Tomoynthesis “3-D” Mammography: Do You Need It In Your Practice?

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Background

Screening mammography has been shown to be the only imaging modality to lower breast cancer mortality \(^{31,32,33}\)

But...we know it’s not perfect
The Problem

• Mammography is a 2 dimensional exam, so in a dense breast, a cancer of similar attenuation can be obscured by normal surrounding fibroglandular elements, decreasing sensitivity.

• Similarly, adjacent normal structures or dense asymmetric areas are sometimes superimposed and questioned to be abnormalities, leading to additional work-up and increase in false positives, decreasing specificity.

• These factors are in part responsible for the differences in sensitivity and specificity in mammography depending on breast density.
  • sensitivity of 87% and specificity of 97% in women with fatty breasts
  • sensitivity of 63% and specificity of 89% in women with dense breasts.
Background

• Technology has helped us improve our detection;
  - xeromammography
  - film-screen mammography
  - digital mammography

• DMIST trial : Pisano et al. NEJM 42 digital mammography demonstrated improvement in cancer detection in patients with:
  - dense breasts
  - pre/perimenopausal
  - age less than 50

......however we still miss cancers in the dense breasts
Is There Anything Else We Can Do?

- **Digital Breast Tomosynthesis (DBT)** ...is a derivative of full-field digital mammography (FFDM) that improves the detection and characterization of breast lesions by reducing the problem of overlapping tissue $^{3,4}$

- First described for breast imaging in 1997 by Niklason $^7$
What is Tomosynthesis?

- Tomosynthesis utilizes x-rays to acquire cross-sectional images or “slices” of breast tissue.

- A series of multiple low-dose projection images are acquired as the x-ray tube is rotated through an angled arc around the compressed breast. These projections are processed by a reconstructive algorithm to generate 1mm thick slices which can be viewed as sequential sections of the breast, which are interpreted clinically.\(^3,4,7,41\)

- DBT primarily has two large effects in the clinical setting: reduction in the rate of false positive recalls and increase in cancer detection rates.\(^{22,36,37,38}\)

- Studies of DBT have determined that it is as accurate as standard two-view FFDM in the diagnosis or triage of breast abnormalities.\(^5\).
Technical Aspects

• Tomosynthesis projections are obtained at the same time as the standard two-view digital mammogram. The patient remains in the same compression.

• The number of images obtained varies depending on the thickness of the compressed breast\textsuperscript{4,5}.

• The total scan time for DBT is about 4 seconds per breast\textsuperscript{6} adding an additional scan time to the 6 seconds for the traditional two-view FFDM - total 10 sec.

1 – X-ray tube; 2 – compression paddle; 3 – breast platform; 4 – Selenium image receptor; 5 – FFDM gantry
• FDA approved tomosynthesis for use in the United States using 2D + 3D (CC and MLO views) in February of 2011

• Currently Hologic Dimensions is the only approved unit in United States

• Other Systems: GE Essential, IMS Giotto TOMO, Philips MicroDose, Planmed Nuance Excel DBT, Siemens MAMMOMAT Inspiration

• FDA requirement: Need initial 8 hour training for MD’s and technologists
Concerns and Limitations

- Increased Radiation dose with traditional DBT is a concern for patients and physicians
  
  The radiation dose ranges from 1-2 X the dose of a regular 2 view mammogram\textsuperscript{13,14}

  Two-dimensional (2D) synthesized images from DBT may eventually replace digital mammograms resulting in radiation doses equivalent to current mammography\textsuperscript{11,12,35}

- Thin cross sectional slices obtained during DBT make perception of microcalcification distribution (ie: cluster) difficult to appreciate\textsuperscript{1,16}

  DBT does allow for assessment of microcalcification morphology\textsuperscript{30}
Concerns and Limitations

- DBT is not proven to offer any benefits over current diagnostic tools such as combined digital mammography and ultrasound\(^\text{18}\)

- Increased time to interpret over digital mammography\(^\text{19}\)
  - Studies have shown that DBT can take twice as long to interpret as digital mammography\(^\text{20}\)
Tomosynthesis Limitations

• Expensive, currently no reimbursement code (code “G”)

• IT requirement: Large files, data set depends on breast size (if breast compresses to 55mm, then 1/55 slices. Tomo can add 160-320 more images to your data set. On average need 10X storage /patient. If standard 4 view is 20MB, 2D+3D is 200MB often

• False negative – Need long term data
Clinical Uses

• DBT is most effective when used as part of the screening exam.
  • When used as a screening tool in conjunction with digital mammography or synthetic 2D views, recall rates have been shown to be significantly reduced from 11.9% to 4.9%, 8.7% to 5.5% and 12% to 8.4% in multiple different studies\textsuperscript{5,10,11,22}.
  • The addition of DBT increases screening sensitivity by increasing cancer detection rates, especially invasive cancers, by as much as 30\%\textsuperscript{3,5}.

• As a diagnostic tool DBT results in:
  • Improvement in mass characterization and size assessment\textsuperscript{3}.
  • Increased accuracy in classification of lesions as malignant or benign when used in conjunction with digital mammography\textsuperscript{12}.
  • The increased sensitivity of DBT may allow for more accurate assessment of the extent of disease (multifocal and multicentric disease).
Synthesized Mammography

- Has preliminary FDA panel approval May 2013

- Perform tomosynthesis scan only and synthesize the 2-D images from a reconstruction algorithm, called the “C-view”. This would look similar to standard 2D images and serve as an overview, or roadmap to the 3D data set. Need 2D to see asymmetry, compare with priors, assess microcalcifications

- This would eliminate the additional radiation from the standard 2D images, making the total comparable to current 2D imaging but still maintain the benefit of 3D

- Preliminary data; Skaane RSNA 2013
Current Literature

- Early studies - Small numbers of cases, mostly observer performance studies (Poplack SP, et al., Gur D, et al)

- 5 sites: MGH, Dartmouth, Iowa, McGee Women’s, Yale
- 12 readers; rad 2D and a different time 2D+tomo
- Conclusion; with the addition of 3D to 2D, diagnostic accuracy improved (7.2% and 6.8% gain) and diagnostic sensitivity improved (10.7% and 16%)
- Recall rates decreased for every reader (38.6% )
Current Literature

• Observational study of the Initial experience in clinical practice in US (Houston)
• Rose SL, et al. Implementation of breast tomosynthesis in a routine screening practice. AJR, June 2013. 10
• 13,856 screening mammo, 9499 with tomosynthesis
• Significant decrease in recall rate from 8.7% to 5.5% (37%)
• Significant increase in cancer detection rate from 4.0 to 5.4/1000 (35%)
• Increase in invasive cancer from 2.8 to 4.3/1000 (54%)

• Haas B et al. 46 Radiology Dec 2013, 13,158 mammo , 6100 with tomo
• Significant decrease recall rate from 12% to 8.4% (29.7%),
• Significant for all densities except fatty, all ages except >70 with greatest reduction were in dense breasts and patients < 50 y.o.
• Increase in cancer detection rate 5.2 to 5.7/1000 (9.5%) not significant
Oslo Tomosynthesis Screening Trial

- OTST Largest prospective study to date, Oslo Norway
- Single institution, 12,621 eligible subjects. Compared standard 2 view 2D with 2D+2 view DBT on commercially available Hologic unit (not a prototype)
- 25 additional invasive cancers were detected using 2D+3D (increase of 40%). No increase in detection of DCIS
- Results: 27% increase in cancer detection rate (invasive carcinoma)
- 15% decrease in recall rate
- Interpretation time was doubled using 2D+3D
STORM

- Italian based trial in Trento and Verona, prospective, non-randomized study comparing conventional 4 view mammography with combined digital mammography and tomosynthesis Ciatto S, et al. 38
- Screening with Tomosynthesis or Standard Mammography (STORM) 7292 women
- Early results reported at Eur Congress of Radiology 2012 and Lancet 2013
- DBT Detected 8.1 cancers/1000 screens, compared with 5.3 /1000 screens with 2D only, Incremental cancer detection rate attributable to 2D + 3D was 2.7 cancers/1000 screens an increase in over 50%
- Recall rate decreased by 17.2%
Ongoing Trials

- OSLO Tomosynthesis Screening Trial – Norway 18,000 women
- STORM – Italy
- Malmö Breast Tomosynthesis Screening Trial (MBTST) ongoing: Principal Investigators: Sophia Zackrisson MD Phd, Ingvar Andersson MD, will accrue 15,000 women, started 2010, due for completion 2014
- UK trial, TOMosynthesis with Digital Mammography (TOMMY) will include 7,000 women recalled after a positive screen
- TMIST – United States
- Need more data, need long term F/U to these trials to see that we are not missing cancers as well
Tomosynthesis: Diagnostic Use

- Can determine if true mass vs. asymmetry \(^{26,27}\)

- Characterize the borders/margins of the mass therefore better able to distinguish benign findings from malignant findings, more accurate size as well as localize the mass and go directly to US \(^{26,27}\).

- more readily reveals architectural distortions.

- DBT similar to mammo spot compression view, may decrease number of diagnostic images and streamline diagnostic work-up \(^{40}\).

- Calcifications continue to be an area where FFDM outperforms DBT, although one study demonstrated that the difference in visibility was not statistically significant \(^{17}\).
Cost Effectiveness

- Viviek Kalra, et al. RSNA 2012

- Immediate Direct cost savings - avoid recall for unilateral, bilateral mammo or US

- Decreased recall rate from 10.9% with FFDM to 7.0% with combined DBT resulted in statistically significant decreased number of immediate diagnostic studies: unilateral mammo 9.6% vs. 5.8%, bilateral mammo 1.0% vs. 0.1%, ultrasound 7.7% vs. 5.5%.

- Using regional Medicare reimbursement rates the decrease resulted in a direct cost savings of $10,185 per 1000 women screened with combined DBT (Yale study)

- Intangible cost- patient anxiety and stress following a false + callback or pain/suffering from a biopsy

- Indirect cost savings- transportation costs, work days lost, Insurance paperwork, facility costs, rescheduling costs
DBT Biopsy

• Tomosynthesis Biopsy device now available as an add-on device

• Currently at Magee Women’s, just over 100 patients performed by Dr. Zuley and Dr. Sumkin (not published)
Summary

• The increased sensitivity and reduction in call back rates are two of the most important ways that the addition of tomosynthesis to a screening protocol benefits patients.
  • Reduction in recall rates may decrease the unnecessary stress patients must undergo.
  • Reduction in recall rates may decrease health care costs.

• Tomosynthesis is often used as an additional diagnostic tool to further characterize lesions seen on 2D digital mammography, however, its greatest impact seems to be when it is utilized in a screening population.

• There is currently no data to suggest that tomosynthesis can be used without 2D digital mammography; as improvements in DBT technology continue, the future may allow for replacement of 2D digital mammography by synthesized 2D tomosynthesis images\textsuperscript{21,29,35}.

• The additional cancers detected by DBT are often significant. The majority of additional cancers detected by DBT were invasive, node-negative cancers\textsuperscript{21}.

• DBT limitations include:
  • No proven lesion detection benefits over combined digital mammography and ultrasound.
  • Slightly increased radiation dose to patient.
  • 2D digital mammography has a greater capacity to assess microcalcifications.
As always, with any new therapy or technology we have to be sure we are not doing more harm.

So to answer the question.....

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..........you probably will!
References


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