Influence of available information on the correct assessment of interval carcinomas (ICA) - a pilot study

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Purpose

In Germany a systematic assessment of interval cancers is demanded as part of the national screening program. The matching of cancer registry data and screening data is supported by law. However, obtaining additional clinical information and diagnostic mammograms is impossible to obtain for part of the cases due to data protection. A first data set of consecutive interval carcinomas has become available. As known, the available information and the way of review will influence the results (1). The study served to evaluate the reliability of the classification of interval carcinomas depending on the available package of information.
Methods and Materials

-66 consecutive interval cancers of one screening unit (SU) were available for the study.

The study was performed in several rounds of reading (blinded independent reading, non-blinded independent classification based on different packages of information including available images, and a consented final classification based on all available information).

The consented final classification based on all available information for each case was considered the goldstandard.

Based on the gold standard correctness and completeness of the available information from different sources was rated.

Next, 3 independent readings were performed by 4 directors of reference centers (blinded to each others' diagnoses):

- Reading 1 (screening mammograms only, blinded to the final diagnoses). This reading is not evaluated in this study.
- Reading 2 (based on screening mammograms and info from cancer registry)
- Reading 3 (based on screening mammograms, info from cancer registry, clinical info and -where available- diagnostic mammograms)

Finally a consensus followed based on all available data and readings.

The study was evaluated with respect to the goldstandard, as follows:

First correctness and completeness of the information from the different sources was analysed.

Next the readings of each reviewer were evaluated:

Cases, considered as not classifiable by consensus, were identified and excluded from further analysis.

The recorded readings were rated as correct (with respect to the final reading), underestimate or overestimate with respect to the gold standard. Diagnosis of a final classification of "no sign" as
"false negative" was considered a "severe overestimate"; diagnosis of an agreed "false negative" as "no sign" was considered a severe underestimate.

Finally the number of evaluable cases rated as under- or overestimate or non-classifiable were counted per reading round and the change of accuracy depending on the available information was evaluated.

Source of information (number of cases with the corresponding information)

- Screening mammograms (66)
- Data from cancer registry (66): mostly with TNM, type of cancer, laterality; some cases with info on quadrant (38)
- Clinical data at the time of diagnosis (38)
- Diagnostic mammograms (36)

the diagnosis had to include information on:

- Lesion location (laterality, clock position, distance to nipple
- Lesion type and size
- Classification of IVC (no sign, minimal sign, false negative, not classifiable

For the final consented diagnosis a case was considered "classifiable", if

- Consensus that the screening mammogram was unsuspicious (irrespective of the available information)
- Diagnostic mammogram was not available, but info on location was unequivocal based on cancer registry and documented clinical info
- Diagnostic mammogram available and info on location was compatible with cancer registry data, clinical information and consensus

Disadvantage: possible underrepresentation of minimal signs
Results

Cases considered "not classifiable" by consensus

4/11 cases with a diagnostic mammogram:
- clin. info und CR-info inconclusive (2) with inconclusive DXMX
- clin. info und CR-info insufficient (1) and DXMX equivocal
- CR-info insufficient, clin. info and DXMX not compatible (1)

7/11 cases without a diagnostic mammogram:
- clin. info and CR-info insufficient, SCRMX equivocal (5)
- discrepancy of clin. info, CR-info and SCRMX (2)

Example case:

This example demonstrates the problem of accurate classification and the need for information that is as complete as possible and the value of consensus reading of IVCs:

CR info was quite detailed indicating a cancer in the right upper inner quadrant. However, it is still insufficient for distinguishing, which density on the cc mammogram eventually proved an IVC. Clinical info indicating a cancer on the right was insufficient in this case. The true

location of the IVC is proven by the DXMX only.

Based on CRinfo and SCRMX the case was read: 3 x minimal sign, 1 x fneg. The consensus was: minimal sign. However, according to the opinion of some of the authors a Classification as "no sign" might also be justified, since the very faint density that eventually turned out to become an IVC is indistinguishable from normal nodularity and was by far less obvious than the neighbouring density posteriorly.

Evaluation of prospective reading:

- Available data sets 4 x 66
- Available data sets: 264 readings
- 108 readings of cases with final diagnosis "no sign"
- 72 readings of cases with final diagnosis "minimal sign"
- 40 readings of cases with final diagnosis "false negative"

**Result of reading based on different information:**

- Some of the cases considered as not classifiable could only be correctly recognized based on all available information

- The number of over- and underestimates among classified cases is higher if limited information is available

- Severe overestimates occurred in 4 cases with limited info (reading 2) and in 2 cases with full info (reading 3). One severe underestimate occurred in 1 case with limited info (reading 2) and in no case with full info (reading 3).
### Table 1: Accuracy and completeness of data sources (55 classifiable IVC) * 3 cases with insufficient CR and clin. info, but obvious findings on SCRMX were classified as fneg by consensus ** 4 cases could only be correctly classified based on the DXMX

<table>
<thead>
<tr>
<th>Data source</th>
<th>Cases with sufficient, correct and unequivocal info for classification</th>
<th>Insufficient or discrepant info</th>
<th>Incorrect info</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer registry only</td>
<td>36 (65%)</td>
<td>17 (31%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Clinical info only</td>
<td>38 (69%)</td>
<td>17 (31%)</td>
<td>0</td>
</tr>
<tr>
<td>Clin and CR info together</td>
<td>48 (87%)</td>
<td>7 (13%)</td>
<td>0</td>
</tr>
<tr>
<td>Clin and CR info + consensus (3* cases)</td>
<td>51 (93%)</td>
<td>4 (7%)**</td>
<td>0</td>
</tr>
</tbody>
</table>
Fig. 1: Final Classification

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Fig. 2: Example case: SCR-MX: RCC and LCC

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Fig. 3: Example case: SCR-MX: RMLO and LMLO

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Fig. 4: Example case: DX-MX: RCC and LCC 18 month later

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Fig. 5: Example case: DX-MX: RMLO and LMLO

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**Fig. 6:** Example case: SCR-MX and DXMX: RCC

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Fig. 7: Example case: SCR-MX and DXMX: RMLO

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Fig. 8: Reading 2: based on SCRMX and CR-info

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<table>
<thead>
<tr>
<th>FINAL DX</th>
<th>ov-est-Diagn</th>
<th>und-est Diagn</th>
<th>&quot;not classified&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>no signs</td>
<td>26</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>min signs</td>
<td>32</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>f neg</td>
<td>0</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>ALL</td>
<td>58</td>
<td>11</td>
<td>9</td>
</tr>
</tbody>
</table>

Fig. 9: Reading 3: based on SCRMX, CR-info, clin info and DXMX where available

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Fig. 10: Reading 2: based on SCRMX and CR-info

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Fig. 11: Reading 3: based on SCRMX and CR-info, clin. Info, DXMX/where available

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Conclusion

- All data sources may contain incomplete or incorrect information in a significant percentage of cases

- A maximum of information and redundant information is needed for correct classification and countercheck of reliable information

- Even with complete information classification may be impossible in a certain percentage of cases and errors are difficult to exclude

- Accuracy increases with increasing information

- Diagnostic mammograms are important and were essential for the correct classification of 4/66 cases

- Due to significant interobserver variability significant experience with reading of IVC and consensus reading are essential

- In case of discrepant reading no classification may be preferrable

Limitations of this study include:

- Remaining uncertainty with the gold standard

- Some Bias for "no sign" und "false negative diagnoses" among those IVC rates as "classifiable"

- Small number

- Learning curve of the readers (in spite of screening experience)

CLASSIFICATION OF IVC IS DIFFICULT REQUIRING DILIGENT AND CRITICAL ANALYSIS
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