Implant appears effective for treating inflammatory disease within the eye

January 10 2011

An implant that releases the medication dexamethasone within the eye appears safe and effective for the treatment of some types of uveitis (swelling and inflammation in the eye's middle layer), according to a report posted online today that will appear in the May print issue of *Archives of Ophthalmology*.

"Uveitis refers to a group of intraocular inflammatory diseases that cause 10 percent to 15 percent of blindness in the developed world," the authors write as background information in the article. "Despite advances in immunosuppressive treatments, corticosteroids remain the mainstay of therapy." However, some patients cannot tolerate or do not respond to systemic corticosteroids, in part because the medications do not cross the blood-retinal barrier. Eye drops containing corticosteroids are effective only for anterior uveitis, closer to the front of the eye. Injections of corticosteroids directly into the eye have been effective in forms of intermediate or posterior uveitis, but require repeated treatments every two to three months and are associated with cataracts and other adverse effects.

To address these issues, an intravitreal (within the vitreous fluid of the eye), bioerodible, sustained-release implant has been developed to deliver a glucocorticoid medication, dexamethasone, to the back of the eye chamber. Careen Lowder, M.D., Ph.D., of the Cleveland Clinic Cole Eye Institute, and colleagues in the Ozurdex HURON Study Group conducted a 26-week randomized controlled trial involving 229 patients with intermediate or posterior uveitis. A total of 77 patients received an

implant with a 0.7-milligram dose of dexamethasone, 76 received an implant with a 0.35-milligram dose and 76 underwent a sham procedure which followed the same protocol but used a needleless applicator.

After eight weeks, the eyes were evaluated for the presence and degree of vitreous haze, or inflammation that obscures visualization. Vitreous haze was scored from zero to four, with zero indicating no inflammation and four indicating the most severe inflammation, obscuring the optic nerve. At the beginning of treatment, participants had an average vitreous haze score of two.

At the eight-week follow-up, a vitreous haze score of zero was observed in 47 percent of eyes with the 0.7-milligram implant, 36 percent of those with the 0.35-milligram implant and 12 percent of those who underwent the sham procedure. There was no significant difference between the two treatment doses, and the benefit associated with the implant persisted through the 26-week study.

In addition, the percentage of eyes that achieved at least a 15-letter improvement in visual acuity was two- to six-fold greater in both implant groups than in the control group throughout the study.

"Typically, the most common adverse events associated with intravitreal corticosteroids, which may have impacted use in the past, including increases in intraocular pressure [pressure within the eye] and cataract. On any given follow-up visit in the present study, substantial increases in intraocular pressure (to 25 millimeters of mercury or greater) occurred in less than 10 percent of treated eyes," the authors write. In addition, only one of 62 phakic (with lenses) eyes required surgery to remove a cataract.

"In conclusion, the present study demonstrated that in patients with non-infectious intermediate or posterior uveitis, a single dose of the

dexamethasone intravitreal implant was well tolerated and produced significant improvements in intraocular inflammation and visual acuity that persisted for six months," the authors conclude. "Overall, the 0.7-milligram dexamethasone intravitreal implant demonstrated greater efficacy than the 0.35-milligram dexamethasone intravitreal implant, with similar safety."

More information: Arch Ophthalmol. Published online January 10, 2011. doi:10.1001/archophthalmol.2010.339

Provided by JAMA and Archives Journals