Insert to
RETINA TODAY

PART II

BEYOND THE CLINICAL TRIALS

An educational series on the implications of managing the ocular manifestations of diabetes in real world settings.

Coordinating the care of a patient with diabetes among many providers can be a tremendous challenge. Even when all members of a patient's health care team are speaking in concert, a patient may hear the same message delivered by different individuals in strikingly different ways. But patients with diabetes may also be confused when they hear conflicting messages from their primary care physician, endocrinologist, retina specialist, and any other health care provider he or she may interact with—and not to mention the (not always accurate) plethora of information available on the Internet.

Still, patients with diabetes require a great deal of education about their disease and encouragement to stay current with their medical therapy. In part 2 of this educational series, Gary Scheiner, MS, CDE, a certified diabetes educator, talks about the comanagement of patients and the difficulties all members of a patient's health care team have in educating about diabetes and motivating patients to be adherent to their care regimen. But, as Mr. Scheiner explains, "The bottom line is: diabetes can and will rob you of your quality of life today if you do not manage it well … patients have to manage their lives now so they can perform well in their daily activities."

Also in this installment is a case presented by David M. Brown, MD, director of Greater Houston Retina Research Foundation and a physician with Retina Consultants of Houston and the Houston Methodist Hospital, that demonstrates how difficult it sometimes is to treat diabetic macular edema in real world settings, especially as care is coordinated among several providers.

Supported by advertising from Allergan Inc., and Heidelberg Engineering

The Comanagement of Patients With Diabetes: Coordinating Care to Achieve Better Outcomes

AN INTERVIEW WITH GARY SCHEINER MS, CDE

Can you explain what Certified Diabetes Educators (CDE) are and what their role is in the care of patients with diabetes?

Gary Scheiner, MS, CDE: I see the role of CDEs as filling the gap between what patients with diabetes need to know to manage their disease successfully and what they can effectively get from their physicians in terms of knowledge and direction. Diabetes is a complicated disease. It has a multitude of lifestyle influences that require guidance and coaching. In a lot of cases, there is quite a bit of number crunching involved, especially for those who are on insulin. That is a difficult thing for many patients to understand and manage on their own.

Diabetes is a disease patients have to learn how to manage independently. Understandably, very few physicians have the time or the expertise to provide patients with the education and direction they may need. Physicians, by training, are used to diagnosing and prescribing medication and ordering laboratory work. But diabetes is a disease that requires a significant amount of patient education. Those who care for patients with diabetes have to stay on top of a plethora of new medications, new technology, management techniques, and that requires a lot of attention to detail as well.

When do CDEs typically become involved with patients? Is it soon after the diagnosis? How are patients referred to their services or how does a CDE become involved in that interaction?

Mr. Scheiner: CDEs are an extension of the physician in terms of caring for and helping manage patients, so they are typically brought in very soon after the diagnosis is made. There is a lot of teaching that has to take place for patients to be able to manage this disease successfully. Patients are taught how to self-monitor glucose, how to interpret the results, the physiology of the disease, the comorbidities and complications, and that is not even getting into the medical and lifestyle treatments, and a lot of things about which patients have to be taught and instructed.

The education is usually done during a period of time. Some clinics still provide patient education in a class format, although I think there has been gradual movement away from that model and toward individualized care for patients with diabetes.

How is your particular practice different?

Mr. Scheiner: My practice focuses primarily on intensive insulin therapy, so I work mostly with patients who have type 1 diabetes. I tend to work with patients who have had diabetes for a long time but who have never quite gotten a grip on the management of their disease.

How well do patients typically understand their disease by the time they get to a CDE? Do they comprehend the steps they need to get through?

Mr. Scheiner: Patients understand very little about diabetes until they get to a good educator. Think about how much time a physician has to really teach them properly. Most physicians who interact with patients with diabetes have not received training in how to teach patients about their disease—these are just not things that are a point of emphasis in medical school. Physicians are equipped to diagnose and treat; the whole teaching process is something that is a bit foreign to them. Educating patients may be something that they are not particularly skilled at, and motivating patients may be the last thing on their mind.

How many care providers does an individual with diabetes typically interact with?

Mr. Scheiner: These patients will have a primary care doctor and they may or may not have a diabetes educator to work with. Some, particularly those who transition to insulin or other injectable therapies, will see an

STRATEGIES FOR IMPROVING DIABETES CARE

Recommendations

- Care should be aligned with components of the Chronic Care Model to ensure productive interactions between a prepared proactive practice team and an informed activated patient.
- When feasible, care systems should support team-based care, community involvement, patient registries, and embedded decision support tools to meet patient needs.
- Treatment decisions should be timely and based on evidence-based guidelines that are tailored to individual patient preferences, prognoses, and comorbidities.

A patient-centered communication style should be used that incorporates patient preferences, assesses literacy and numeracy, and addresses cultural barriers to care.

Source: American Diabetes Association

CATEGORIES OF INCREASED RISK FOR DIABETES (PREDIABETES)[a]

- Fasting plasma glucose 100 mg/dL (5.6 mmol/L) to 125 mg/dL (6.9 mmol/L) (impaired fasting glucose)
- 2-h plasma glucose in the 75-g oral glucose tolerance test 140 mg/dL (7.8 mmol/L) to 199 mg/dL (11.0 mmol/L) (impaired glucose tolerance)
- A1C 5.7% to 6.4%

[a] For all three tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at higher ends of the range.

Source: Standards of Medical Care in Diabetes—2014. Diabetes Care Volume 37, Supplement 1, January 2014[[doi: 10.2337/dc14-S014 Diabetes Care January 2014 vol. 37 no. Supplement 1 S14-S80]]

endocrinologist. In addition, they will often have a nurse, a dietician, and a good diabetes center will also have a mental health component, so there might be a psychologist or social worker. There might be an exercise specialist. Plus, there are specialists and subspecialists that all patients with diabetes are encouraged to see, including an ophthalmologist. Because the majority of patients with type 2 diabetes already have comorbidities, they might be seeing a vascular specialist, a podiatrist, and certainly oral hygiene/dental care is a key part of their care. Several health care providers are part of the team.

Is that number of interactions ever a detriment to compliance or in how closely patients follow up with advice from 1 or more members of the care team?

Mr. Scheiner: Any time more and more individuals become involved in the care of a patient, there will be gaps in communication, and it becomes difficult for the patient to see all of these caregivers in a timely manner. Very few centers across the country have all of the various care providers needed to serve patients with diabetes under 1 roof, and so many of the services are based on referrals. That understandably leads to a certain amount of disconnect.

There is another aspect of all these interactions that may also prove to be a challenge for patients. Their various care providers may not be delivering a consistent message to the patient. Even well-intentioned health care professionals may unknowingly mislead patients who are hearing advice and education from a variety of sources; at the same time, patients may hear the same message told to them by 2 different individuals but receive it differently from each 1, perhaps leading the patient to misunderstand a critical piece of information.

What do you tell patients about compliance with their medical therapies and monitoring their disease?

Mr. Scheiner: We try not to use the term *compliance*. That has an instant negative connotation. *Adherence* is a more appropriate term.

Diabetes is not a disease anybody asks to get. You got it for whatever reason. You have it. The bottom line is: diabetes can and will rob you of your quality of life today if you do not manage it well. Some people talk to patients about long-term complications, which is a scare tactic that does not work that well. However, patients have to manage their lives now so they can perform well in their daily activities.

I try to empathize with each patient something that is of particular interest to him or her. If it is a young person, it might be sports or it might be how well a person performs in bed. It might be weight, body image, mental function, or even mental capacity. It is about finding something that is of value to the patient that gives him or her some incentive to be mindful of their health.

I think it really helps patients to be instructed by people who really know what they are doing, who are not just going to throw them on a bunch of medications willy-nilly and hope for the best. It takes a team of professionals to really understand the disease and to make good use of new tools and technologies.

Approximately 42% of the patients who received OZURDEX® (dexamethasone intravitreal implant) were subsequently treated with IOP lowering medications during the study. In the sham control group, IOP lowering medications were used in approximately 10% of patients.

The increase in mean IOP was seen with each treatment cycle, and the mean IOP generally returned to baseline between treatment cycles (at the end of the 6 month period).

USE IN SPECIFIC POPULATIONS

Pregnancy Category C

Risk Summary

There are no adequate and well-controlled studies with OZURDEX® in pregnant women. Animal reproduction studies using topical ocular administration of dexamethasone were conducted in mice and rabbits. Cleft palate and embryofetal death in mice and malformations of the intestines and kidneys in rabbits were observed. OZURDEX® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal Data

Topical ocular administration of 0.15% dexamethasone (0.375 mg/kg/day) on gestational days 10 to 13 produced embryofetal lethality and a high incidence of cleft palate in mice. A dose of 0.375 mg/kg/day in the mouse is approximately 3 times an OZURDEX® injection in humans (0.7 mg dexamethasone) on a mg/m2 basis. In rabbits, topical ocular administration of 0.1% dexamethasone throughout organogenesis (0.13 mg/kg/day, on gestational day 6 followed by 0.20 mg/kg/day on gestational days 7-18) produced intestinal anomalies, intestinal aplasia, gastroschisis and hypoplastic kidneys. A dose of 0.13 mg/kg/day in the rabbit is approximately 4 times an OZURDEX® injection in humans (0.7 mg dexamethasone) on a mg/m2 basis.

Nursing Mothers: Systemically administered corticosteroids are present in human milk and can suppress growth and interfere with endogenous corticosteroid production. The systemic concentration of dexamethasone following intravitreal treatment with OZURDEX® is low. It is not known whether intravitreal treatment with OZURDEX® could result in sufficient systemic absorption to produce detectable quantities in human milk. Exercise caution when OZURDEX® is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of OZURDEX® in pediatric patients have not been established.

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

No adequate studies in animals have been conducted to determine whether OZURDEX® (dexamethasone intravitreal implant) has the potential for carcinogenesis.

Although no adequate studies have been conducted to determine the mutagenic potential of OZURDEX®, dexamethasone has been shown to have no mutagenic effects in bacterial and mammalian cells *in vitro* or in the *in vivo* mouse micronucleus test. Adequate fertility studies have not been conducted in animals.

PATIENT COUNSELING INFORMATION

Steroid-related Effects

Advise patients that a cataract may occur after repeated treatment with OZURDEX®. If this occurs, advise patients that their vision will decrease, and they will need an operation to remove the cataract and restore their vision.

Advise patients that they may develop increased intraocular pressure with OZURDEX® treatment, and the increased IOP will need to be managed with eye drops, and, rarely, with surgery.

Intravitreal Injection-related Effects

Advise patients that in the days following intravitreal injection of OZURDEX® patients are at risk for potential complications including in particular, but not limited to, the development of endophthalmitis or elevated intraocular pressure.

When to Seek Physician Advice

Advise patients that if the eye becomes red, sensitive to light, painful, or develops a change in vision, they should seek immediate care from an ophthalmologist.

Driving and Using Machines

Inform patients that they may experience temporary visual blurring after receiving an intravitreal injection. Advise patients not to drive or use machines until this has been resolved.

What do you tell patients about ophthalmic complications?

Mr. Scheiner: The message is that it is far too common for patients with diabetes to develop ocular manifestations, but the key to prevention is regular eye care. People who are seeing an ophthalmologist and who have an annual dilated retinal examination are much less likely to progress to the point where the eye disease affects their quality of vision and quality of life. I tell people there is a huge difference between going blind and having a treatment for some minor eye problem that can be reversed or effectively treated. I emphasize that catching things early is critical. That, coupled with glycemic control, is absolutely essential to keeping your eyes healthy long term.

It sounds like you stress a lot of the quality-of-life issues to patients. Is that something you have found to be effective in getting your message across to patients?

Mr. Scheiner: I have. You can talk until you are blue in the face about what might happen in 10 or 20 years if you do this right or this wrong, but that does not have intrinsic value for most people. It is really difficult to get people motivated if you tell them that if they do 1000 things right, something may not happen. That is a hard message to get across. On the other hand, if

CRITERIA FOR THE DIAGNOSIS OF DIABETES

A1C ≥ 6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.*

--or--

Fasting plasma glucose ≥ 126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.*

--or--

Two-hour plasma glucose ≥ 200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test. The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.*

--or--

In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).

*In the absence of unequivocal hyperglycemia, result should be confirmed by repeat testing.

Source: Standards of Medical Care in Diabetes—2014. Diabetes Care Volume 37, Supplement 1, January 2014[[doi: 10.2337/dc14-S014 Diabetes Care January 2014 vol. 37 no. Supplement 1 S14-S80]]

DIFFICULT-TO-MANAGE DME IN A PATIENT WHO TRAVELS FREQUENTLY

By David M. Brown, MD

The understanding of the pathophysiology of diabetic macular edema (DME) is still evolving, yet it is well known that there are many mechanisms that contribute to the development of edema in the eyes of patients with diabetes mellitus. As a result, DME can be a very difficult disease to manage, as our current array of options for treating DME may not target all of the relevant mechanisms of edema. Notably, however, antiinflammatory agents, as single agents or in combination with other modalities, may often be necessary for maximum control.

As this case demonstrates, treating DME often requires critical decision making, perhaps some out-of-the-box thinking, and careful coordination of care when a patient who travels frequently requires consistent and diligent follow up.

CASE REPORT

A 50-year-old male oil and gas attorney with diabetes mellitus presented with diffuse DME. He had been receiving care for his condition in Asia but was also regularly seeing an ophthalmologist in Los Angeles.

The patient was taking Avandia (rosiglitazone maleate, SB Pharmco) for his diabetes mellitus and his blood sugar levels were under control. The ocular history included a cataract extraction in his right eye in 2008, 3 previous focal grid laser treatments, and panretinal photocoagulation in both eyes. The patient had 20/200 visual acuity in both eyes for about 1 year; due to his restricted vision, he had hired a driver to take him to work and anywhere he needed to go.

Images obtained from the referring retina specialist showed a massively edematous retina. Leakage was apparent on angiogram. He had been treated with ranibizumab (Lucentis, Genentech), which was not approved for this indication at the time, so he paid for it out of pocket. There was some improvements anatomically and in visual acuity, but he remained about 20/100 despite monthly 0.5-mg intravitreal injections of ranibizumab. Diffuse macular edema was also apparent on repeat angiograms.

The patient had received 12 ranibizumab injections by the time of his referral to my clinic. It was my impression that he was having ongoing ocular manifestations of his diabetes despite well-controlled systemic disease and underlying hypertension. However, we decided to stop Avandia and switch him to alternate oral agents, because Avandia is known to cause macular edema. We also continued with ranibizumab injections off label. Another important finding was a progressing cataract in the left eye.

The decision was made to try a 0.8-mg dose of ranibizumab, which would temporarily resolve the edema before the patient would need an additional injection. We then attempted a trial with bevacizumab (Avastin, Genentech) to see if a different agent would be effective. The patient reported, however, that while the ranibizumab afforded him a few extra days, bevacizumab seemed to have no effect. We can confirm this clinically, as the patient's acuity reached 20/400 under treatment with bevacizumab.

A video of Dr. Brown presenting this case can also be found at eyetube.net/?v=ohimi or by following the QR code below

The next course of action was to perform an anterior chamber tap and to inject a 2.0-mg dose in both eyes. There was a reduction in edema but the visual acuity did not improve; however, the edema returned 2 weeks later and the patient was subject to high-dose intravitreal injections of ranibizumab on a biweekly basis.

After 10 injections the visual acuity improved to 20/100 and the patient was able to get a restricted driver's license. However, there were still some cysts present and the cataract was getting worse in the left eye. As a result, we scheduled the patient for cataract surgery with a presurgical regimen of 2.0 mg ranibizumab with the addition of a dexamethasone intravitreal implant (Ozurdex, Allergan). The addition of the implant dramatically improved the anatomical findings on optical coherence tomography and the visual acuity improved to 20/60 in the right eye and 20/40 in the left eye.

CONCLUSION

This was the first case that convinced me that there are many mechanisms that can contribute to edema in eyes of patients with diabetes and that a steroid may be necessary for maximum control. The addition of the dexamethasone intravitreal implant also added durability, as the patient is being cared for with the implant every 3 months and only occasional anti-VEGF injections. The patient continues to travel around the world, and we are able to coordinate care with physicians in various locales to maintain the continuity of his care. ■

David M. Brown, MD, is director of the Greater Houston Retina Research Foundation and practices at Retina Consultants of Houston and the Houston Methodist Hospital in Houston, Texas. Dr. Brown may be reached at dmbmd@houstonretina.com.

patients realize and experience the fact that they feel better and they perform better on a daily basis if their diabetes is well managed, then the importance of compliance and proper management of their disease rings truer.

It seems like there might be a similar message that can come from a patient's retina specialist in terms of functional vision as a surrogate for quality of life issues. Is that potentially analogous?

Mr. Scheiner: Absolutely.

What should retina specialists/eye care providers know about managing patients with diabetes? What is important for them to be aware of? What are the issues?

Mr. Scheiner: They should certainly be asking patients for their A1C levels. That is the 1 number that we have that we know correlates with maculopathy and macular edema, so that is something that they need to be asking for. It really is sad how many do not even bother to ask. If I were to ask someone what was his or her blood sugar was this morning, it is meaningless, and it does not tell you anything. But the A1C certainly does.

Retina specialists should also be asking how much variability there is in a person's blood sugar, not just what the fasting reading is. Ask what it is later in the day, what does it do after meals, etc. We should be encouraging people to monitor their glucose frequently or use a continuous glucose monitor if it is available to them.

They should also ask patients if they are working with a diabetes educator, and if they are not, they should have the names of people they can send them to. I think it is important for anyone who deals with patients with diabetes to have a bank of qualified people to refer patients to. You should have dieticians you can send them to. You should have nurse practitioners or nurse educators you can send people to. Having those resources at your disposal is key. A retina specialist may not want to refer those kinds of services out of a fear of upsetting the patient's primary care doctor; but the thing is, if that physician is going to get bent out of shape over something like that, then that is the kind of doctor you can do without.

Do you have any advice for coordinating care with a patient's care team?

Mr. Scheiner: Correspondence is invaluable, and it can be facilitated by electronic medical records systems. Even written or e-mailed or faxed correspondence can be very valuable. As a CDE, I appreciate it when ophthalmologists, nephrologists, and neurologists copy me on a letter to a patient's physician so I know what is going on with that patient. I know when he or she has been seen, and I know what the results of the examination and any testing were. All of that information is helpful when I am interacting with that patient.

I do not think an ophthalmologist should be trying to teach a patient how to manage his or her blood sugar. But clearly, they should emphasize the importance of it and that the patient should be seeing a diabetes educator. I am not going to do a dilated fundus examination and tell someone their eyes are healthy, and in the same vein, the ophthalmologist should be teaming up with the diabetes educators and maybe some of the better endocrinologists in the area to make sure patients are getting good diabetes care.

Is there a "leader" on a patient's care team? Is it the primary care physician or is it a shared responsibility situation? Is 1 of those strategies more effective than the other?

Mr. Scheiner: It depends. If the patient is going to an endocrinologist, the endocrinologist often becomes the captain of the team. If the patient is not seeing an endocrinologist, then the primary care provider would become the head of the team. Some patients work with a nurse practitioner, and it has been my experience that those nurse practitioners can be a real asset to patients' care, and they are sometimes even more effective than primary care providers. In addition to having the clinical expertise, nurse practitioners also tend to have that ability to teach and to communicate effectively, and both of those things are important for patients to achieve success.

What advice would you offer to ophthalmologists for talking with patients?

Mr. Scheiner: I think it is worthwhile for eye care providers to explain eye diseases to patients in terms they can understand. I find that a patient who is well educated about his or her disease—who is not just given pamphlets but who has their particular diseases state explained to him or her using models or using good diagrams, and who understand exactly what happens when diabetes is uncontrolled and when they go too long between appointments—these patients tend to understand the process much better and have better outcomes as a result. I have found that you can teach anyone, whether they have a college degree or they dropped out in sixth grade, if you take the time to do it and have a proper approach to education. ■

Gary Scheiner, MS, CDE, is owner and clinical director of Integrated Diabetes Services LLC in Wynnewood, Pennsylvania. His practice provides diabetes education to patients worldwide via phone and the Internet. Mr. Scheiner may be reached at gary@integrateddiabetes.com.