Digital Mammography: A Radiologist’s Perspective

Robert L. Gutierrez, MD
Breast Imaging Section
University of Washington Medical Center
Seattle Cancer Care Alliance

Topics

• Overview of breast cancer in the U.S.
• Film-screen mammography vs. Digital Mammography
• Advantages/disadvantages of FFDM
• CAD and Digital Mammography

2009 Estimated US Cancer Cases*

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>766,130</td>
<td>713,220</td>
</tr>
<tr>
<td>Lung &amp; bronchus</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Colon &amp; rectum</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>7%</td>
<td></td>
</tr>
<tr>
<td>Melanoma of skin</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Non-Hodgkin lymphoma</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Kidney &amp; renal pelvis</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Leukemia</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>Oral cavity</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>Pancreas</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>All Other Sites</td>
<td>15%</td>
<td></td>
</tr>
</tbody>
</table>

*Includes breast and sarcoma with site specified but in situ carcinoma except urinary bladder.
Source: American Cancer Society, 2009.

SURVIVAL BY STAGE

[Graph showing survival rates by stage over years after diagnosis]
5 YEAR SURVIVAL

- I— 2 cm or less, no nodes: 98%
- IIa— 2-5 cm, no nodes: 88%
- IIb— 2-5 cm, axillary nodes: 76%
- IIIa— Axillary nodes and tissue: 56%
- IIIb— Chest nodes and wall: 49%
- IV— Spread to other tissues: 16%

Current Standards

- Mammography: Imperfect, but the single method with proven efficacy in decreasing late stage disease and decreasing mortality from breast cancer for women aged 40 and above.

Screening Mammography

- Results in decreased rate of death from breast cancer
- Detection of cancers at smaller size/earlier stage
- Confirmed by meta-analyses of 8 large randomized controlled trials

Screening Mammography

- 50-69 y.o.: mortality reduction 16-35%
- 40-49 y.o.: mortality reduction 15-20%
  - Lower incidence
  - Rapidly growing tumors
  - Dense breasts
Film-screen vs. Digital Mammography

Film-Screen Mammography (FSM)
- Technique used in the screening trials
- Proven benefit
- Also has limitations

Limitations of FSM
- Sensitivity
  - Range: 0.45 to 0.88
  - Reduced as breast density increases
    • Breast density = moderate risk factor for breast cancer
  - 20% cancers found w/in 1 year of negative mammogram

Limitations of FSM
- Specificity
  - False positives: approximately 60-75% of breast biopsies are benign
- Opportunities for improvement
Full Field Digital Mammography (FFDM) Background

- February 2000, first FFDM system approved by FDA
  - GE Senographe 2000D
  - For screening and diagnosis
  - Hardcopy presentation (softcopy approved November 2000)

FFDM Background

- Several systems now FDA approved
  - Fischer Imaging
  - Hologic
  - Fuji Medical

Expansion of Digital Mammography in the U.S.

Why Convert to Digital?

- Film-screen
  - Film: A vehicle for image acquisition, display and storage
- Digital
  - Decouples these functions
    - Allows post-processing of images
    - Provide diagnostic information without need for additional images/radiation
Why Convert to Digital?

- Image manipulation
  - Contrast/brightness, enlargement/zoom
- Data transfer
  - Remote interpretation/consultation for difficult cases
- Elimination of film processing
- Faster image acquisition/shorter exam time (half that of FSM)
- Lower average radiation dose
- Expedite procedures
- Improved Accuracy?

Image Manipulation

Especially useful for evaluation of patients with implants

Case Example
Digitally magnified and adjusted at workstation

Digitally magnified and adjusted at workstation

Digitally magnified and adjusted at workstation

SPOT/MAG Medial-Lateral View
SPOT/MAG Medial-Lateral View, digitally magnified and optimized

Data transfer
- Remote interpretation
- Remote consultation
- Potential to increase access to underserved areas/groups

Elimination of film processing

Elimination of films
Expedites Procedures:
- Localizations
- Ductography

Expedites Procedures: Tangential views

FFDM Versus FSM Image Quality
- Spatial resolution FFDM < FSM
  - 12 lp/mm versus 15 to 20 lp/mm
- Offset by
  - Greater image contrast
    - Helpful in areas with low FSM contrast = dense
  - Ability to manipulate image to optimize
    - Contrast, brightness, magnification
FFDM Diagnostic Accuracy

• Is FFDM more accurate than FSM for breast cancer screening?

FFDM Diagnostic Accuracy

• 2001 to 2004: 4 large prospective studies comparing FFDM to FSM
  – For screening
  – All found no significant difference in accuracy between FFDM and FSM
  – Limitations
    • Each 1 type digital system
    • Insufficient power to identify small differences in accuracy

Prior Studies

• Lewin et al.
  – 4945 women
  – Both FFDM and FSM, interpreted independently
  – 35 cancers
  – Detection rate: no significant difference
  – Recall rate: FFDM 11.5% < FSM 13.8%
  

Prior Studies

• Lewin et al.
  – 6746 women
  – Both FFDM and FSM, interpreted independently
  – 42 cancers
  – Detection rate: no significant difference
  – Recall rate: FFDM 11.2% < FSM 14.9%

Prior Studies

- Skaane, et al.
  - 3683 women
  - Both FFDM and FSM, interpreted independently
  - 31 cancers
  - Detection rate: no significant difference
  - Recall rate: FFDM 4.6% > FSM 3.5%


Prior Studies

- Skaane et al.
  - 6,997 FFDM, FSM 17,911 FSM
  - 41 cancers (0.59%) FFDM, 73 cancers (0.41%) FSM
  - Detection rate: Trend toward greater detection in >50 y.o., but no significant difference
  - Recall rate: FFDM (3.7-3.8) > FSM (2.5-3.0)


2005: Digital Mammography Imaging Screening (DMIST) Trial

- 42,760 asymptomatic women
- 33 sites in U.S. and Canada
- 5 FFDM systems
- Both FFDM and FSM, interpreted independently

Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening

DMIST Results: Diagnostic Accuracy

- FFDM = FSM for entire population
- FFDM > FSM for specific subgroups
  - < 50 y.o.
  - Dense breasts
  - Pre- or perimenopausal

DMIST Results: Diagnostic Accuracy

- FFDM = FSM for other subgroups
  - Race
  - Breast cancer risk
  - FFDM system
- Recall rate: 8.4% for both FFDM and FSM

Case example

![FSM and FFDM Images]
Cancer detected only on digital mammogram

Making the Transition: Challenges

- Cost
  - FFDM systems 1.5-4.0 times > than FSM
  - ~500K for first DM unit
    - Display monitors
    - Laser Printers
    - Training of technologists and Radiologists
    - Redesign of facilities
  - Costs offset by increased productivity?

Making the Transition: Challenges

- Prior mammograms
  - Comparison with priors is **essential**
  - Hard copy vs. Soft copy
    - Light boxes/alternators→luminance issues
    - Digitized priors—diagnostic quality?
    - Digitizers are not FDA approved for primary interpretation
    - What and how much should be digitized?

Making the Transition: Challenges

- Ease of Review
  - ~2X longer than FSM
  - Improves with
    - experience
  - Hanging protocols - an essential
  - Digital comparisons
Making the Transition: Challenges

Calcifications or asymmetries seen on FFDM but not clearly seen on comparison FSM...

• How to manage?
  – Treat as new/developing and biopsy?
  – Consider the first digital as a new "baseline?"
    • Categorize as "probably benign?"

Routine screening mammogram, first time digital…

Grouped calcifications in the UOQ
Grouped punctate and round calcifications in the UOQ

FSM Prior - CC view  FFDM CC view

Routine screening mammogram, first time digital…
Focal Asymmetry seen only on the CC view. New or merely normal tissue accentuated by differences in exam technique?

Making the Transition: Challenges

DIGITAL STORAGE

- Pros
  - Rapid access to large amounts of data
  - Prevents lost films

- Cons
  - Large memory requirements
  - Training
Case example
Digital Mammography and Computer Aided Detection (CAD)

“Thus, for every true positive mark resulting from CAD that is associated with an underlying cancer, radiologists encounter nearly 2000 false positive marks.”


Digital Mammography and Computer Aided Detection (CAD)

• Software designed to assist radiologists in identifying suspicious mammographic findings
• Approved by FDA in 1998
• Reimbursed by Medicare and many private insurers
• Rapidly adopted

Digital Mammography and Computer Aided Detection (CAD)

• For FSM, use of CAD systems requires digitization of images for analysis
• For FFDM, digital platform facilitates its use—integrated into the hanging protocol
• Mixed data regarding its utility...


Digital Mammography and Computer Aided Detection (CAD)

• 19.5 % increase in detected breast cancers when CAD was used*
  – looked at 12,860 mammograms interpreted with assistance from the CAD system over a 12-month period.
**Digital Mammography and Computer Aided Detection (CAD)**

"Use of the [CAD] could result in earlier detection of up to 23.4% of the cancers currently detected with screening mammography in those women who had a prior screening mammogram 9-24 months earlier."

FDA Claim, February 5, 2002.

Digital Mammography and Computer Aided Detection (CAD)

<table>
<thead>
<tr>
<th></th>
<th>Before CAD</th>
<th>After CAD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>80.4%</td>
<td>84%</td>
<td>p=(0.32)</td>
</tr>
<tr>
<td>Specificity</td>
<td>90.2%</td>
<td>87.2%</td>
<td>p&lt;(0.001)</td>
</tr>
<tr>
<td>PPV</td>
<td>4.1%</td>
<td>3.2%</td>
<td>P=(0.01)</td>
</tr>
</tbody>
</table>

No significant difference in cancer detection rates (4.15 vs. 4.2 cases per 1000)


**Future Applications**

- Can serve as platform to develop new technologies
  - Telemammography
  - Breast tomosynthesis/3D digital mammography
  - Contrast Enhanced DM

Summary

• FFDM is superior to FSM in detecting cancer in specific subgroups of women

• Transition to DM is costly, but numerous benefits

• Radiologists face unique challenges when transitioning to digital

• Mixed data regarding utility of CAD, but it remains widely utilized.

Thank you!