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

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Purpose

To validate a predictive model for DR progression in type-2 diabetic patients with mild NPDR [Lobo *et al.*, Arch Ophthalmol. 2004; 122(2):211-7] using noninvasive examinations (Color Fundus Photography and OCT).

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

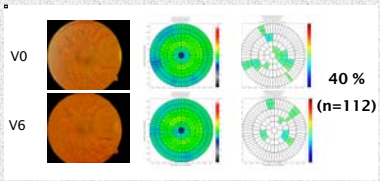
- Phenotype 1: MAFR ≤ 2 & Normal RT
- Phenotype 2: MAFR ≤ 2 & Increased RT
- Phenotype 3: MAFR > 2 & Normal or Increased RT

* Automated MA turnover is availiable now from Critical Health, SA. http://www.critical-health.com

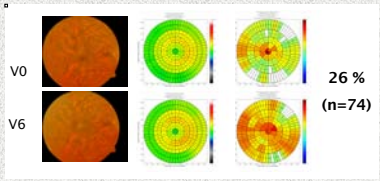
Results

Phenotypes of mild NPDR

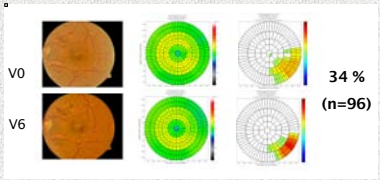
Phenotype 1 – Low MAFR & Normal RT



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

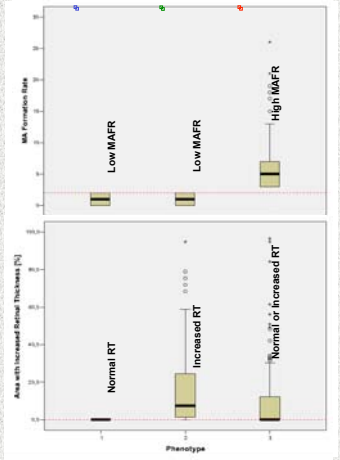
Significant Differences between Phenotypes

Table 1. Baseline – Systemic Characteristics.

	Fenotype 1	Fenotype 2	Fenotype 3	P
Age [Years]	62.2 ± 7.7	62.2 ± 8.0	60.0 ± 8.9	0.104
Diabetes Duration [Years]	9.6 ± 4.6	10.2 ± 5.1	9.9 ± 5.2	0.466
Systolic Blood Pressure [mmHg]	154.2 ± 22.1	152.3 ± 23.1	150.1 ± 20.6	0.515
Diastolic Blood Pressure [mmHg]	76.1 ± 10.6	75.9 ± 10.7	76.4 ± 11.2	0.921
HbA1c [%]	**7.8 ±1.5**	**8.1 ± 1.3***	**8.3 ± 1.7***	**0.033**
Cholesterol [mg/dl]	195.5 ± 38.9	198.6 ± 40.6	196.2 ± 43.1	0.984
HDL [mg/dl]	52.0 ± 13.0	50.2 ± 10.6	50.1 ± 12.1	0.638
LDL [mg/dl]	127.1 ± 29.4	128.1 ± 33.9	126.7 ± 33.3	0.968
Triglycerides [mg/dl]	179.6 ± 82.9	171.8 ± 106.0	184.8 ± 138.1	0.775

- 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).

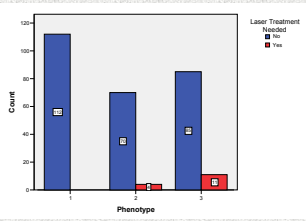


MAFR and Area with Increase RT for the 3 phenotypes (P<0.001).

Progression to Clinically Significant Macular Edema (CSME)

15 patients developed CSME after the 6-month follow-up period (P≤0.001)

- Phenotype 1: No CSME (0 %)
- Phenotype 2: 4 CSME (5 %)
- Phenotype 3: 11 CSME (12 %)



CSME needing laser treatment in each Phenotype (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.

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