CLINICAL DECISION SUPPORT FOR THE CLASSIFICATION OF DIABETIC RETINOPATHY: A COMPARISON OF MANUAL AND AUTOMATED RESULTS.

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Diabetes Mellitus and Diabetic Retinopathy

• Diabetic retinopathy (DR) is the leading cause of visual impairment in working-age adults worldwide.

• Proportion of people who have a predominantly sedentary lifestyle and are overweight is growing worldwide.

• The prevalence of type 2 DM and thus of DR is continuously increasing, burdening healthcare systems all over the world.
Diabetes Mellitus and Diabetic Retinopathy

• DM and DR need to be examined regularly by various specialists: At least one general practitioner and one ophthalmologist are involved in a patient’s routine check-ups.

• Follow-up intervals should depend on the current stage of disease progression.
Aim of this study

• We are not aware of any published efforts to use clinical decision support (CDS) technology in the classification of DR.

• To compare the results of manual classification of DR with those of a CDS-based automated classification and assess the applicability and safety of the CDS-based automated with the manual method for disease classification.
Diabetic Retinopathy

- Microaneurysms
- Hemorrhages
- Intraretinal Microvascular Anomaly
- Cotton Wool Spots
- Hard Exudates
- Hemorrhages
# International Clinical Disease Classification Scale

<table>
<thead>
<tr>
<th>Severity Level</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>No retinopathy</td>
<td>No abnormalities</td>
</tr>
<tr>
<td>Mild DR</td>
<td>Microaneurysms only</td>
</tr>
<tr>
<td>Moderate DR</td>
<td>More than just microaneurysms but less than severe DR</td>
</tr>
<tr>
<td>Severe DR</td>
<td><strong>Any of the following:</strong></td>
</tr>
<tr>
<td></td>
<td>• More than 20 intraretinal hemorrhages in each of four quadrants</td>
</tr>
<tr>
<td></td>
<td>• Venous beading in two or more quadrants</td>
</tr>
<tr>
<td></td>
<td>• Prominent IRMA in one or more quadrants</td>
</tr>
<tr>
<td></td>
<td>.. and no signs of proliferative DR</td>
</tr>
<tr>
<td>Proliferative DR</td>
<td><strong>One or both of the following:</strong></td>
</tr>
<tr>
<td></td>
<td>• Neovascularization</td>
</tr>
<tr>
<td></td>
<td>• Vitreous/pre-retinal hemorrhage</td>
</tr>
</tbody>
</table>
Manual Classification

- Observable findings
- Disease classification
  - No Classification or no retinopathy
  - Mild (M1), Moderate (M2), Severe (M3), Proliferative Retinopathy (M4)
- Retreatment Interval
- No mandatory fields + no check for consistency
Automated Classification: Arden MLM

IF ((vitreous_hem_od = "true") OR (nvd_od = "true") OR (nvd_od = "active")
OR (nvd_od = "fibrotic") OR (nvd_od = "fibrotic with traction") OR (nve_od = "true")
OR (nve_od = "active") OR (nve_od="fibrotic") OR (nve_od = "fibrotic with traction")
OR (rub_od = "true"))
THEN
    result.ScoreOD := 4; # proliferative DR
Results

• 5727 visits
• 1303 out-patients between 2012 and 2015
• 11454 eye examinations
Results

Manual classification
7530 eyes

Automated classification
10293 eyes

Includable subset: 7169 eyes
Missing Manual Grading

• All eyes which had not presented with DR or no classification had been documented: 34.3% (n=3924) of all screened eyes

• No manual grading, but automated classification: 27.3% (n=3124) of all screened eyes
Impossible Automated Grading

• Missing findings documentation
  10.1% (n=1161) of all screened eyes

• Automated classification not possible, but manual classification present:
  3.2% (n=361) of all screened eyes
No Grading

- No manual or automated classification was available for 7% (n=800) of all screened eyes
Results

0: no retinopathy
1: mild DR
2: moderate DR
3: severe DR
4: proliferative DR
## Results

<table>
<thead>
<tr>
<th></th>
<th>A0</th>
<th>A1</th>
<th>A2</th>
<th>A3</th>
<th>A4</th>
</tr>
</thead>
<tbody>
<tr>
<td>M1</td>
<td>3.8% (n=275)</td>
<td>4.2% (n=300)</td>
<td>5.2% (n=376)</td>
<td>0.4% (n=32)</td>
<td>0.5% (n=37)</td>
</tr>
<tr>
<td>M2</td>
<td>4.3% (n=306)</td>
<td>5.9% (n=421)</td>
<td>8.9% (n=638)</td>
<td>2.5% (n=176)</td>
<td>1.7% (n=125)</td>
</tr>
<tr>
<td>M3</td>
<td>3.3% (n=237)</td>
<td>2.4% (n=172)</td>
<td>3.1% (n=224)</td>
<td>5.1% (n=368)</td>
<td>4.7% (n=334)</td>
</tr>
<tr>
<td>M4</td>
<td>6.4% (n=459)</td>
<td>3.1% (n=224)</td>
<td>3% (n=212)</td>
<td>2.6% (n=186)</td>
<td>28.8% (n=2067)</td>
</tr>
</tbody>
</table>

0: no retinopathy. 1: mild DR. 2: moderate DR. 3: severe DR. 4: proliferative DR.
Results

Differences

Difference in severity grades

eyes

-4 -3 -2 -1 0 1 2 3
Results

1: mild DR
2: moderate DR
3: severe DR
4: proliferative DR
Discussion

• The overall agreement proportion between both methods was 47%
• Not satisfactory
• Tertiary care center with focus on the management of more advanced disease: agreement proportion 65.7% amongst proliferative cases
Discussion

- High patient load
- Findings, Classification, Reexamination Interval: redundant data (linked by guidelines)
- Most important piece of information:
  - Intervention necessary?
  - If not: reexamination interval
Discussion

Goal:

- Preserve EHR **usage flexibility**
- CDS **facultative**
  
  • If used: follow documentation rules (verified by UI)
Conclusion

The implementation of a CDS system for automated disease severity classification in an outpatient clinic treating patients with diabetic retinopathy is technically and medically feasible. Specific adaptation to the EHR structure is required in order to yield reliable results.