Scanning the Horizon of Treatments for DME

This year has the potential to be exciting for retina specialists who treat diabetic eye disease. With the potential for US Food and Drug Administration (FDA) approvals of the dexamethasone intravitreal implant (Ozurdex, Allergan), aflibercept (Eylea, Regeneron), and the fluocinolone acetonide implant (Iluvien, Alimera) for treatment of diabetic macular edema (DME), we will have 4 proven pharmacotherapeutic options for this sight-robbing disease. Ranibizumab (Lucentis, Genentech), since its FDA approval for this indication in August 2012, has been used successfully to treat DME, but we are learning that not every patient responds adequately, even when injections are done early and in conjunction with laser.

We also have off-label treatments available such as bevacizumab (Avastin, Genentech) and the steroid triamcinolone acetonide in several forms (Kenalog [Bristol-Myers Squibb], and Triesence [Alcon]).

Ranibizumab seems more effective than bevacizumab for DME in my clinical experience; we will have comparative data forthcoming from a randomized clinical trial. In patients for whom anti-VEGF therapy is insufficient, corticosteroids can be very helpful, although at this time we have no approved corticosteroids for DME. This is about to change. Currently for steroid injections, I prefer to use Triesence in the clinic because it is not compounded and is designed specifically for use in the eye. The downside to steroids, of course, is the side effects. I use bolus injections more sparingly because cataract and increased IOP are well-known side effects. The FDA and retina surgeons will be looking carefully at the IOP side effect profile of any corticosteroid; I'm far less concerned about cataract because we have a highly efficacious procedure to solve that concern.

Corticoteroids will remain an important part of our treatment regimens for DME. Inflammation likely plays a significant role in the pathobiology of DME and that steroids work directly and quickly to address inflammation and reduce macular edema is advantageous to our patients Having a short-acting, sustained-release steroid in the form of the dexamethasone intravitreal implant will be of great benefit to specialists because of its potential efficacy for DME nonresponders, its more benign side-effect profile, and the possibility for reducing the frequency of anti-VEGF injections.

I am also eagerly anticipating the availability of an additional anti-VEGF option for DME: aflibercept. The results presented at recent meetings suggest that this agent will be effective for DME at less frequent dosing schedules, which is a clear benefit for patients and physicians. I am looking forward to using aflibercept for DME and seeing how it compares to my current therapy choices.

In that regard, another exciting pending development is the release of data from the Diabetic Retinopathy Clinical Research Network's Protocol T, which evaluated bevacizumab, ranibizumab, and aflibercept head-to-head-to-head for efficacy and safety. These data will most likely be available in late 2014 or early 2015. At the end of the day, it will be advantageous to have several DME treatment options because individual patients do not invariably fit within the guidelines established from study populations.

The FDA is also evaluating the fluocinolone acetonide implant (Iluvien, Alimera) for use in DME. In fact, as we were putting finishing touches on this issue the company announced that it has received a Prescription Drug User Fee Act date of September 26 from the FDA in response to its resubmission of data. This, after a period of uncertainty because of questions raised in the FDA's complete response letter last year, is positive news because it may provide us with 1 more therapeutic option to treat this multifactorial disease. Along with laser treatment, which will of course continue to be a significant tool for DME, these newly available pharmacologic agents, either alone or in combination, will put us in a much better position to preserve and improve vision in our patients. ■

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