Treating stage 1 macular hole without surgery by injecting microplasmin

Author: Peter Stalmans, Meive, Belgium

Advantages:
Vitrectomy for vitreomacular traction/early stage macular holes has inherent disadvantages and risks, and induces increased patient morbidity.

Methods:
A phase II randomized, double-masked clinical trial with control sham injection in patients with vitreomacular traction was designed. Patients in each of four cohorts were randomized to treatment or sham injection in a 4:1 ratio, each cohort including 15 patients. In the first three cohorts, increasing doses of microplasmin (75, 125 and 175 µg) were injected intravitreally. In the fourth cohort, a 125 µg dose was injected at baseline and after four weeks, if no release of traction, a second dose (no sham) was injected, and after an additional four weeks, if still no release of traction, a third dose (no sham) was injected.

Effectiveness / Safety:
Patients were examined at several time intervals up to six months using ultrasound B-scan and OCT to determine the adherence of the posterior vitreous on the macula and occurrence of posterior vitreous detachment. No serious adverse events related to the study drug were observed. After administration of 75 µg of microplasmin, a traction release was found in 33% of the patients. This increased to 46% in the 125-µg group, which did not increase using 175 µg. When the 125-µg dose was repeated up to 3 injections, traction release was observed in 58% of the patients. In 8 microplasmin-treated patients with a stage II macular hole at baseline, closure of the hole was seen in patients.

Take home message:
Nonsurgical release of vitreomacular traction with microplasmin is a safe and effective treatment of stage I macular holes.