<tbody>
<tr>
<td>Benign</td>
<td>34</td>
</tr>
<tr>
<td>High Risk</td>
<td>2</td>
</tr>
<tr>
<td>Malignant</td>
<td>3</td>
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Cancer Detection

- Overall CA yield: 3.3/1000
  - 4.4/1000 in HD and ED
  - Literature: 2.7-4.6/1000
- Age: 39-64 yo
- Tumor histology:
  - 1 IDC, 1 ILC, 1 IMC
- Mean tumor size: 1.2 cm (1.0-1.3 cm)
- All node negative
- All in HD breasts

Automated Scanning

- Effect on call back rate?
- False negatives/positives
- Learning curve
  - 2000-5000 images at 10 fps over 4-10 minutes
  - hard not to have a lapse in concentration of a few seconds, even more problematic if doing multiple consecutive cases
- Need CAD assistance

Automated Whole Breast Ultrasound
Ultrasound Tomography for Breast Imaging

Cost comparison

1. Annual mammo plus WBUS program in average risk women with dense breast
   - Cost, time, false positive, short-term follow-ups and over diagnosis
2. Vascular base screening every 2 or 3 years as a stand alone test
Thank You!