

Ocriplasmin

Thrombogenics, Inc. has just gotten FDA approval of its new drug, ocriplasmin, which has the trade name of Jetrea. This drug became available at the end of January 2013, indicated for treating vitreomacular adhesion, or VMA. The drug is injected intravitreally to lyse adhesions of the vitreous to the retina.

Ocriplasmin, which is the same thing as microplasmin, is the brain child of Mike Trese MD and George Williams, MD, both with Associated Retina Consultants of Detroit. They have spent the last 17 years developing a drug that would lyse vitreoretinal adhesions without vitrectomy, and finally settled on microplasmin. The trick was finding something that would digest the vitreous without digesting the retina.

Ocriplasmin was recently tested in the phase 3 MIVI-TRUST trial. (You may not have seen it because it was published in the New England Journal of Medicine (N Eng J Med 2012 367:607-15). Why anyone would publish an important ophthalmic article in the New England Journal of Medicine is a mystery to me.) In the study, 464 eyes were injected with ocriplasmin, and 188 injected with saline as placebo. All eyes had a vision

of 20/50 or less, or a stage 2 macular hole. The primary endpoint was resolution of vitreomacular adhesion on OCT at 28 days; this was achieved in 26% of the ocriplasmin eyes and 10% of the placebo eyes. The average visual improvement was 7 Snellen letters in the ocriplasmin group and 3 letters in the placebo group. At 6 months, 44% of the ocriplasmin group vs. 29% of the placebo group had a two line visual improvement. While some patients had an early inflammatory reaction, there were no significant safety concerns with intravitreal injection in either group.

There were more interesting results of the study: The drug is more effective in phakic patients under the age of 65, and in eyes with VMA of less than 1500 microns in diameter. Although vitreous adhesions may be lysed, there was no improvement in eyes with epiretinal membranes, and the drug is not recommended for those eyes. Small macular holes (less than 400 microns) were closed, but larger holes were not. Macular holes of less than 250 microns – and these are small holes – had the highest closure rate. Obviously patient selection has a big influence on success with ocriplasmin.

While we at University of Louisville Physicians - Eye Specialists have begun to use Jetrea, there are important considerations to bear in mind. First, only one dose can be given, because when a second injection was given after 28 days in monkeys, 100% had dislocated lenses. Thus if there is no improvement in 28 days, the patient becomes a candidate for vitrectomy. Jetrea must be stored at minus 20 degrees and a special freezer is needed. The cost of the drug is quite high - \$3950 – and patients must go through an approval process to make sure that insurance coverage is available. This may take one to two weeks. Given that the total cost of vitrectomy for macular hole is about \$4,500 (includes hospital, surgeon and anesthesia) with an 80 – 90% success rate, and the relatively low success rate with Jetrea, we must ask which is most cost effective for the patient. Nonetheless, a single in office injection of Jetrea is an attractive alternative for selected patients.

By: Charles C. Barr, MD

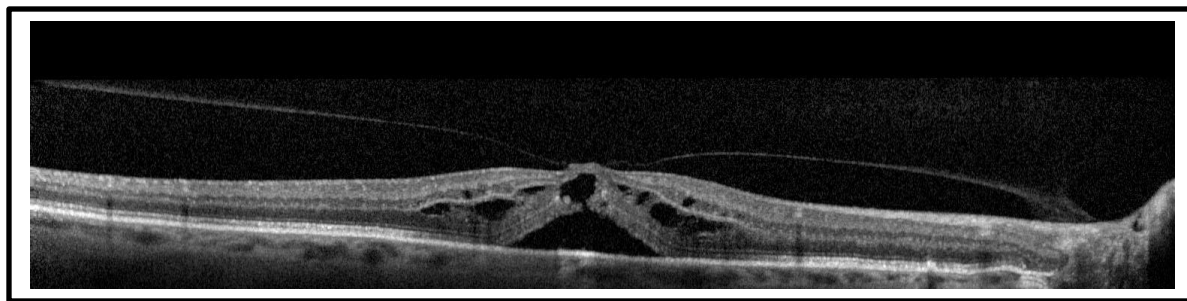


Fig. 1 – This patient would be a good candidate for Jetrea

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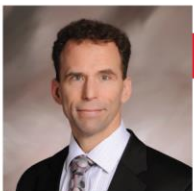
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