Implementing Screening Breast Ultrasound Into Your Practice

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Screening Breast Ultrasound

- Legislation
- Technique
- Improving Outcomes
  - What is the current data
- Other issues
  - Legal
  - Scheduling
  - Cost, controversies, & critics
Breast Density Notification 2016

- 24 states with laws
  CT, TX, VA, NY, CA, HI, MD, TN, AL, NV, OR, NC, PA, NJ, AZ, MN, RI, MA, MO, OH, MI, ND, DE, LA

- 8 states currently working on laws
  WA, OK, IA, MS, KY, SC, GA, FL, VT, NH

- Ongoing national efforts

  Legislation
  - H.R .716 & S. 370

  Regulation
  - FDA considering MQSA amendment

http://densebreast-info.org
SBUS Screening

• Metanalysis of 75,000+ SBUS*
  13 studies (1995-2012)
  CDR = 3.4/1000
  94% of cancers invasive
    • Mostly <1 cm, low grade
  PPV 3 = 9.9%

Screening US

• Supplemental

• Prior mammogram necessary
  - Screening or diagnostic
    • within prior 6-12 months
  - Determine breast density
    • usually subjective assessment by radiologist
    • new computerized/volumetric density programs, accuracy is not established
  - Correlate US findings with mammo
Scanning Technique

• Operator dependent
• Meticulous attention to scanning technique is necessary
• Scan is usually performed by technologist
• Radiologists greatly benefits from hands on scanning
  - real-time evaluation of images
  - correlate with Mammo/MRI/PE
Technique: Handheld SBUS

- Scan the entire breast
  - posterior chest wall to nipple
  - axilla and retroareolar regions
- Initial depth setting
  - pectoralis muscle along posterior margin of FOV
- Initial gain setting with TGC
  - even insonation
  - fat mid-level gray
  - echogenicity compared to fat
Technique: Handheld SBUS

- Identification of lesion
  - adjust depth/FOV
  - multiple focal zones ok
    decreased frame rate not significant with superficial structures
  - single focal zone
    centered at same level /minimally posterior to area of interest
Handheld Screening US: Technique

- 12-5-18-5 MHz linear transducer
  - 12-5 MHz: deeper lesions, depth 4-5 cm
  - 18-5 MHz: superficial lesions, depth < 3-4 cm
Handheld Screening US: Technique

- 12-5- 18-5 MHz linear transducer
  - 12-5 MHz: deeper lesions, depth 4- 5 cm
  - 18-5 MHz: superficial lesions, depth < 3-4 cm

Initial scan (12-5 mHz):
- oval circumscribed mass
- BI-RADS 2 or 3

Repeat scan (18-5 mHz):
- lobulated, indistinct & angular margins
- BIRADS 4c: IDC
Handheld Screening US: Technique

- Patient position
  - arm flexed behind head
  - medial lesions scanned pt supine
  - lateral lesion scanned contralateral semi-oblique position
  - elimination of potential artifact b/c of poor compression
Handheld Screening US: Technique

• Scan in radial and anti-radial planes
  - Radial: visualization of ductal abnormalities
  - Anti-radial: margin analysis

• Label: Rt/Lt, clockface, nipple distance, transducer orientation
  - Lesions other than simple cysts require orthogonal views +/- Doppler
Handheld Screening US: Technique

- Document a negative exam
  - 4 quadrants/12, 3, 6, 9 o’clock
  - retroareolar region
  - +/- axilla
  - Yale “negative” = 12 images
  - MD checks any questionable or suspicious findings
  - Exam time: q30 min
Lesion Measurements

- Use split screen
  - Keeps images organized, easier for follow-up comparison
SBUS: Should Axilla Be Scanned?

• ACRIN 6666, BI-RADS 5th edition: elective

• Advantages
  Posterior /peripheral tissue/accessible /HHUS
  Axillary breast tissue 0.6-6% of general population
  Abnormal axillary LN 2° to subtle/ occult cancer

• Disadvantages
  Possible increase false +/over calling reactive LN
  • cortical thickening > 3mm may be normal in screening population
  • Time

Who Should Perform Handheld SBUS?

• Most studies reported MD exams
  – ACRIN 6666: avg. time 13 min by year 3
    • Early: 19 min (range 13-90 min)

• MD performed exams not feasible in high volume practice
Can Technologists Perform Handheld Screening SBUS?  **YES**

- Must have experience in diagnostic/targeted US
  
  Operator dependent
  - Only lesions documented by tech are evaluated

  CDR of technologist exams = 2.5/1000*
  - Slightly lower than MD exams

Technologist Training

- Experience in diagnostic/targeted US
- Sonographers or mammo techs
- 25-50 exams under supervision of radiologist
- 100 exams/2-3 months under supervision of experienced technologists
  - Screening, targeted, procedures
- Breast US ARDMS or ARRT certification
  - Not specific to screening

Berg & Mendelson. Radiology 2014
Technologist Training

- Japan: Formal 2 day training course
  - Still images, videos, & real-time scanning
  - MDs and technologists

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<tr>
<th></th>
<th>Video</th>
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<th>Still Images</th>
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<tr>
<td></td>
<td>Tech</td>
<td>MD</td>
<td>p</td>
</tr>
<tr>
<td>SN</td>
<td>85.9%</td>
<td>84%</td>
<td>0.037</td>
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<tr>
<td>SP</td>
<td>80.3%</td>
<td>79.4%</td>
<td>0.35</td>
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- ↑clinical experience ↑performance*
  - Techs & MDs: < 100 exams worse performance

*Tohno, et al. Breast Cancer 2012*
Feedback

- Berg et al:
  - radiologist who scanned after tech performed slightly worse than those who scanned after fellow
  - all performed better with feedback

- Feedback
  - Rescanning
  - Review of interesting cases

Berg W A et al. AJR 2012;199:224-235
Technologist Performed SBUS

- Technologists are generally responsible for detecting the findings, but the physician is responsible for interpretation.

- MD should be available to check any questionable findings.
Radiologists Should be Available to Check Technologist Exams

• Philpotts, et al. ARRS 2014
  - 412 technologist performed exams
  - 336 (82%) were BI-RADS 1/2
  - 76 (18%) with findings
    • MD disagreed with 5 cases
    • 1% of all scans/7% of scans with + findings
Automated SBUS

- Relies less on technologist experience
  - More reproducible
    - 1000+ images
    - Less operator fatigue
- Dedicated equipment
  - Supine units with 15 cm probe
  - Mechanical arm fixed to standard US unit/probe
  - Prone units in development
Automated Screening SBUS

- Kuzmiak, et al.
  30 BI-RADS 4/5 lesions, HH SBUS + ABUS, 5 readers
  23% (7) malignant lesions: equal confidence
  76% (23) benign lesions: ABUS higher confidence
  - Shape, margins p<0.001

- An et al.
  - 411 lesions HH SBUS + ABUS
  - 97.1% identical image quality
  - 2.9% ABUS inferior/HHUS superior
    - Peripheral lesions, irregular shape, BI-RADS 4/5

• 173 lesions: 46 malignant, 160 benign
  All had both HHUS and ABUS

  Detection rate (overall): 83% ABUS vs 94% HHUS

  • 25 benign lesions not detected on ABUS, small
  • ABUS avg size
    • detected: 1.52 cm
    • not detected: 0.96 cm

• Sensitivity: 96% ABUS and HHUS
  Both missed malignant Ca++

• Specificity: 76% ABUS vs. 49% HHUS
Improving Outcomes
Effect of MD Experience

- Yale: Year 1 vs. Year 3 SBUS
- All studies: Significant in BIRADS 3 & 4
- CDR maintained
- Interval cancer rate 0.5-1/1000
  - 0.5-1/1000 interval cancer rate in women with fatty breasts

T Zonouz, R Hooley et al. ARRS 2014
Yale SBUS Experience

• Combined/overall CDR
  2/1000 (10/4937)
• Mammo CDR
  2-7/1000
• Cancers: 1 DCIS, 8 IDC, 1 ILC
  Size: Median = 7 mm
  • ACRIN 6666 Median = 12 mm
Effect of MD Experience

- Year 2 SBUS in CT
- 10,282 SBUS at 5 sites
  - 87% (8,972) BI-RADS 1/2
  - 9% (875) BI-RADS 3
  - 4% (435) BI-RADS 4
  - CDR = 2.3/1000
  - PPV = 9%
Lesion Management:
What About ALL of Those Benign Findings?

- Cysts, cysts, cysts
- Fibroadenomas & other benign appearing masses
- Post biopsy changes
3 Types of Breast US

- Screening, Targeted, MR-directed
  - Lesion pretest probability different
  - Management must be different to achieve acceptable specificity
  - Higher threshold for oval hypoechoic masses seen on SBUS

- Post-test probability depends on pre-test probability
  - Pre-test CDR
    - Screening - 3/1000
    - Diagnostic - 50/1000
    - New cancer/staging MR - 400/1000
Simple Cysts

- ACRIN 6666: Cysts in 47% of participants
- Document the largest cyst in each quadrant
  - Single longest dimension without calipers
  - Orthogonal views unnecessary
  - Don’t image multiple cysts in a quadrant

Complicated Cysts

- Common: ACRIN 6666 - 14% participants
- Document orthogonal views +/- color Doppler
- 12 mo fu is adequate for most
  - Exception: Solitary or new cystic appearing masses in BRCA+, high risk, hx of lymphoma, melanoma

B9 cyst with debris

Melanoma

Clustered Microcysts

- Tiny echogenic foci individually < 2-3 mm
- Thin (<0.5mm) intervening septations
- No discrete solid component
- Targeted US: occasionally BI-RADS 3
- Screening US: BI-RADS 2
  - multiple cysts
Complicated Cysts: Risk of Malignancy

• Review of multiple studies*:
  1400 complicated cysts & clustered microcysts:
  *malignancy rate 0 – 0.8%

* Berg et al. Rad Clin North Am 2010
Improving Specificity

- Complicated cysts, circumscribed solid masses
  12 mo fu is adequate for most
  - Exception:
    - BRCA+, high risk, hx of lymphoma, melanoma
    - consider short interval fu or aspiration/bx

Berg et al. Radiology 2013;268(3):673-83
Barr et al. Radiology 2013;269(3):701-12
BI-RADS 3 Masses

- ACRIN 6666

BI-RADS 3 category lesions have a low malignancy rate (0.8%)*

- 0.1% of cancers showed change at 6 mo follow-up
- 1 year diagnostic follow-up may also be appropriate

*Barr et al. Radiology 2013;269(3):701-12
Bilateral Circumscribed Masses

• ACRIN 6666
  - 6% (135/2172) MB circumscribed masses
    ▪ Screening mammo – 1.7%
    ▪ No malignancies at 2y follow-up

• 12,187 SBUS

14.6% BI-RADS 3 (ACRIN 6666 protocol)

0.7% malignancy rate

• Mean 6.8 mm (range 3-11)

• All T1N0M0

Supports possibility to FU BI-RADS 3 lesions at 12 mo
SBUS: Lesion Analysis

• Orthogonal scanning & margin analysis essential, assess multiple lesions individually

F/42, False (-) Bi-RADS 3 IDC GR 1

F/52, True (+), BI-RADS 4, IDC
Benign Solid Masses

Fibroadenoma with Ca++ & mammo correlate
Not all irregular shadowing masses are CA. Correlation with mammography is essential.
Asymptomatic Intraductal Lesions

- Usually retroareolar
- Use color Doppler
- **NO** guidance in literature
- Biopsy vs FU
- BI-RADS 3 or 4
Asymptomatic Intraductal Lesions

- Kim, et al. AJR 2013
- 71 asymptomatic intraductal lesions
  - 3/71 (4.1%) malignant
  - 2/71 (2.8%) with no mammographic findings
    - Both low grade DCIS
- Benign intraductal lesions
  - Small (<1 cm)
  - Retroareolar
  - Partially fill duct
  - Low risk patients
Post-Operative Scars

- Don’t ignore
- Document
- Establish baseline
- Correlate with hx
- Search for tract to skin
- Use color Doppler
Other Issues
Issues: Legal

• Potential liability
  - 1° MDs
    - ? If he/she does not refer a pt with dense breasts for SBUS & pt develops interval CA
  - Radiologists
    - Determination of breast density is subjective
    - Some radiologist “overcall breast density”
    - Fear by some that a woman with SFG density develops cancer after a (-) mammo and no SBUS
    - ? another rad testifies the mammo dense
Scheduling

• Advise pts of breast density & need to talk to primary care MD about SBUS

• Automatic
  - “reflex to US if dense”
  - “bilateral US if necessary”
  - mammogram BI-RADS 0
Interpretation: ? Batch Read vs. Online

• Batch read
  - Screening US can be done off hours/no MD present
    • Orthogonal views (except simple cysts)
    • Cine loop for any questionable/suspicious findings
  - High recalls in addition to mammo recalls
  - Pt may require 2 exams
  - US offered at all screening satellites
Interpretation: ? Batch Read vs. Online

- **Online**
  - MD available to check any questionable findings
  - No US recalls
  - Single US exam
    - Efficient for patients
  - May decrease mammo recalls
    - Efficient for radiology facility
Scheduling

• Should SBUS be done same time as mammo?
  - Yale protocol:
    • Mammo must be done within 12 mo of SBUS
    • 40% have SBUS on same day as mammo
    • Many patients choose to alternate exams at 6 mo
      - High risk, anxious

• Dave H, Hooley R, et al. ARRS 2014
  - 2823 normal mammograms + screening US
  - Same day vs different days
  - No significant difference: US BI-RADS, CDR
Screening mammography recall rates:

- Mammo + US same day: 6.2% (50/810)
- Mammo + US different day: 10.7% (176/1649)

42% reduction in mammography BI-RADS 0/recall

CDR maintained
Possible to reduce mammo recall rate when combining mammo with SBUS

11,753 women screened
- 974 women had mammo & SBUS performed on the same day

Mammo recall rate/CDR
- Mammo only: 4.9% /0.22
- Mammo + US: 2.6%/0.31
What is the Best US Screening Interval?

• Limited guidance in literature
• Most studies are prevalence screens or mixed
### Prevalence vs. Incidence Screen:

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<th>PREVALENCE (year 1)</th>
<th>INCIDENCE (year 2)</th>
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<tbody>
<tr>
<td></td>
<td>Yale *</td>
<td>ACRIN 6666**</td>
</tr>
<tr>
<td>Positive biopsies</td>
<td>Positive biopsies = 3/46</td>
<td>Positive biopsies = 21/233</td>
</tr>
<tr>
<td>PPV 3</td>
<td>PPV 3 = 6.5%</td>
<td>PPV 3 = 9%</td>
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<tr>
<td>Cancer detection</td>
<td>Cancer detection = 3.2/1000</td>
<td>Cancer detection = 4.2/1000</td>
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<tr>
<td></td>
<td>** Overall cancer detection rate 4.8/1000</td>
<td>** Positive biopsies = 31/266</td>
</tr>
<tr>
<td></td>
<td>** PPV 3 = 11.7%</td>
<td>** PPV 3 = 11.7%</td>
</tr>
<tr>
<td></td>
<td>** Cancer detection = 3.7/1000</td>
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* *Ibrahim, et al. RSNA 2012, **Berg et al. JAMA 2012*
9 mm IDCA on incident SBUS
Tomosynthesis: Is Screening US Necessary?

- Screening US or DBT
  - Increased CDR in addition to FFDM alone
  - Mostly small invasive cancers
    - US: 2nd exam, primarily for dense breasts, low ppv
    - DBT + 2D is a single exam, all breast densities, less recalls, increased PPV
TOMOSYNTHESIS: IS SCREENING US NECESSARY?

- Cost effectiveness & CDR of supplemental screening US may decrease
  - Tomo/incidence exams CDR = little data
  - US/incidence exams CDR = 2-3.7/1000
Tomo vs. Screening Breast US

- US detects slightly more cancers than tomo

Small, tomo occult IDC x 3
• 1042 patients

Mixed population
• Screening US, targeted US
• Cancer enriched
• Breast density SFG, HD, ED
• Siemens Inspiration
  • Tomo MLO or Tomo MLO +CC

Retrospective single reader study
Additional US or DBT after digital mammography: which one is the best combination?

Arlette Elizalde, Luis Pina, Jon Etxano, Pedro Slon, Romina Zalazar and Meylin Caballeros

Fig. 3. The AUCs of DM and the different combination of techniques, as well as the statistical significance.
US BI-RADS 5th Edition
Follow-up & Outcomes Monitoring

• Screening Breast US
  - Comparable to screening mammography recall
  - # Routine screening images determined by individual facility
  - Considered test (+) if any additional images are recorded
    - Discourages use of orthogonal views for benign findings
    - Even if a single screening report is issued & a single screening exam is performed & assessed as BI-RADS 1/2
    - Artificially low specificity & high “false (+)”

  - Counter response to BI-RADS 5th ed audit guidelines
Critics, Cost, and Controversies

- Low PPV
- Increased anxiety, healthcare costs, unnecessary treatments
- Over-diagnosis
- No long term RCT/mortality benefit unknown
- But interval cancer rates decreased
  - Argues against over-diagnosis
  - Supports potential decreased mortality
FAST MR Screening

• Proposed for average risk women with dense breasts

• Kuhl et al. JCO 2014
  - 606 exams/427 women with dense breasts
  - Mild-moderate risk/nl mammo
  - Acquisition time of 3 min
    pre/post T1WI, + subtraction/IV contrast
  - Supplemental CDR = 11/606 (18.2/1000)
  - 2 y validation: No interval cancers
  - NPV MR 99%
  - SP/PPV: 94.3/24.4 (similar to full MR protocol)
• 3 rounds mammo + SBUS, followed by MR
• 1215 eligible women
  - 42% (512) declined MR
    - 25% claustrophobia
    - 18% time constraints
    - 12% financial concerns
    - 9% PCP would not provide referral/ unnecessary
    - 8% not interested
    - 8% medically intolerant
    - 7% IV contrast concern/allergy
• Study based on theoretical modeling of supplemental SBUS after a normal mammogram in women 50-74 years and dense breast tissue
  - SBUS in women with dense breasts would substantially increase costs with relatively small benefit
  - Suggests biennial screening or only screening women with extremely dense breasts would be more cost effective
  - Suggests that breast density legislation should be evaluated from “variable perspectives”

• Underestimates the benefits and overestimates the harms of SBUS
Summary

• Handheld screening US is a good and practical supplemental screening tool
• With proper training & experience, technologists can successfully perform HH-SBUS
  - Supplemental CDR: 2-3/1000
• Real-time MD scanning is important to increase specificity
• Audit practice
  - BI-RADS 3s, 4s, PPV, recalls, interval cancer rate
Summary

• Here to stay
  Well tolerated
  Relatively inexpensive, accessible

• Specificity
  Improved with experience and data
  Higher threshold for FU/bx

• Sensitivity
  Comparable to mammography
  Will decrease slightly
  • Incidence scans
  • Tomo

• Interval cancer rates very low
Thank you 😊

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