Intravitreal Triamcinolone for DME Shows Lasting Efficacy

Although the safety of this drug is questionable when used in diabetic patients, results from this follow-up study suggest that side effects are manageable.

BY LAURA SUAREZ, ASSOCIATE EDITOR

The efficacy of intravitreal triamcinolone acetonide (IVTA) in the treatment of diabetic macular edema (DME) is still seen at 2 years. Follow-up results were presented at the Association for Research in Vision and Ophthalmology (ARVO) 2005: Global Networking. Initial results were presented at last year's meeting.

During this year's presentation, Mark Cedric Gillies, MD, PhD, an ophthalmologist at the University of Sydney, recapped 3-month results showing that patients treated with IVTA had a "very significant improvement in vision ... and a much reduced risk of losing vision." Overall, Dr. Gillies noted a three- to four-fold increase in the chance of improved vision at 3 months with IVTA treatment and a twofold increase over 2 years.

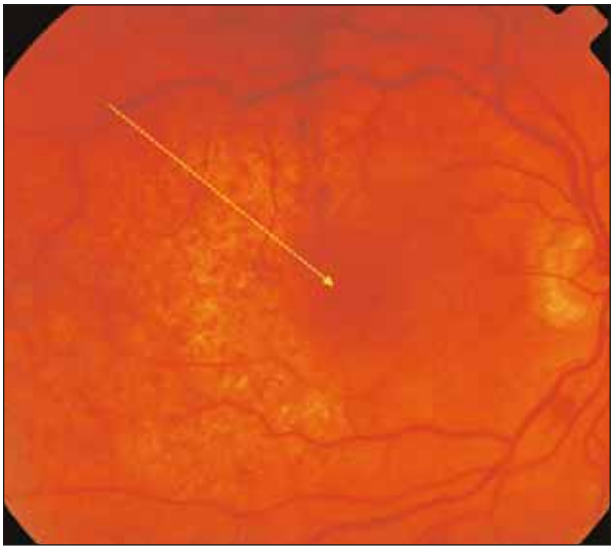

Figure 1. After extensive laser treatment, this patient still experienced persisting cystoid macular edema.

> The studied eyes were matched according to glycemic control, blood pressure and macular thickness.

PERSISTENT, RECURRENT DME

A total of 43 patients with DME participated in the study. Thirty-four eyes received the IVTA treatment (4 mg of IVTA) and 35 eyes received placebo (subconjunctival saline). All patients were randomized and previously underwent laser treatment for DME, which either persisted or recurred after treatment (Figure 1). Both eyes in 26 patients were eligible for study, Dr. Gillies said, adding that this allowed for a precise matching of glycemic control, blood pressure and macular thickness in these eyes.

At baseline, the groups had similar rates of visual acuity, semiquantitative contact lens grading and cataract. Optical coherence tomography was also similar between the treatment and placebo group (Figure 2).

Dr. Gillies and colleagues considered retreatments every 6 months followed by laser treatment if appropriate. At 2 years, 90% of treatment patients and 80% of placebo patients were still followed, and IVTA continued to benefit those patients who received the treatment. Patients remaining in the study at 2 years had persistent DME and ≥5 letter increase in best-corrected visual acuity.

The primary outcome of 2-year results was ≥5-letter improvement in best-corrected visual acuity, Dr. Gillies said. "Usually in diabetic retinopathy, it is a 10- or 15-letter improvement, but we wanted to include patients who were 20/30 because we felt that once you get edema affecting macular function, you might want to treat those patients earlier."

ELIGIBLE FOR ANOTHER INJECTION

Dr. Gillies said that during a typical treatment with IVTA, a patient's vision would improve, and then 6 months later would deteriorate again. "Then they would become eligible for treatment with another injection [of study medication] if the edema returned in association with reduction of vision," he said. "This is perhaps one of the advantages of triamcinolone injections compared with other more long-acting preparations because you don't necessarily need to give it continuously."

The median number of injections needed was three, however half of the patients needed as few as one or two injections over the 2-year study. Only 6% of patients received the maximum possible five injections.

More patients in the placebo treated group experienced an improvement in vision that was ≥5 letters than investigators expected. This may have been because patients started controlling their glucose levels better.

"[The improvement in visual acuity in both groups] also underscores the importance of randomized clinical trials in treatments for [DME], because nearly one-third of patients are going to get better by themselves," he said, adding that a greater reduction of central macular thickness in the IVTA treated group also attested to the efficacy of the injections.

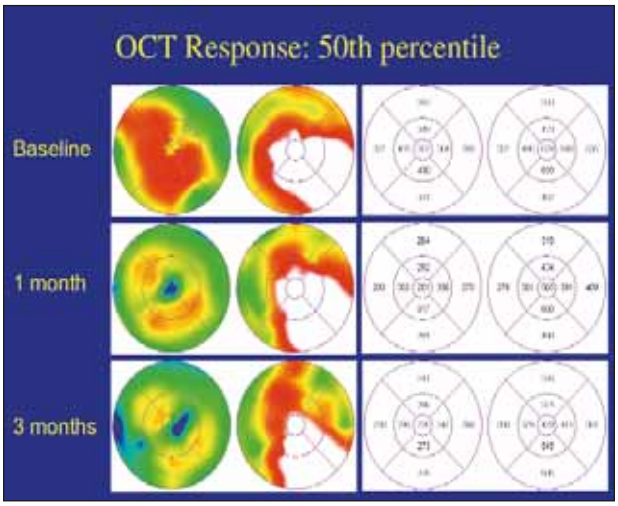

Figure 2. OCT responses at baseline and months 1 and 3.

TABLE 1. 2-YEAR STUDY RESULTS FROM 28 EYES IN 18 PATIENTS

	IVTA (25 eyes)	Placebo (34 eyes)
Increased 5 letters	19 (56%)	9 (25%)
No change	9 (26%)	13 (27%)
Decreased five letters	6 (18%)	13 (37%)

(*P*=.006)

SIDE EFFECTS

The safety profile of IVTA shows significant side effects, Dr. Gillies said. Eyes in the treatment group had a higher instance of elevated IOP by ≥5 mm/Hg compared to the placebo group (64% vs 9%). Progression of cataract was also higher in this group (36% vs 9%). Cataract usually did not appear until the second year, but at the end of 2 years, 55% of IVTA treated eyes had required cataract surgery compared with zero of the placebo treated eyes. A repeated injection of triamcinolone was given at the time of surgery. The mean visual acuity increased by 10 letters in operated eyes, and central macular thickness did not increase. "So that does suggest that you can perform cataract surgery in these patients with diabetic macular edema under cover of triamcinolone."

The short-term results of IVTA in the treatment of DME were mimicked at the 2-year mark. Dr. Gillies and colleagues will continue the study for 3 more years to see if IVTA treatment is safe and beneficial beyond 2 years. He has been researching the use of IVTA for 15 years, and is embarking on another study with the Australian Retinal Collaboration to see if using IVTA improves the efficacy of laser treatment by drying out the edema before laser is applied. ■

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Gillies MC. A randomized, placebo-controlled trial of intravitreal triamcinolone acetonide for diabetic macular edema that persists or recurs after laser treatment – 2-year results. Presented at ARVO 2005: Global Networking. May 1-5, 2005. Ft Lauderdale, Fla.