

# Dexamethasone Implant Improved Uveitis

*Close to half of eyes that were treated with the 0.7-mg implant had a vitreous haze score of 0.*

BY JEFFREY S. EISENBERG

FROM ARCHIVES OF OPHTHALMOLOGY

A single dose of an intravitreal dexamethasone implant produced significant improvements in intraocular inflammation and visual acuity that lasted 6 months in patients with noninfectious intermediate or posterior uveitis, according to research published online.

The dexamethasone (DEX) implant, Ozurdex (Allergan Inc.), currently is approved for treatment of macular edema associated with retinal vein occlusions. Dr. Careen Lowder of the Cole Eye Institute, Cleveland, and her colleagues in the Ozurdex HURON Study Group sought to determine the safety of the DEX implant in the treatment of noninfectious intermediate and posterior uveitis.

She and her colleagues conducted a 26-week, prospective, multicenter, masked, parallel-group, sham-controlled clinical trial, in which they randomized 229 patients with a diagnosis of noninfectious intermediate or posterior uveitis to receive a sham procedure or treatment

with a 0.7-mg or 0.35-mg DEX implant (Arch. Ophthalmol. 2011 Jan. 10 [doi:10.1001/archophthalmol.2010.339]).

The mean age of the patients was 45 years, more than 60% were women, and more than 60% were white. Of the 229 patients, 217 (95%) completed the 26-week study, 2 in the 0.7-mg group dropped out because of adverse events, and 1 in the 0.35-mg group discontinued because of a lack of efficacy.

The primary outcome measure was the vitreous haze score at 8 weeks, as measured by a standardized photographic scale ranging from 0 (no inflammation) to 4 (optic nerve head not visible).

Patients in all groups had a mean vitreous haze score of +2 (moderate blurring of the optic nerve head) at baseline.

At the 8-week follow-up, a vitreous haze score of 0 was observed in 47% of eyes with the 0.7-mg implant, 36% of those with the 0.35-mg implant, and 12% of those that had the sham procedure, the investigators said.

There was no significant difference between the two treatment doses, and the benefit associated with the implant

## VITALS

**Major Finding:** A single dexamethasone intravitreal implant significantly improved intraocular inflammation and visual acuity in patients with noninfectious intermediate or posterior uveitis.

**Data Source:** A 26-week, prospective, multicenter, masked, randomized, parallel-group, sham-controlled clinical trial of 229 patients with noninfectious intermediate or posterior uveitis.

**Disclosures:** This study was sponsored by Allergan, which participated in the design of the study, analysis of the data, and interpretation. Allergan also supervised the preparation of the manuscript and approved the final version. Five authors of the study are employees of Allergan.

persisted through the 26-week study.

In addition, one or more cells were present in the anterior chamber in 14.5% of the 0.7-mg group and 20.3% of the 0.35-mg group, compared with 38.7% of the sham group. And, two to six times as many eyes in the DEX implant groups vs. the sham group gained 15 or more letters of best-corrected visual acuity, a significant difference.

"The results of the present study demonstrate that the DEX implant has a favorable safety profile and can effectively reduce inflammation and substantially improve vision in eyes with noninfectious intermediate or posterior uveitis," the researchers stated.

The findings suggest that the DEX implant may be used to safely and effectively treat intermediate and posterior uveitis. "Typically, the most common

adverse events associated with intravitreal corticosteroids, which may have impacted use in the past, include increases in intraocular pressure and cataract," the researchers wrote. "On any given follow-up visit in the present study, substantial increases in intraocular pressure (to 25 mm Hg or greater) occurred in less than 10% of treated eyes."

One limitation in the study, however, was that patients were treated with a single DEX implant and followed for only 6 months. This limits the ability to assess the risk of cataract. "Future studies will be needed to explore the long-term effects of repeated treatment with the DEX implant in patients with uveitis and to evaluate the potential of this therapy in other retinal disorders beyond retinal vein occlusion," the researchers wrote. ■

# Statin Had No Effect on Atherosclerosis in Lupus Patients

BY SHERRY BOSCHERT

FROM ANNALS OF THE RHEUMATIC DISEASES

Atorvastatin therapy did not improve subclinical measures of atherosclerosis or disease activity, compared with placebo, in a 2-year, randomized, double-blind study of 200 adults with systemic lupus erythematosus.

The results surprised the investigators because atorvastatin had seemed to be an ideal choice to interrupt the accelerated atherosclerosis seen in SLE, reported Dr. Michelle A. Petri.

Previous studies had shown some potential benefits from the anti-inflammatory effects of statins in other autoimmune diseases, including rheumatoid arthritis and multiple sclerosis. Findings from one small study of pravastatin in

patients with SLE found that it reduced total cholesterol and LDL cholesterol levels but did not reduce C-reactive protein levels.

In the current study, there was no significant difference between the patients who were randomized to 40 mg/day atorvastatin and those receiving placebo in progression of coronary artery calcium, carotid intima media thickness, or carotid plaque.

There also were no significant differences between groups in measures of disease activity, inflammation, or endothelial cell activation, reported Dr. Petri, professor of medicine at Johns Hopkins University, Baltimore, and her associates (Ann. Rheum. Dis. 2011 Dec. 21 [doi: 10.1136/ard.2010.136762]).

The atorvastatin group, however, was more likely to develop elevations in liver function tests, even as late as 18 months into the study.

The lack of any evidence of an anti-inflammatory benefit from the statin suggests that something besides statins should be considered to manage the accelerated atherosclerosis of SLE, the investigators suggested.

Patients with SLE and hyperlipidemia should continue to be treated with statins and other lipid-lowering medications, they added, but with

closer monitoring of liver function tests even if the statin dosage doesn't change, reported Dr. Petri, who is also the director of the lupus center at Johns Hopkins as well as the director of the Hopkins Lupus Cohort, and her associates.

At the start of the study, the groups

**Patients with SLE and hyperlipidemia should continue to be treated with statins, but with closer monitoring of liver function tests even if the statin dosage doesn't change.**

were similar and none of the patients had taken statins for at least 3 months. They underwent helical CT scanning to assess coronary artery calcium and carotid duplex to assess carotid intima media thickness and carotid plaque. These tests were repeated at the 2-year follow-up.

Records of disease activity in the 2 years prior to starting the study were compared with quarterly measures of disease activity during the study.

In all, 96 patients on atorvastatin and 91 on placebo completed the study.

At baseline, 42% of patients in the atorvastatin group and 43% in the placebo group had coronary artery calcium. Carotid plaque was seen in 20% of the atorvastatin group and 15% of the placebo group, a difference that was not statistically significant.

Coronary artery calcium scores changed in 51% of those on atorvastatin and in 54% of those on placebo, with no significant differences between groups in the proportions whose scores increased or decreased, or by how much. All patients with carotid plaque at baseline also had it at follow-up. Among patients without carotid plaque at baseline, 25% in the atorvastatin group and 23% on placebo progressed to having plaque at follow-up, Dr. Petri and her associates said.

The mean carotid intima media thickness was 0.59 mm in the atorvastatin group and 0.57 mm in the placebo group at baseline, and 0.66 mm in both groups after 2 years. In a post hoc analysis of the proportions of patients in whom carotid intima media thickness improved, stayed the same, or got worse, results favored atorvastatin, the investigators noted.

Changes in the levels of total cholesterol and lipoprotein differed significantly between groups.

In the atorvastatin group, total cholesterol decreased by 31 mg/dL (or 17%), compared with an increase in the placebo group of 6 mg/dL (or 3%). In the atorvastatin group, lipoprotein levels increased by 8 mg/dL (or 12%), compared with a decrease in the placebo group of 7 mg/dL (or 10%).

Disease activity was measured using the Safety of Estrogens in Lupus: National Assessment revision of the SLE Disease Activity Index. ■

## VITALS

**Major Finding:** Atorvastatin 40 mg/day did not affect subclinical measures of atherosclerosis or disease activity in patients with SLE, compared with placebo.

**Data Source:** Randomized, double-blind, placebo-controlled trial in 200 patients with SLE who were followed for 2 years.

**Disclosures:** Dr. Petri was formerly an adviser and speaker for Pfizer, which markets atorvastatin. None of her coauthors had conflicts of interest. The study was funded by the Alliance for Lupus Research, the Arthritis Foundation, the Hopkins Lupus Cohort, and the National Center for Research Resources.