

BREAKING NEWS IN RETINA

Chaired by Prof. Tariq ASLAM



SUMMARY

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INTRODUCTION

In developed countries no other ocular condition is a bigger threat to eyesight than age-related macular degeneration (AMD). As suggested by its nomenclature, AMD preferentially affects the elderly and is therefore increasing in prevalence in all the countries facing demographic aging¹. As a result, AMD treatment expenses are on the rise and pose a challenge both to individuals and to society as a whole, making it evident that innovation in prevention, screening, diagnosis and quality of life in AMD is urgently needed.

In the last years OCT-Angiography (OCT-A) has found its way into clinical routine and because of its advantages, as compared to conventional angiographic methods, it is revolutionizing the way blood vessels are imaged on the retina and is altering the diagnostic algorithms in various retinal diseases.

While evidence-based therapeutic approaches are crucial to provide every patient with the individual therapy needed, preventing the necessity for treatment, i.e. prophylaxis, is even more important. To reach that goal, more and more has been learnt about risk factors for AMD onset and progression, which has made it possible to estimate the risk of AMD development with scales. One of them, the STARS[®] questionnaire, is a validated, fast tool to widen the net to catch patients at risk of AMD and to provide them with advice on the management of modifiable risk factors.

Great effort has been put into the field of nutrition for prevention of AMD progression and both AREDS and AREDS2 showed that certain nutritional supplements can influence disease progression in AMD patients. Lately, the possible role of vitamin D in this process has been under closer investigation and *in-vitro* data suggest a beneficial additive effect of vitamin D supplementation in AMD.

More emphasis has to be put on the quality of life of AMD patients, as converging evidence suggests that they have much higher rates of depression and anxiety than age-matched controls without AMD. Ophthalmologists are therefore encouraged to face this issue more thoroughly.

Prof. Tariq ASLAM

1. García-Layana A et al. Early and intermediate age-related macular degeneration: update and clinical review. Clin Interv Aging. 2017 Oct 3;12:1579-1587.



■ Prof. Remzi AVCI

OCT ANGIOGRAPHY OF THE RETINA

Though being a relatively new diagnostic tool, Optical Coherence Tomography-Angiography (OCT-A) has already led to substantial changes in the daily routine of ophthalmologists specialized in retinal pathologies. Most frequently the fast and easy handling, the redundancy of dye and the automatic segmentation for specific visualization of vascular structures in different retinal layers are stated as the main advantages when compared to the conventional dye injection-based angiographic procedures, fluorescein angiography (FA) and indocyanine green angiography (ICGA). The four different retinal vascular plexi which can be differentiated are the radial peripapillary vascular plexus, the superficial vascular plexus, the intermediate vascular plexus and the deep vascular plexus. These segments of the vascular bed are located in the optic

nerve fiber layer, the ganglion cell layer, the inner plexiform layer and the outer plexiform layer respectively. While the first three sheaths of vasculature belong to the arterial retinal capillary network, the deep vascular plexus is assigned to the venous side. OCT-A also plays a great role in the diagnostic imaging of choroidal neovascularisations (CNVs) (Figure 1), which will be further discussed hereinafter.

In AMD, OCT-A can serve as a clinically relevant diagnostic tool mainly in two different settings: first, the diagnosis of different types of exudative CNVs and retreatment decisions upon follow-up of anti- VEGF treated CNVs and second, the detection of non-exudative (quiescent) CNVs. The latter is defined by the detection of a CNV in OCT-A without haemorrhage, leaking or exudation in FA/

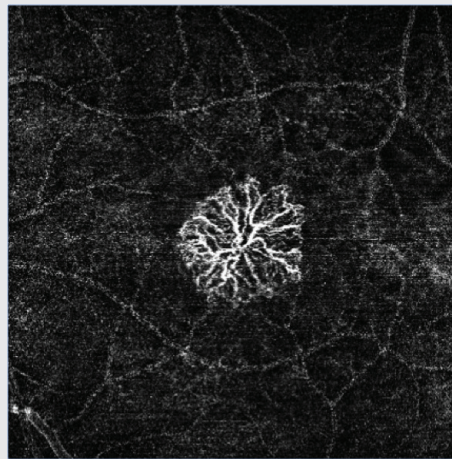


Figure 1: with permission from Prof. Avci

ICGA and no exudation in B-scan OCT. While an immediate onset of anti- VEGF treatment is not indicated in cases of non-exudative CNV, longitudinal data point at the urgent necessity to increase the frequency of follow-up examinations: in a cohort of 253 eyes with dry AMD, 19 eyes (7.5%) presented with nonexudative neovascular (NV)-AMD. After a mean follow- up of 12.7 months, as much as 47% (9/19) progressed to exudative NV-AMD². In another study 51 dry AMD eyes were followed over time. Of these, 9 eyes (17.6%) were primarily diagnosed with non- exudative NV-AMD. 24 months later 77.8% (7/9) had developed exudative NV-AMD while of the 42 eyes with non-exudative AMD without CNVs only 4 eyes (9.5%) progressed to exudative NV-AMD³.

In diagnosis of exudative CNVs OCT-A helps to reduce the necessity for conventional dye- based angiographic procedures. Inoue et. al. compared OCT-A and OCT-B scan with the gold- standard diagnostic

combination FA and OCT-B scan in type 1 CNVs and were able to correctly diagnose them in 85.7% of cases with the new combination⁴. Correlations for type II and type III CNVs were reported to be 100% when comparing FA and OCT-A^{5,6}. Therefore, Cohen et. al. suggested a new diagnostic algorithm (Figure 2) for CNVs in AMD⁷. While they clearly state that FA and ICGA will still be needed in doubtful cases and in clinical studies, they point out that this practical algorithm could avoid invasive angiographic procedures in obvious situations. Practical experience shows that this algorithm can in fact reduce FA and ICGA use in the described setting by more than 80%.

While complex and expertise demanding artefacts are currently relevant drawbacks of OCT-A, its great advantages and impact on state-of-the-art retinal diagnostics are equally undeniable.

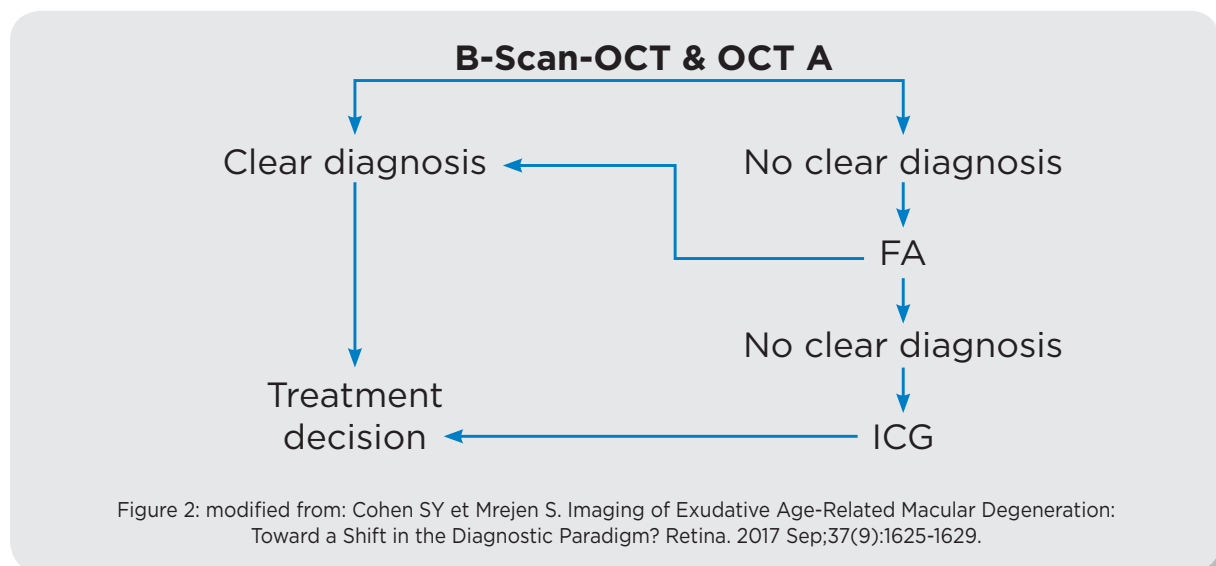


Figure 2: modified from: Cohen SY et Mrejen S. Imaging of Exudative Age-Related Macular Degeneration: Toward a Shift in the Diagnostic Paradigm? Retina. 2017 Sep;37(9):1625-1629.



IN CONCLUSION

OCT-A is a developing technology and we are still learning. While not demanding instant therapeutic steps, quiescent CNVs need to be followed up continuously. OCT A and B-Scan OCT can be sufficient in the diagnosis of exudative AMD in the majority of cases and therefore reduce the need to apply FA or ICGA routinely in exudative AMD before treatment decision.

2. Chen et al. ; Rome OCT-A Symposium December 2017.
3. Bailey et al. ; Rome OCT-A Symposium December 2017.
4. Inoue M et al. A comparison between optical coherence tomography angiography and fluorescein angiography for the imaging of type 1 neovascularization. Invest Ophthalmol Vis Sci 2016;57:OCT314–OCT323.
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7. Cohen SY et Mrejen S. Imaging of Exudative Age-Related Macular Degeneration: Toward a Shift in the Diagnostic Paradigm? Retina. 2017 Sep;37(9):1625-1629.



■ Prof. Angelo M. MINNELLA


HOW TO IDENTIFY PATIENTS AT RISK OF AMD IN ROUTINE CLINICAL PRACTICE

The influence of several risk factors on onset and progression of AMD is well documented as many studies towards risk factor identification have been conducted in the last couple of years^{8,9}. They led to a deeper knowledge on the factors associated with an increased risk of AMD development. Age, ethnicity, smoking, over 50 genetic polymorphisms, and low dietary intake in nutrients such as lutein zeaxanthin, omega 3 fatty acids, resveratrol and vitamin D were found to be strongly associated with AMD. Other risk factors such as gender, cardiovascular disease history, iris colour, hyperopia, cataract surgery, high BMI and hypertension are more loosely linked, but can of course have a vast impact upon accumulation. While some of the above-mentioned aspects are not modifiable, others are and therefore represent important tools for disease prevention.

However, fast and easy identification of individuals at risk still poses a challenge and thus, calculation of an individual risk score is highly favourable. Hence, the STARS[®] questionnaire (Simplified Thea AMD Risk Assessment Scale) was developed¹⁰ (Figure 3). The main goals were to establish a simple risk score, based on a self-completed questionnaire for large scale detection of patients at risk of AMD and to more comprehensively include environmental risk factors, which was not the case in some other tools for AMD risk calculation.

The derivation sample for this scale was a cohort of 12639 included by Italian ophthalmologists. The results of this

sample were validated by a French study, in which 6837 patients were included. For every factor in the scale an odds ratio was calculated, and this individual value led to a certain amount of points added

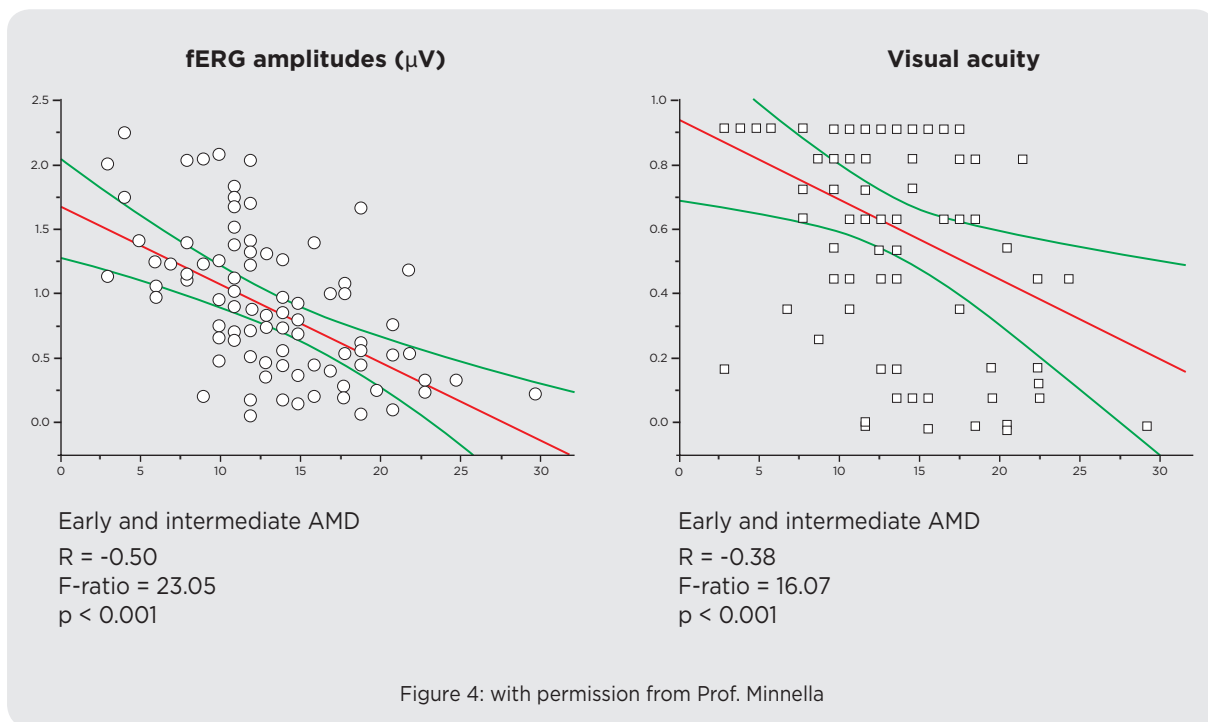


	Marks
Gender	Male <input type="checkbox"/> 0 Female <input type="checkbox"/> 1
Age (years)	< 65 <input type="checkbox"/> 0 65-74 <input type="checkbox"/> 2 75-85 <input type="checkbox"/> 4 >85 <input type="checkbox"/> 9
Ethnic origin	Caucasian <input type="checkbox"/> 0 North-African <input type="checkbox"/> 5
Family history of AMD (brothers, parents)	Yes <input type="checkbox"/> 7 No <input type="checkbox"/> 0
BMI (kg/m ²)	BMI < 25 <input type="checkbox"/> 0 BMI between 25 and 30 <input type="checkbox"/> 1 BMI > 30 <input type="checkbox"/> 2
Smoker	Never smoked <input type="checkbox"/> 0 Current smoker <input type="checkbox"/> 2 Former smoker (interrupted by less than 10 years) <input type="checkbox"/> 3 Former smoker (interrupted for over 10 years) <input type="checkbox"/> 2
History of Arterial hypertension	<input type="checkbox"/> 3
History of Myocardial infarction	<input type="checkbox"/> 3
History of Hypercholesterolemia	<input type="checkbox"/> 2
History of atherosclerosis	<input type="checkbox"/> 4
Cataract surgery	Yes <input type="checkbox"/> 5 No <input type="checkbox"/> 0
Refractive errors	Myopia <input type="checkbox"/> 2 Hyperopia <input type="checkbox"/> 5
Iris colour	Dark <input type="checkbox"/> 0 Light <input type="checkbox"/> 0
Your score : <input style="width: 50px;" type="text"/> <small>When you have your score, get closer to your ophthalmologist</small>	
<div style="background-color: #4CAF50; color: white; padding: 5px; display: inline-block; border-radius: 5px;">Score 0-9: Low risk for AMD</div> <div style="background-color: #FFC107; color: white; padding: 5px; display: inline-block; border-radius: 5px;">Score 10-19: Moderate risk for AMD</div> <div style="background-color: #F44336; color: white; padding: 5px; display: inline-block; border-radius: 5px;">Score > 20: High risk for AMD</div>	
<small>*Development and Validation of a Risk Score for Age-Related Macular Degeneration: The STARS Questionnaire. Delcourt C, Souied E, Sanchez A, Bandello F; STARS Survey Group. Invest Ophthalmol Vis Sci. 2017 Dec 1;58(14):6399-6407.</small>	

Figure 3: with permission from Laboratoires Théa

to the final score upon positive answer by the subject under investigation. In its final version the STARS® is a simple and quick 13-item questionnaire without the need for biological samples. The final score reflects one of three possible assessment results: low (0-9 points), medium (10-19 points) or high (≥ 20 points) risk of AMD. The design as a self-assessment allows its use in large population samples for early and straight-forward evaluation of AMD risk, making it a good screening tool for general practitioners and ophthalmologists not specialized in retinal diseases and/or lacking sophisticated diagnostic possibilities. The STARS® has been successfully used in clinical studies^{11,12}, to gain real-life experience with this scale and one of them investigated its correlation with macular function. In this real-world

study the influence of systemic risk factors on macular function, as measured by focal electroretinography (fERG) in 140 patients with early or intermediate macular degeneration was measured and the predictive value of STARS® on macular function was evaluated¹¹. The first prominent result was that, diabetes is a risk factor exerting a huge influence on macular function, as even a short history of NID diabetes had negative impacts on fERG amplitudes pointing out its prominent role in early stages of disease progression. The second result was that STARS® score best correlates with fERG amplitudes rather than with visual acuity (Figure 4). The latter suggests that STARS® is a good marker for macular function in early and intermediate AMD.





IN CONCLUSION

The STARS® questionnaire is an easy-to-use, 13-item, self-assessment tool validated by clinical and real-life studies, useful to identify patients at risk of AMD and to estimate macular function in early and intermediate AMD. This study confirms the accuracy of the STARS® questionnaire to screen patients at risk of AMD.

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12. Minnella A , Picardi M, Falsini B. Macular Function in Early and Intermediate Age-related Macular Degeneration: role of STARS questionnaire. Presented to ARVO 2018 meeting, Honolulu.



■ Prof. Alfredo GARCÍA LAYANA

NEW TRENDS IN AMD PREVENTION

Fueled by findings that high vitamin D concentrations are protective against AMD, and low concentrations are associated with late AMD¹³, much research has been performed on the influence of vitamin D in pathogenetic pathways relevant to AMD. It is suggested that vitamin D is involved in prevention of oxidative stress, chronic inflammation and angiogenesis¹⁴.

An *in-vitro* study was performed to evaluate the potential effects of vitamin D in some of the mechanisms mentioned above by exposing different cell cultures to lipopolysaccharide (LPS) or H₂O₂ to induce inflammation or oxidative stress before treating them with one of three different formulations. The cells used were ARPE-19 (human retinal epithelium cells) HERC (human endothelial retinal cells) and RF6A (monkey endothelial choroidal cells) and the treatment included either vitamin D (D), Nutrof® Total (N), or vitamin D + Nutrof® Total (ND). Nutrof® Total (Laboratoires Théa, Clermont-Ferrand) is a nutritional supplement containing vitamin C and E, zinc, copper, omega 3 fatty acids,

lutein, zeaxanthin and resveratrol intended for AMD prophylaxis.

The first highly interesting finding was that vitamin D₃ (calcitriol, the active form of vitamin D) synthesizing components are expressed in HERC and RF6A cells. While this has already been shown for human retinal pigment epithelial cells (ARPE-19), this is the first time it has been reported for endothelium of retinal and choroidal vessels (HERC and RF6A).

When exposing the cell lines to oxidative stress (H₂O₂), vitamin D, Nutrof® Total and the combination of both could protect retinal epithelium and endothelium cells from metabolic damage as estimated by cellular proliferation (BrdU) and cellular viability (MTT) (Figure 5). Furthermore, apoptosis was sufficiently prevented and cell integrity preserved. Moreover, DNA damage as measured by production of 8-O-Hydroxydeoxyguanosine (8-O-HdG) could be reduced by all the three treatment arms in the above mentioned two cell lines.

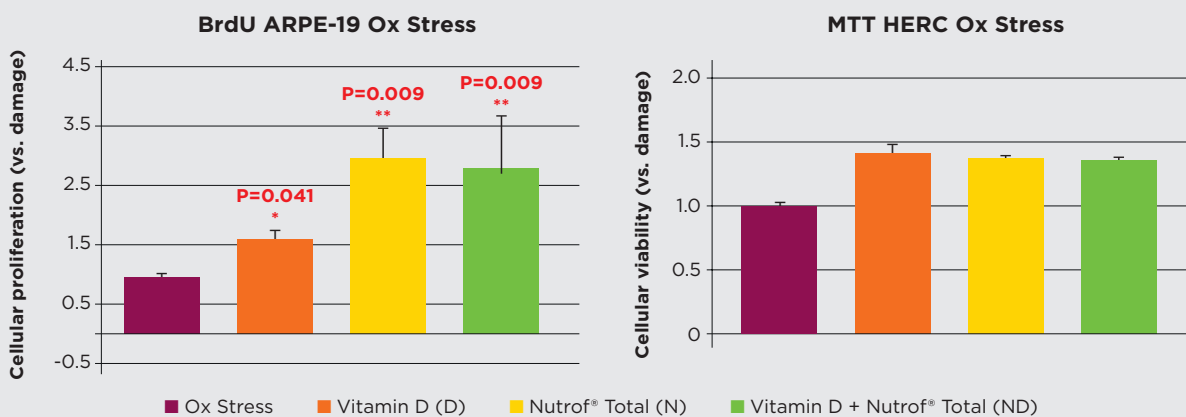


Figure 5: with permission from Prof. Garcia Layana

Inducing inflammation by LPS did not alter cell proliferation and the intercellular connections remained stable, so specific cytokines and factors known to be increased by inflammation stimuli in the retina were analysed. Among them were IL-8, MCP1, IL-6, TNF- α and VEGF. While the increase of IL-8, MCP1 and IL-6 expression and VEGF-levels were reduced by all three treatment regimens in RPE cells, LPS induced IL-6, MCP1 and TNF- α rise was found to be attenuated in retinal endothelial cells, suggesting an anti-inflammatory effect of Nutrof[®] Total and vitamin D in both of these two cell types.

As Nutrof[®] Total alone already exerted a very strong effect in all the above-mentioned experiments the question arose, if adding vitamin D has a beneficial effect on the cells under investigation. Therefore IFN- γ , IL-18 and IL-12p70 levels were analysed upon LPS induced inflammation and shown to be more efficiently reduced by adding vitamin D to the regimen in retinal endothelial cells (Figure 6). These cytokines have been linked to the inflammasome, which is an emerging target in AMD, and other macrophage-connected, inflammatory pathways^{15,16,17,18}.

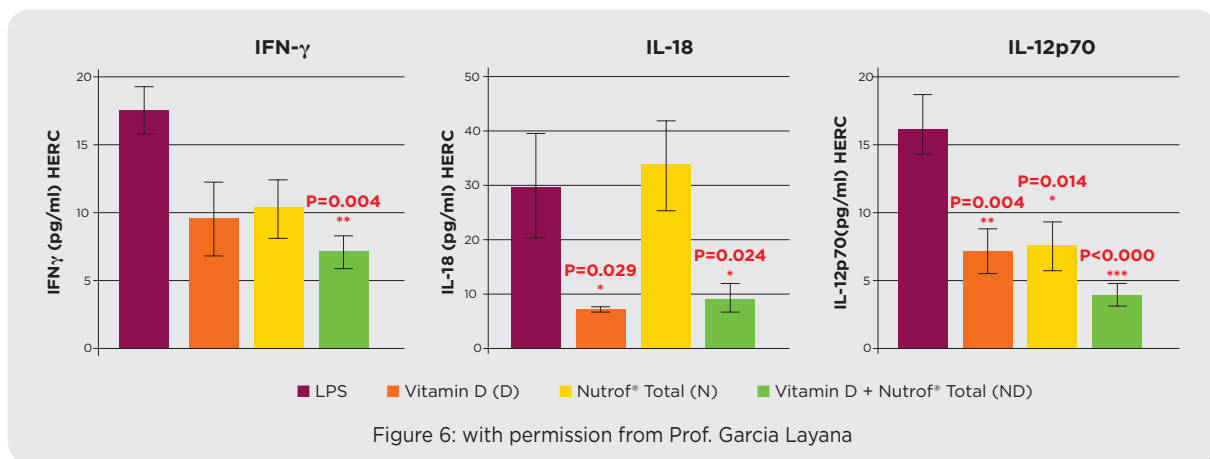


Figure 6: with permission from Prof. Garcia Layana

IN CONCLUSION

Both retinal and choroidal cells express the machinery for vitamin D metabolism. After oxidative stress, vitamin D and Nutrof[®] Total have shown a protective effect in human retinal cells and upon induction of inflammation both formulations decreased inflammatory cytokines and VEGF. The addition of vitamin D to Nutrof[®] Total increases the protective effect by modulating inflammasome-related and other macrophage inflammatory pathways. This result suggests a beneficial effect in AMD prevention that must be further investigated.

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■ PROF. Tariq ASLAM

PATIENT WELL-BEING IN AMD

In the era of ever-new diagnostic and therapeutic strategies leading to the preservation of visual acuity in a large amount of AMD patients, it is of great importance that patients do really feel to benefit from these significant improvements in AMD management.

While most clinicians might think that this is definitely the case and that patient well-being is of course much higher nowadays than in the pre-injection era, studies tell a completely different story.

In fact, by analysing independent psychologists' interviews with 300 AMD patients at Manchester Royal Eye Hospital, the «Psychological impact of macular degeneration study» (POPPIES)¹⁹ was able to show that depression and anxiety is significantly higher than in the general population and even similar to adults with

irreversible vision loss. Moreover, and even more concerning was that many sources of anxiety were completely unnecessary from the ophthalmologists' point of view and could have been easily addressed if the clinician had been aware of them (Table 1). Also, other studies^{20,21} in different settings came to similar conclusions, suggesting that this a world-wide and underestimated problem (Table 2).

The importance of tackling this issue is founded on the fact that mental health is the fourth leading contributor to the global disease burden and depression is associated with poor adherence to treatment, lower physical activity, poor diet and behavioural effects which lead to worse outcome in chronic medical diseases^{22,23,24}.

Results From Survey About Patient Concerns and Sources of Anxiety Related to Anti-VEGF Treatment (N= 300 subjects)

Concerns/Anxieties Associated With Anti-VEGF Treatment	N (% of Total Sample)
Fear of going blind because of injections/fear of the needle in the eye	118 (39.3%)
Hope the treatment works properly/fear of getting worse because the treatment did not work (treatment effectiveness)	111 (37.0%)
Waiting in the waiting room/anticipatory anxiety	104 (34.7%)
Fear of the unknown in relation to treatment outcomes and disease progression	91 (30.0%)
Anxiety caused by being in the eye hospital for a medical appointment, examination, or eye treatment	52 (17.3%)
Fear of pain when receiving an injection	10 (3.3%)
Fear of side effects	8 (2.6%)

Table 1: modified from: Senra H et al. Experience of Anti-VEGF Treatment and Clinical Levels of Depression and Anxiety in Patients With Wet Age-Related Macular Degeneration. Am J Ophthalmol. 2017 May;177:213-224.

While ophthalmologists are fully occupied with their core ophthalmic issues, it is still crucial that they take the first actions as many ophthalmic mechanisms for psychological impact are described in literature. They range from the loss of functional capacity²⁵ and control over life and environment²⁶, to a perceived poor outlook worse than the real prognosis²⁷ and increased stress levels because of having to come to the clinic on a regular basis and having injections in such a sensitive region as the eye globe¹⁸.

The measures indicated to be taken by ophthalmologists can be roughly divided into three fields: supportive care, screening and onward referral.

Supportive care can involve continuous update of information packs according to latest research, avoiding any potential stressors due to misunderstanding by checking patient comprehension and

returning patient control by providing them with a diary in which treatment plans, diagnostic outcomes and personal contribution (smoking, nutritional habits, supplement use) can be documented.

Screening should be done in all patients regardless of AMD stage. For example, by giving two leading questions at the beginning of the Patient Health Questionnaire-9 (PHQ-9). Upon positive response, the remaining questions can be presented. Similarly, the Generalized Anxiety Disorder 7-item scale (GAD-7) can be used for anxiety.

Onward referral might be subject to national or regional structures and institutions but should, dependent on what the main problem is, involve optometrists in case of low vision, social workers for functional capacity support and, upon detection of clinical symptoms of depression or anxiety, GP referral.

Literature on the topic
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Table 2: Literature on psychological impact of macular degeneration management.



IN CONCLUSION

Patient well-being is an underestimated issue in AMD and should be carefully screened for in every patient. While raising awareness of this problem is only the first step, it will be of great importance to educate health care professionals to provide their patients with adequate strategies and advise on how to handle situations and conditions, which are heavily influencing the patients' quality of life and potentially also their somatic disease(s).

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IN CONCLUSION

Despite significant progress in its management, AMD is still one of the most urgent issues in the ophthalmologic field. Ensuring a constant improvement in handling the big spectrum of challenges is of the highest priority and therefore ongoing research is absolutely vital.

While OCT-A is already changing the algorithms on treatment decisions and patients' follow-up, helping clinicians to reduce more invasive diagnostic procedures, some obstacles related to artefacts and lack of experience are yet to be overcome.

Advising on measures to be taken to prevent AMD or its progression is still an aspect to be improved in patient management. While the STARS® questionnaire is a fast and easy way to more efficiently implement suggestions on life-style changes, it also enables clinicians to estimate macular function, making it a good tool in daily practice.

Vitamin D, considered a promising factor in AMD prevention for several years, has now been shown to alleviate the deleterious effects of oxidative stress and inflammation in an *in-vitro* model. It will be highly interesting in the future to see *in-vivo* data on this fascinating interaction.

Besides all the other challenges it will be pivotal to consider patients' mental health more closely and take the right measures if necessary. Thereby we will ensure that the patients' quality of life really improves as a result of the ever-evolving diagnostic and therapeutic options, which has not always been the case in the past.

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BREAKING NEWS IN RETINA

Chaired by Prof. Tariq ASLAM

THEA SYMPOSIUM
SATURDAY, 22ND SEPTEMBER 2018
EURETINA

SUMMARY