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RT Retina Today

THE ART & SCIENCE OF MANAGING DIABETIC EYE DISEASE

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The Art & Science of Managing Diabetic Eye Disease

CONTENT SOURCE

This continuing medical education (CME) activity captures content from a virtual roundtable discussion.

ACTIVITY DESCRIPTION

A group of retina specialists from across the country discusses the benefits of consistent treatment for diabetic eye disease and how to improve patient adherence to follow-up visits, as well as expand communication with the patient's care team in order to improve visual outcomes with currently available therapies.

TARGET AUDIENCE

This certified CME activity is designed for retina specialists.

LEARNING OBJECTIVES

Upon completion of this activity, the participant should be able to:

- **Discuss** the benefits of consistent anti-VEGF treatment.
- **Explain** why patients with diabetic retinopathy (DR) and diabetic macular edema (DME) are so often lost to follow-up.
- **Execute** patient education plans on the importance of frequent DME treatment to improve treatment and exam compliance.
- **Apply** best practices and strategies in a cross-disciplinary approach to diabetes management to better manage patients.

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DIGITAL EDITION

This supplement is part of a larger curriculum, including video case discussions, webinars, and an additional supplement. To view the full curriculum, go to https://evolvemeded.com/course-group/managing-the-diabetic-eye-real-world-strategies-for-improving-compliance-and-visual-outcomes.

To view the online version of this supplement, go to https://evolvemeded.com/course/2124-supp2.

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PRETEST QUESTIONS

PLEASE COMPLETE PRIOR TO ACCESSING THE MATERIAL AND SUBMIT WITH POSTTEST/ACTIVITY EVALUATION/ SATISFACTION MEASURES FOR CME CREDIT.

1. Please rate your confidence in your ability to explain why patients with diabetic retinopathy (DR) and diabetic macular edema (DME) are so often lost to follow-up (based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident).

a. 1
b. 2
c. 3
d. 4
e. 5

2. Please rate how often you execute patient education plans designed to improve treatment and exam compliance (based on a scale of 1 to 5, with 1 being never and 5 being always).

a. 1
b. 2
c. 3
d. 4
e. 5

3. What percentage of patients with diabetes do not have annual diabetic eye exams?

a. 40%
b. 50%
c. 60%
d. 70%

4. According to the panelists, recommended strategies to increase treatment and follow-up adherence in patients with diabetes include: (Select all that apply)

a. Have clinic hours on weekends
b. Ask patients to come in for fewer appointments
c. Take a "tough love" approach the next time you see them after a long lapse
d. Employ telemedicine

5. Why are patients with diabetes so often lost to follow-up (LTFU)? (Select all that apply)

a. They don't care about their health
b. They are often of working age and can't get off work
c. They have too many competing medical appointments
d. They don't want to make the necessary changes to manage their disease

6. _____ found that patients with center-involved DME and good vision (20/25 or better) can be initially managed with observation.

a. Protocol S
b. Protocol V
c. Protocol W
d. Protocol T

7. A 45-year-old patient with type 2 diabetes lives in rural Appalachia, about 2 hours from the nearest retina specialist. She works as an hourly employee, and does not get paid sick leave. Her diabetes is moderately controlled, with an HbA1c around 8%. She does her best to keep up with her many medical appointments but, because the retina office is so far away, she often misses her annual exams. She presents after LTFU for 18 months, complaining of reduced vision and floaters bilaterally. Upon exam, she's diagnosed with PDR. What would be considered the best first-line treatment for this patient?

a. PRP in both eyes
b. Immediate anti-VEGF therapy
c. Anti-VEGF therapy first, followed by PRP in both eyes
d. Pars plana vitrectomy

8. Of the following, which imaging modality is considered most useful to educate patients about their disease?

a. Fluorescein angiogram
b. Indocyanine green angiography
c. Fundus autofluorescence
d. Ultra-widefield

9. The reported compliance rate in Protocol V was _____.

a. 90%
b. 80%
c. 70%
d. 60%

10. A key conclusion from Protocol AB is that _____.

a. PRP and ranibizumab are both good options for the treatment of PDR, with similar results at 5 years.
b. There were no differences in VA between ranibizumab alone or ranibizumab plus dexamethasone intravitreal implant.
c. There is no difference in VA between aflibercept or vitrectomy and PRP in patients with vitreous hemorrhage from PDR.
d. Aflibercept offers the most VA improvement in patients with moderate or worse vision loss from DME.

The Art & Science of Managing Diabetic Eye Disease

Diabetes is a growing public health crisis.[1] As more patients are diagnosed with diabetes, more patients are appearing in the retina office with diabetic macular edema (DME) and proliferative diabetic retinopathy (PDR). In the United States, approximately 500,000 people have clinically significant DME, and approximately 700,000 have PDR.[2] DME is the most common cause of visual loss in those with DR and is increasing in prevalence; approximately 11% of patients with DR have DME.[3] Today, we have at our disposal many treatment options for diabetic eye disease, including anti-VEGF therapies, corticosteroids, laser, surgery, or a combination. Although guidelines and clinical trial data influence treatment selection, patients with diabetes have unique challenges with compliance and follow-up, necessitating a thoughtful, nuanced approach to treatment. One size does not fit all. The following roundtable brings together thought leaders in retina to discuss the latest literature and the real-world complexities of treating patients with diabetic eye disease.

— Allen C. Ho, MD, FACS – Program Chair

FIRST THINGS FIRST: GETTING DIABETIC PATIENTS SCREENED

Q | **Dr. Ho:** In some ways, I think of diabetes mellitus as the other pandemic we were living in before the COVID-19 pandemic set upon us nearly 2 years ago. There is a growing number of patients globally with diabetes. About a half billion people are living with diabetes worldwide, and that number is projected to increase by 25% in 2030 and by 51% in 2045.[1] Although the numbers vary, we can assume 50 to 60% of diabetic patients in the United States do not adhere to their annual diabetic eye exam.[4] Dr. Khan, how can we do better?

M. Ali Khan, MD: The problem starts with screening. There are so many patients with diabetes that we don't have enough ophthalmologists or retina specialists to examine them all; it's untenable given the numbers. We need better ways to screen people effectively. There is evidence that teleophthalmology and telemedicine are viable ways to screen patients more efficiently.[5,6] A variety of retinal imaging technologies exist for telemedicine, including digital imaging systems, hand-held fundus cameras, and nonmydriatic cameras. Smartphones can also be used as fundus cameras.[7] Cameras could be placed in a primary care physician's office or standalone image-based centers could be created in places where diabetics go frequently. I expect a recurring theme of our discussion to be ways to avoid vision loss in our patients, and the first step is screening and catching those individuals earlier in the disease process.

Dr. Ho: Dr. Berrocal, you practice in Puerto Rico where presentations of late-stage diabetic eye disease is common. Are there any strategies for diabetic awareness in Puerto Rico?

Maria H. Berrocal, MD: The problem with diabetes is that a large percentage of the people with severe diabetic disease in the United States are uninsured and/or unaware of their disease. Nearly 3% of all US adults and 21% of all US adults with diabetes are undiagnosed.[8] I see many patients with proliferative disease, and they don't know they're diabetic. From the public health standpoint, we must start screening for diabetes earlier.

What is really disheartening is the number of children and adolescents with type 2 diabetes, which is directly associated with the obesity epidemic. The SEARCH for Diabetes in Youth study found that between 2002 and 2012, the rate of type 2 diabetes in children and adolescents increased by nearly 5%.[9] Many of those patients will not be diagnosed until much later. That is a huge public health issue. Our patients who are 65 years and older are well covered because diabetes exams are required under Medicare. But younger diabetics oftentimes don't see a doctor. They are underinsured or uninsured, and those are the patients we need to reach. First, we need to get them diagnosed. Then we need to treat them for their diabetes and screen them for retinal disease.

Dr. Ho: The United Kingdom has a single-payer system, and everyone is insured. Under the National Health System, everyone with diabetes is required to have a diabetic eye exam, and they have much better compliance.[10] To be clear, I am not advocating for a single-payer US system, but there can be certain advantages on public health issues, DR is one example.

Q | **Dr. Ho:** Dr. Gupta, you've seen diabetic patients on both coasts of the United States, and no matter where you go, they often have problems with treatment and compliance. What are your strategies for talking to patients about the treatment options, including laser, medication, or observation? How do you get patients to comply and come in for follow-up exams?

Mrinali Gupta, MD: Compliance can be a challenge for

patients with diabetes.[11-14] This is a younger, working-age population with many medical appointments—endocrinology, cardiology, nephrology, etc. Some patients are on dialysis 3 days a week, and they're not available to come in for ophthalmology appointments. It doesn't help if the ophthalmology appointments are long, whether related to wait times or related to dilation and testing.

While there are some things we can't change, there are also some things we can do. First, we can improve patient education. I spend a lot of time early on explaining what DR is, how it affects the eyes, and driving home the point that there's a big space of time and disease between asymptomatic, minimal disease and blindness during which we can do things in the office to reduce the risk of surgery and/or vision loss. I explain that if they optimize their medical conditions and if they come in for treatments, we can maintain and improve their vision and reduce the risk of vision loss significantly. In addition, we as physicians can continue to make the office visit burden as manageable as possible, whether it's through clinic efficiencies, injection visits/clinics, etc. The good news is most of us have pretty smooth injection visits, where patients are in and out quickly. I try to emphasize after the first visit, which is often longer due to testing like angiography, that most visits will not be as long or as testing heavy. Since moving to California, I have had a Saturday morning clinic, which has been really valuable for the patients with diabetes who have a hard time getting off work during the week.

Dr. Ho: Dr. Maturi, you've had a lot of experience in clinical trials exploring different aspects of DR. Although we're guided by clinical trial results for choosing different therapy or observation for patients, there's much discussion about the differences between clinical trial and real-world populations.[15] Maybe clinical trial patients have better glycemic control and HbA1c, and maybe they're more likely to comply with treatment and follow-up appointments. Is that something we should consider when we're looking at clinical trial data and applying it in the real world?

Raj K. Maturi, MD: Yes, very much so. If we look at follow-up in the PDR protocol (Protocol S) as well as the NPDR protocols (Protocol W, V, AA), for example, the best we could get at 2 years was about an 80% compliance rate with follow-up.[16-18] Protocol V was a little higher, but that is all we achieved in Protocol W at 2 years. If we look at real-world data, the average patient with DME is treated three or four times per year.[19] This is far less than would be expected based on Protocol T, which on average you would expect eight injections in the first year of treatment.[20,21] Undertreatment is a big issue for the diabetic population.

Where I practice in Indiana, it's a bit more rural. We have about a 13% incidence of diabetes. Our goal is to always treat patients on their first visit, which helps emphasize the importance of prompt treatment.

I also work hard at not blaming the patient for missing visits. Making them feel guilty makes them return to your office less. Even when you're frustrated because they haven't seen you in 6 months and now have PDR, it's critical not to say what you're thinking. I like the idea of creating a Saturday clinic. We need to think beyond injections alone so we can decrease the number of visits for these patients.

"I've also found that showing the patient their pathology on a widefield photograph may help motivate them to be more compliant."

—Allen C. Ho, MD, FACS

Dr. Ho: I've also found that showing the patient their pathology on a widefield photograph may help motivate them to be more compliant. You can use that over time to show them regression, potentially, or no progression. You can show them the images from their optical coherence tomography (OCT) and, instead of blaming them, you can show them something positive to encourage compliance. Let's move forward and dig into some cases, all courtesy of Eric Nudleman, MD, PhD.

CASE 1: PDR SHOCK IN A YOUNG PATIENT WITH TYPE 1 DIABETES

Dr. Ho: The first case is a 35-year-old woman with a longstanding history of diabetes who was diagnosed since age 10. Her HbA1c level has been excellent for many years and is currently in the 6% range. She complains of floaters. She's has a continuous glucose monitor, and she happens to be an emergency room physician. Figure 1 shows her baseline images from 2012. Dr. Khan, what do you see here?

Dr. Khan: This is a nonwidefield photograph of both retinas that provides a good image of the optic nerve, vessels, and macula. I don't see signs of any neovascularization of the discs (NVD), and there are no obvious hard exudates or anything to suggest DME. The vessels look pretty good, at least in the magnification seen here. Nothing screams high-risk disease at this point.

Q | Dr. Ho: Dr. Gupta, what testing to do you obtain on a patient with diabetes during an initial evaluation?

Dr. Gupta: Before I see a new patient, they are dilated. All patients also undergo an OCT before I see them. If there is significant retinopathy (moderate NPDR or worse) on examination, I also perform fluorescein angiography (FA).

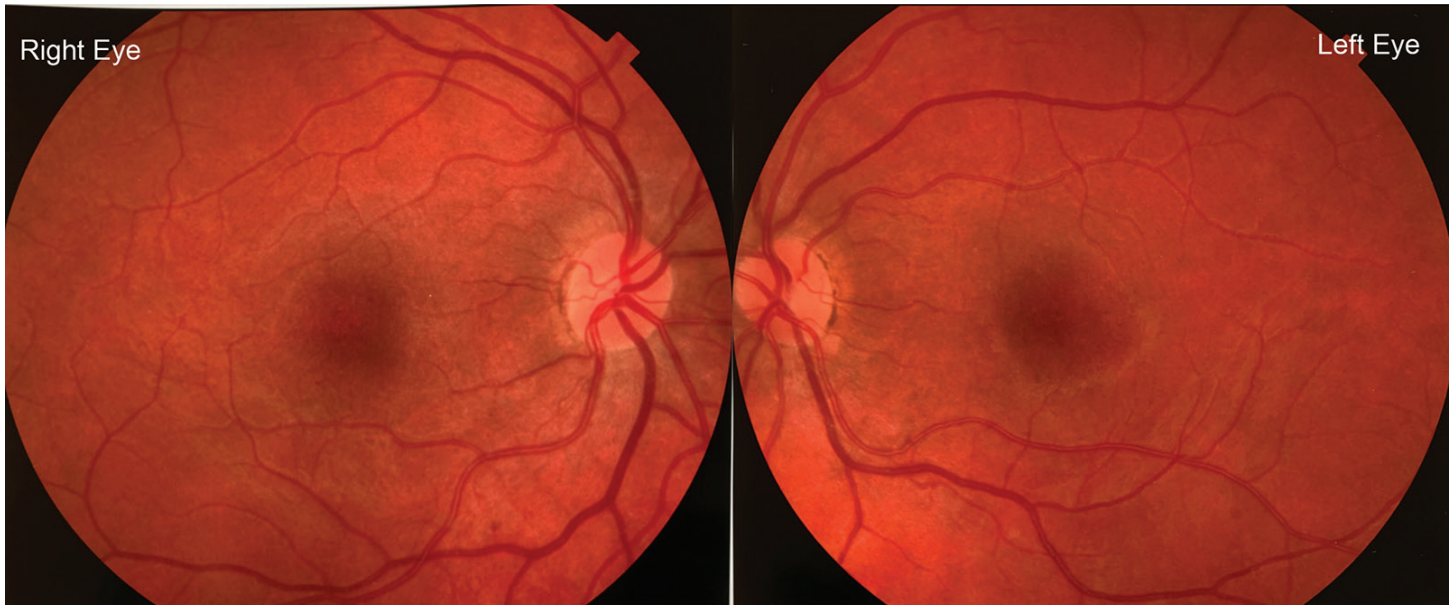

Figure 1. Case 1: Baseline non-widefield imaging.

Dr. Maturi: I agree with your approach, Dr. Gupta. I also consider an Optos widefield FA because it's a fantastic education tool. It's important to not only document the severe ischemia, but also to show the patient exactly where the pathology and what you're trying to avoid.

Dr. Berrocal: I always obtain an OCT for my patients. I may consider Optos if I see a retinal detachment. If they have a lot of blood, I'll choose an FA.

Dr. Ho: We don't have Optos in every office in my practice at this time, but there is value in it for diabetic evaluation and education. Returning to the case, Figure 2 shows her color fundus photograph and FAs. Dr. Berrocal, what do you see from these images?

Dr. Berrocal: This is something that happens frequently in patients with type 1 diabetes. The fundus may not look that bad, but when we perform ultrawidefield imaging, we see extensive ischemia in the periphery and significant neovascularization in the right eye. There's NVD and neovascularization elsewhere (NVE) and a subhyaloid hemorrhage. This is very common in young patients with diabetes. The hyaloid starts separating maybe minimally and then they bleed in the subhyaloid in the area that is slightly separated. The left eye already has proliferative disease with extensive ischemia in the periphery.

Dr. Ho: What's your management plan for this patient?

Dr. Berrocal: I would treat the left eye with panretinal photocoagulation (PRP). In my opinion, the left eye is not a candidate for anti-VEGF alone because the anti-VEGF won't do anything for the ischemia. I would offer the patient surgery for her right eye. I may pretreat the right eye with PRP in the ischemic areas and far periphery before taking them to the operating room.

Dr. Ho: The patient's VA is 20/20 in the right eye. The first time you meet the patient you're taking them to the operating room?

Dr. Berrocal: Well, no. In this case, the assumption is I've been following them yearly. If this was the first time I saw them, I'd show them their imaging and tell them that if this worsens it could lead to a retinal detachment, which we may not be able to fix. I'd offer them PRP and follow-up in a month to see what happens with the blood. I oftentimes tell them to watch their vision and check for metamorphopsia so they can tell if they are getting worse within that month. These eyes can progress very quickly to retinal detachment in as short as 3 weeks, especially in patients with type 1 diabetes, even if they are well controlled.

Dr. Ho: Dr. Khan, how would you manage this patient? You've been following them for a while, she comes in with these new floaters, and you have these images.

Dr. Khan: I'd wait on treating the left eye, which has significant ischemia but no active vitreous hemorrhage. For the right eye, I'd treat with one to three anti-VEGF injections to calm down the disease before proceeding with PRP. Once the right eye is stable, I'd move on to the left eye, likely starting with PRP laser without anti-VEGF injections. But I also agree that surgery for this patient is a reasonable idea. I bring up surgery much earlier than I used to with these patients.

Dr. Ho: Dr. Gupta, if you were going to do scatter laser treatment or PRP for one or both of these eyes, how would you do it? Would you do it equator and out? Would you try and do it targeted based on the FA?

Dr. Gupta: I try to get in a full good PRP, especially in that right eye that has a lot of disease. I would start at the edge of the ischemia, but I'd also do 360° treatment.

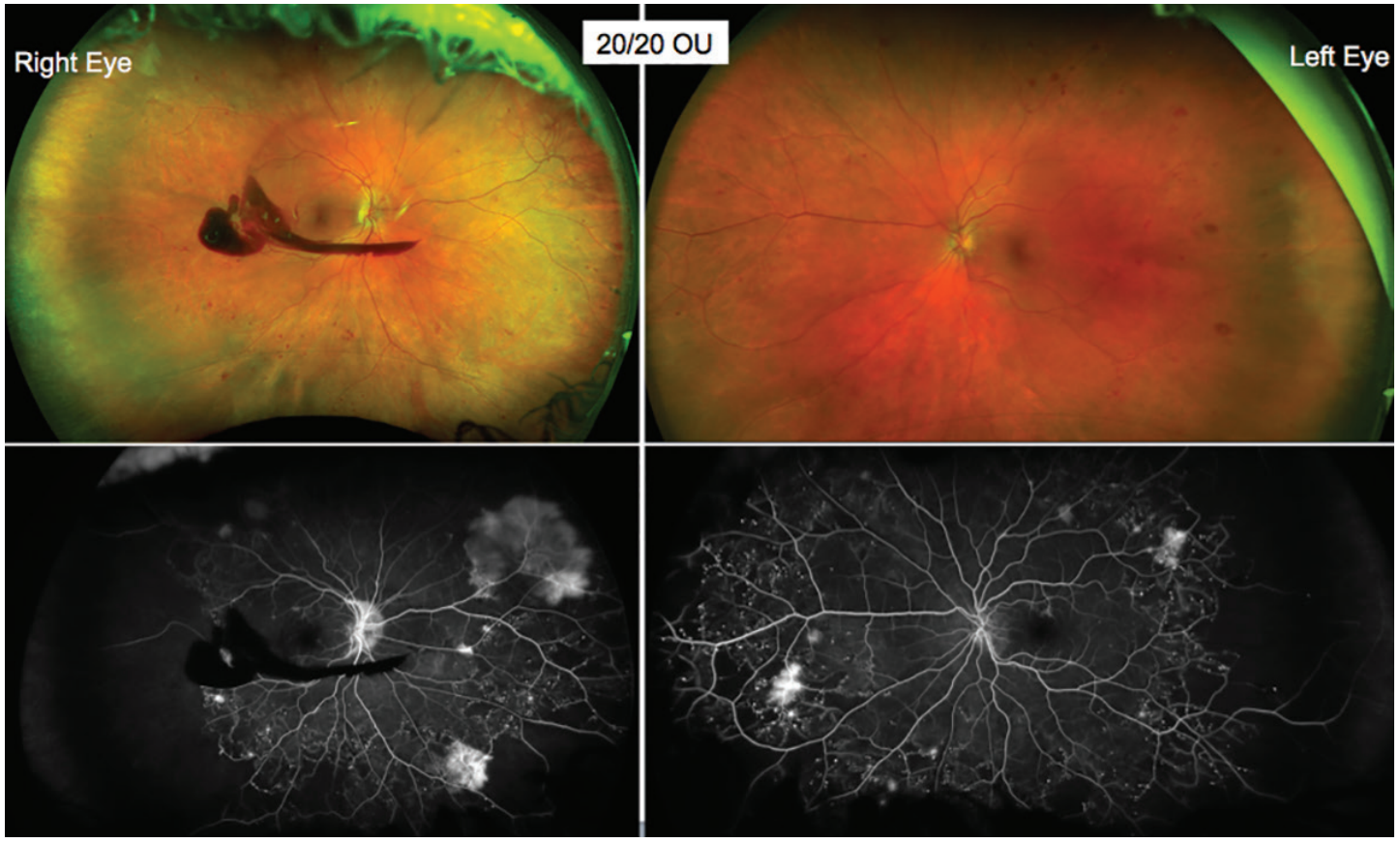

Figure 2. Case 1: Color fundus and fluorescein angiography.

Dr. Maturi: My technique is a little different based on what we found in Protocol S as well as the CLARITY PRP study from England.[16,22] The tables and the supplements of both studies show there's a significant increase in central macular edema after PRP.[22-24] I've changed my approach based on these data. I would treat this patient with 0.7 mg intravitreal dexamethasone implant for the left eye and have them come back for a PRP over 2 visits.[25,26] I would treat every area of ischemic that you see on Figure 2 and extend it toward the area of neovascularization. Everything anterior to the neovascularization is generally treated. I do it this way because I know they will not lose any visual field if I only treat the ischemic retina. On the right eye, I would probably do the same thing in the beginning and see how that hemorrhage clears. But there's a very good chance I'll be taking that patient to surgery much sooner than later.

Dr. Ho: Dr. Khan says first-line anti-VEGF, then quiet the disease, then do laser. Dr. Maturi says first-line dexamethasone implant and then add laser. Very interesting. What do you think, Dr. Berrocal?

Dr. Berrocal: I think first-line treatment with the intravitreal dexamethasone implant and then adding laser is a brilliant idea because of the reduction of edema. I use either dexamethasone or triamcinolone in diabetic patients with present or past history of macular edema who are undergoing cataract surgery or combined phaco-vitrectomy. I feel it really reduces the risk of macular edema postoperatively. You also don't have to worry about having some crunch effect if fibrovascular tissue is present and the hyaloid is not detached—as can happen with anti-VEGF injections. I am going to try this approach. These discussions are so valuable because we learn so much. Our field is an art; it's not a cookbook recipe. All patients are different, and there are nuances to treatment.

"Our field is an art; it's not a cookbook recipe. All patients are different, and there are nuances to treatment."

—Maria H. Berrocal, MD

Dr. Maturi: I would also look back to Protocol U, which showed that even though visual acuity was the same after 6 months in treatment-experienced patients with DME, the amount of edema was significantly more in the anti-VEGF treated eyes than the steroid treated eyes.[27]

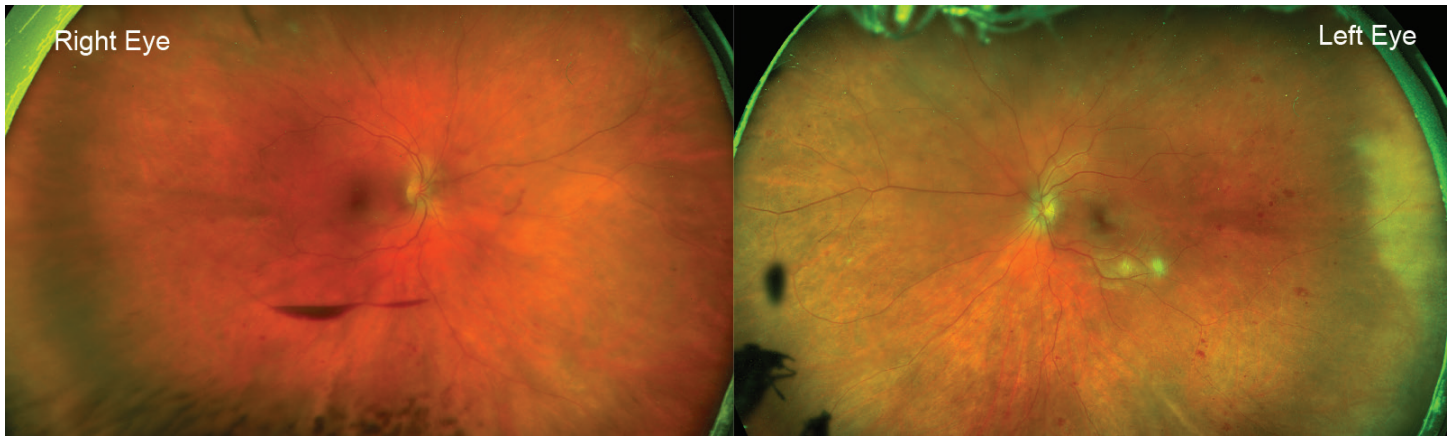

Figure 3. Case 1: Imaging posttreatment.

Dr. Ho: To summarize, don't throw out your laser, don't forget about steroids, and consider anti-VEGF and early vitrectomy. Figure 3 shows our patient posttreatment. Dr. Gupta, what are your observations?

Dr. Gupta: It looks like this patient received two rounds of bevacizumab in her right eye and has cleared some prehyaloid hemorrhage. I cannot tell if the view is a little hazy overall, but in general it looks like things are improving with just two injections in the right eye. I don't see much change in the left eye, and no evidence of laser treatment.

Q | **Dr. Ho:** This patient had some clearing of that blood and two anti-VEGFs in the right eye; the left eye was observed. Would anyone have treated the left eye based on the course of the right eye and the images that we saw earlier with NVE?

Dr. Berrocal: Yes, I would have treated the left eye with laser to all of the ischemic areas.

Dr. Khan: I would also treat the left eye. I'd also assess if the patient was comfortable treating both eyes at the same time. I've had some patients not necessarily come back or want to come back if they felt overwhelmed. I'd get a sense for their tolerance for treatment and first focus on the right eye, then if they're okay with moving to the left eye, treat it with laser.

Dr. Ho: Paying attention to the tolerance of your patient in the chair is good advice. If I didn't have a widefield fundus photograph and FA to show them what was brewing in the left eye, it would be more difficult to justify an intervention. But considering I have those images, I would encourage them to consider laser treatment.

CASE 2: MONOCULAR PATIENT WITH UNCONTROLLED TYPE 2 DIABETES OFF MEDICATION

Dr. Ho: Our next case is a 67-year-old Japanese professor who has had diabetes for 11 years. His HbA1c is not well-controlled and is currently 10.2%. He stopped his medicines because he wanted to work on controlling his hyperglycemia off medication. He's functionally monocular because the left eye has had poor vision since childhood. Figure 4 shows his imaging. Dr. Maturi, what are your observations?

Dr. Maturi: His right eye has a VA of 20/32 with significant hemorrhages near the optic nerve. The horizontal scan of the fovea of the right eye shows no central edema, but a scan of about a millimeter or so above the horizontal shows significant exudates centrally. I suspect there's some thickening clinically, but I can't see that on the image. On the left eye, there's significant exudate throughout the superotemporal arcade extending right to the fovea with larger exudate at the foveal center. That might account for some of the vision loss, but the left eye shows it's been there for quite some time.

Dr. Ho: How would you approach this patient?

Dr. Maturi: I would explain that treatment would help save the left eye should something happen to his right eye. Given the significant central exudate, I would use a drug that has the most potential and potency for treating significant edema with exudate. I would probably use aflibercept in the left eye.

In the right eye, I'd suggest focal laser based on the FA. The amount of retinopathy is still in the moderate range. Because it's moderate, a focal laser to the few microaneurysms that are present may stabilize the vision. However, I don't see anything wrong with an intravitreal injection and focal laser; both are reasonable. But given the microaneurysms and the location, I think focal laser would probably make sense here. With VA of 20/32, the vision is worse than you'd expect for Protocol V, where VA had to be 20/25 or better.[28] This would be a case in which we would use Protocol T as a roadmap because the VA is worse than 20/25, but still good enough for aflibercept to be effective.[20]

Q | **Dr. Ho:** As you know, our retinal trainees do not commonly use focal laser. What are your best strategies for executing focal laser?

Dr. Maturi: I've coauthored a free book titled *Diabetic*

Retinopathy for the Comprehensive Ophthalmologist (a free download is available at https://drcobook.com/download). Dr. Jonathan Walker is an expert of focal laser and authored two chapters on this specifically. In the book, he describes exactly how he does it.

To summarize, use any part of the retina that's actually flat without edema, find a spot that just barely changes color, go back to the area of microaneurysm that you can see on the fluorescein, and aim for the microaneurysm. It's okay if the patient moves. It's also important to disassociate your hand from your foot, as there's a tendency to move both initially. Once you learn to use a focal laser appropriately, then you can actually treat the microaneurysm and see a significant decrease in the size without causing significant artery damage. The worst mistake we can make is to overtreat the retina because that is what causes retinal pigment epithelial atrophy, which generally grows over time.

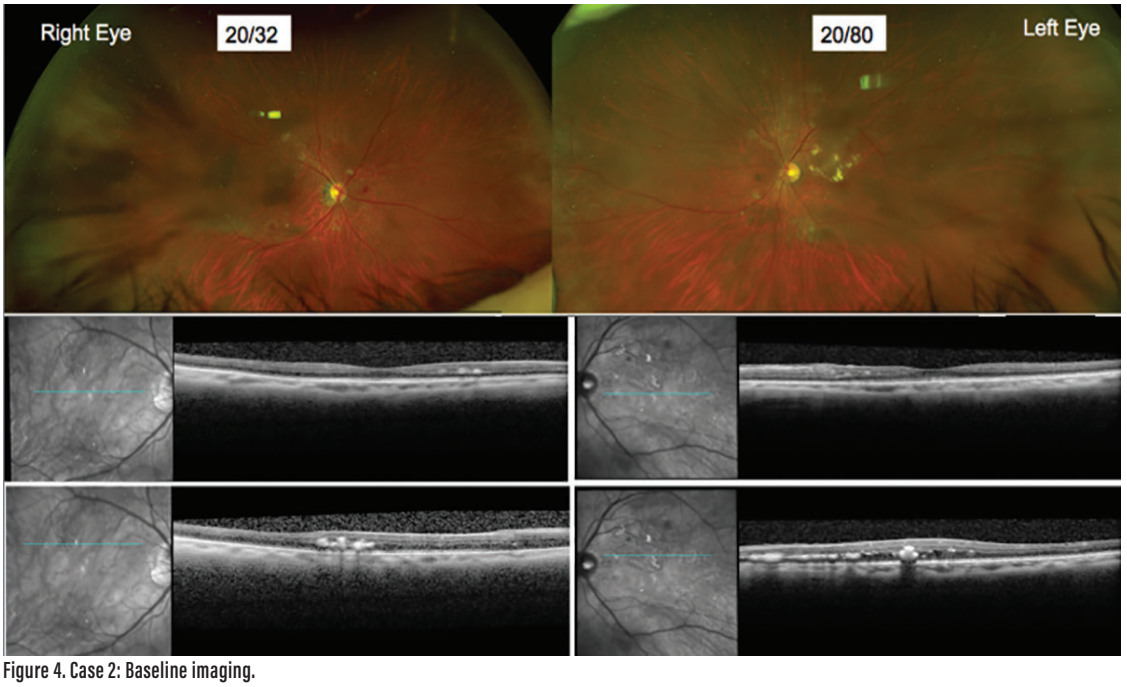

Figure 4. Case 2: Baseline imaging.

Dr. Khan: What Dr. Maturi mentions about finding an area away from the edema and looking for a color change is also what I do. Focal laser is a dying art. Part of that is because not everyone is obtaining an FA, and it's a lot quicker and faster to do an injection in today's world than a laser treatment.

For this patient, I'd ask him to go back on systemic medications before doing anything. If that resolves the edema, then nothing is necessary. Sometimes giving the patient an option of either eye injections or laser is enough to motivate them to be compliant with systemic treatment. I would offer him a few options, feel out his response, and see what he'd like to do.

Dr. Gupta: I would probably observe the right eye in the setting of getting them back on their medication, given the lack of central edema on the OCT scan. I would watch it closely. The left eye does have central edema and exudates, so I would start the left eye with aflibercept, based on Protocol T data. If the left eye does not improve quickly, I would use steroids earlier rather than later, because I think it is very useful, especially in chronic DME, which is likely the case here based on OCT features like prominent exudate.

Dr. Ho: Dr. Maturi, please take us through what you've distilled from Protocol V.

Dr. Maturi: Protocol V was a large study of nearly 900 subjects.[28] Eyes were randomly assigned to 2.0 mg of intravitreous aflibercept (n = 226) as frequently as every 4 weeks, focal/grid laser photocoagulation (n = 240), or observation (n = 236). If any patient in the observation group developed clinically significant edema, with visual loss of at least 10 letters at a visit or 5 letters at two visits, they were treated. At the end of the study, about seven patients in the observation group were treated. The implications were that patients with center-involved DME and good VA (20/25 or better) can be initially managed with observation and close follow-up. To me, the question is: what is better, immediate or delayed treatment? This study showed that if the vision is good, delayed treatment does not affect their long-term prognosis (Figure 5).

Dr. Ho: Excellent synthesis. I find the most compelling reason not to have that hard VA 20/25 rule apply to Protocol V in my clinic, is that an ETDRS refraction takes a 20/50 patient down to 20/25 almost every time. I can't translate that particular visual acuity threshold to my nonrefracted pinhole vision, even in my clinic.

CASE 3: YOUNG TYPE 1 DIABETIC WITH SUDDEN PDR DESPITE WELL-CONTROLLED DISEASE

Dr. Ho: Our next case is of a 37-year-old patient with type 1 diabetes who noted floaters in her left eye for 1 month. She has lived with a diabetes diagnosis for more than 20 years. Her diabetes is well-controlled on an insulin pump with a last HbA1c of 7%. She has no other significant medical issues.

Her VA is 20/20 in the right eye and 20/40 with floaters in the left eye. Her intraocular pressures are good: 17 mm Hg in her right eye and 15 mm Hg in her left. Anterior segment exam is unremarkable. Figure 6 shows her fundus photographs. Dr. Gupta, please describe what you see in Figure 6.

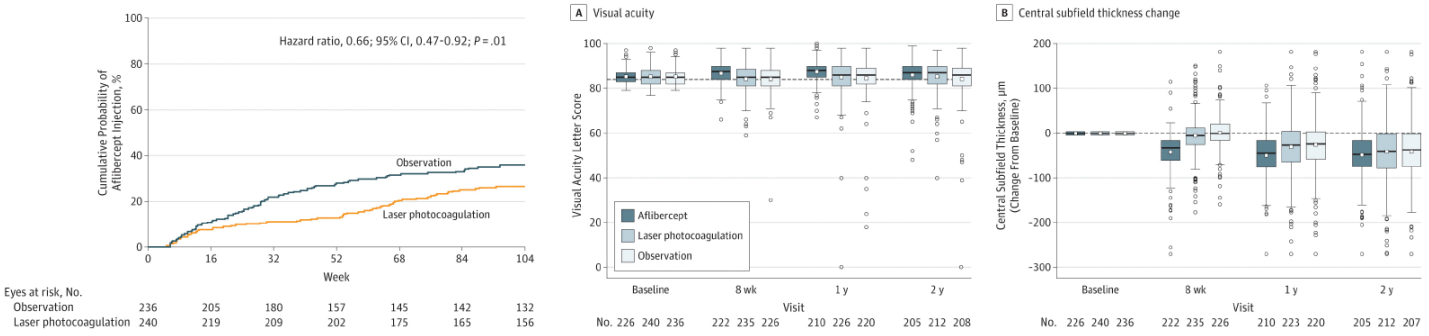

Figure 5. Key results from Protocol V.[17]

Dr. Gupta: Her right eye shows no signs of vitreous hemorrhage. I don't see any significant findings other than some dot and blot hemorrhages. Of course, I'm curious to see what the FA will show, especially given what is going on in the left eye. The left eye looks like there's some vitreous hemorrhage, subhyaloid hemorrhage, an area of possible NVD and an area of NVE superotemporally.

Dr. Ho: Figure 7 shows that FA you were wondering about. What do you see here?

Dr. Gupta: The right eye has pretty significant NVE and some localized areas of capillary nonperfusion. The left eye has hemorrhage and NVE as well and some localized, small areas of nonperfusion. This patient has PDR in both eyes.

"I never do bilateral PRP because it's a lot for a patient to handle. I will, however, do bilateral injections."

—Raj K. Maturi, MD

Q | Dr. Ho: I agree with you—PDR in both eyes. How would you manage the right eye?

Dr. Gupta: I would promptly treat both eyes with anti-VEGF. I'd actually treat the left eye sooner than the right eye. I would then start adding PRP. I usually begin with anti-VEGF to quiet things down and because it starts working immediately, and then I start PRP, which of course can take longer to have an effect.

Dr. Khan: I'd also focus on the left eye, which has more of the high-risk pathology. I'd also start with anti-VEGF before PRP. I'd assess if they were okay with treating both eyes at the beginning. If I feel they want to run out of the room, I first treat the left eye and then defer the right eye for later.

Dr. Maturi: I would probably treat with the 0.7 mg intravitreal dexamethasone implant in the left eye because it may have a slightly higher risk for traction development. I don't like to use the dexamethasone implant in both eyes at the same time because of the side effects of steroids. I'd inject anti-VEGF in the right eye. I'd treat both eyes at the first visit so they're stable.

When they come back, I would start the PRP early on the left eye and then give them another anti-VEGF injection or dexamethasone in the right eye so I can follow up with PRP at the next visit. I never do bilateral PRP because it's a lot for a patient to handle. I will, however, do bilateral injections. It depends on the patient. What is a barrier for them? Is it the inconvenience of coming to the office or the pain and discomfort of injections?

Dr. Ho: Dr. Berrocal, do we need a prospective randomized clinical trial on pars plana vitrectomy (PPV) versus another therapy versus observation for patients with significant DR? Significant DR could be severe nonproliferative diabetic retinopathy (NPDR) in a 30-year-old, early PDR, or advanced PDR.

Dr. Berrocal: My answer is, of course, yes, but I think the crux of these patients is the status of the hyaloid. Let's say the right image of Figure 7 was on someone with a complete posterior vitreous detachment (PVD). In that case, I wouldn't worry too much because that patient will not likely bleed. Even though they have a lot of neovascularization, which has to be treated, but there's no immediate urgency. There was a study by Ono et al of 403 patients followed for 3 years that showed patients who have a full PVD with collapse have no progression of the retinopathy.[29] If they have a partial PVD with thickened posterior hyaloid, 100% show disease progression. If they don't have a PVD, only 43.8% show retinopathy progression. In these cases, the status of vitreous is key. On the left side of Figure 7, you can see that neovascularization is a little elevated, which tells you the hyaloid is starting to separate there. That is what is worrisome.

Where I practice in Puerto Rico, many patients have a difficult time traveling, some fly in from the Caribbean islands. I may not see

a patient like this come in for 6 months or longer, and they may not receive any follow-up care where they live. For those reasons, I would use PRP in both eyes. However, if a patient can come in every month, then I may start with anti-VEGF injections in the right eye and PRP in the left. I oftentimes treat both eyes in the same visit, because, depending on their hardship or situation, they may never come back.

That's really the most important thing with compliance. We need to assess if the patient is paying out of pocket, because they may not have the funds to come again. They may not have enough money for injections. We also need to consider the distance they must travel to come to appointments. Maybe the patient is nervous about a laser and doesn't want to do it. Maybe they fear injections more than laser. These are all factors that impact compliance. Our field is an art, and our treatments must be personalized. We need to remember we are treating a patient, not just an eye.

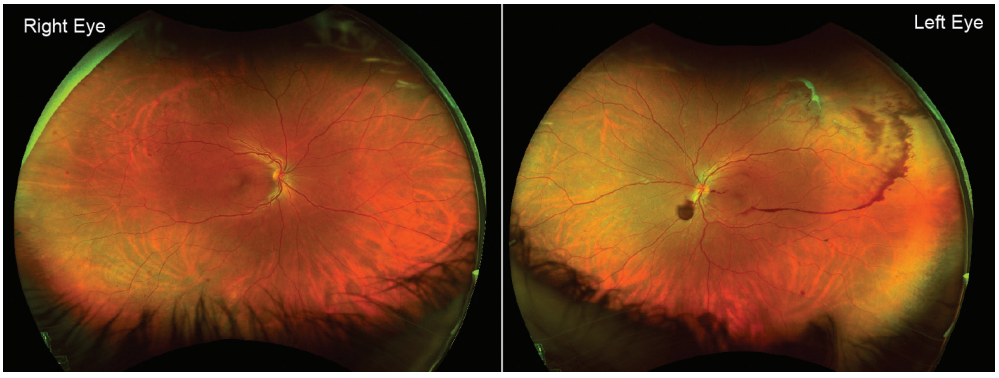

Figure 6. Case 3: Baseline fundus photos.

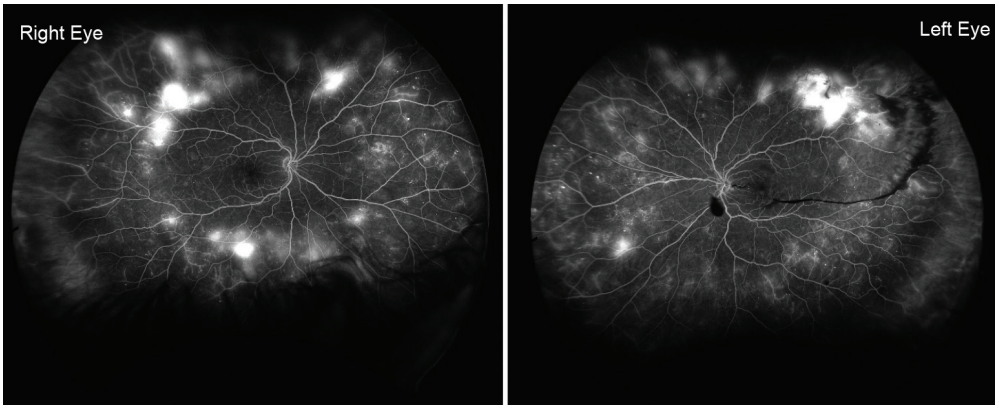

Figure 7. Case 3: Baseline fluorescein angiogram.

Dr. Ho: Well said. Continuing with our case, the patient was started on anti-VEGF and subsequent scatter laser for the right eye, and anti-VEGF and scatter laser for the left eye. The patient developed more vitreous hemorrhage and underwent surgery. Figure 8 shows the left eye after anti-VEGF, some laser in the office, and then surgery. The patient is doing really well. Is this a surgical cure or PDR? I don't know.

I do have a lot of patients who look like this, which is one reason I think a prospective surgical trial would be very interesting. I do notice there is some sparing in the left eye of the 3 and 9 o'clock positions. I'll do that often in the office, in the OR setting with controlled anesthesia, where pain is not so much of a problem. The right eye did develop more bleeding, and the physician decided to intervene earlier with surgery. This patient would have possibly benefited from earlier vitrectomy.

CLOSING COMMENTS

Q | Dr. Ho: Gupta, do you have closing comments?

Dr. Gupta: It's an exciting time in our field as we get more data on different ways to treat these patients. For example, in this last case, I think it's reasonable to do an early PPV in either eye as soon as they have a vitreous hemorrhage. It's also reasonable to treat with anti-VEGF for a few months and follow-up with laser. As we've alluded to, treatment decisions must be patient-centric. Protocol AB showed no long-term difference in vision, whether you go directly to the operating room or watch them for a period of time with anti-VEGF therapy.[30] There may be some benefits to going to the operating room faster and getting that hyaloidal traction off and a really complete PRP. Although there was no long-term vision difference in that study, the PPV group had vision improvement way earlier, and they were less likely to have recurrent hemorrhages, new tractional detachments, or persistent NVE. But at the end of the day, 30% of the PPV group ended up having anti-VEGF injections and 30% of the anti-VEGF medical management group ended up going to the operating room anyway.[30]

The take-home message is there are many different ways to treat a patient. What we ultimately decide to do depends on their ocular and systemic comorbidities, the status of the other eye, their socioeconomic situation, and the patient's own comfort with various degrees of aggressive treatment. This is not an algorithm—while our field is very scientific and evidence-driven, there is some art involved as well.

Dr. Khan: I agree; every patient is different. For this last case, in particular, these patients can worsen even when you're treating them appropriately. You need to cultivate a relationship with the patient and let them know they can get a vitreous hemorrhage, etc., in the other eye. It helps build trust. Ultimately if you can get in a good PRP, I think most people tend to do okay long term.

Q | Dr. Ho: Dr. Maturi, what do you think will happen at year 4 for Protocol W? Do you have an update on when that data may be available?

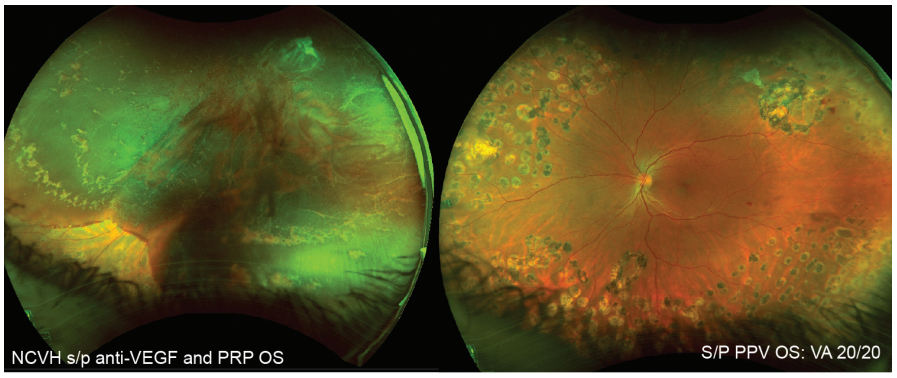

Figure 8. Case 3: Left eye following surgery.

Dr. Maturi: We only have 90 patients left, and we should have results in 2022. We do know that patients who get treated earlier with anti-VEGF, even though they have the same vision, their retinopathy does not progress as much, and in many cases reverses. The second thing we know is that even though their OCT central subfield thickness doesn't look very different between groups, the OCT volume scans show a significant difference, favoring the treatment group. Therefore, treatment does reduce the macular edema that is present in the fovea, but we don't always appreciate it because we're so focused on the foveal center with the central subfield thickness value being the key value. Over 4 years, there might be a visual difference in which case early treatment would make sense. In the observed group, those with severe NPDR, about 70% progressed to PDR within 2 years. And, about 50% progressed to PDR with high risk criteria. That's a very, very high number and even treating them five times in the first year and three times in the second year, 30% of the treated group progressed to PDR.

Severe NPDR is a significant disease. It's important to remember that severe NPDR is almost as bad as PDR itself in terms of vision loss and progression. In my hands, I treat severe NPDR more aggressively, starting with anti-VEGF or even PRP early on. Many of the severe NPDRs have significant peripheral ischemia, and I believe they are the ones who progress the fastest.

Dr. Berrocal: It's clear from this discussion that we have a lot of good ways to approach these patients. When I see a patient who comes in with NPDR, I try to see if the vitreous is attached or not, which is not always easy. I like a wide-angle FA and I gauge the age of the patient, the degree of ischemia, and the severity of illness. Are they hypertensive, do they have anemia, renal disease, peripheral vascular disease? The sicker the patient, the more I lean toward performing PRP to the ischemic areas and maybe early vitrectomy.

We saw significant disease progression during the height of the COVID-19 pandemic. Patients had minimal neovascularization, and within a few months they came in with massive neovascularization, fibrosis, and tractional retinal detachments. Poorly controlled diabetics with associated medical conditions can have severe disease progression in a very short time. I'm very wary of just doing anti-VEGF because they can need hospitalizations and miss appointments and get crunch or rebound retinopathy. All this goes back to the prescient point that we need to consider the whole patient and their circumstances, not just the eye, when determining our treatment course.

Dr. Ho: Many thanks to the faculty for a great discussion. Thank you for providing your insights into the personalized management of the diabetic patient and DR. We look forward to continuing these conversations and appreciate your expertise and experience. I would like to thank Dr. Nudleman again for sharing these illustrative cases for discussion. ■

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INSTRUCTIONS FOR CME CREDIT

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DEMOGRAPHIC INFORMATION

Profession
___ MD/DO
___ OD
___ NP
___ Nurse/APN
___ PA
___ Other

Years in Practice
___ >20
___ 11-20
___ 6-10
___ 1-5
___ <1

Patients Seen Per Week (with the disease targeted in this activity)
___ 0
___ 1-15
___ 16-30
___ 31-50
___ >50

Region
___ Northeast
___ Northwest
___ Midwest
___ Southeast
___ Southwest

LEARNING OBJECTIVES

Did the program meet the following educational objectives?	Agree	Neutral	Disagree
Discuss the benefits of consistent anti-VEGF treatment.	_____	_____	_____
Explain why patients with diabetic retinopathy and diabetic macular edema (DME) are so often lost to follow-up.	_____	_____	_____
Execute patient education plans on the importance of frequent DME treatment to improve treatment and exam compliance.	_____	_____	_____
Apply best practices and strategies in a cross-disciplinary approach to diabetes management to better manage patients.	_____	_____	_____

POSTTEST QUESTIONS

Please complete at the conclusion of the program.

1. Based on this activity, please rate your confidence in your ability to explain why patients with diabetic retinopathy (DR) and diabetic macular edema (DME) are so often lost to follow-up (based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident).

a. 1
b. 2
c. 3
d. 4
e. 5

2. Based on this activity, please rate how often you execute patient education plans designed to improve treatment and exam compliance (based on a scale of 1 to 5, with 1 being never and 5 being always).

a. 1
b. 2
c. 3
d. 4
e. 5

3. What percentage of patients with diabetes do not have annual diabetic eye exams?

a. 40%
b. 50%
c. 60%
d. 70%

4. According to the panelists, recommended strategies to increase treatment and follow-up adherence in patients with diabetes include: (Select all that apply)

a. Have clinic hours on weekends
b. Ask patients to come in for fewer appointments
c. Take a "tough love" approach the next time you see them after a long lapse
d. Employ telemedicine

5. Why are patients with diabetes so often lost to follow-up (LTFU)? (Select all that apply)

a. They don't care about their health
b. They are often of working age and can't get off work
c. They have too many competing medical appointments
d. They don't want to make the necessary changes to manage their disease

6. _____ found that patients with center-involved DME and good vision (20/25 or better) can be initially managed with observation.

a. Protocol S
b. Protocol V
c. Protocol W
d. Protocol T

7. A 45-year-old patient with type 2 diabetes lives in rural Appalachia, about 2 hours from the nearest retina specialist. She works as an hourly employee, and does not get paid sick leave. Her diabetes is moderately controlled, with an HbA1c around 8%. She does her best to keep up with her many medical appointments but, because the retina office is so far away, she often misses her annual exams. She presents after LTFU for 18 months, complaining of reduced vision and floaters bilaterally. Upon exam, she's diagnosed with PDR. What would be considered the best first-line treatment for this patient?

a. PRP in both eyes
b. Immediate anti-VEGF therapy
c. Anti-VEGF therapy first, followed by PRP in both eyes
d. Pars plana vitrectomy

8. Of the following, which imaging modality is considered most useful to educate patients about their disease?

a. Fluorescein angiogram
b. Indocyanine green angiography
c. Fundus autofluorescence
d. Ultra-widefield

9. The reported compliance rate in Protocol V was _____.

a. 90%
b. 80%
c. 70%
d. 60%

10. A key conclusion from Protocol AB is that _____.

a. PRP and ranibizumab are both good options for the treatment of PDR, with similar results at 5 years.
b. There were no differences in VA between ranibizumab alone or ranibizumab plus dexamethasone intravitreal implant.
c. There is no difference in VA between aflibercept or vitrectomy and PRP in patients with vitreous hemorrhage from PDR.
d. Aflibercept offers the most VA improvement in patients with moderate or worse vision loss from DME.

ACTIVITY EVALUATION

Your responses to the questions below will help us evaluate this activity. They will provide us with evidence that improvements were made in patient care as a result of this activity.

Rate your knowledge/skill level prior to participating in this course: 5 = High, 1 = Low _____

Rate your knowledge/skill level after participating in this course: 5 = High, 1 = Low _____

This activity improved my competence in managing patients with this disease/condition/symptom. _____ Yes _____ No

Probability of changing practice behavior based on this activity: _____ High _____ Low _____No change needed

If you plan to change your practice behavior, what type of changes do you plan to implement? (check all that apply)

Change in pharmaceutical therapy _____

Change in nonpharmaceutical therapy _____

Change in diagnostic testing _____

Choice of treatment/management approach _____

Change in current practice for referral _____

Change in differential diagnosis _____

My practice has been reinforced _____

I do not plan to implement any new changes in practice ___

Please identify any barriers to change (check all that apply):

_____ Cost

_____ Lack of consensus or professional guidelines

_____ Lack of administrative support

_____ Lack of experience

_____ Lack of time to assess/counsel patients

_____ Lack of opportunity (patients)

_____ Reimbursement/insurance issues

_____ Lack of resources (equipment)

_____ Patient compliance issues

_____ No barriers

Other. Please specify: _____

_____

_____

The design of the program was effective for the content conveyed. ___ Yes ___ No

The content supported the identified learning objectives. ___ Yes ___ No

The content was free of commercial bias. ___ Yes ___ No

The content was relative to your practice. ___ Yes ___ No

The faculty was effective. ___ Yes ___ No

You were satisfied overall with the activity. ___ Yes ___ No

Would you recommend this program to your colleagues? ___ Yes ___ No

Please check the Core Competencies (as defined by the Accreditation Council for Graduate Medical Education) that were enhanced through your participation in this activity:

_____ Patient Care

_____ Practice-Based Learning and Improvement

_____ Professionalism

_____ Medical Knowledge

_____ Interpersonal and Communication Skills

_____ System-Based Practice

Additional comments:

_____

_____ I certify that I have participated in this entire activity.

This information will help evaluate this activity; may we contact you by email in 3 months to ask if you have made changes to your practice based on this activity? If so, please provide your email address below.

_____