

Experience with introduction of AI in Breast Cancer Screening in Capital Region of Denmark

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Retrospective Simulation Studies

A collaboration between two Institutes at University of Copenhagen (Computerscience and Public Health), a professor and founder of the AI from Radboud University, NL and Capital Mammography Screening Programme

Two retrospective simulation studies based on

- Results of Double blind readings by experienced full time breast radiologist of 114.421 consecutive womens screening exams versus AI
- Sampling period January 2014 December 2015. 2 year follow up.
- 791 screen detected cancers, 327 interval cancers and 2107 false positives

Preliminary simulation study:

Al only (no radiologist readings) with a sensitivity matched to experienced breast radiologists sensitivity

- 100% work load reduction
- Lower specificity than the radiologist (94.9% versus 98.1%)
- Signifikant rise in FP: 276,5% rise 5825 women compared to 2107

"An Artificial-Intelligence-based Mammography Screening Protocol for Breast Cancer: Outcome and Radiologist Workload". Radiology 2022.

Retrospective simulation studies



Main simulation study:

- Al^{*}only reader on the lowest risk group (<5 on a risk score on a scale from 1-10)
- Double blind readings by experienced breast radiologists (risk score ≥5 9,989)
- Direct recall of women with a risk score on ≥ 9.989

Results

- Sensitivity: AI 69.7% versus breast radiologist 70.8%
- Specificity: Al 98.6% versus breast radiologist 98.1%
- Numbers of false positive reduced with 25%

★Transpara version 1.7.0

"An Artificial-Intelligence-based Mammography Screening Protocol for Breast Cancer: Outcome and Radiologist Workload". Radiology 2022.



Mammog / Compute University

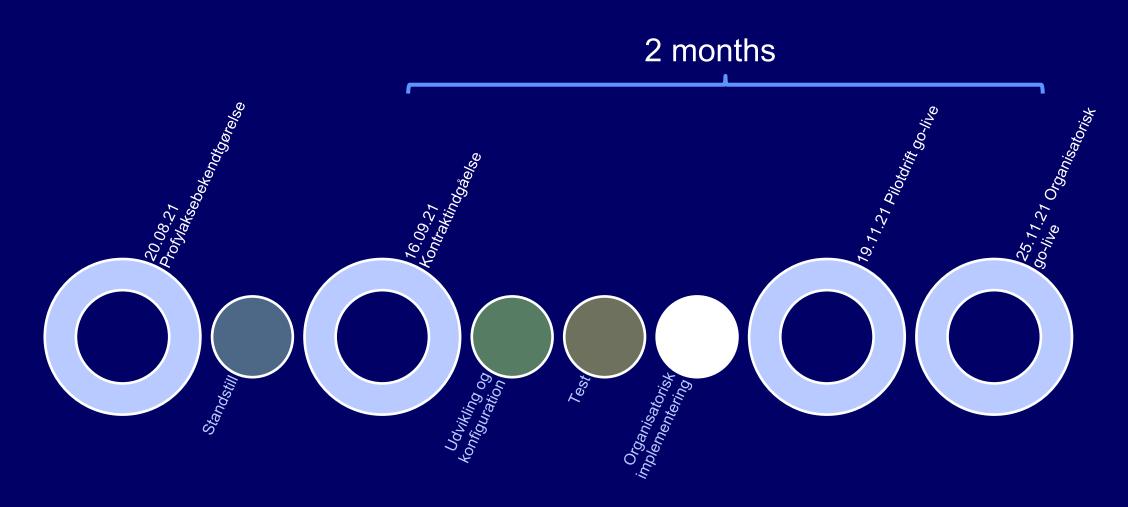
Al we have used is

- Transpara version 1.7.0
- CE and FDA approved
 - Trained on > 1 mio. processed
 mammograms
- 791 : inter
- from different vendors in Europe and USA

Resulta

- Sens
- Spec
- Data from our regional screening programme was raw data
- ..and not included in the training (no bias!)

tut for Iboud Procurement and implementation completed in a compressed process of 3 months – in a strong collaboration between CIMT, Human Bytes / Transpara and clinical staff from the Breast Cancer Screening Program in RegionH



Implementation of AI in Capital Mammography Screening Programme in Denmark

Main goal has been to reduce radiologist workload keeping quality indicators stable

Screening mammography

- 2 standardized views: CC + MLO
- No clinical examination or UL



Time consumption

- 6-10 minutes in the examination room at the screening clinics (radiographers)
- <1-3 min. x 2/ exam centralized double blind readings (two radiologists)</p>

Screening mammography

2 standardized vie

No clinical examir

Hard competion considering

workload reduction

but...



Time consumption 6-10 minutes in the Centralized double

Target group in DK ≥735.000 Q aged 50-69 år; 220.000 Q in RegionH

Extended offer to breast cancer treated women aged 70-79 years; 8150 Q in Capital Region

ns are working)

5 Screening Clinics in Capital Region, DK













Mammograms analyzed by Transpara Al



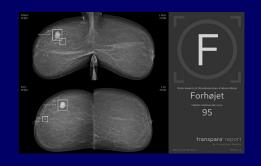
Local regional score



Selection of highest regional score



Stratification into risk categories on a scale from 1-100





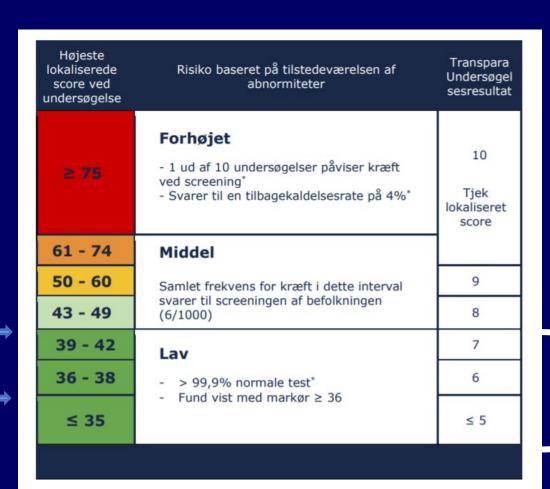


Relation between scores

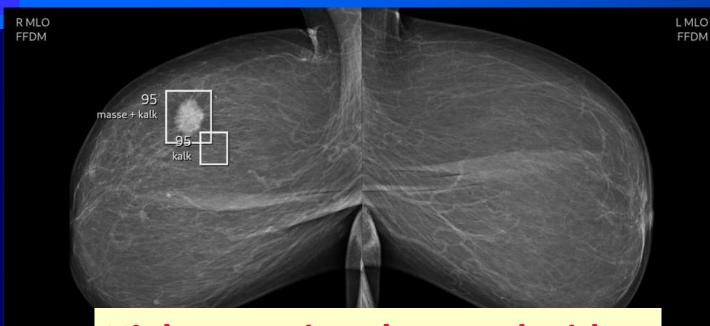
Capital Region: Score 78 = recall rate på 2,5%

3th of May 2022 AI first reader of whole low risk group

18th of November 2021



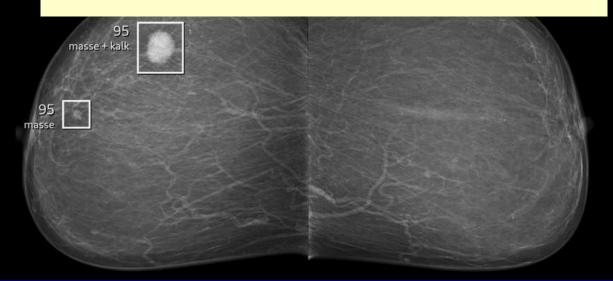
>70%



Highest regional score decides the final risk score

RCC

FFDM



Risiko baseret på tilstedeværelsen af abnormiteter

Forhøjet

Højeste lokaliserede score

95

transpara® report

By ScreenPoint Medica

Ikke til primær granskning

LCC

FFDM

Version 1.7.0



Al has no previous exams to compare with- but the radiologists have them!

R CC
FFDM

95
masse + kalk

95
masse



Risiko baseret på tilstedeværelsen af abnormiteter

Forhøjet

Højeste lokaliserede score

95

transpara® report

By ScreenPoint Medical

Ikke til primær granskning

Version 1.7.0

Workflow in Capital Region DK Al+Single or double reading?

Women with low risk score

from $3/5\ 2022\ all\ with\ score \le 42\ (<36\ from\ 18/11\ 2021-3/5\ 2022)$

Al (first reader) + one breast radiologist (second reader)

Consensus list in case of disagreement Allways a radiologist who decide!

Women with **intermediate or high risk score**

Double blind readings as usual by two breast radiologists (with AI assistance)

(no direct recall)

Danish National Mammography Screening program 2008-2020

National Performance Indicators

(Danish Quality Database for Mammography Screening)

Performance		Invitation	round				
Indicator (Number)	First 2008-	Second 2010-	Third 2012-	Fourth 2014-	Fifth 2016-2018	Sixth 2018-2020	7th 2020-
2 a. Participation (%invited)	2009/2010 76%	2011/12 82%	2013/14 84%	2015/16 83%	83%	84%	2023 83%
b. Coverage (% target)	75%	75%	77%	76%	79%	79%	79%
4. Recall rate	3%	2,7%	2,7%	2,5%	2,4%	2,4%	<mark>2,4%</mark>
False-positive rate	2.0%	2.1%	2.1%	1.9%	1,8%	<mark>1,8%</mark>	<mark>1,7%</mark>
Detection rate (IC+DCIS)	0.93%	0.62%	0.67%	0.61%	0.62%	<mark>0,61%</mark>	0,66%
5. Interval cancer rate (Interval IC / Interval IC+ screen detected < 12 / 12-24 months after)	NA	NA	12% 21%	11% 19%	11% 20%	12,4% 21%	12,4% 20,6%
6. Invasive % (IC / IC+DCIS)	87%	86%	86%	86%	87%	<mark>85%</mark>	83,8%
7. Lymph node neg %	70%	75%	78%	81%	76%	<mark>78%</mark>	<mark>76%</mark>
8. Small tumor ≤1cm %	37%	39%	37%	37%	37%	37%	<mark>37%</mark>
9. Benign : malign operation ratio	1:6	1:7	1:8	1:9	1:10,5	1:10	1:10
10.BCS % (BCS / BCS+ mastectomy)	80%	81%	83%	No longer in use	Not in use	Not in us)

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4. Recall rate		l increase	in recai	i rate de	creases	<mark>,4%</mark>	
False-positive rate the	the benefit! ,8%						
Detection rate (IC+DCI						<mark>61%</mark>	
5. Interval cancer rate (Interval IC / Interval IC+ screen detected < 12 / 12-24 months a det							
6. Invasive % (IC / IC+DCIS and evt. needle biopsy) matches = 30-50 single readings 5%							
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Early data on Recall rate

6.Screening Round (1.July 2018- 31.September 2020):

2,5%

7.Screening Round Before Al. (1st October 2020- 17th of November 2021; 63.682 q):

3.09%

Women with a previous breast cancer diagnosis was highly prioritized over the normal screening population; same distribution (4.6% / 4.7%) of Q having history of BC operation before and after AI

After Al (18^{th,} November 2021- 31st of December 2022; 79.270 q):

Recall rate **before** increase of threshold: **2.72%**

Recall rate **after** increase of threshold: **2.29**%

In total with AI: 2.46%

Recall rate for low risk: 0.40% (14 cancers/ 53.438 us= detection rate 0,026%)

Recall rate for **intermediate and high:** 6.65%

Screening with AI as 1st reader (18th Nov. 2021- 31st December 2022) = 67.41% (53.438 / 79.270 screenings)

Early data on Recall rate

6.Screening Round (1.July 2018- 31.September 2020):

2,5%

7.Screening Roun

Low risk group

Women with a previou distribution (4.6% /4.7

 14 cancers amongst 215 recalled women

• All cancers were new or lesions changed since last exam

Recall rate **before**Recall rate **after** in **In total** with AI:

 Al has no previous images to compare with- radiologists do! g population; same

q):

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Work load reduction for radiologists reading

(18/11 2021 – 17/10 2022)

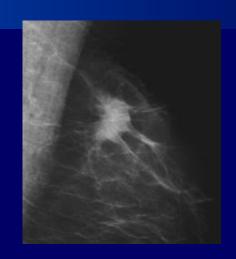
66.9% read by AI as 1st reader





(≥35% after change of level)

Cancer detection rate



Before AI: 60.751 screenings from 1/10-2020 to 17/11-2021

With AI: 56,894 screenings from 18/11-2021 to 17/10-2022

Look ahead: ≥ 180 days.

CDR (before AI) = 0.70%

CDR (with AI) = 0.82% (P < .01)

Cancer Detection (Early Indicators)

Before AI: 60.751 screenings from 1/10-2020 to 17/11-2021 **With AI:** 56,894 screenings from 18/11-2021 to 17/10-2022

Based on a needle biopsy or pathology following surgery within ≥ 180 days from screening visit positive for IC and/or DCIS.

Percentage screen detected small invasive cancers ≤ 1 cm

Small cancer rate (before AI) = 36.60%

Small cancer rate (with AI) = 44.93% (P = .02)

Percentage lymph node neg. screen detected Invasive cancers

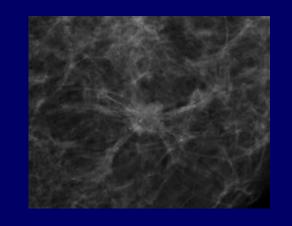
Node negative rate (before AI) = 76.67%

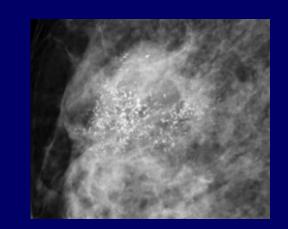
Node negative rate (with AI) = 77.78% (P= .73, NS)

Distribution of screen detected IC versus DCIS

IC/IC + DCIS (before AI) = 84.87%

IC/IC + DCIS (with AI) = 79.58% (P=.04)

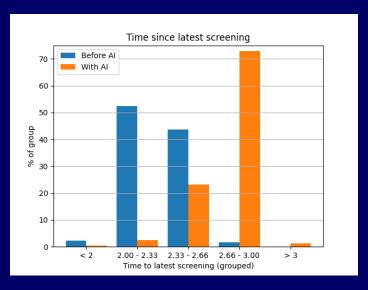




Population characteristics and possible bias

	BEFORE AI 1/10-2020 to 17/11-2021	WITH AI 18/11-2021 to 17/10-2022
SCREENED WOMEN	60,751	58,246
MEDIAN AGE (IQR)	58 (54, 64)	58 (54, 64)
MEAN BI-RADS DENSITY (± STD)	1.8 (±0.8)	1.8 (±0.8)
PREVIOUS BC SURGURY	2,799 (4.6%)	2,736 (4.7%)
AVG. SCREENING INTERVAL	2 year, 121 days	2 years, 256 days

Cancer Detection Rate and Screening Interval before and after Al



Group	CDR, Before Al	CDR, With Al	P-value
2.00 - 2.33 years	0.73% (0.63%, 0.84%)	1.03% (0.45%, 1.61%)	0.25 (ns)
2.33 - 2.66 years	0.64% (0.53%, 0.75%)	0.96% (0.77%, 1.15%)	0.002 (**)
2.66 - 3.00 years	0.66% (0.08%, 1.25%)	0.77% (0.68%, 0.87%)	0.74 (ns)

Conclusion



 Background for implementation: Very promising results in our large retrospective simulations study

Prospective results:

- AI is a valuable tool for risk stratification on basis of analysis of the mammograms (> 70 % stratified as low risk)
- Substantial workload reduction in readings for breast radiologists (≥35%)
- ≥ 20% reduction in recalls
- Early quality indicators show at least as good results as previously
- Whats next?
 - -Data on interval cancers

Thank you for your attention!

