Two different initial treatment regimens of ranibizumab in myopic choroidal neovascularization: 12-month results from a randomized controlled study.

Li S, Ding X, Sun L, et al.

**Importance:** The optimal treatment regimen for myopic choroidal neovascularization (mCNV) is essential to understand but currently poorly studied.

**Background:** To date, there is still no consensus on the optimal dosage and frequency of anti-VEGF injections in treating mCNV.

**Design:** A prospective, single-center, single-blind, randomized controlled study.

**Participants:** Adult patients with active mCNV.

**Methods:** Patients were randomized 1:1 to one or three doses initial ranibizumab treatments. Additional injections were administered pro re nata (PRN) over 12 months.

**Main Outcome Measures:** Number and frequency of injections.

**Results:** Fifty patients participated in the study. Patients in both 1+prn or 3+prn groups experienced similar best-corrected visual acuity (BCVA) gain and anatomic improvement, including central retinal thickness (CRT), CNV thickness, area of CNV, and area of leakage. Over 12 months, patients in the 1+prn group received fewer ranibizumab injections (2.04 ± 1.22) compared with the 3+prn group (3.58 ± 0.72, p<0.0001), but no statistic difference of the injection received was observed in the PRN period. During the follow-up, 15 of 26 eyes in the 1+prn group and 10 of 24 eyes in the 3+prn group received additional injections after initial dosing (p = 0.2575). Cox regression analysis showed that 1+prn, female, age>55y and CRT>300μm are risk factors for retreatment.

**Conclusions and Relevance:** The eyes with a single loading dose achieved parallel anatomical and functional visual improvement, while required less injections over one year. The risk factors for retreatment include 1+pm, female, older age and thick retina thickness.

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Treatment of diabetic macular edema with intravitreal antivascular endothelial growth factor and prompt versus deferred focal laser during long-term follow-up and identification of prognostic retinal markers.


**PURPOSE:** Long-term follow-up of patients with diabetic macular edema (DME) treated with intravitreal antivascular endothelial growth factor (anti-VEGF) combined focal laser and identification of prognostic morphological characteristics.

**METHODS:** Prospective clinical trial (50 treatment-naive eyes) with DME randomized 1:1 receiving intravitreal ranibizumab (0.5 mg/0.05 ml) and prompt grid laser compared with ranibizumab and deferred laser. Morphological characteristics potentially relevant for prognosis were assessed at baseline, month 6, month 9, and years 1, 2, 3, 4, and 5 of follow-up.

**RESULTS:** Although functional results were slightly higher in the prompt group at week 12 (0.5; 20/40 Snellen (SD = 0.04, 0.3 logMAR) versus 0.4; 20/50 Snellen (SD = 0.04, logMAR: 0.4), p=0.4) and month 9 (prompt group: 0.5; 20/40 Snellen (SD = 0.03, 0.3 logMAR) versus deferred group: 0.4; 20/50 Snellen (SD = 0.04, 0.4 logMAR), p=0.4), these were statistically insignificant. There was no significant benefit regarding functionality during long-term follow-up in the prompt group compared to the deferred group. BCVA in the eyes with clusters of hyperreflective foci in the central macular region was inferior compared with the eyes without these alterations at year 5 (0.39; 20/50 Snellen, (SD = 0.22, 0.2 logMAR) versus 20/80 Snellen (SD = 0.22, 0.2 logMAR), p < 0.01).

**CONCLUSION:** Grid laser and ranibizumab therapy are effective in DME management during the long-term follow-up. Intraretinal hyperreflective material in SD-OCT is negatively related to BCVA.

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a mean (SD) CST of 738.36 (175.54) μm. A successful L-CRA was created in 24 of 29 participants (83%) in the combination group. The mean number of injections from month 7 to month 24 was 3.2 (95% CI, 2.5-3.8) in the combination group and 7.1 (95% CI, 6.0-8.0) in the ranibizumab alone group. The ratio of the number of injections in the combination group compared with the ranibizumab alone group was 0.46 (95% CI, 0.36-0.61; P < .001). Mixed-effects regression modeling showed a difference in mean BCVA at 2 years between the combination and ranibizumab alone groups (combination, 70.3 letters [Snellen equivalent, 20/40]; ranibizumab alone, 61.6 letters [Snellen equivalent, 20/60]; difference, 8.8 letters; 95% CI, 0.2-17.3; P = .05). There was also a difference in CST at 2 years between the combination and ranibizumab alone groups (mean CST: combination, 303.6 μm; ranibizumab alone, 394.5 μm; difference, 90.9 μm; 95% CI, 24.3-157.5; P = .01). Four participants (14%) in the combination group required a vitrectomy for early macular traction or vitreous hemorrhage.

CONCLUSIONS AND RELEVANCE: For macular edema caused by CRVO, an L-CRA significantly reduced the number of ranibizumab injections required.

TRIAL REGISTRATION: anzctr.org.au Identifier: ACTRN12612000004864.

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Early retinal and choroidal effect of photodynamic treatment in patients with polypoidal choroidal vasculopathy with or without anti-vascular endothelial growth factor: An optical coherence tomography angiography study.

Eris E, Vural E.

PURPOSE: To evaluate the early retinal and choroidal effects of the anti-vascular endothelial growth factor (anti-VEGF) therapy combined with photodynamic therapy (PDT) for polypoidal choroidal vasculopathy (PCV).

METHODS: Patients diagnosed as having PCV were included in the study. In group 1, intravitreal ranibizumab and PDT was applied to six eyes. In group 2, PDT treatment only was applied to four eyes. Optical coherence tomography (OCT) angiography images and best-corrected visual acuity (BCVA) were taken from all patients before treatment and 3 days after surgery.

RESULTS: The mean age of the patients was 66.00 ± 6.28 years. In group 1, the initial BCVA was 0.70 ± 0.35 logMAR and the final BCVA was 1.1 ± 0.78 logMAR. In group 2, the initial BCVA was 0.47 ± 0.17 logMAR and the final BCVA was 0.50 ± 0.21 logMAR. In group 1, flow rate significantly decreased in the superficial area (p = 0.028), the flow rate also decreased in other layers but they were not statistically significant (p < 0.05). In group 2, the flow rate decreased but these changes were not statistically significant (p > 0.05). Vascular constriction and choroidal ischemia were seen in two patients in group 1.

CONCLUSION: In the short term, retinal and choroidal blood flow decreased after PDT treatment. However, statistically significant changes were seen only in the superficial area in group 1.

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Loss to follow-up among patients with neovascular age-related macular degeneration who received intravitreal anti-vascular endothelial growth factor injections.


IMPORTANCE: Loss to follow-up (LTFU) after anti-vascular endothelial growth factor (anti-VEGF) injections increases the risk of vision loss among patients with neovascular age-related macular degeneration (nAMD).
**OBJECTIVE:** To report rates of LTFU among patients with nAMD after anti-VEGF injections and to identify risk factors associated with LTFU in this population.

**DESIGN, SETTING, AND PARTICIPANTS:** This retrospective cohort study of data from 9007 patients who received anti-VEGF injections for treatment of nAMD was performed at an urban, private retina practice with multiple locations from April 1, 2012, to January 12, 2016.

**MAIN OUTCOMES AND MEASURES:** Rates of LTFU after anti-VEGF injections. Loss to follow-up was defined as receipt of 1 or more injections with no subsequent follow-up visit within 12 months.

**RESULTS:** Among the 9007 patients (mean [SD] age, 81.2 [8.8] years; 5917 [65.7%] female; 7905 [87.8%] white), 2003 (22.2%) were LTFU. Odds of LTFU were greater among patients 81 to 85 years of age (odds ratio [OR], 1.58; 95% CI, 1.38-1.82; P < .001), 86 to 90 years of age (OR, 2.29; 95% CI, 2.00-2.62; P < .001), and more than 90 years of age (OR, 3.31; 95% CI, 2.83-3.86; P < .001) compared with patients 80 years of age and younger. Odds of LTFU among African American patients (OR, 1.47; 95% CI, 1.00-2.16; P = .05), Asian patients (OR, 2.63; 95% CI, 1.71-4.03; P < .001), patients of other race (OR, 3.07; 95% CI, 1.38-6.82; P = .006), and patients of unreported race (OR, 2.29; 95% CI, 1.96-2.68; P < .001) were greater than odds of LTFU among white patients. Odds of LTFU were greater among patients with regional adjusted gross income of $50 000 or less (OR, 1.52; 95% CI, 1.30-1.79; P < .001), $51 000 to $75 000 (OR, 1.35; 95% CI, 1.17-1.56; P < .001), and $76 000 to $100 000 (OR, 1.28; 95% CI, 1.08-1.50; P = .004) compared with patients with incomes greater than $100 000. Odds of LTFU for patients living 21 to 30 miles (OR, 1.33; 95% CI, 1.05-1.69; P = .02) and more than 30 miles (OR, 1.55; 95% CI, 1.28-1.88; P < .001) from clinic were greater compared with patients who lived 10 miles or less from the clinic. Odds of LTFU were greater among patients who received unilateral injections (OR, 1.44; 95% CI, 1.28-1.61; P < .001) than among patients who received bilateral injections.

**CONCLUSIONS AND RELEVANCE:** We found a high rate of LTFU after anti-VEGF injections among patients with nAMD and identified multiple risk factors associated with LTFU among this population. Although our results may not be generalizable, data on LTFU in a clinical practice setting are needed to understand the scope of the problem so that interventions may be designed to improve outcomes.

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### Other treatment


**Saffron therapy for the treatment of mild/moderate age-related macular degeneration: a randomised clinical trial.**

Broadhead GK, Grigg JR, McCluskey P, et al.

**PURPOSE:** To assess the efficacy and safety of oral saffron, a natural antioxidant, in treating mild/moderate age-related macular degeneration (AMD).

**METHODS:** Randomised, double-blinded, placebo-controlled crossover trial of 100 adults (>50 years) with mild/moderate AMD and vision >20/70 Snellen equivalent in at least one eye. Exclusion criteria included confounding visual lesions, or significant gastrointestinal disease impairing absorption. Participants were given oral saffron supplementation (20 mg/day) for 3 months or placebo for 3 months, followed by crossover for 3 months. Participants already consuming Age-Related Eye Diseases Study (AREDS) supplements or equivalent maintained these. Primary outcomes included changes in best-corrected visual acuity (BCVA) and changes in multifocal electroretinogram (mFERG) response density and latency. Secondary outcomes included safety outcomes and changes in mFERG and BCVA amongst participants on AREDS supplements.
**RESULTS:** Mean BCVA improved 0.69 letters (p = 0.001) and mean-pooled mFERG latency reduced 0.17 ms (p = 0.04) on saffron compared to placebo. Amongst participants on AREDS supplements, mean BCVA improved 0.73 letters p = 0.006) and mean-pooled mFERG response density improved 2.8% (p = 0.038). There was no significant difference in adverse event occurrence (p > 0.10).

**CONCLUSION:** Saffron supplementation modestly improved visual function in participants with AMD, including those using AREDS supplements. Given the chronic nature of AMD, longer-term supplementation may produce greater benefits.

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**Potential treatment of retinal diseases with iron chelators.**

Shu W, Dunaief JL.

**ABSTRACT:** Iron is essential for life, while excess iron can be toxic. Iron generates hydroxyl radical, which is the most reactive free radical, causing oxidative stress. Since iron is absorbed through the diet but not excreted from the body, it accumulates with age in tissues, including the retina, consequently leading to age-related toxicity. This accumulation is further promoted by inflammation. Hereditary diseases such as aceruloplasminemia, Friedreich's ataxia, pantothenate kinase-associated neurodegeneration, and posterior column ataxia with retinitis pigmentosa involve retinal degeneration associated with iron dysregulation. In addition to hereditary causes, dietary or parenteral iron supplementation has been recently reported to elevate iron levels in the retinal pigment epithelium (RPE) and promote retinal degeneration. Ocular siderosis from intraocular foreign bodies or subretinal hemorrhage can also lead to retinopathy. Evidence from mice and humans suggests that iron toxicity may contribute to age-related macular degeneration pathogenesis. Iron chelators can protect photoreceptors and RPE in various mouse models. The therapeutic potential for iron chelators is under investigation.

PMID: 30360383 DOI: 10.3390/ph11040112


**The 'Developing Regorafenib Eye drops for neovascular Age-related Macular degeneration' (DREAM) study: an open-label phase II trial.**


**AIMS:** This program investigated topical regorafenib, a multikinase inhibitor, in patients with neovascular age-related macular degeneration (nAMD).

**METHODS:** Topical regorafenib was investigated in an open-label, phase IIa/b study in which patients with choroidal neovascularization (CNV) secondary to nAMD received regorafenib (25 μL, 30 mg/mL TID) for 12 weeks. The primary endpoint of the phase II/a/b study was mean change in best-corrected visual acuity (BCVA) from baseline to weeks 4 and 12.

**RESULTS:** In nAMD patients (N = 51), mean changes in BCVA were +1.2 (90% CI -0.61 to 2.97) and -2.4 (90% CI, -4.18 to -0.54) letters at weeks 4 and 12, respectively. Ocular treatment-emergent adverse events (TEAEs) (study eye) were reported in 21 patients by week 12. There was 1 serious ocular TEAE (visual acuity reduced) that was not drug related. Twenty patients required rescue (intravitreal ranibizumab).

**CONCLUSIONS:** The program was terminated after phase IIa ended because efficacy was less than with current nAMD treatments. According to elaborate post hoc analyses, the most likely reason was insufficient exposure in the target compartment (back of the eye).

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Diagnosis


Artificial intelligence and deep learning in ophthalmology.

Ting DSW, Pasquale LR, Peng L, et al.

ABSTRACT: Artificial intelligence (AI) based on deep learning (DL) has sparked tremendous global interest in recent years. DL has been widely adopted in image recognition, speech recognition and natural language processing, but is only beginning to impact on healthcare. In ophthalmology, DL has been applied to fundus photographs, optical coherence tomography and visual fields, achieving robust classification performance in the detection of diabetic retinopathy and retinopathy of prematurity, the glaucoma-like disc, macular oedema and age-related macular degeneration. DL in ocular imaging may be used in conjunction with telemedicine as a possible solution to screen, diagnose and monitor major eye diseases for patients in primary care and community settings. Nonetheless, there are also potential challenges with DL application in ophthalmology, including clinical and technical challenges, explainability of the algorithm results, medicolegal issues, and physician and patient acceptance of the AI 'black-box' algorithms. DL could potentially revolutionise how ophthalmology is practised in the future. This review provides a summary of the state-of-the-art DL systems described for ophthalmic applications, potential challenges in clinical deployment and the path forward.

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The possibility of the combination of OCT and fundus images for improving the diagnostic accuracy of deep learning for age-related macular degeneration: a preliminary experiment.

Yoo TK, Choi JY, Seo JG, et al.

ABSTRACT: Recently, researchers have built new deep learning (DL) models using a single image modality to diagnose age-related macular degeneration (AMD). Retinal fundus and optical coherence tomography (OCT) images in clinical settings are the most important modalities investigating AMD. Whether concomitant use of fundus and OCT data in DL technique is beneficial has not been so clearly identified. This experimental analysis used OCT and fundus image data of postmortems from the Project Macula. The DL based on OCT, fundus, and combination of OCT and fundus were invented to diagnose AMD. These models consisted of pre-trained VGG-19 and transfer learning using random forest. Following the data augmentation and training process, the DL using OCT alone showed diagnostic efficiency with area under the curve (AUC) of 0.906 (95% confidence interval, 0.891-0.921) and 82.6% (81.0-84.3%) accuracy rate. The DL using fundus alone exhibited AUC of 0.914 (0.900-0.928) and 83.5% (81.8-85.0%) accuracy rate. Combined usage of the fundus with OCT increased the diagnostic power with AUC of 0.969 (0.956-0.979) and 90.5% (89.2-91.8%) accuracy rate. The Delong test showed that the DL using both OCT and fundus data outperformed the DL using OCT alone (P value < 0.001) and fundus image alone (P value < 0.001). This multimodal random forest model showed even better performance than a restricted Boltzmann machine (P value = 0.002) and deep belief network algorithms (P value = 0.042). According to Duncan's multiple range test, the multimodal methods significantly improved the performance obtained by the single-modal methods. In this preliminary study, a multimodal DL algorithm based on the combination of OCT and fundus image raised the diagnostic accuracy compared to this data alone. Future diagnostic DL needs to adopt the multimodal process to combine various types of imaging for a more precise AMD diagnosis. Graphical abstract The basic architectural structure of the tested multimodal deep learning model based on pre-trained deep convolutional neural network and random forest using the combination of OCT and fundus image.
Multi-line adaptive perimetry (MAP): a new procedure for quantifying visual field integrity for rapid assessment of macular diseases.

Thurman SM, Maniglia M, Davey PG, et al.

PURPOSE: In order to monitor visual defects associated with macular degeneration (MD), we present a new psychophysical assessment called multiline adaptive perimetry (MAP) that measures visual field integrity by simultaneously estimating regions associated with perceptual distortions (metamorphopsia) and visual sensitivity loss (scotoma).

METHODS: We first ran simulations of MAP with a computerized model of a human observer to determine optimal test design characteristics. In experiment 1, predictions of the model were assessed by simulating metamorphopsia with an eye-tracking device with 20 healthy vision participants. In experiment 2, eight patients (16 eyes) with macular disease completed two MAP assessments separated by about 12 weeks, while a subset (10 eyes) also completed repeated Macular Integrity Assessment (MAIA) microperimetry and Amsler grid exams.

RESULTS: Results revealed strong repeatability of MAP and high accuracy, sensitivity, and specificity (0.89, 0.81, and 0.90, respectively) in classifying patient eyes with severe visual impairment. We also found a significant relationship in terms of the spatial patterns of performance across visual field loci derived from MAP and MAIA microperimetry. However, there was a lack of correspondence between MAP and subjective Amsler grid reports in isolating perceptually distorted regions.

CONCLUSIONS: These results highlight the validity and efficacy of MAP in producing quantitative maps of visual field disturbances, including simultaneous mapping of metamorphopsia and sensitivity impairment.

with a speckled pattern, delineate areas of prior subretinal hemorrhage long after its resolution in patients with neovascular age-related macular degeneration. Potential mechanisms for the development of this pattern are proposed.

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Semivariogram and semimadogram functions as descriptors for AMD diagnosis on SD-OCT topographic maps using Support Vector Machine.

Santos AM, Paiva AC, Santos APM, et al.

**BACKGROUND:** Age-related macular degeneration (AMD) is a degenerative ocular disease that develops by the formation of drusen in the macula region leading to blindness. This condition can be detected automatically by automated image processing techniques applied in spectral domain optical coherence tomography (SD-OCT) volumes. The most common approach is the individualized analysis of each slice (B-Scan) of the SD-OCT volumes. However, it ends up losing the correlation between pixels of neighboring slices. The retina representation by topographic maps reveals the similarity of these structures with geographic relief maps, which can be represented by geostatistical descriptors. In this paper, we present a methodology based on geostatistical functions for the automatic diagnosis of AMD in SD-OCT.

**METHODS:** The proposed methodology is based on the construction of a topographic map of the macular region. Over the topographic map, we compute geostatistical features using semivariogram and semimadogram functions as texture descriptors. The extracted descriptors are then used as input for a Support Vector Machine classifier.

**RESULTS:** For training of the classifier and tests, a database composed of 384 OCT exams (269 volumes of eyes exhibiting AMD and 115 control volumes) with layers segmented and validated by specialists were used. The best classification model, validated with cross-validation k-fold, achieved an accuracy of 95.2% and an AUROC of 0.989.

**CONCLUSION:** The presented methodology exclusively uses geostatistical descriptors for the diagnosis of AMD in SD-OCT images of the macular region. The results are promising and the methodology is competitive considering previous results published in literature.

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**Epidemiology and public health**

Appl Health Econ Health Policy. 2018 Oct 25. [Epub ahead of print]

Using post-market utilisation analysis to support medicines pricing policy: an Australian case study of aflibercept and ranibizumab use.

Kemp-Casey A, Pratt N, Ramsay E, Roughhead EE.

**OBJECTIVES:** To describe how post-market utilisation analysis in Australia informs cost-effectiveness assessment and pricing decisions, using aflibercept and ranibizumab as case studies.

**METHODS:** Pharmaceutical claims were used to identify initiators of aflibercept and ranibizumab in the year after aflibercept-listing (December 2012), and ranibizumab initiators in the year before aflibercept listing. The dispensing rates for each cohort were calculated, and their demographic and clinical characteristics compared using Kruskal-Wallis tests.

**RESULTS:** Aflibercept and ranibizumab each accounted for half the age-related macular degeneration market following ranibizumab listing. Aflibercept initiators had similar dispensing rates to ranibizumab
initiators in the pre- and post-aflibercept era (~three scripts during the first 90 days, and eight to nine scripts during the following 12 months). All cohorts were similar in terms of their age, sex, residential aged-care status and geographic remoteness, and no differences were observed in their overall co-morbidity scores and history of thromboembolic events.

**CONCLUSIONS:** Contrary to clinical trial protocols, post-market utilisation research for ranibizumab and aflibercept demonstrates equivalent use in practice in terms of dose frequency, and the demographic and clinical characteristics of initiators. This supports Australia’s decision to pay the same price for each rather than giving a premium to aflibercept. Many other countries are likely overpaying for aflibercept if their utilization patterns are similar to Australia’s, and could benefit from incorporating routine utilisation assessment.

PMID: 30362070 DOI: 10.1007/s40258-018-0440-4

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**Genetics and gene therapy**


**Gene therapy and the adeno associated virus in the treatment of genetic and acquired ophthalmic diseases in humans: trials, future directions and safety considerations.**

Ramlogan-Steel CA, Murali A, Andrzejewski S, et al.

**ABSTRACT:** Voretigene neparvovec-rzyl was recently approved for the treatment of Leber Congenital Amaurosis, and the use of gene therapy for eye disease is attracting even greater interest. The eye has immune privileged status, is easily accessible, requires a reduced dosage of therapy due to its size, and is highly compartmentalized, significantly reducing systemic spread. Adeno-associated virus (AAV), with its low pathogenicity, prolonged expression profile and ability to transduce multiple cell types, has become the leading gene therapy vector. Target diseases have moved beyond currently untreatable inherited dystrophies to common, partially treatable acquired conditions such as exudative AMD and glaucoma, but use of the technology in these conditions imposes added obligations for caution in vector design. This review discusses the current status of AAV gene therapy trials in genetic and acquired ocular diseases, and explores new scientific developments which could help ensure effective and safe use of the therapy in the future.

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**Association between genetic variation of complement C3 and the susceptibility to advanced age-related macular degeneration: a meta-analysis.**


**BACKGROUND:** The purpose of this study is to discuss whether genetic variants (rs2230199, rs1047286, rs2230205, and rs2250656) in the C3 gene account for a significant risk of advanced AMD.

**METHODS:** We performed a meta-analysis using electronic databases to search relevant articles. A total of 40 case-control studies from 38 available articles (20,673 cases and 20,025 controls) were included in our study.

**RESULTS:** In our meta-analysis, the pooled results showed that the carriage of G allele for rs2230199 and the T allele for rs1047286 had a tendency to the risk of advanced AMD (OR = 1.49, 95% CI = 1.39-1.59, P <
0.001; OR = 1.45, 95% CI = 1.37-1.54, P < 0.001). Moreover, in the subgroup analysis based on ethnicity, rs2230199 and rs1047286 polymorphisms were more likely to be a predictor of response for Caucasian region (OR = 1.48, 95% CI = 1.38-1.59, P < 0.001; OR = 1.45, 95% CI = 1.37-1.54, P < 0.001). Besides, pooled results suggested that the G allele of rs2230199 could confer susceptibility to advanced AMD in Middle East (OR = 1.62, 95% CI = 1.33-1.97, P < 0.001).

**CONCLUSION:** In our meta-analysis, C3 genetic polymorphisms unveiled a positive effect on the risk of advanced AMD, especially in Caucasians. Furthermore, numerous well-designed studies with large sample-size are required to validate this conclusion.


**Case Reports**


A case of Leber's miliary aneurysms with diffuse peripheral retinal vascular sheathing.

Lee A, Baek J, Ra H.

**ABSTRACT:** A 30-year-old female presented with macular edema and discoid exudation at the posterior pole. Diffuse vascular sheathing was observed at the peripheral retina. Fluorescein angiography revealed multiple microaneurysms at the posterior pole and leakage from the peripheral vessels. Two monthly intravitreal bevacizumab led to minimal improvement, and resolution of macular edema was achieved by an additional intravitreal triamcinolone. The findings at the posterior pole resembled those of Leber's miliary aneurysm. However, this case also demonstrated a peculiar vascular sheathing at the periphery and showed response to triamcinolone, which are evidences for an inflammatory condition.

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