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With Eyes Wide Open: New Strategies for Managing Diabetic Retinopathy

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Dr. Shechtman:
When it comes to diabetic retinopathy, the study and the new data are in a constant state of flux. Are we keeping up with the progress being made? Do we know the information and what it means to us as optometrists and how it can impact our patients in the management of the overall disease?

This is CME on ReachMD. I’m Dr. Diana Shechtman and I’m joined today by Dr. Carolyn Majcher.

Dr. Majcher:
Thank you so much for having me, Diana. It’s a pleasure to be here.

Dr. Shechtman:
There’s about 34 million Americans living with diabetes today. We really often look at the evaluation of both the duration, their A1C, the comorbidities, and identify the high-risk factor of developing diabetic retinopathy. The way I see this is kind of like the patient with severe nonproliferative stage looking over a cliff. Unfortunately, if they jump over, they reach the proliferative diabetic stage, and it’s really hard to come back from that. So that edge, we’re going to come back to it over and over again during the lecture. I think it’s such an important point. Once, like I said, we reach that edge, we like to try to push them back if there’s any ability to do so.

As you can look at the next slide, there’s about an 80% chance of developing proliferative diabetic ret within the next 5 years of a patient in a stage of severe nonproliferative diabetic ret.

So, Carolyn, what is the risk of blindness in patients with diabetic retinopathy?

Dr. Majcher:
Diana, we know that patients initially presenting in the more advance stages of the disease are at higher risk of sustained blindness should treatment be withheld. And just earlier this year, study results were released from a large retrospective analysis of the American Academy of Ophthalmology IRIS or Intelligent Research In Sight registry that included nearly 50,000 patients. And this study showed that patients newly diagnosed with proliferative diabetic retinopathy had a 4 times increased risk of sustained blindness compared to patients with mild-stage nonproliferative disease at 2 years after that initial diagnosis. And they defined sustained blindness in this study of at least 2 acuity measures of 20/200 or worse, 3 or more months apart.

And similarly, patients newly diagnosed with severe nonproliferative retinopathy had a 3.6 times increased risk of sustained blindness compared to patients with mild-stage nonproliferative disease. And I think these findings really underscore the importance of early retinopathy detection so that patients in this severe nonproliferative stage can be treated to preserve vision and reduce that substantial risk for future blindness. It also emphasizes the vital role that optometrists play in educating our patients on the importance of compliance and follow-up with referral recommendations.

Dr. Shechtman:
Carolyn, that was beautifully said. I couldn't agree with you more. But I do find it really hard to kind of bring these patients back year after year, potentially every 3 or 6 months, depending on the stage; it becomes very difficult. And even though you want them to become a part of their management plan, it becomes quite difficult. These are young adults in the working field, so they don't have that flexibility to take off as often. Since I find this to be such a critical aspect, I actually did a video with one of my own patients, which you are more than welcome to share with your own patients. You can find this at EyeHealthAcademy.org/SaveSight.

Let's talk a little bit about the new protocols that have come out, Protocol W and the PANORAMA study. As you are well aware, these new studies, in my opinion, have definitely had a paradigm shift in the way we manage our patients. Both studies looked at the anti-VEGF treatment of these patients and the effects on both the severity of the stage of the disease, as well as the sight-threatening complications. What I find this to be most interesting is, as you know, most of these patients were treated with anti-VEGF when they developed diabetic macular edema, proliferative diabetic stage. So this is the first time we're actually seeing an impact on a patient who doesn't have those clinical complications.

So, Carolyn, can you remind us a little bit about the staging of the disease, particularly moderate and severe nonproliferative stage?

Dr. Majcher:
Absolutely, Diana. The diabetic retinopathy severity scale, or the DRSS for short, is primarily used in clinical trials to evaluate disease progression or improvement, but some of its classification features are very clinically relevant to help us identify those patients who should be referred and considered for treatment.

So moderate nonproliferative retinopathy is characterized by findings like intraretinal hemorrhaging, exudate, or cotton wool spots that are less extensive than moderately severe stage nonproliferative disease. And then severe nonproliferative retinopathy is characterized by the presence of any of the following 4-2-1 rule factors, of course assuming no proliferation is present. So the 4-2-1 rule factors are 4 quadrants of severe intraretinal hemorrhaging, and that's about 20 hemorrhages per quadrant, at least 2 quadrants of definite venous beading, and 1 quadrant or more of prominent IRMA [intraretinal microvascular anomalies]. As I'm sure we've all experienced firsthand, accurate and precise staging of retinopathy can be a challenge clinically, especially when patients who are uncooperative or may have significant media opacities. And unfortunately, these challenges may result in mistakenly under classifying the stage of retinopathy.

Dr. Shechtman:
In addition to being able to identify diabetic severity, as you so eloquently put it, Carolyn, it really is critically important to identify the peripheral – or at least be able to evaluate the peripheral aspect of the disease. We all kind of concentrate on the posterior pole, but the periphery actually holds quite a bit of ischemia.

So, Carolyn, do you have some images and can you eloquently explain some of these images in regards to evaluating the peripheral retina?

Dr. Majcher:
Of course, Diana. And I agree that accurately identifying diabetic retinopathy and staging the severity is essential for many reasons, and incorporating multimodal imaging technology into your practice is going to highlight pathology for you. Being able to more easily visualize pathology means greater efficiency and more accurate staging of diabetic retinopathy. But first off, the wide-field and ultra-widefield fundus imaging can be very valuable in detecting and documenting peripheral diabetic retinopathy lesions. This is of incredible prognostic value, since research has shown that eyes with predominantly periphery retinopathy were the majority of the diabetic retinopathy lesions, like the hemorrhages are outside that standard 7-field ETDRS area are at the greatest risk for progression. And in fact, eyes with predominantly peripheral retinopathy had nearly a 5-fold increased risk for progression to proliferative staged disease compared to eyes where the majority of the retinopathy was confined to the posterior pole.

And then secondly, OCT [optical coherence tomography] angiography provides high-resolution microvascular detail that highlights vascular abnormalities that may be invisible or very subtle with just clinical fundus exam alone. And these vascular abnormalities include, for example, like microaneurysms, retinal nonperfusion, or even mild IRMA.

Peripheral nonperfusion is nearly invisible with ophthalmoscopy but is readily identifiable with wide-field montage OCT angiography. And eyes with massive mid-peripheral nonperfusion are at high risk for progression to proliferative disease if not already there. And the

presence of such extensive nonperfusion may also tip the scales towards earlier treatment versus just observation alone. The retinal ischemia is nonreversible and may even continue to progress despite adequate treatment. So preventing retinal nonperfusion from occurring in the first place, I think, may be a very reasonable management strategy.

And OCT angiography provides us with a volumetric dataset and therefore can reliably differentiate between IRMA, which are dilated telangiectatic capillaries still confined within the retina, from small-size neovascularization elsewhere, which is growing up on top of the retina. These vitreous or the vitreoretinal interface preset enface display on angiography is going to isolate out data from just above the retina and can be used to easily identify areas of proliferation. You can also practice your diagnostic skills in our image-based activity by going to EyeHealthAcademy.org/SaveSight

Dr. Shechtman:
For those just tuning in, this is CME on ReachMD. I'm Dr. Diana Shechtman, and today I'm joined by Dr. Carolyn Majcher. We are discussing the changes in our practice with the new evidence of both the Protocol W and PANORAMA study.

We've been talking about patients with moderate to severe nonproliferative diabetic retinopathy. Let's take a look at the Protocol W and PANORAMA study. Early treatment of moderate and severe nonproliferative diabetic retinopathy reduces the risk of vision-threatening complications. I mean, this is absolutely critical. We're talking about being able to have an impact on both diabetic macular edema and proliferative diabetic retinopathy. Now, the PANORAMA study, as you can see in this slide, really is a landmark study. It evaluated patients who were treated with anti-VEGF versus sham in order to determine if there was an impact on the severity scale, as well as the vision-threatening complications. These findings had a major paradigm shift in the way we manage our patients. Additionally, it improved the diabetic retinopathy staging of these patients through the use of anti-VEGF therapy. It was the first time ever that we were able to turn back the clock on these patients. As we can see here in the next following slide, you can see patients with a severe diabetic retinopathy stage. Look at all the hemorrhages. And after several injections, all those hemorrhages are gone and the patients look like they barely have moderate diabetic retinopathy.

Protocol W actually confirmed similarly to the PANORAMA study. You can see on the next slide some of its impact, both on the severity scale as well as vision-threatening complications. It has an impact of reducing by 83% the risk of developing diabetic retinopathy complications. I mean, that is a huge impact.

So, Carolyn, what do you think about all this? Do you have any changes in how you evaluate your patients or how you manage them today?

Dr. Majcher:
Certainly. I couldn't agree more that in light of these new research findings, it's critical to refer retinopathy earlier on in the course of the disease. And diabetic retinopathy is progressive. And recall we just reviewed that the risk of future blindness in eyes with severe nonproliferative retinopathy is similar in magnitude to the risk of blindness with proliferative stage disease. So why wait for these vision-threatening complications to occur when we can prevent them from the get-go. And we're fortunate enough to have treatment options nowadays available that can stabilize and even in some cases, as you presented, improve the stage of retinopathy. So I personally believe that earlier treatment, especially for those with high-risk factors for progression, puts patients in the best position to maintain good vision and preserve their quality of life.

And Diana, I'd love to hear your side of it as well. Let me ask you, how are you managing patients with mild or moderate nonproliferative disease today based on these findings?

Dr. Shechtman:
I use all my diagnostic modalities in a comprehensive eye exam to dictate the management of my patients and the understanding that it is critical to refer at a much earlier stage than before. Any patient who has severe nonproliferative diabetic retinopathy will be seen by a retinal specialist. Of note, if one does not have the proper diagnostic modalities, even moderate nonproliferative diabetic retinopathy stages should be followed by a retinal specialist. We often underestimate the severity of the patient.

Here's a perfect example. Carolyn, can you describe to me what you see in the right and left eye?

Dr. Majcher:
Sure, Diana. Both eyes, it looks like there's some cotton wool spots and some intraretinal hemorrhaging. I would've classified this as moderate-stage disease in both eyes.

Dr. Shechtman:
And certainly, I would have agreed. But when we did the ultra-wide FA, we can actually see it looks quite different. The one eye looks like there's quite a bit of severe nonproliferative stage with a lot of capillary nonperfusion, particularly in the periphery. As you had

mentioned in the past, looking at the periphery is of critical importance. And on the left eye, one can see a very distinct hot spot signifying neo growth, so it is a proliferative diabetic retinopathy stage.

Carolyn, what are your thoughts regarding this?

Dr. Majcher:
Yeah, I couldn't agree more that in the light of these new research findings, it's critical to refer retinopathy earlier on in the course of the disease, and diabetic retinopathy is progressive. Recall that the risk of future blindness in eyes with severe nonproliferative disease is similar in magnitude to the risk of blindness with proliferative stage. And we're fortunate enough in this day and age to have treatment options available that can stabilize and even in some cases improve the stage of retinopathy. So I believe that earlier treatment, especially in those patients that have risk factors like poor glycemic control, hypertension, etc., is really going to put patients in the best position to maintain good vision and preserve their quality of life.

Dr. Shechtman:
As we wrap up today, Carolyn, what is your key take-home message that you want the audience to note?

Dr. Majcher:
Accurate staging of retinopathy is essential and ultra-widefield imaging plays a very important role in the diagnosis of diabetic retinopathy. And remember that eyes with predominantly peripheral retinopathy are at significantly greater risk of disease progression and the development of proliferation.

Dr. Shechtman:
I would reemphasize and add the following: that the PANORAMA and Protocol W study results underscore the consideration of early referral for nonproliferative diabetic retinopathy patients, particularly to the retinal specialists and, in fact, if we don't have the definitive diagnostic testing. It is important to understand that the implementation of treatment in the early stage of the disease may now result in the ability to turn back the clock. As we talked about that patient, we can get them off the ledge. Helping the patient never to actually jump off the ledge and develop proliferative diabetic retinopathy or other vision-threatening complications.

Carolyn, thank you for your time today to discuss these clinical implications in regards to Protocol W and the PANORAMA study. It was such a pleasure to speak to you today.

Dr. Majcher:
The pleasure is all mine, Diana. Thank you so much for having me today.

Announcer:
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