Validation of a predictive model for diabetic retinopathy progression in type-2 diabetic patients with mild nonproliferative diabetic retinopathy

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#4693

Purpose


Methods

Study Design
2-years observational, prospective (months 0, 6 and 24)
412 type-2 diabetic patients with mild NPDR

Population (initial 6-month follow-up period)
282 patients/eyes (3 withdraw consent and 2 were treated before V6)

Vital signs and blood tests were assessed (Systolic and Diastolic Blood Pressure; HbA1C; Cholesterol; HDL and; Triglycerides).

Image Analysis (Non-Invasive Procedures)
- Color Fundus Photography for semi-automated Microaneurysm Formation Rate (MAFR).
- Retinal Thickness (RT) measurements and Increased RT maps (Stratus OCT – Carl Zeiss Meditec, USA) using proprietary software.

Phenotypes
- Phenotype 1: MAFR < 2 & Normal RT
- Phenotype 2: MAFR ≥ 2 & Increased RT
- Phenotype 3: MAFR > 2 & Normal or Increased RT

Results

Phenotypes of mild NPDR

- Phenotype 1 - Low MAFR & Normal RT

- Phenotype 2 - Low MAFR & Increased RT

- Phenotype 3 - High MAFR & Normal or Increased RT

First 6-months follow-up (V0 & V6)
282 patients (176 males and 106 females)
- Age: 61.5 ± 8.3 years and Diabetes Duration: 10.0 ± 5.0 years

Significant Differences between Phenotypes

<table>
<thead>
<tr>
<th>Phenotype 1</th>
<th>Phenotype 2</th>
<th>Phenotype 3</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>62.2 ± 7.7</td>
<td>62.2 ± 8.0</td>
<td>60.0 ± 8.9</td>
</tr>
<tr>
<td>Diabetes Duration [Years]</td>
<td>9.6 ± 4.6</td>
<td>10.2 ± 5.1</td>
<td>9.9 ± 5.2</td>
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<tr>
<td>Systolic Blood Pressure [mmHg]</td>
<td>154.2 ± 22.1</td>
<td>152.3 ± 23.1</td>
<td>150.1 ± 20.6</td>
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<tr>
<td>Diastolic Blood Pressure [mmHg]</td>
<td>76.1 ± 10.6</td>
<td>75.9 ± 10.7</td>
<td>76.4 ± 11.2</td>
</tr>
<tr>
<td>HbA1C [%]</td>
<td>7.8 ± 1.3</td>
<td>8.1 ± 1.3*</td>
<td>8.3 ± 1.2*</td>
</tr>
<tr>
<td>Cholesterol [mg/dl]</td>
<td>195.5 ± 39.9</td>
<td>198.6 ± 40.6</td>
<td>196.2 ± 43.1</td>
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<tr>
<td>HDL [mg/dl]</td>
<td>52.0 ± 13.0</td>
<td>50.2 ± 10.6</td>
<td>50.1 ± 12.1</td>
</tr>
<tr>
<td>LDL [mg/dl]</td>
<td>127.1 ± 29.4</td>
<td>128.1 ± 33.9</td>
<td>126.7 ± 33.3</td>
</tr>
<tr>
<td>Triglycerides [mg/dl]</td>
<td>179.6 ± 82.9</td>
<td>171.1 ± 106.0</td>
<td>184.8 ± 138.1</td>
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</tbody>
</table>

- Only the HbA1C levels at baseline showed a statistically significant difference between phenotypes (P=0.033).

- Ophthalmological Parameters showed a statistically significant difference between phenotypes (P<0.001).

Conclusions

Preliminary data, based only on non-invasive imaging techniques, Color Fundus Photography and OCT, confirms the existence of 3 different phenotypes of DR progression.

The distribution of the 3 phenotypes is respectively of 40%, 26% and 34% and risk for CSME development is found only for Phenotypes 2 and 3.

Support: PTDC/SAD-084431/2006 (Fundação para a Ciência e Tecnologia); CR: None; Clinical Trial: NCT00840541 cntm@aibili.pt