Lessons Learned from Computer-Aided Detection in Medical Imaging

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Lessons Learned

- Most important factor in developing a CADe system is a high quality, large database
- Most important aspect of clinical implementation is the psychology of radiologists using CADe
- How CADe output is presented to the radiologist can affect radiologists' performance

Financial Disclosure

Robert Nishikawa:

- **shareholder in and receives royalties & research funding from Hologic, Inc.**
- **Paid consultant to Hologic, Inc and iCAD, Inc.**

Outline

1. Need for CAD
2. Commercial offerings
3. How a CAD system is developed from a clinical and technical point of view
4. Technical description of one application
5. Regulator approval
6. Clinical findings

1. Need for CAD in Mammography

- In mammographic screening:
  - FN rate is ~50%
  - FP rate is ~10%
- Cancer prevalence is 0.5%
- Nevertheless, screening mammography can reduce breast cancer mortality by up to 40%

1. Need for CAD

- Interpretation of an image is subjective
- Intra- and inter-reader variability
- Breast cancer screening is a dichotomy:
  - detection of microcalcifications
    - » small high contrast
    - » need to zoom image
  - detection of masses
    - » large low contrast
    - » masked or obscured by normal breast tissue
    - » pseudo-lesions

2. Commercial Systems

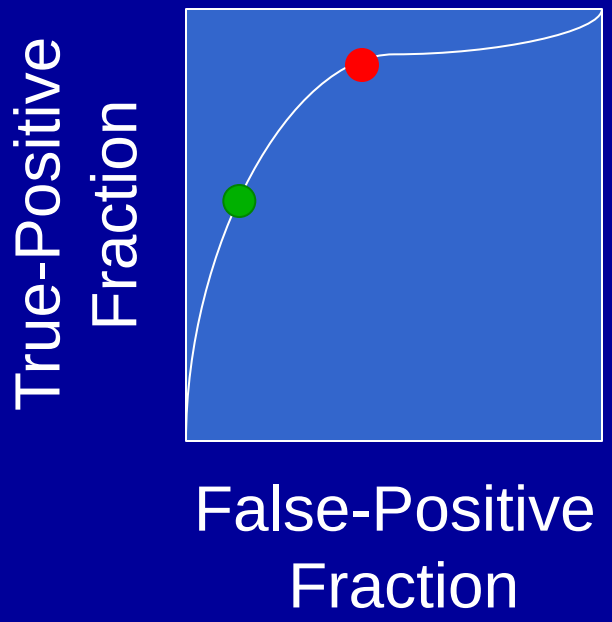
- CADe mammography
  - 4 approved systems in the USA
  - >75% of mammograms read with CADe
- CADe lung cancer
  - chest x-ray
  - chest CT
- CADe colon cancer
  - CT colonography

3. CADe System Development

- Develop database
  - ~1000 abnormal, ~1000 normal
  - Establishing truth can be difficult
    - » biopsy or follow-up
    - » consensus of experts
  - divide into 3 sets: development, training, testing
- Separate evaluation database
  - <~1000 cases

3. CADe System Development

- **Develop algorithm**
- **Train classifier (ROC analysis)**
- **Test (ROC analysis)**
- **Select operating point on ROC curve**



4. Technical Description of One CADe Application

- **Omitting**

5. Regulatory Approval

- FDA ensures safety and effectiveness
- CADe requires FDA PMA
- Changes to an approved system requires 510K approval
- PMA requires an observer study
  - 300 cases (new set of cases)
  - 15 radiologists
  - >$1,000,000
  - >1 year to complete study

6. Clinical Findings

- 7 clinical studies found 9.3% increase in sensitivity and a 12.4% increase in recall rate
- study design to evaluate CADe can be tricky
  - 4 clinical studies with flawed design
  - bias in estimating sensitivity

Clinical Issues

Medical

- indolent cancers

- benign lesions
- FN on aggressive cancer can be fatal
- FP adds cost and affect workflow

Parallels: CADe to ATR

Medical	Security
• indolent cancers	• guns carried by non-terrorists
• benign lesions	• water bottles
• FN on aggressive cancer can be fatal	• FN on targets can be fatal
• FP adds cost and affect workflow	• FP adds cost and affect workflow

Differences

- Mammography has 2 views of each breast and temporal comparisons
- Need to be concerned about radiation dose
  - retakes for ambiguous findings are not done

CADe as a Second Reader

0 radiologists detected without CADe

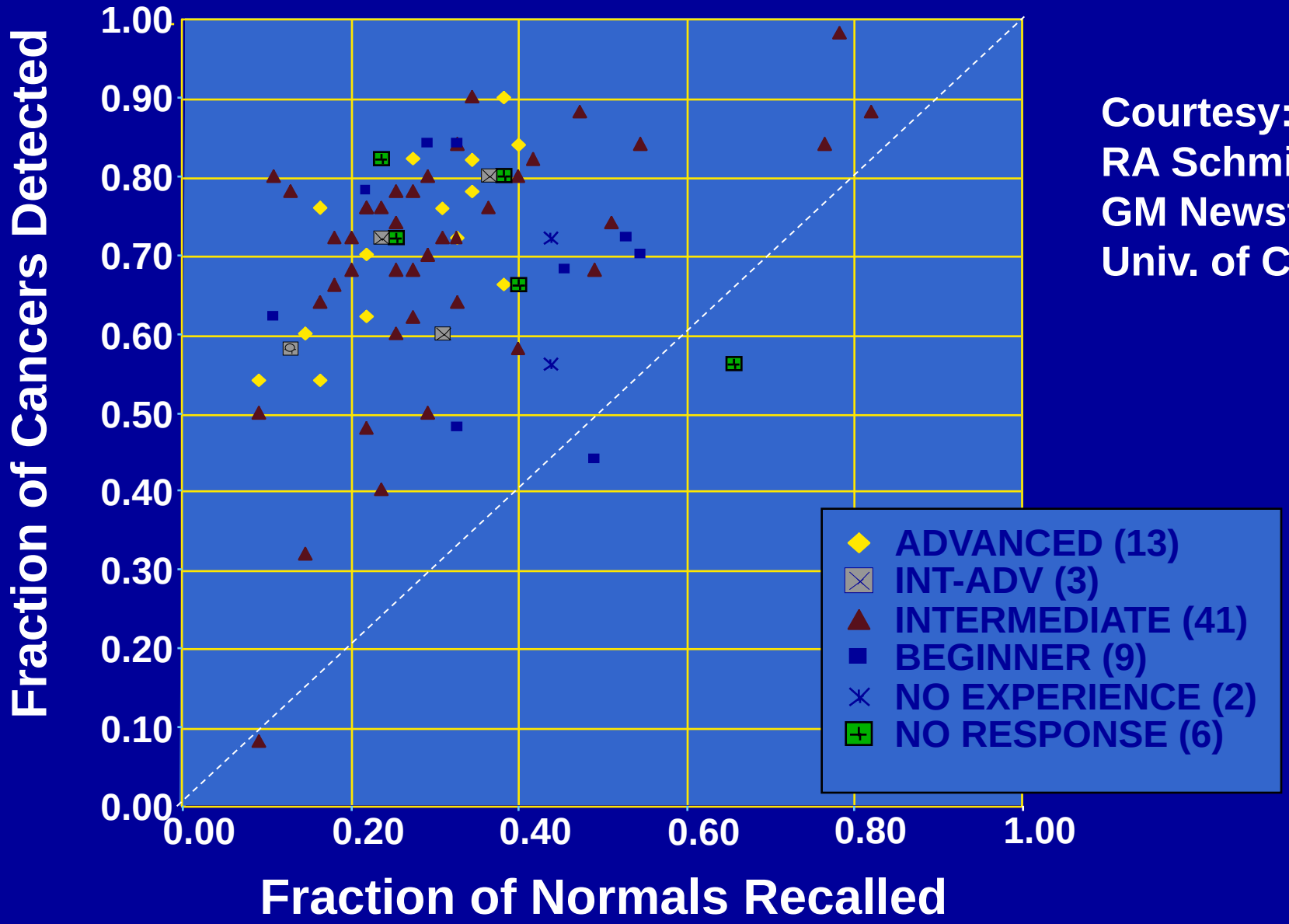
3 radiologists detected with CADe

5 radiologist ignored the correct CADe mark (lower asterisk)

Observer Study

- 8 radiologists reading 300 screening exams
- 69 cancers (all missed clinically)
- reading without CADe sensitivity = 0.549
- reading with CADe sensitivity = 0.603
- 9.9% in sensitivity (12.4% increase in recall rate)
- radiologists ignored 70% of TP marks

Radiologists' Variation in Screening Mammography



Courtesy:
RA Schmidt,
GM Newstead,
Univ. of Chicago

Psychology of Using CADe

- **Radiologist need to believe that CADe will be helpful**
  - **missed caner prevalence is 2 in 1000**
  - **CADe may mark 50% or 2 TP marks in 1000 cases**
  - **CADe FP marks will be 2000 marks**
  - **1 true mark for every 999 false marks**
  - **no feedback when you correctly found cancer or when you missed a cancer**

Human Detection Performance at Low Cancer Prevalence

- **Jeremy Wolfe et al.**

Prevalence	Miss Rate
50%	12%
1%	30%

- **“cognitively impenetrable"**

The CADe Learning Curve

Dean et al. (AJR 2006)

Time Period	Recall Rate	% Increase
Before CADe	6.2% (65/1047)	---
Months 1 - 2	13.4% (50/374)	116%
Months 3 - 21	7.8% (326/4157)	25%
Months 22 - 26	6.75% (59/874)	10%

(Increase in sensitivity was 7.6%)

Concurrent Reading with CADe

- CADe microcalcification detection is 98%
- Concurrent reading with CADe may reduce reading times
- Higher likelihood of a radiologist FN, if CADe did not mark the cancer
  - CADe mass detection is ~85%

Interactive CADe

- Karssemeijer has proposed using CADe interactively
- Radiologist queries suspicious lesions and is shown the CADe output
- Can reduce interpretation errors by radiologist
- Can improve radiologists' performance more than 2nd reader method

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