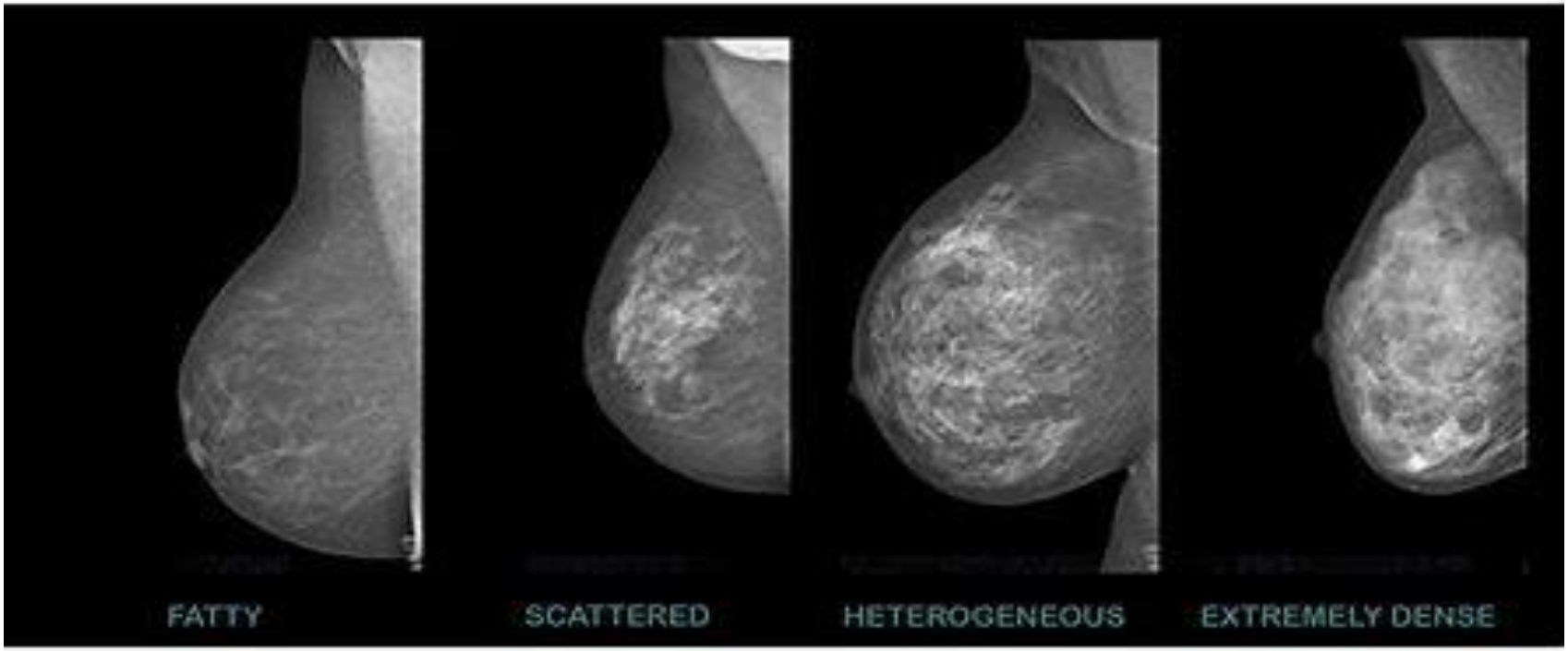
UMC Utrecht

Diagnostic value of Three-dimensional UltRasound in breast cancer screening participants referred with a BI-RADS 0 test result: a comparison of imaging strategies (TURBO)

Bianca den Dekker, MD - PhD student

Prof dr R.M. Pijnappel
Prof dr H.M. Verkooijen
Dr M. Broeders

Breast density



- High breast density reduces sensitivity of mammography[1]
- High breast density is a risk factor for breast cancer[2]

1. Boyd, N.F., et al., *Mammographic density and the risk and detection of breast cancer.* N Engl J Med, 2007. **356**(3): p. 227-36.
2. Pisano, E.D., et al., *Diagnostic performance of digital versus film mammography for breast-cancer screening.* N Engl J Med, 2005. **353**(17): p. 1773-83.

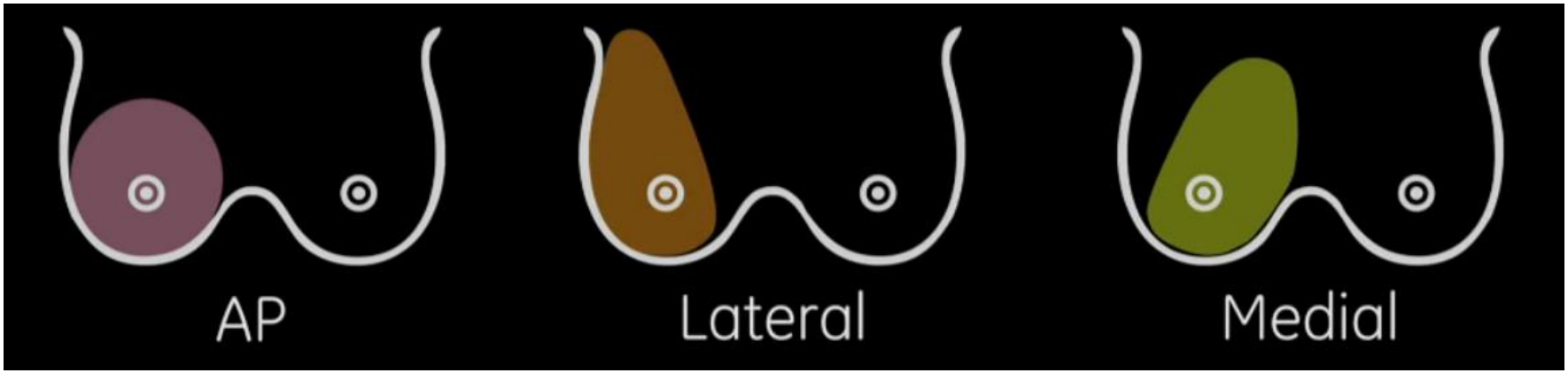
Breast Ultrasound

- High inter-observer variability
- Time consuming

3-Dimensional Automated Breast Ultrasound

Invenia ABUS

Invenia ABUS


AP
Lateral
Medial

Invenia ABUS

Advantages 3D ABUS

- Standardized image acquisition protocol
- Image acquisition by technician
- Digital storage
  - Enables re-evaluation, double reading, CAD[3]

3. van Zelst, J.C., et al., *Improved cancer detection in automated breast ultrasound by radiologists using Computer Aided Detection.* Eur J Radiol, 2017. **89**: p. 54-59.

SomoInsight Study[4]

- **Design**: Multicenter observational study
- **Population**: 15.315 women, mean age 53.3, with heterogeneously (50-75%) or extremely (>75%) dense breasts
- Addition of ABUS to screening mammography

4. Brem, R.F., et al., *Assessing improvement in detection of breast cancer with three-dimensional automated breast US in women with dense breast tissue: the SomoInsight Study*. Radiology, 2015. **274**(3): p. 663-73.

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- **Population**: 15.315 women, mean age 53.3, with heterogeneously (50-75%) or extremely (>75%) dense breasts
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Results

- Additional 1.9 detected cancers per 1000 (95% CI 1.2-2.7, p-value <0.001)

  93.3% of additional cancers were invasive
- Increase in recall rate 284.9 per 1000 (95% CI 278-292, p-value <0.001)

4. Brem, R.F., et al., *Assessing improvement in detection of breast cancer with three-dimensional automated breast US in women with dense breast tissue: the SomoInsight Study.* Radiology, 2015. **274**(3): p. 663-73.

EASY Study[5]

- **Design**: single center observational study
- **Population**: 1.668 asymptomatic women, mean age 49.5, with heterogeneously (50-75%) or extremely (>75%) dense breasts
- Addition of ABUS to mammography

5. Wilczek et al. Adding 3D Automated Breast Ultrasound to mammography screening in women with heterogeneously and extremely dense breasts. Report from a hospital-based, high-volume, single-center breast cancer screening program. European Journal of Radiology 85 (2016) 1554–1563

EASY Study[5]

- **Design**: single center observational study
- **Population**: 1.668 asymptomatic women, mean age 49.5, with heterogeneously (50-75%) or extremely (>75%) dense breasts
- Addition of ABUS to mammography

Results

- Additional 2.4 detected cancers per 1000
  95% CI 0.6-4.8, p-value < 0.001
- Additional 9.0 recalls per 1000
  95% CI 3.0 – 15.0, p-value 0.004

5. Wilczek et al. Adding 3D Automated Breast Ultrasound to mammography screening in women with heterogeneously and extremely dense breasts. Report from a hospital-based, high-volume, single-center breast cancer screening program. European Journal of Radiology 85 (2016) 1554–1563

Rationale TURB0 study

- BI-RADS 0 referral
  - 88% false positive result[6]
  - 20% undergoes invasive diagnostic procedures[6]

→ Optimize the imaging strategy in women referred with a BI-RADS 0 result

6. Monitor bevolkingsonderzoek borstkanker juli 2017 via http://www.rivm.nl/dsresource?objectid=490f8bcc-965e-466f-afb4-9a823c5a41be&type=pdf&disposition=inline

Objective TURB0 study

To investigate the diagnostic accuracy of 3DUS as a standalone imaging modality as well as in combination with conventional imaging modalities to diagnose breast cancer in Dutch breast cancer screening participants referred with a BI-RADS 0 mammography result.

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Secondary objectives

- To investigate the diagnostic accuracy among subgroups of patients based on mammographic density and age.
- To determine the biopsy referral rate for the different imaging strategies.
- To assess the interobserver reliability for 3DUS.

Study design

Multicenter diagnostic study

Study design

Multicenter diagnostic study

Participating hospitals

Elisabeth TweeSteden Ziekenhuis Tilburg

Rijnstate Ziekenhuis Arnhem

Catharina Ziekenhuis Eindhoven

Study design

Multicenter diagnostic study

Participating hospitals

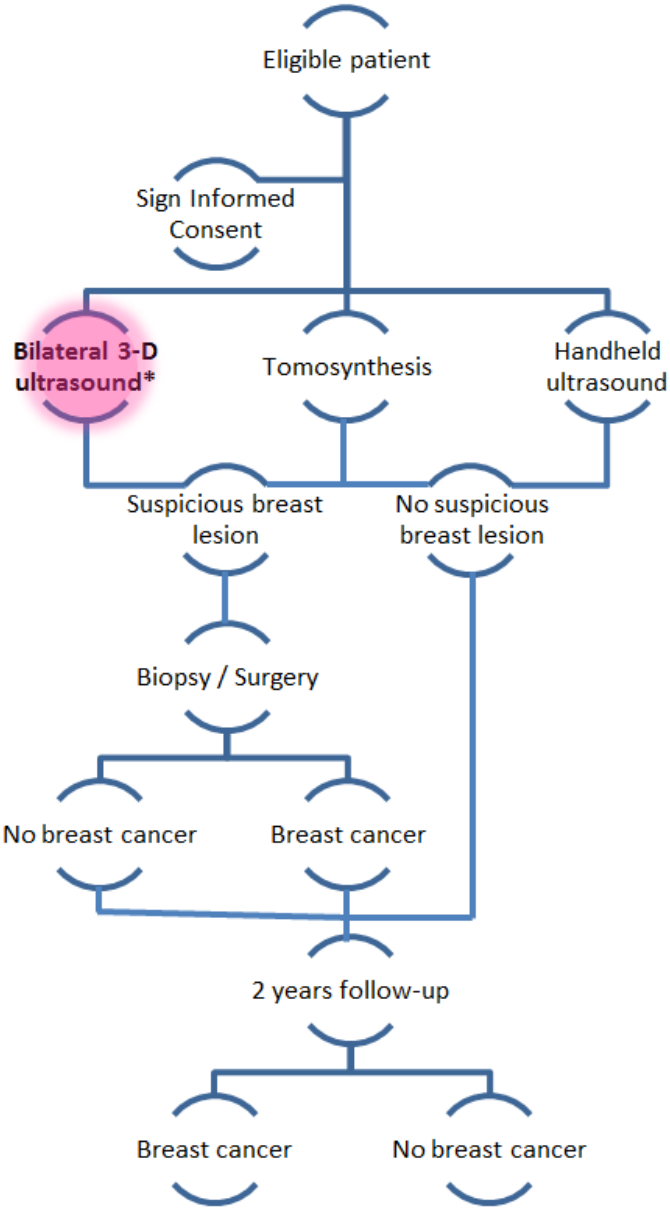
Elisabeth TweeSteden Ziekenhuis Tilburg

Rijnstate Ziekenhuis Arnhem

Catharina Ziekenhuis Eindhoven

Study population: Dutch breast cancer screening participants with a BI-RADS 0 mammography result, who are referred to one of the participating hospitals for further diagnostic work-up

Sample size: 600



*3-D ultrasound image acquisition has to be completed before any intervention is performed

Reader study

- Independent assessment of different imaging strategies
  - **3D ABUS**
  - **Tomosynthesis + HHUS (‘current practice’)**
  - **Tomosynthesis + 3D ABUS**
  - **Tomosynthesis + HHUS + 3D ABUS**

Planning

Time period	Activities
April 2018 – October 2019	Patient inclusion Data collection
End of 2019	First results (histopathological outcome)
End of 2021	Final results (follow up outcome)

B.M. den Dekker

Department of Radiology

UMC Utrecht Q1.4.43

PO box 85500, 3508 GA Utrecht

☎ **06 39636265**

B.M.denDekker-3@umcutrecht.nl