7/30/2023 12:00 am

Wet AMD Symposium 2

Subretinal Delivery of RGX-314: Gene Therapy for Neovascular Age-Related Macular Degeneration

- Ashkan Abbey, MD, FASRS, FAAO

Objective: Evaluate safety and efficacy of RGX-314 in patients previously treated with intravitreal anti-VEGF for neovascular AMD through two years, and additional long-term follow up.
Purpose: Frequent anti-VEGF injections approved to treat neovascular age-related macular degeneration (nAMD) have been shown to reduce the risk of blindness in clinical trials. Real world evidence shows patients often lose visual acuity over time, possibly due to the high treatment burden of current anti-VEGF injections. RGX-314 is a single administration gene therapy utilizing an adeno-associated viral vector (AAV), AAV8, designed to deliver a transgene for a soluble anti-VEGF Fab, with the goal of providing continuous anti-VEGF therapy. A Phase I/IIa trial in previously treated nAMD eyes provides evidence for sustained anti-VEGF levels through 2 years post RGX-314 subretinal delivery. These subjects are now enrolled in a long-term safety follow-up study.
Methods: A Phase I/IIa multicenter, open-label trial evaluated five escalating dose levels of a single subretinal administration of RGX-314 in previously treated nAMD subjects (n = 42) with a demonstrated response to ranibizumab prior to RGX-314 delivery. Patients were encouraged to enroll in a LTFU study to assess long-term safety, efficacy and need for supplemental anti-VEGF injections, up to 5 years post RGX-314 administration. A Phase II, open-label study is currently evaluating whether different doses of RGX-314 from two different formulations (clinical versus commercial formulation) perform the same in humans when delivered by subretinal administration.
Results: Cohorts 1-5 have completed enrollment in the Phase I/IIa study (n=42). As of August 29th, 2022, RGX-314 continued to be generally well-tolerated in 37 patients enrolled in the LTFU study, with no new drug-related ocular adverse events reported in Cohorts 1-4 and one drug-related adverse event of significantly decreased BCVA in Cohort 5. A durable treatment effect was demonstrated, with stable to improved visual acuity in Cohort 3 (mean +12 letters) at 4 years and Cohort 4 (mean -5 letters) at 3 years. Patients had a decreased annualized injection rate in Cohort 3 (2.4 injections) at 4 years and Cohort 4 (4.4 injections) at 3 years, a 67.0% and 58.4% reduction from the year prior to RGX-314 administration, respectively.
Conclusion: Results out to 4 years for Cohort 3 and out to 3 years for Cohort 4 show potential for a one-time administration of RGX-314 to provide sustained clinical outcomes in the treatment of nAMD, with meaningful reductions in anti-VEGF injection burden.

IRB APPROVAL Yes

7/30/2023 12:00 am

Wet AMD Symposium 2

Suprachoroidal Delivery of RGX-314 for Neovascular AMD: Results of the Phase II AAVIATE Study

- David Boyer, MD

Objective: To evaluate the safety, tolerability, and efficacy of RGX-314 via suprachoroidal delivery in patients previously treated with intravitreal anti-VEGF injection for neovascular AMD (nAMD).

Purpose: Optimal treatment of nAMD requires frequent anti-VEGF injections. RGX-314, a single gene therapy utilizing an AAV8 vector to deliver a soluble anti-VEGF fab transgene, has shown a durable treatment effect on anatomy and vision through 4 years with subretinal delivery in a Phase I/IIa trial and subsequent follow-up. Suprachoroidal RGX-314 is being investigated as a potential treatment for nAMD with a one-time in-office treatment.

Methods: AAVIATE is a Phase II study that evaluates the efficacy, safety, and tolerability of suprachoroidal delivery of RGX-314 at three doses ($2.5x10^{11}$GC/eye, $5.0x10^{11}$GC/eye, and $1.0x10^{12}$GC/eye) in 6 cohorts using the SCS Microinjector, an in-office route of administration. The trial will enroll 115 patients with wet AMD, and patients in the first two cohorts are randomized to receive RGX-314 or monthly 0.5 mg ranibizumab intravitreal injections at a 3:1 ratio and all patients in Cohorts 3-6 receive RGX-314. Cohort 6 will receive short-course prophylactic ocular steroids following RGX-314. Safety and efficacy assessments are being conducted with the Primary Endpoint at Week 40 and followed through Week 52. Measurements include adverse events, best corrected visual acuity (BCVA), central retinal thickness (CRT), and additional anti-VEGF injections needed post-RGX-314 administration.

Results: As of August 1, 2022, RGX-314 suprachoroidal delivery was reported to be well tolerated across 85 patients dosed in Cohorts 1-5. Fifteen SAEs were reported, none of which were considered related to RGX-314. No cases of chorioretinal vasculitis or occlusion, or hypotony were observed. Mild intraocular inflammation was reported at similar incidence in the first and second dose levels, with an increase in incidence in mild to moderate inflammation seen at the third dose level (Cohort 4). All resolved with topical corticosteroids. RGX-314 treated patients had stable vision and retinal thickness, with a meaningful reduction in treatment burden across all dose levels. The highest reduction in treatment burden was seen in Cohort 4 (Dose 3), with an 85% reduction in annualized injection rate and 67% of subjects injection free through 6 months. No meaningful differences in patient outcomes with and without baseline AAV8 Nabs was observed.

Conclusion: RGX-314 has the potential to provide sustained clinical outcomes in the treatment of nAMD with a one-time in-office suprachoroidal administration.

IRB APPROVAL Yes

7/30/2023 12:00 am

Wet AMD Symposium 2

ENVISION Trial 24-Week Data: Phase 2 Study of UBX1325, a New Senolytic Agent for Patients With Wet AMD

- Raj Maturi, MD
- Sharon Klier, MD, MPH
- Josh Rathmell, MA
- Lauren Masaki, BA
- Tia Boonyapredee
- Sara Huang, BSC
- Przemyslaw (Mike) Sapieha, PhD
- Jamie Dananberg, MD

Objective: To assess the safety, tolerability, and evidence of activity of a repeat intravitreal injection of UBX1325 in patients with neovascular AMD
Purpose:
Cellular senescence is implicated in retinal microvascular pathology that drives neovascular (or wet) AMD (nAMD). UBX1325, a novel small molecule BCL-xL inhibitor, is a potent senolytic agent. This Phase 2 study assessed the safety, tolerability, and evidence of activity of a repeat intravitreal injection of UBX1325 in patients with nAMD.
Methods:
This Phase 2 study (NCT05275205) is a prospective, multi-center, randomized, double-masked, active-controlled study comparing 2 injections of UBX1325 10µg 4 weeks apart vs. aflibercept 2mg every 8 weeks for the first 6 months of the study. The study is conducted at 14 sites in the US.

The study enrolled patients ≥50 years of age with nAMD and BCVA between 70 - 20 ETDRS letters, with presence of intra- or sub-retinal fluid despite ≥3 anti-VEGF injections in the 6 months period before enrollment.

51 patients were enrolled and randomized 1:1 to receive, 4-8 weeks after a run-in aflibercept intravitreal (IVT) injection, either 2 IVT injections of UBX1325 10µg 4-weeks apart or aflibercept 2mg every 8 weeks. Patients were followed for 48 weeks with primary endpoint assessment occurring at 24 weeks and includes safety and change from baseline in BCVA. Additional endpoints include change in CST, the number of anti-VEGF rescue treatments received during the study period, presence of intra- or sub-retinal fluid, and changes in choroidal blood flow by OCTA and FA.

Results: The data for 24-weeks primary endpoint will be presented from all patients enrolled in this ongoing study. These data of UBX1325 in a Phase 2 study in nAMD represent evaluation of the therapeutic potential of a unique senolytic agent in retinal disease. The data presented will include safety and tolerability of UBX1325, change from baseline in UBX1325 vs. aflibercept-treated patients in BCVA, CST, proportion of patients gaining ≥5 and ≥10 ETDRS letters, and proportion of patients requiring anti-VEGF rescue treatment.
Conclusion: UBX1325 is a novel senolytic agent that is being investigated for the treatment of DME and nAMD. These Phase 2 nAMD data represent the first clinical corroboration of preclinical data observing improvement in retinal function (ERG), leakage and reduced neovascularization. Such data represent the potential proof-of-concept for the safety and tolerability and the effect of a senolytic agent on visual function and on retinal structure in patients with nAMD. As this mechanism of action is orthogonal to anti-VEGF therapy, UBX1325 could provide an important benefit as a stand-alone treatment, in combination regimen, or for use in patients who have a suboptimal response to current standard of care treatments for nAMD.

IRB APPROVAL Yes

7/30/2023 12:00 am

Wet AMD Symposium 2

Subgroup Analyses of the Phase 1 DAVIO Trial of EYP-1901 Showing Reduced Treatment Burden in Wet Age-related Macular Degeneration

- Philip Storey, MD, MPH
- Sunil Patel, MD, PhD
- Mark Barakat, MD
- Vrinda Hershberger, MD, PhD
- William Bridges, MD
- David Eichenbaum, MD, FASRS
- David Lally, MD
- Monica Roy, OD, MPH
- Jay Duker, MD
- Dario Paggiarino, MD

Objective: Assess the anti-VEGF treatment burden among subgroups of patients with wAMD in the DAVIO study of EYP-1901
Purpose: A significant proportion of unsatisfactory visual outcomes in wet age-related macular degeneration (wAMD) treated with anti–vascular endothelial growth factor (anti-VEGF) therapies outside clinical trials may be caused by undertreatment, which may be related to nonadherence resulting from a high treatment burden. This analysis examined the reduction in treatment burden in patient subgroup analyses in the DAVIO trial, a phase 1, multicenter, open-label, dose-escalation trial evaluating the safety of EYP-1901, a sustained-delivery therapy supplying the tyrosine kinase inhibitor vorolanib in a bio-erodible form of Durasert® given via intravitreal injection.
Methods: Previously treated eyes with wAMD received EYP-1901 with up to 48 weeks of follow-up. The primary endpoint was the rate of ocular and systemic adverse events. Secondary endpoints included best-corrected visual acuity (BCVA), optical coherence tomography (OCT) measurements, the proportion of eyes receiving supplemental anti-VEGF injections, and the median time to first supplemental injection.
Results: Seventeen eyes received EYP-1901 440 µg (n=3), 1,060 µg (n=1), 2,060 µg (n=8), or 3,090 µg (n=5). Investigator-reported adverse events were mostly mild in nature and related to the intravitreal injection procedure; no reported adverse events were related to EYP-1901. The mean (SD) change in BCVA from baseline was –2.5 (12.66) ETDRS letters at 6 months and –4.1 (13.59) letters at 12 months. The mean (SD) change in OCT central subfield thickness (CST) from baseline was –3.4 (89.83) µm at 6 months and –2.8 (94.99) µm at 12 months. The median time to supplemental anti-VEGF was 12 months among 9 eyes with no excess fluid at screening, 12 months among 8 eyes supplemental injection–free at 6 months, and 6 months across all treated eyes. Average monthly treatment burden at 12 months was reduced by 94% among eyes supplemental injection–free at 6 months and 89% among 6 eyes without excess fluid at screening receiving EYP-1901 2,060 or 3,090 µg.
Conclusion: EYP-1901 had a favorable ocular and systemic safety profile at the doses evaluated. Sustained delivery was achieved as demonstrated by long-term stability in functional and anatomic outcomes and reduction in treatment burden. Certain subgroups showed a particularly reduced burden after 1 injection. EYP-1901 has progressed to larger phase 2 clinical trials.

IRB APPROVAL Yes

7/30/2023 12:00 am

Wet AMD Symposium 2

Long-Term Efficacy and Safety of the Port Delivery System With Ranibizumab in Patients With nAMD: Results of the Portal 5-year Subgroup Analysis

- Jared Nielsen, MD, MBA
- James Howard, MD
- Melina Cavichini Cordeiro, MD, MS
- Natasha Singh, Pharm D
- Shamika Gune, MD

Objective: To present the long-term efficacy and safety data of the Port Delivery System with ranibizumab (PDS) for the subgroup of Portal patients from Ladder treated with PDS for at least 5 years.
Purpose: The PDS is an innovative drug delivery system for the continuous delivery of a customized formulation of ranibizumab into the vitreous. The Portal extension trial (NCT03683251) is evaluating long-term safety and tolerability of the PDS with ranibizumab 100 mg/mL (PDS 100 mg/mL) and includes patients with neovascular age-related macular degeneration (nAMD) who have completed the phase 2 Ladder (NCT02510794) trial.
Methods: Portal is an ongoing, multicenter, open-label extension study enrolling patients who completed the Ladder or Archway (NCT03677934) trials, or who will have participated in the Velodrome trial (NCT04657289). At the time of submission of this abstract, Roche/Genentech has voluntarily recalled the PDS Ocular Implant and Insertion Tool Assembly and paused implantations. Ladder patients received the PDS (10, 40, or 100 mg/mL) with pro re nata (PRN) refills or monthly intravitreal ranibizumab 0.5 mg injections (monthly ranibizumab). Once rolled over to Portal, patients received PDS 100 mg/mL with fixed refill-exchanges every 24 weeks from day 1. Efficacy outcomes were assessed for Ladder-to-Portal patients treated with PDS 100 mg/mL for at least 5 years. Long-term safety data will be pooled to include any patient in the 10, 40, and 100 mg/mL groups of Ladder who had the PDS for at least 5 years.
Results: For Ladder-to-Portal patients, best-corrected visual acuity remained stable for 60 months from the Ladder baseline visit in the prior PDS 100 mg/mL PRN treatment arm (n = 46; patients received a mean of 2.9 intravitreal injections before randomization in Ladder); mean (95% CI) change from baseline at month 60 was –1.8 (–8.1, 4.4; n = 17) Early Treatment Diabetic Retinopathy Study letters. Center point thickness and central subfield thickness were also overall stable, with mean (95% CI) changes from baseline of –17.5 µm (–52.1, 17.0) and –7.8 µm (–32.9, 17.3), respectively, at month 60.
Conclusion: Results from Portal suggest that vision and anatomical outcomes with PDS 100 mg/mL are generally stable over 60 months. The long-term safety profile of the PDS will also be reported.

IRB APPROVAL Yes

7/30/2023 12:00 am

Wet AMD Symposium 2

Efficacy and Safety of Biosimilar Ranibizumab-nuna and Ranibizumab-eqrn in Clinical Use by a Consortium of Retina Practices

Efficacy and safety of biosimilar ranibizumab-nuna and ranibizumab-eqrn in clinical use by a consortium of retina practices

- Carl Awh, MD, FASRS
- Charles Wykoff, MD, PhD, FASRS

Objective: Are there unexpected outcomes from treatment with new commercially-available ranibizumab biosimilar agents?
Purpose: New pharmacologic therapies may have effects that were not observed or anticipated in clinical research trials but that become apparent in clinical use. This analysis of eyes treated by multiple retina specialists in different practices across the United States can provide useful information about the treatment response to the biosimilar agents ranibizumab-nuna (Ran-N) and ranibizumab-eqrn (Ran-E). These outcomes may be of interest to retina specialists and patients as they consider treatment with these new biosimilar agents.
Methods: This is a retrospective, non-randomized, consecutive case series of eyes receiving either Ran-N or Ran-E at a large consortium of retina practices across the US. Electronic medical records (EMR) were reviewed for each patient with follow-up of at least 28 days following the first injection (defined as the baseline injection) with either biosimilar agent. Clinical information was recorded; including baseline demographics, diagnosis, the number of prior anti-VEGF injections, visual acuity (VA), and the biosimilar agent used. At subsequent visits, VA, the presence of cells in the anterior chamber (AC) or vitreous, diagnosis of uveitis or vasculitis, or other adverse events were recorded. IRB approval was obtained.
Results: Among 16 retina-only group practices 5085 eyes (OD=2493 (49.03%); OS=2592 (50.97%)) of 3964 patients (Female=61.38%; Male=38.62%; Mean Age=77.8 ±11.9) were identified that received Ran-N (2001 (39.35%) eyes) or Ran-E (3084 (60.65%) eyes) and had undergone at least 28 days of clinical follow-up. 3957[3054 patients] eyes had been previously treated with anti-VEGF (mean of 5.6 (±2.6) prior injections). Mean baseline VA was 0.564 ±0.564 LogMar. Mean VA of 5085 eyes examined at approximately 1, 2, and 3 months post-baseline was 0.564 (±0.564), 0.565 (±0.565), and 0.563 (±0.563) LogMar. There was no statistically significant difference in overall vision change at any time point post biosimilar injection. 3 (0.059%) eyes with serious anterior and vitreous reaction (acute endophthalmitis) were identified. 9 eyes developed non-serious AC or vitreous cells that did not lead to alteration of treatment with biosimilar ranibizumab. There were no cases of vasculitis.

Details of the 3 eyes that developed endophthalmitis are as follows:
1 (one) eye developed severe AC and vitreous inflammation (endophthalmitis) 4 days after the 2nd injection of Ran-eqrn. The eye was treated with intravitreal antibiotics (ceftazidime and vancomycin) and vitrectomy. Cultures showed no growth. Vision prior to the 1st dose of Ran-eqrn was 20/60, HM before vitrectomy and 20/400 within 1 month of vitrectomy. Of note is that the fellow eye was also treated with Ran-eqrn, without evidence of inflammation.

1 (one) eye developed endophthalmitis 3 days following the 1st injection of Ran-nuna. The eye was treated with intravitreal ceftazidime and vancomycin and vitrectomy (vit). Cultures obtained at vit showed no growth but were

obtained after in-office intravitreal antibiotics. Vison was 20/40 before 1st injection of Ran-nuna, decreased to HM, and returned to baseline 20/30 following vitrectomy.

1 (one) eye developed severe AC and vitreous inflammation (panuveitis) 3 days after the 2nd injection of Ran-nuna. The eye was treated with intravitreal Vancomycin, Ceftazidime and Dexamethason. No cultures were obtained. Vision was 20/50 on day of Ran-nuna injection and decreased to LP, with dense vitreous debris. The fellow eye was also treated with Ran-nuna, without evidence of inflammation. The patient was medically unable to undergo vitrectomy.

9 (0.18%) eyes developed rare (+0.5) to +2.0 cell and flare in the AC or vitreous post biosimilar injection with no loss of vision and no subsequent change in biosimilar treatment. 3 eyes out of 9 eyes had +0.5 cells whereas the remaining 5 eyes had +1.0 cells and flare in either AC or vitreous. Of note, only 2 eyes were reported to have AC cells prior to the first biosimilar injection.
Conclusion: To date, 3 cases of endophthalmitis of indefinite etiology but consistent with infectious endophthalmitis and 9 cases of minimal inflammation have been identified following treatment of 5085 eyes with commercially-available biosimilar agents ranibizumab-nuna and ranibizumab-eqrn. Overall visual acuity remained stable. There was no evidence of serious drug-related inflammation.

IRB APPROVAL Yes

7/30/2023 12:00 am

Wet AMD Symposium 2

Safety and Tolerability of Suprachoroidal Injection of CLS-AX in Neovascular AMD Patients With Persistent Activity After Anti-VEGF Therapy

- Rahul Khurana, MD, FASRS
- Mark Barakat, MD
- David Brown, MD
- Allen Hu, MD
- Dennis Marcus, MD
- Joel Pearlman, MD, PhD
- Charles Wykoff, MD, PhD, FASRS
- Thomas Ciulla, MD, MBA, FASRS

Objective: Evaluate the safety and tolerability of suprachoroidal CLS-AX in nAMD patients in Phase 1/2A OASIS and extension studies.

Purpose: To assess the safety and tolerability of a single dose of CLS-AX (axitinib injectable suspension), a tyrosine kinase inhibitor, for suprachoroidal (SCS) injection in patients with active subfoveal choroidal neovascularization secondary to neovascular age-related macular degeneration (nAMD) after anti-VEGF standard of care therapy.

Methods: Eligible nAMD patients had undergone >= 2 previous injections of an intravitreal (IVT) anti-VEGF agent in the preceding 4 months, with reading center confirmation of persistent active disease, and demonstrated stable visual acuity. Patients received 2 mg IVT aflibercept in the study eye at the first visit, then received 1 treatment CLS-AX via SCS injection 1 month later, with monthly follow-up for 3 months in the primary study (OASIS) and up to a total of 6 months including the Extension Study. Criteria for supplemental treatment with aflibercept were: loss of >= 10 letters in BCVA from best measurement with exudation, increase in central subfield thickness (CST) > 75 microns, or a vision-threatening macular hemorrhage.

Results: Four dose-escalating cohorts (0.03 mg, n=6; 0.1 mg, n=5; 0.5 mg, n=8; 1.0 mg, n=8) were enrolled with a mean age 81 years, mean duration of nAMD diagnosis 54 months, and mean of 29.9 prior anti-VEGF injections. In all cohorts, there were no serious adverse events, no treatment emergent adverse events related to study treatment, no dose limiting toxicities, and no adverse events related to inflammation, vasculitis, or vascular occlusion.

For Cohorts 3 and 4: There was a 73% reduction in treatment burden at 3 months (n=16), and in the ongoing Extension Study (interim data as of 10/27/22, n=12) there was a 90% reduction in treatment burden from the average monthly injections before CLS-AX. From the ongoing Extension Study, the injection-free rate for supplemental treatment was 88% up to month 5 (7/8 patients not receiving additional therapy) and 75% to month 6 (3/4 of patients not receiving additional therapy). Through 6 months stable mean BCVA and anatomic signs of biological effect, including stable mean CST, were observed.

Conclusion: Suprachoroidal injection of CLS-AX for nAMD was well-tolerated in all cohorts. There were signs of biologic effect and durability in anti-VEGF treatment-experienced nAMD patients with persistent activity with a 90% reduction in treatment burden in the extension study.

IRB APPROVAL Yes

7/30/2023 12:00 am

Wet AMD Symposium 2

Accuracy and Residual Volume of Commonly Used Syringes for Intravitreal Injection and the Impact on Intraocular Pressure

- Gustavo Melo, MD, PhD, FASRS
- Alexander Sverstad
- Lydianne Agra
- Rodrigo Araújo
- Thiago Chagas
- Larissa Oliveira
- Olav Kristianslund
- Goran Petrovski
- Morten Moe
- Øystein Jørstad

Objective: This study assesses the accuracy and residual volume of commonly used syringes for intravitreal injection (IVI) and the impact on intraocular pressure (IOP).
Purpose: Since most commonly used syringes for IVI have not been developed for this purpose, and due to the low drug volume, we decided to assess their accuracy and residual volume, and the IOP spike of different volumes.
Methods: Eight syringe models (BBraun Injekt-F 1 mL, BBraun Omnifix-F 1 mL, BD Plastipak Brazil 1mL, BD Plastipak Spain 1 mL, BD Ultra-Fine 0.3 mL, HSW Norm-Ject 1 mL, Zero Residual 0.3 mL, and Zero Residual Silicone Oil-free 0.2 mL) were tested with 2 different needle setups (TSK and Zero Residual), with 2 different solutions (distilled water or glycerin) and target volumes (50 and 70 µL). Ten samples were included in each subgroup, totaling 80 samples for 7 syringe models (half with each needle model) and 40 for the BD Ultra-Fine (own staked-in needle). Syringe-needle setups were weighed with a 0.1 mg precision scale before liquid withdrawal, with the liquid, and after its release. The residual and the delivered volumes were then obtained. To determine the IOP rise, an experimental eye model was created. After the system had reached steady-state pressure, we measured the transient rise in pressure following injection of the following volumes of water into the system: 20, 30, 40, 50, 60, 70, and 80 µL. To administer these volumes accurately, we used a standard Hamilton Microliter Syringe. We repeated the experiment three times for each volume. One-way ANOVA was used for statistical analysis. Data are presented as mean ± standard deviation as well as percentage of exceeding volume from the target.
Results: A total of 600 syringe-needle setups were tested. BD Ultra-Fine (0.34 ± 0.28 µL), Zero Residual (1.53 ± 1.15 µL) and Zero Residual Silicone Oil-free (1.40 ± 1.16 µL) showed the lowest residual volume (p=0.000) [MCM1] in comparison to the others (range: 24.86 ± 1.78 µL for Injekt-F to 51.97 ± 3.37 µL for Omnifix-F). Regarding accuracy, the most accurate setups were: Zero Residual Silicone Oil-free (0.70% of volume excess), Zero Residual (4.49%), BD Ultra-Fine (7.83%), Injekt-F (9.42%), Norm-Ject (15.88%), Omnifix-F (16.96%), BD Plastipak Brazil (17.96%), and BD Plastipak Spain (19.41%). A pair-wise comparison showed a statistically significant difference between the ZR Silicone Oil-free to all others (p=0.000[MCM2]), except when compared to the Zero Residual (p=0.029). The peak pressure ranged from 32.3 (SD 1.4) mmHg for 20-µL injection volume to 76.5 (SD 1.0) mmHg for 80 µL injection volume. For the standard 50 µL injection volume, the peak pressure was 50.7 (SD 0.1) mmHg, and the duration of the pressure rise was 28 (SD 2) minutes.
Conclusion: There are significant differences in accuracy and residual volume across multiple syringes used for IVI. Increased intraocular pressure might be of concern as a consequence of volume excess.

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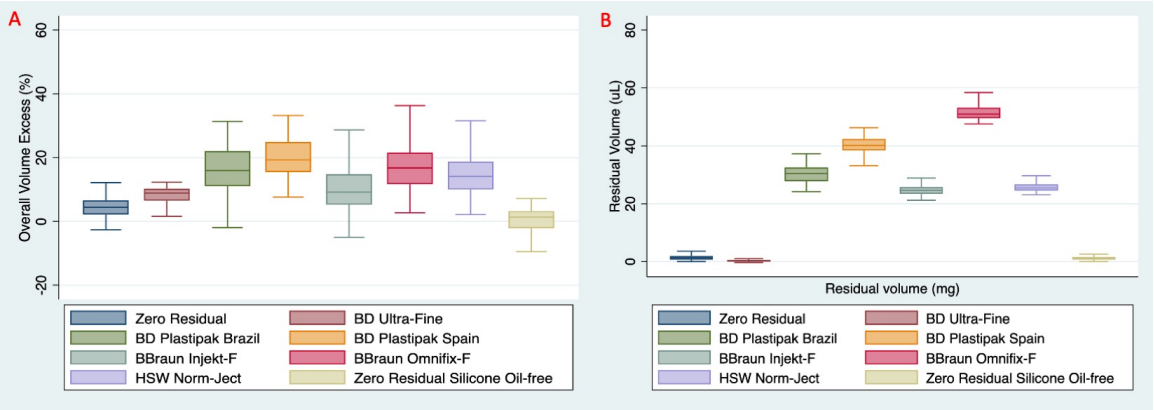
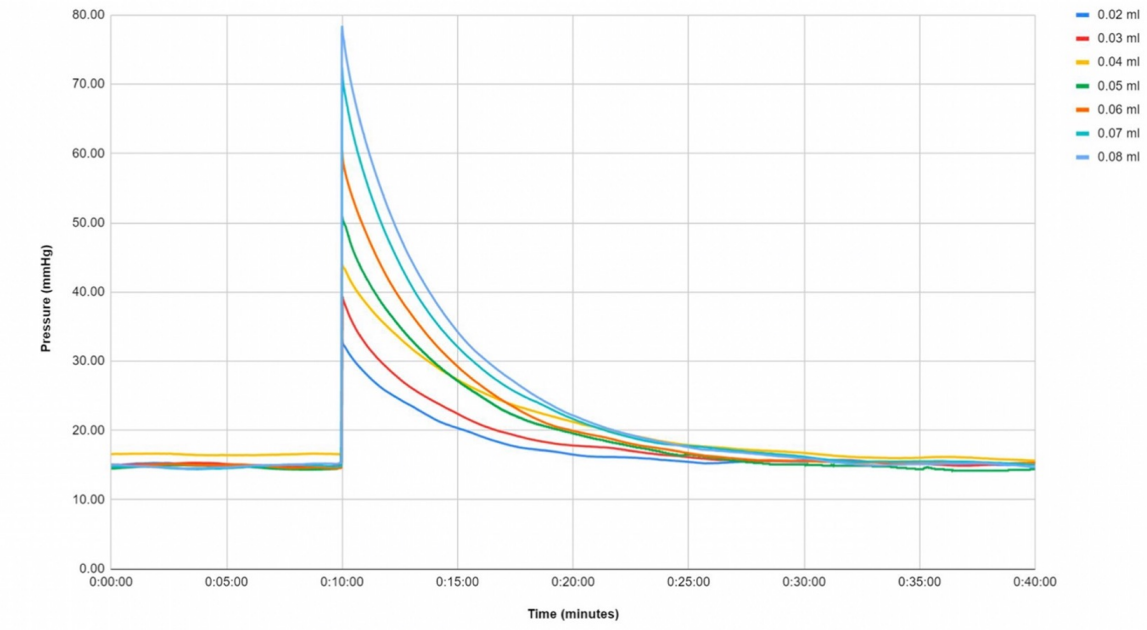


A. Combined volume excess (%); B. Residual volume in the dead space (uL)



Dynamic pressure transducer display during injection of increasing volumes

7/30/2023

Daily Imaging With Home Optical Coherence Tomography Among Treatment-Naïve Neovascular Age-Related Macular Degeneration Participants
Daily Imaging with Home Optical Coherence Tomography Among Treatment-Naïve Neovascular Age-Related Macular Degeneration Participants

- Kevin Blinder, MD, FASRS

Objective: To assess the feasibility of daily home optical coherence tomography (OCT) imaging among patients with treatment-naïve neovascular age-related macular degeneration (nAMD).
Purpose: Understanding the feasibility and usefulness of Notal Vision Home Optical Coherence Tomography (NVHO) in clinical practice is important. Whether NHVO-guided monitoring can improve visual acuity outcomes, reduce treatment burden, and lead to earlier detection of disease progression in the fellow eye is unknown. This feasibility study is the first step in answering these crucial questions.
Methods: Participants were recruited from three centers. Study eyes were eligible if they had active, untreated nAMD and visual acuity of 20/20 to 20/320. Participants were instructed to scan both eyes daily using NVHO for six months. Retina specialists managed treatment according to their standard practice, without access to the Home optical coherence tomography (OCT) data. The presence of fluid detected by a reading center from in-office spectral domain OCT scans was compared to fluid volumes measured by the Notal OCT Analyzer (NOA). Participants completed a survey on their NVHO experience at the study's conclusion. We used descriptive statistics to summarize the results.

Results: Among 40 participants meeting ocular eligibility criteria, 14 (35%) completed the study. Planned travel (n=7, 17.5%) and inadequate cell reception for upload of images (n=5, 12.5%) were the most frequent reasons for not participating. Considering scans of the study eye only, the mean (SD) number of scans obtained per participant per week was 6.3 (0.6), taking an average of 47 (31) seconds per scan. Among 2,304 scans, 86.5% were eligible for fluid quantification. All participants agreed that scanning became easier over time and only one would not want to continue daily scanning. For 35 scan pairs judged as having fluid by in-office OCT 15 (43%) had >0 to <10 nL and 4 (11%) had 0 nL as measured by NOA. There was no instance of an NOA fluid level ≥10 nL when the in-office OCT showed no fluid.

Conclusion: Patient selection for home monitoring is important. Accommodations for travel and Wi-Fi connectivity could improve the uptake of the Home OCT device. For patients with nAMD who initiated home scanning, frequency and quality of scanning, and accuracy of fluid detection were sufficient for monitoring fluid remotely. The overall patient experience was very positive as well. A randomized trial is needed to fully assess the utility of Home OCT in clinical practice.

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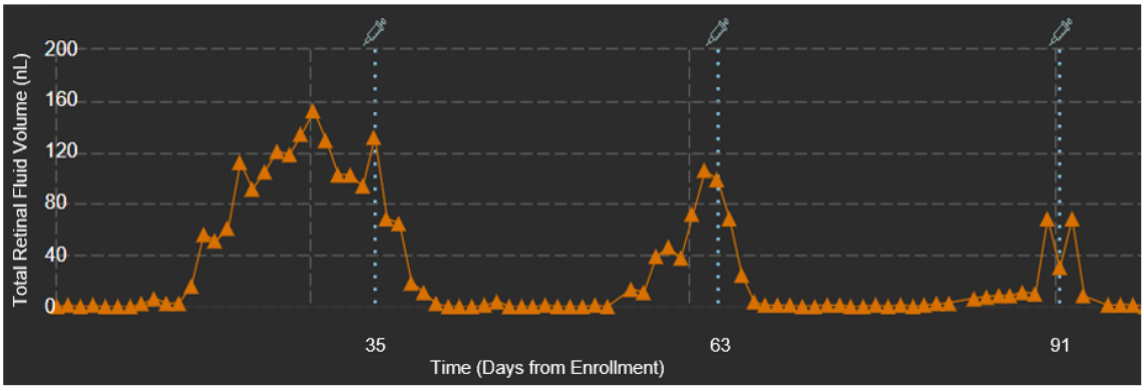
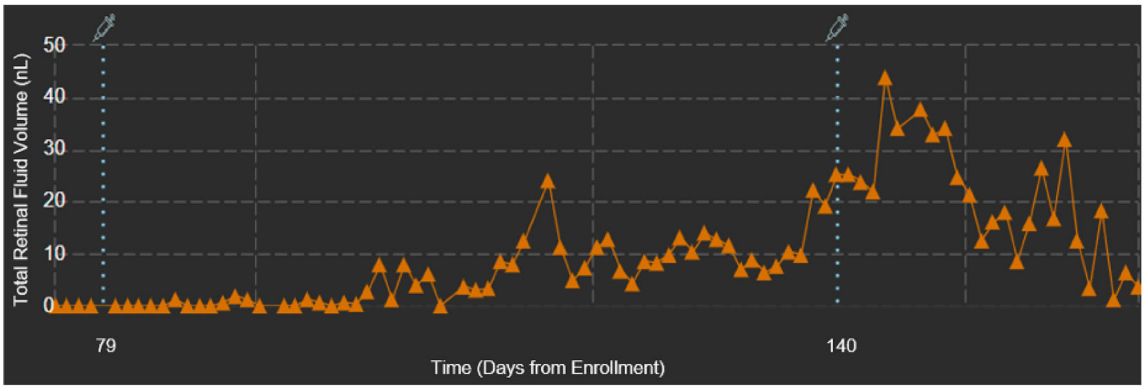


NVHO provides a better understanding of fluid between injections



NVHO could identify eyes needing earlier treatment