AMD – A Metamorphopsia Detector

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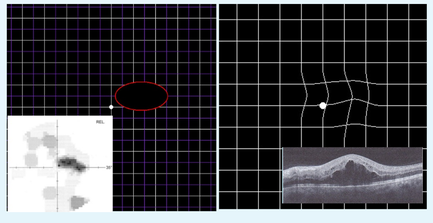
Purpose

The computer based App AMD – A Metamorphopsia Detector® was developed to provide a home monitoring tool to detect, measure and control the degree and size of metamorphopsias and scotomas. This study was performed to examine sensitivity and specificity of AMD - A Metamorphopsia Detector® and its correlation with anatomical course, functional development and quality of life. Our goal was to make metamorphopsias measurable, lower the diagnostic threshold and enhance persistence and adherence for diagnosis and therapy in order to detect macular pathology in time.
AMD – A Metamorphopsia Detector® is based on the Amsler grid[2]. The software uses the conception of a negative image: a distorted image can be straightened by moving the mouse. Degree and dimension of distorted lines or scotoma are transformed into indices, central findings are over-represented.

Method

I. In a pretest sensitivity, specificity, objectivity, reliability and construct validity of the AMD – A Metamorphopsia Detector® Metamorphopsia Module were examined in 34 patients (68 eyes) age 37-91: 13 exsudative age-related maculopathy, 40 normal macula, 1 keratokonus[1] without macular pathology, 1 macular edema due to central venous thrombosis, 1 macular pucker, 10 macular drusen[2], 1 diabetic macular edema, 1 central serous maculopathy[2].
II. In a second step 19 eyes (age 24-91) with SD-OCT documented maculopathies performed the metamorphopsia module alone or in combination with the scotoma module as well as the gold standard Amsler Test (age-related macular degeneration with macular edema = 5, age-related macular degeneration with macular drusen = 10, macular pucker = 2, myopic macular degeneration = 1, central serous retinopathy (RCS*) = 1).
III. In a prospective observational clinical pilot study we examined monocular best corrected distance visual acuity (logMAR, BCVA),vision related quality of life (National Eye Institute Visual Function Questionnaire NEI VFQ 25), slit lamp and dilated fundus exam, SD-OCT (spectral domain optical coherence tomography), Optomap fundus photography, and performed Amsler grid and the AMD – A Metamorphopsia Detector® Metamorphopsia Module with appropriate near correction in 13 eyes of 13 caucasian patients (6 male, 7 female, age 37-91) with macular edema before and after a therapy cycle of 3 intravitreal injections with an anti-vascular endothelial growth factor. The diagnoses for treatment were age-related wet MD = 12, myopic MD = 1) Accompanying ocular diseases were glaucoma in 1 eye; 1 eye developed clinically significant cataract during treatment.
All data were collected according to GCP (good clinical practice) and GSP (good statistical practice) as described in the Helsinki 1995 resp. Edinburgh 2000 declaration. Prior to the study all patients signed informed consent.



Results

I. Pretests confirmed objectivity, reliability and construct validity. In healthy eyes both Amsler test and AMD showed no pathological findings. Reliability was proved by repeating AMD in the same setting several hours later. When screening for macular pathology, sensitivity of AMD was 88%, specificity was 97%. x^2-Test lead to rejection of the zero hypothesis ($x^2 > 3.84$; freedom degree = 1, alpha = 0.05).

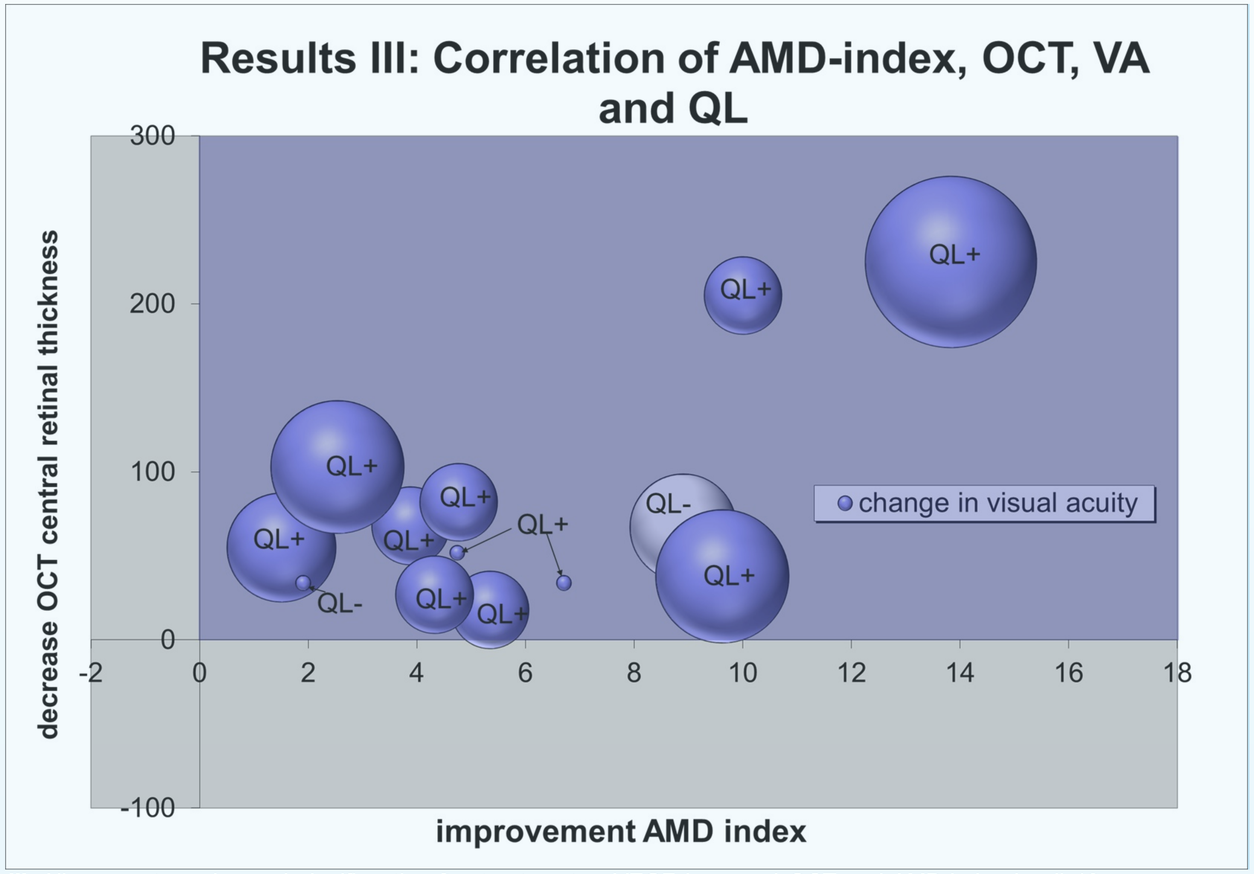
AMD result	OCT +	OCT -
AMD positive	24 correct positive	1 false positive[1]
AMD negative	3 false negative[2]	40 correct negative

Fig. 1: Results I

II. When a wider range of macular pathologies was included, addition of the scotoma module increased sensitivity from 0.88 to 0.94.
One eye* with RCS was detected by neither module. The likelihood to detect macular pathologies without metamorphopsias was improved (OR 3.37; 95% CI: 0.94 - 5.67) by combining both app modules.

n = 19	AMD positive	AMD negative
without visual field module	16	3
with visual field module	18	1*

Fig. 2: Results II



III. All parameters changed significantly after treatment: a-VEGF improved OCT and AMD-index in all 13 eyes: average decrease of central retinal thickness (CRT) was 77.54 µm (median 55 µm; SD 49.99; CI 111.74; 43.33), average decrease of metamorphopsia index was 6.0 (median 4.76; SD 3.5; CI 7.9; 4.1). BCVA improved in 9 (big blue bubbles), deteriorated in 1 (grey bubble) and was stable in 3 patients (small bubbles). Geometric mean BCVA was 0.38 logMAR (SD 0.28) before and 0.25 logMAR (SD 0,21) after treatment (CI 0.21; 0.03). NEI VFQ 25 increased (QL+) in 11 (mean 8.77; median 19; SD 12.39; CI 17.74; 3.65) and got worse (QL-) in 2 patients: one developed cataract and VA deteriorated as well, one was stable in VA but experienced visual field problems due to glaucoma. AMD-index results represented the majority of trends in OCT, BCVA, Amsler Test and NEI -VFQ 25.

Discussion

As an easy to use, economic mobile or at home test, the AMD App can possibly enhance self-efficacy, persistence and adherence in diseases associated with macular edema by lowering the diagnostic threshold and support early detection of macular pathologies and recurrences. In remote areas without easy access to ophthalmology services, the AMD App may play a role as a public health instrument and support early diagnosis and control of macular diseases. The WAVE, AURA and COMPASS Study[4,5,6] revealed that in clinical reality too few injections were given. By increasing the number of patients showing up for diagnostic procedures and control in time, AMD - A Metamorphopsia Detector® can help to reduce the economic burden of visual disability[7] and improve vision related quality of life[3].

Bias

Intensified contact with the ophthalmologist while performing the AMD Test might lead to response bias. Selection bias may occur when patients with low VA and those who are dissatisfied with former therapy are reluctant to participate in the study: they would consequently not be represented. Undiagnosed diseases could be reasons for information bias.

Limitations and Confounders

Interpretation of results is limited by small group size. Confounders: one patient developed cataract during treatment and thus experienced deterioration of visual acuity inspite of decreased index - presumably NEI-VFQ-25 got worse for the same reason.BCVA before therapy, age, sex, a caring and empathic doctor, therapy adherence, transport problems might be considered as a risk (or chance) for the examined result which is associated with exposure but not a cause for it.

Conclusion and Perspective

As a quantitative and operationalizable test AMD - A Metamorphopsia Detector® can support screening, early detection and (tele-)monitoring of macular disease by lowering the threshold for diagnosis, enhancing self-efficacy[1], compliance and adherence for exams and therapy in the treatment of age related macular degeneration and other diseases leading to macular pathology. Encrypted transmission of index, trend analysis and grafical result can supplement ophthalmological diagnosis. By supporting (potential) patients and medical staff, the AMD App may improve quality of life and diminish economical consequences of visual impairment. Ongoing studies examine the correlation between changes in OCT, BCVA and AMD-index by stratification and compare vision related quality of life in groups with and without access to

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