

Clinical Course and Management of a Cluster of Post Intravitreal Bevacizumab Injection Fungal Endophthalmitis in 14 Eyes



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OBJECTIVE Pearls in the diagnosis and management of cluster fungal endophthalmitis caused by two different filamentous fungi following intravitreal injection of bevacizumab.

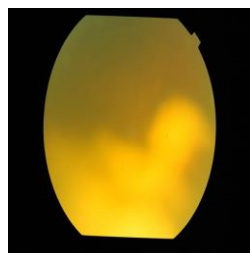
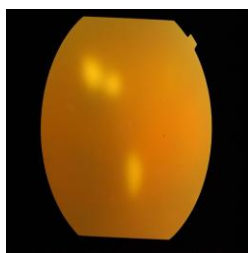
PURPOSE To highlight the distinctive clinical features, course, management & outcome of a cluster of Post Intravitreal Bevacizumab Injection Fungal Endophthalmitis caused by two different filamentous fungi. Role of prolonged vigilance & repeated Intravitreal Antifungals (IOAF) for several months as well as the relative inefficacy of oral antifungals (azoles) in this series is emphasized.

METHODS Retrospective review of 14 consecutive eyes that presented with severe infection 2-12 weeks after intravitreal bevacizumab administered in September 2015. Indications for bevacizumab injection were diabetic macular edema; CNVM associated with AMD, myopia, choroidal osteoma & IPT. All eyes were treated with Pars Plana Vitrectomy (PPV) & Intravitreal Antimicrobials; vitreous underwent smear, culture & nucleic acid analysis. Isolates underwent susceptibility testing. PPV + IOAF (Voriconazole+ AmphotericinB) were repeated as indicated. Oral voriconazole was used for the first 6-8 weeks. Primary outcome measure was inflammation resolution; secondary outcome measure was best-corrected visual acuity (BCVA).

RESULTS Age range was 41-69 years; 7/14 were diabetic; 13/14 eyes were phakic. 9 presented at 2 weeks, 3 at 3 weeks, 1 at 4 weeks & 1 at 3 months after bevacizumab injection. All had severe AC & vitreous inflammation with balls of vitreous exudates. There was florid growth of *Aspergillus terreus* & *Aspergillus versicolor* on vitreous culture; susceptibility was high to azoles & low to amphotericinB. Nucleic acid analysis was negative. Inflammation resolved following the first PPV + IOAF though peripheral balls of “inactive appearing” vitreous exudates persisted in 10 eyes. 12 eyes had recurrent inflammation 7-9 weeks later even while on oral voriconazole and underwent repeat PPV+ IOAF. These eyes are maintained on Vitreous Tap + IOAF every 7-12 days. Inflammation has resolved in all eyes; 8 eyes have significant epimacular membranes with traction; 1 had retinal detachment that was reattached; 13/13 phakic eyes have significant cataract. Mean BCVA 4 months after onset of inflammation is 20/400.

CONCLUSION Fungal infection can present 2-12 weeks after intravitreal injection. Balls of vitreous exudates suggest viable fungus & need for continuing intravitreal antifungal therapy. Close monitoring for several months is indicated as inflammation reactivation is possible even 7-9 weeks after apparent resolution. Repeat IOAF every 7-12 days for several months maybe indicated in these vitrectomised eyes.

TAKE HOME MESSAGE Post-injection Fungal Endophthalmitis can present after 2-12 weeks. Balls of vitreous exudates indicate need for continuing intraocular therapy, sometimes for several months.



HUMAN RESEARCH This study involves human research.

IRB Approval Status: Approved by institutional review board

Suprachoroidal Administration of Triamcinolone Acetonide: Combined Results of Phase 1/2 and Phase 2 Clinical Studies



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OBJECTIVE To present the combined results of the Phase 1/2 and Phase 2 clinical studies of suprachoroidal administration of triamcinolone acetonide for the treatment of non-infectious uveitis

PURPOSE To present a combined post-hoc analysis of the per-protocol populations of two clinical studies that evaluated the safety, tolerability and efficacy of a single suprachoroidal injection of triamcinolone acetonide (TA) in subjects with macular edema associated with non-infectious uveitis.

METHODS A single 4 mg (100 µL) dose of triamcinolone acetonide was administered into the suprachoroidal space (SCS) of subjects with non-infectious uveitis and followed for 2 months (Phase 2) or 6 months (Phase 1/2). To be included in these trials, subjects had to have macular edema (ME) associated with non-infectious anterior, intermediate, posterior or pan-uveitis. Data included in this analysis was collected from weeks 2, 4 and 8 in the Phase 2 study or weeks 1, 2, 4, and 8 in the Phase 1 study.

RESULTS A total of 22 eyes of 22 subjects (7 subjects in the open-label Phase 1/2 study and 15 subjects in the randomized Phase 2 study) who each had ME associated with non-infectious uveitis received a single suprachoroidal injection of TA. Eye pain at or

soon after the time of injection was the most common adverse event in the two studies experienced in 7 subjects (29%). Additionally, no subjects experienced a steroid-induced IOP increase in either study. No treatment-related serious adverse events were reported in either study. A mean gain in visual acuity of 11 letters from baseline to week 8 was seen in these subjects. A mean reduction in central retinal thickness of 182 microns was observed from baseline to week 8.

CONCLUSION This combined, post-hoc analysis of the per protocol populations of two clinical studies of a single, suprachoroidal injection of TA in subjects with macular edema associated with non-infectious uveitis demonstrates a favorable safety to efficacy profile and supports the continued development of suprachoroidal injections of TA for the treatment of non-infectious uveitis.

TAKE HOME MESSAGE Suprachoroidal delivery of triamcinolone acetonide 4mg is a promising and novel approach for the management of non-infectious uveitis.

HUMAN RESEARCH This study involves human research.

IRB Approval Status: Approved by institutional review board

Treatment of Uveitic Macular Edema With Corticosteroids Utilizing a Novel Approach: Suprachoroidal Injector



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OBJECTIVE To describe the value of harnessing a new technology and technique to administer corticosteroids for uveitic macular edema.

PURPOSE The delivery of drugs to the posterior segment of the eye is challenging in that the drugs must reach the target tissues without negatively affecting other parts of the eye. We review the studies evaluating an unconventional approach to this problem utilizing conventional triamcinolone acetonide (TA) and compare to the gold standard intravitreal TA.

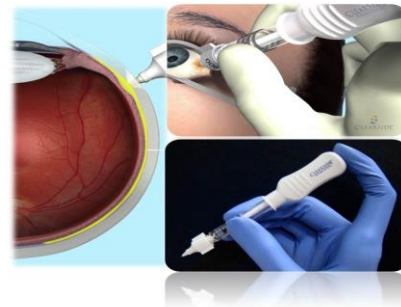
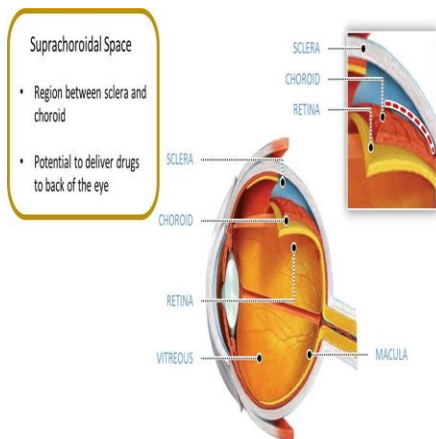
METHODS Pre-clinical studies were conducted administering triamcinolone acetonide (TA) through the suprachoroidal space in swine and rabbit uveitis models. Based on results from these studies, Phase 1 and 2 non-randomized national trials (CLEAR SIDE 1 and 2) were undertaken to evaluate suprachoroidal administration of TA in humans.

RESULTS Pre-clinical studies in the pig uveitis model showed that a lower dose (1/10th) of the intravitreal (IVT) dose administered via suprachoroidal injection provides the same anti-inflammatory benefit as the full IVT dose. Suprachoroidal injection of TA showed more rapid resolution of ocular inflammation compared to oral prednisone, and

was more efficacious at controlling inflammation compared to low-dose oral prednisone. In the rabbit uveitis model, pre-clinical studies showed higher concentrations of the drug in the target tissues (retina/choroid) compared to surrounding tissues (lens/aqueous humor). Phase 1/2 study showed encouraging safety and efficacy profile for TA administered via suprachoroidal injection.

CONCLUSION Suprachoroidal administration has the potential to improve upon existing methods of steroid administration, including intravitreal and systemic, through lowering the dose required to achieve desired effects and reducing unwanted side effects on surrounding structures.

TAKE HOME MESSAGE Corticosteroids used judiciously remains a very effective periocular form of therapy either as primary or as part of augmented regimens. Potentially suprachoroidal delivery may be a very valuable tool.



Fundus Abnormalities in Microcephalic Newborns Presumable Related With Congenital Zika Virus Infection During Epidemic in Brazil



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OBJECTIVE To report the Fundus Abnormalities related to Congenital Zika-Virus Infection

PURPOSE To describe the variables related to the fundoscopic findings of a population of infants born with microcephaly during the Brazilian ZIKV epidemic and presumable intrauterine infection. To assess the fundoscopic findings of mothers and their infants with microcephaly and clinical diagnosis of mother-fetus Zika virus infection.

METHODS This cross-sectional study comprised 40 infants (mean age 2.2 ± 1.2 months; range: 0.1 to 7.3 months) with microcephaly, born in Pernambuco state, Brazil between May and December 2015. Infants and mothers were submitted to fundus examination. Toxoplasmosis, rubella, cytomegalovirus, syphilis, and human immunodeficiency virus (HIV) were ruled out in all infants. Infants were divided in two groups for statistical purposes: with and without fundoscopic alterations.

RESULTS The major symptoms reported by mothers of both groups were rash (65.0%), fever (22.5%), headache (22.5%), and arthralgia (20.0%). None of the mothers referred

conjunctivitis or other ocular symptoms during pregnancy nor presented signs of uveitis at the time of examination. Thirty-seven (46.3%) eyes of 32 (55.0%) infants presented fundoscopic alterations. Macular findings (chorioretinal atrophy and/or pigment mottling) were detected in 24 (30.0%) eyes of seventeen (42.5%) infants and optic disc findings (hypoplasia with the double-ring sign, pallor, and increased cup-to-disk ratio) in 27 (33.8%) eyes of sixteen (40.0%) infants.

CONCLUSION Fundus abnormalities were identified in 55% of the newborns with presumable ZIKV infection during pregnancy and such findings were more frequently observed in lower cephalic diameters at birth as well as in mothers with symptoms of presumable ZIKV infection at the first trimester. The most frequent ocular findings included macular chorioretinal atrophy, mottling and optic disc abnormalities.

TAKE HOME MESSAGE Congenital Zika Virus infection may cause important visual impairment in infants

HUMAN RESEARCH This study involves human research.

IRB Approval Status: Approved by institutional review board

Intravitreal Aflibercept Injection for Choroidal Neovascularization Secondary to Presumed Ocular Histoplasmosis Syndrome (POHS): HANDLE Study 1 Year Results



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OBJECTIVE To evaluate the safety and efficacy of aflibercept for POHS-related CNV.

PURPOSE Evaluate the safety and efficacy of intravitreal aflibercept injection (IAI) in patients with presumed ocular histoplasmosis syndrome (POHS)-related choroidal neovascularization.

METHODS Open-label, randomized, prospective, phase I/II study of IAI in patients with choroidal neovascularization (CNV) due to POHS. Thirty-nine eyes from 39 patients were randomized in 1:1 ratio to two groups. Sustained Group eyes (n=19) underwent monthly IAI for 3 months, then mandatory IAI every 2 months for 12 months (with option for monthly prn dosing if needed). PRN Group eyes (n=20) received one IAI at randomization, then monthly prn IAI for 12 months.

RESULTS Mean age of participants was 50 years (range 19-75), with 16 males and 23 females. Mean baseline LogMar best-corrected visual acuity (BCVA) was 0.321 with Snellen equivalent of 20/42 (20/20-20/160). Mean baseline OCT central subfield

thickness (CST) was 371um (196-780um). Patients in the Sustained and PRN groups received on average 7.5 (5-11) and 4.6 (1-10) injections, over 12 months, respectively. Sustained Group final mean visual acuity was 0.018 and Snellen equivalent of 20/21 (20/13-20/32) indicating an average gain of 12 letters. Mean final OCT CST was 268um indicating an average thinning of OCT CST of 115.1um (574 micron improvement-no change). PRN Group 1 year average visual acuity was 0.107 and Snellen equivalent of 20/26 (20/13-20/63) indicating an average gain of 19 letters. One year mean OCT CST was 250um, with an average thinning of 112um (321um improvement-4um worsening). No reported endophthalmitis, detachments, nor arterial thrombotic events occurred.

CONCLUSION Intravitreal aflibercept resulted in improved visual and anatomic outcomes with a favorable safety profile. PRN IAI dosing required less injections with similar visual and anatomic outcomes compared to sustained dosing.

TAKE HOME MESSAGE One Aflibercept dose followed by monthly evaluation for PRN dosing is a viable, safe and effective therapy for POHS-related choroidal neovascularization

HUMAN RESEARCH This study involves human research.
IRB Approval Status: Approved by institutional review board

Primary Outcomes of the Study of Safety, Tolerability, and Bioactivity of Tocilizumab in Patients With Noninfectious UVEITIS (The STOP-UVEITIS Study)



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OBJECTIVE Intravenous tocilizumab, an interleukin-6 inhibitor, is beneficial for patients with non-infectious uveitis, reducing vitreous haze and improving macular edema.

PURPOSE To evaluate the safety and efficacy of tocilizumab (TCZ) infusions in the STOP-Uveitis Study, which is a randomized, multi-centered, open-label safety, efficacy and bioactivity clinical trial evaluating the role of TCZ, an interleukin-6 inhibitor, in patients with non-infectious intermediate, posterior, or pan-uveitis.

METHODS Patients with NIU were randomized into one of 2 treatment groups in a ratio of 1:1. G1 received intravenous (IV) infusions of 4mg/kg TCZ and G2 received IV infusions of 8mg/kg TCZ. Infusions were given every 4 weeks in both groups until month 6 (primary endpoint). Treatment was given on as needed basis from month 6 onwards until month 12. Primary outcome measures were mean change in visual acuity (VA), vitreous haze (VH) and foveal thickness (FTH) at month 6 in the two groups. Key study inclusion criteria were: 1) diagnosis of NIU; 2) have active uveitis, defined as having at least 1+ VH and/or at least 1+ Vitreous Cell Count; 3) best-corrected ETDRS VA of 20/400 or better in the study eye.

RESULTS A total of 37 patients were randomized in the study. Baseline characteristics were relatively balanced between the two dose groups in many categories. Repeated infusions of TCZ were well tolerated. Two patients had low neutrophil counts secondary to margination that restored to normal with withholding of treatment. VH decreased by 1 step or more in 73.3% and 81.2% of patients in group 1 (low dose) and 2 (high dose), respectively, at month 6. VH decreased by 2 steps or more in 26.6% and 37.5% of patients in groups 1 and 2, respectively, at month 6. Mean change in FTH was -131.5 μ m in group 1 and -38.91 μ m in group 2 at month 6. The mean change in VA at month 6 was +10.9 and +5.5 ETDRS letters in group 1 and 2 respectively.

CONCLUSION Repeated intravenous administrations of TCZ are well tolerated. TCZ (either 4 or 8 mg/kg) is effective in improving VA and reducing VH and FTH. Further monitoring of patients receiving TCZ may be helpful to assess the long term safety and benefits of the drug.

TAKE HOME MESSAGE Interleukin-6 inhibition, as illustrated by tocilizumab, an IL-6 monoclonal antibody, may have therapeutic benefits in patients with non-infectious intermediate, posterior, or pan-uveitis.

HUMAN RESEARCH This study involves human research.

IRB Approval Status: Approved by institutional review board

En Face Optical Coherence Tomography and OCT Angiography of MEWDS



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- Saradha Chexal, MD
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OBJECTIVE To localize the level of abnormalities in multiple evanescent white dot syndrome (MEWDS) by comparing "en-face" OCT and OCT angiography with various conventional imaging modalities.

PURPOSE To localize the exact level of abnormalities in multiple evanescent white dot syndrome (MEWDS) by comparing "en-face" OCT and OCT angiography with various conventional imaging modalities and to gain greater insight into the pathogenesis of spots and dots in this disease.

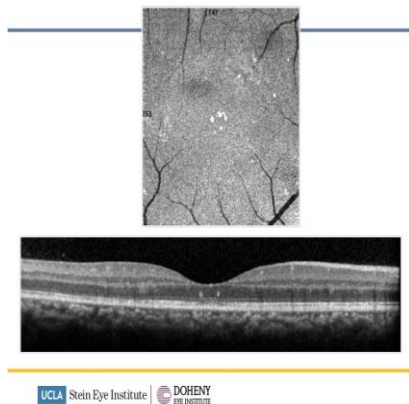
METHODS An multicentered international collaboration was organized and MEWDS cases were collected for retrospective analysis. Multimodal imaging was performed on all subjects and included wide-field fundus autofluorescence (FAF), fluorescein angiography (FA) and indocyanine green angiography (ICGA), and B-scan and "en-face" C-scan enhanced depth imaging and spectral domain OCT. OCT angiography was also performed at the level of the superficial and deep retinal capillary plexus and choroid.

RESULTS A total of 35 MEWDS cases from 9 retinal centers worldwide were meticulously evaluated. Two lesion types were identified with FAF, FA and ICGA. Larger widely scattered "spots" (approximately 200 μ in diameter) were hyper-fluorescent with FA, hyper-autofluorescent with FAF and hypo-fluorescent with ICGA. These "spots" co-localized with hypo-reflective loss of the inner segment ellipsoid zone with en face OCT.

Smaller punctate "dots" (less than 100 μ in diameter) were hyper-fluorescent with FA, hyper- or iso-autofluorescent with FAF and hypo-fluorescent with ICGA and co-localized to the outer nuclear layer with en face OCT. The location of the "dots" in the ONL was further confirmed by structural SD-OCT which showed hyper-reflective fine spicules coalescing into denser, more discrete, oval dots in the outer fovea. OCT angiography of the retinal microvasculature and choriocapillaris and choroid was entirely normal in 100% of our patients.

CONCLUSION Multimodal imaging combined with en face OCT showed that the spots and dots of MEWDS co-localized to the photoreceptor level. OCT angiography failed to demonstrate any choroidal involvement. This study demonstrated primary loss of the outer photoreceptor bands in MEWDS likely due to inflammation or a primary "photoreceptoritis" with complete anatomical recovery over several weeks.

TAKE HOME MESSAGE En Face OCT and OCT angiography co-localized the dots and spots of MEWDS to the photoreceptor level and excluded any choroidal involvement, indicating that MEWDS is a primary photoreceptoritis.



HUMAN RESEARCH This study involves human research.
IRB Approval Status: Approved by institutional review board

Update on the Association of Intracameral Vancomycin and Hemorrhagic Occlusive Retinal Vasculitis (HORV)

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OBJECTIVE To characterize known cases of hemorrhagic occlusive retinal vasculitis (HORV), a syndrome associated with intracameral vancomycin given during cataract surgery.

PURPOSE A syndrome of hemorrhagic occlusive retinal vasculitis (HORV) has recently been described, which occurred after cataract surgery in all eyes in this series. The purpose of this talk is to give an update on the known cases of HORV and its association with intracameral vancomycin. The range of symptoms, findings, and outcomes are discussed.

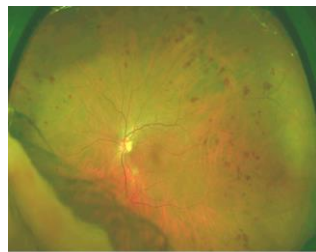
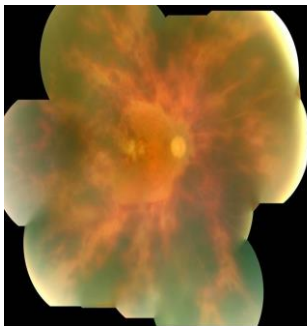
METHODS Retrospective case series. Cases were identified after discussion among retina specialists from around the United States, with the ASRS ReST Committee, and creation of an HORV Task Force (authors listed here). Clinical course and outcomes of 16 previously unreported eyes of 8 patients were compared to our previous report of 11 eyes of 6 patients and another recent case report of 1 eye of 1 patient; data were combined for a comprehensive analysis of 28 eyes of 15 patients. All eyes underwent uncomplicated cataract surgery. HORV was characterized by mild inflammation in the anterior chamber and vitreous, and diffuse intraretinal hemorrhages associated with severe retinal vascular occlusion.

RESULTS Age range was 51-80 years. 10/15 patients were women. 26 eyes of 14 patients received bolus intracameral vancomycin during surgery, while 2 eyes of 1 patient

received vancomycin through the infusion bottle. All 28 eyes presented with findings consistent with HORV between 1-14 days after surgery. In the patient who received vancomycin through the infusion, both eyes remained asymptomatic and retinal findings resolved without treatment. Of the other 26 eyes, only 1 remained asymptomatic. Ocular/systemic evaluations were unrevealing in all patients. Most were treated with systemic steroids. Other treatments included antiviral medication in 6 patients, and PRP and/or anti-VEGF injections in 18 eyes. 6 eyes received additional vancomycin for presumed endophthalmitis, some of which had apparent worsening, and all of which had poor visual outcome (20/400 or worse). Neovascular glaucoma developed in 14 eyes. Final visual acuity was 20/200 or worse in 19 eyes, and 6 eyes had no light perception.

CONCLUSION HORV was associated with vancomycin given during cataract surgery. The reaction seemed dose dependent, as eyes receiving low-dose vancomycin had good outcomes, while eyes that received a second bolus of vancomycin had poor visual outcomes. HORV likely represents a rare reaction similar to vancomycin-induced leukocytoclastic vasculitis. Visual outcomes were often poor despite treatment.

TAKE HOME MESSAGE Hemorrhagic Occlusive Retinal Vasculitis (HORV), likely a type III hypersensitivity reaction, is a potentially devastating retinal disease associated with vancomycin given during cataract surgery.



HUMAN RESEARCH This study involves human research.
IRB Approval Status: Exempt from approval

Qualitative and Quantitative Analysis of Optical Coherence Tomography Angiography in Patients With Retinal Vasculitis

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- Kimberly Baynes, COA
- Peter K. Kaiser, MD
- Sunil Srivastava, MD

OBJECTIVE To describe qualitative and quantitative changes in the retinal microvasculature using optical coherence tomography angiography in patients with retinal vasculitis.

PURPOSE To evaluate the retinal microvasculature in a cohort of patients with retinal vasculitis using optical coherence tomography angiography (OCTA).

METHODS This is a retrospective cohort study of patients with retinal vascular inflammation imaged with OCTA (Optovue Avanti RTVue-XR). OCTA images were evaluated for qualitative changes and compared to fluorescein angiography images where available. Quantitative analysis of the superficial and deep retinal capillaries was performed using flow density software on the Optovue Avanti RTVue-XR.

RESULTS 26 patients with retinal vasculitis were identified. Mean age was 44 years and included 15 women and 11 men. The diagnostic spectrum included 11 patients with Susac syndrome, 5 patients with idiopathic retinal vasculitis, 5 patients with Behcet's disease, and one patient each with anti-synthetase syndrome, intermediate uveitis, lupus, polymyalgia rheumatica, and multiple sclerosis. OCTA imaging on 13 patients revealed findings not visible on fluorescein angiography. These included loss of retinal blood flow in the superficial and deep vascular layers, capillary remodeling, and normal

capillary flow in eyes with exudates. Quantitative analysis showed decreased flow density in both the superficial and deep retinal capillaries in eyes with vascular inflammation involving the macula compared to eyes without macular involvement. In eyes with asymmetric involvement of the macula, decreased flow density values were identified in areas of retinal vascular loss.

CONCLUSION OCT angiography provides information on capillary blood flow in patients with retinal vasculitis. In some patients, OCTA revealed capillary abnormalities that were not visible on fluorescein angiography. Quantitative analysis demonstrated decreased flow density in areas of retinal vascular loss.

TAKE HOME MESSAGE OCT angiography provides information on capillary blood flow in patients with retinal vasculitis and, in some patients, reveals capillary abnormalities not visible on fluorescein angiography.

HUMAN RESEARCH This study involves human research.

IRB Approval Status: Approved by institutional review board

Quantification of Blood Flow in Retinal Vasculitis Using Optical Coherence Tomography Angiography



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- Phoebe Lin, MD, PhD

OBJECTIVE To compare the vessel density and flow indices in patients with retinal vasculitis to normal subjects using optical coherence tomography angiography (OCTA).

PURPOSE Retinal vasculitis is an inflammation of the retinal vessels, typically assessed with fluorescein angiography, that can result in macular ischemia, neovascularization, and cystoid macular edema. We demonstrate the utility of OCTA as a non-invasive tool to quantify the blood flow in patients with retinal vasculitis.

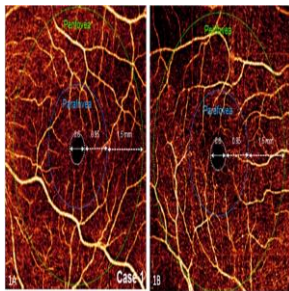
METHODS This prospective case series compared 11 eyes of 7 patients with retinal vasculitis of varied etiologies to 8 normal controls. Subjects were imaged with a 3x3 mm scan by a (70 kHz) 840 nm spectrometer-based OCT system SD-OCT (Optovue RTVue XR Avanti). The split-spectrum amplitude decorrelation angiography (SSADA) algorithm was used to compute angiograms from the internal limiting membrane to the outer plexiform layer. Retinal vessel density was defined as the percentage area occupied by vessels on the *en face* angiogram. Flow index included the SSADA-derived flow velocity in capillaries and the area of large vessels on the *en face* angiogram. A Mann–Whitney U test analyzed flow characteristics.

RESULTS The parafoveal retinal vessel density via OCTA was significantly lower in retinal vasculitis patients compared to normal subjects (mean parafoveal vessel density 81.6 vs.

89.7, $p=0.0003$). The parafoveal retinal flow index was significantly lower in retinal vasculitis compared to normal subjects (0.065 vs. 0.085, $p=0.0007$). Choriocapillaris vessel density was significantly lower in patients with retinal vasculitis compared to normal eyes (95.9 vs 98.5, $p=0.001$). In 1 subject with lupus retinal vasculitis who improved after immunosuppression, OCTA quantified an improvement in parafoveal flow indices from 0.060 and 0.050 to 0.068 and 0.067 in the right and left eyes, respectively.

CONCLUSION Retinal blood flow in the parafoveal area of patients with retinal vasculitis is reduced when compared to age similar subjects.

TAKE HOME MESSAGE Retinal blood flow in the parafoveal area of patients with retinal vasculitis is reduced when compared to age similar subjects.



HUMAN RESEARCH This study involves human research.

IRB Approval Status: Approved by institutional review board