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Overcoming Barriers for Vulnerable Patients with Diabetic Eye Disease

Announcer:
Welcome to CME on ReachMD. This activity, titled **"Overcoming Barriers for Vulnerable Patients with Diabetic Eye Disease,"** is provided by Prova Education.

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Dr. Vega:
Unfortunately, racial disparities exist in the care of diabetic eye disease, and this can lead to poor outcomes. Regular monitoring and treatments are key to maintaining good vision. So how can recent advances in treatment improve the management for vulnerable patients?

This is a CME on ReachMD, and I'm Dr. Chuck Vega. I'm very happy to have with me today Dr. Sharon Solomon. Welcome to the program.

Dr. Solomon:
Chuck, thank you for having me. It's great to be here.

Dr. Vega:
We know that managing diabetes and its associated comorbidities is one of the best ways to maintain good vision in this patient population. There are more advanced therapies available to manage blood glucose levels, but there are also new treatments available to manage diabetic macular edema that have the added benefit of reducing treatment burden. Let's start with faricimab. What is it, and what are some of those recent data about it?

Dr. Solomon:
You're absolutely correct, Chuck, that the first line of therapy is always managing the underlying disease, the diabetes, in order to prevent loss of vision. Glycemic control is really crucial to eye health. However, when diabetic retinopathy and especially diabetic macular edema develop, there are treatments available to save vision while reducing treatment burden.

Faricimab is the first bispecific monoclonal antibody to target both vascular endothelial growth factor [VEGF] and angiopoietin-2. It works by blocking these 2 key signaling pathways to improve vessel integrity. Two major clinical trials of faricimab in patients with diabetic macular edema, YOSEMITE and RHINE, showed robust vision gains and anatomic improvements with extended durability of up to every-16-week dosing that was maintained over 2 years. At least 60% of patients eligible for extended dosing with faricimab could be treated every 4 months at 2 years, and they maintain those vision improvements from the first year of therapy.

A key finding in these trials also was that treatment with faricimab resulted in greater reduction in macular leakage, possibly because of inhibition of angiopoietin-2. Post hoc analyses have shown that at 16 weeks macular leakage area was more than 50% smaller in faricimab-treated eyes, and nearly twice as many faricimab-treated eyes showed resolution of leakage compared to eyes treated with aflibercept. Interestingly, patients who had a less robust response to therapy and who experienced persistent macular leakage tended

to be younger, Hispanic, had worse vision, and had a worse diabetic retinopathy score at baseline.

Dr. Vega:
That's great data. I always know that it's important to treat diabetic eye disease as early as possible for better outcomes. How important is it to achieve macular drying in the first few months of treatment?

Dr. Solomon:
Chuck, it's extremely important. Early resolution of fluid translates into better visual acuity for patients, which can then encourage better compliance with lifestyle choices that affect overall health. In addition, achieving macular drying during the first few months of treatment, as marked by the absence of fluid on OCT [optical coherence tomography], is also likely a marker for the ability to achieve increased durability with faricimab. Instead of waxing and waning response to therapy with recurrence of fluid on OCT, there's a consistently dry OCT with visual acuity gains that are more likely to be maintained over time.

Dr. Vega:
Well, so great data on faricimab as a novel molecule. What about other durable treatments when you're seeing patients with diabetic macular edema or diabetic retinopathy?

Dr. Solomon:
Another great question. In pseudophakic patients with diabetic macular edema where vascular endothelial growth factor inhibitors are contraindicated because of a previous thromboembolic event, or where there has been a suboptimal response to previous anti-VEGF therapy, I consider a sustained-release steroid implant such as dexamethasone or fluocinolone acetonide. Both promote functional and anatomic improvements in patients with diabetic macular edema that can be durable, with less treatment burden compared to anti-VEGF agents alone.

However, patients have to be monitored for the development of significant side effects, such as increases and intraocular pressure that could require therapeutic intervention, including surgery.

In addition, while eyes receiving intravitreal steroids tend to show a good response with respect to regression of diabetic macular edema, they are less likely to show regression of peripheral diabetic retinopathy, as eyes receiving anti-VEGF agents do. So peripheral retinopathy has to also be carefully monitored. In pregnant and nursing women with diabetic macular edema, I still consider focal laser photocoagulation as a therapeutic option and would defer using any intravitreal form of therapy as long-term safety outcomes are not known.

Dr. Vega:
For those of you who are just tuning in, you're listening to CME on ReachMD. I'm Dr. Chuck Vega, and here with me today is Dr. Sharon Solomon. We're about to discuss new durable treatments for diabetic macular edema and how they might be used to address existing treatment disparities.

Great. Yeah, it's nice to have that full armamentarium of different types of responses for, as you mentioned, different types of patients. But there's more. What about the future? There are other treatment modalities in development, correct?

Dr. Solomon:
Correct. There are several interesting treatment modalities in development. There's a novel formulation of aflibercept that has a fourfold higher molar dose being evaluated in the clinical trial of patients with diabetic macular edema, the PHOTON trial. After giving loading doses, patients were randomized to receive either aflibercept 2 mg every 8 weeks, 8 mg of aflibercept every 12 weeks, or 8 mg of aflibercept every 16 weeks. Both 8-mg aflibercept groups have met the primary endpoint of noninferiority in mean change in visual acuity, compared to the 2-mg aflibercept group, and have shown similar reductions in central retinal thickness on OCT. The vast majority of patients receiving 8 mg of aflibercept have maintained a dosing interval of 12 weeks. So this may be another promising option to increase therapeutic durability and to lessen treatment burden for patients.

Another potential treatment modality is the port delivery system with ranibizumab, an innovative intraocular drug delivery system designed to continuously deliver ranibizumab into the vitreous for at least 24 weeks. The phase 3 PAGODA results have shown that ranibizumab at 100 mg/mL, delivered via the port delivery system with a 24-week refill rate was noninferior to monthly ranibizumab in patients with diabetic macular edema with respect to change in visual acuity from baseline. More than 95% of patients treated with the port delivery system did not receive any supplemental treatments between refills of ranibizumab, which is incredibly exciting. In addition, the port delivery system with ranibizumab is under investigation in the PAVILION trial in patients with diabetic retinopathy and no diabetic macular edema to assess whether they achieve a 2-step or greater improvement in diabetic retinopathy, while also assessing impact on visual acuity compared to observation alone.

Dr. Vega:
Fantastic. So, we have some older and established treatments for diabetic eye disease, some newer treatments, and then some that are forthcoming that really could make a difference in the way we take care of patients.

I know that you're strongly interested in health equity in this space, so can you tell us a little bit about how newer treatments might be able to help those who are most vulnerable to not only diabetic eye disease but its complications?

Dr. Solomon:
Chuck, it's important to remember that diabetic retinopathy is the leading cause of vision loss in working-age adults. And the most common reason for these patients to suffer vision loss is secondary to diabetic macular edema. Moreover, as you mentioned, certain ethnic groups such as individuals of African or Hispanic descent are at least 2 times more likely than individuals of European descent to develop sight-threatening disease. The COVID pandemic certainly showed us that these at-risk populations are also less likely to have access to routine care for a number of reasons. The availability of these durable treatments for diabetic eye disease is a real game changer. They will allow for greater compliance with therapy by these working-age adults who can enjoy longer periods with stable good vision between treatments and less time missed from work.

Dr. Vega:
Right. For my patients, working in a community health center, the day they miss work may be the day they lose their job. And it's hard to find other resources for, say, childcare. So reducing the overall treatment burden with less visits and easier-to-follow treatments really makes a difference. And I really look forward to working with my ophthalmology colleagues to improve these patients' outcomes overall and, honestly, give them a better experience as well.

Do you have any final take-home message for our audience today?

Dr. Solomon:
Yes, as retina specialists, we have never before been better equipped to care for all of our patients, especially those that belong to more vulnerable populations. With these new treatments on the horizon, we'll be able to maximize our patients' vision while minimizing their burden of treatment.

Dr. Vega:
Yeah, absolutely. So it's definitely some time to be optimistic.

Unfortunately, that's all the time we have for today. Sharon, thank you so much for these great insights and your valuable experience. It was wonderful speaking with you today.

Dr. Solomon:
Thank you for having me, Chuck. It was great being here.

Announcer:
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