Supplement to

April 2013

CME ACTIVITY

RETINA TODAY

Applying New Data to Improve the Standard of Care in Retinal Disease

The Management of Posterior Noninfectious Uveitis

By Thomas Albini, MD

Release date: April 2013. Expiration date: April 2014.
Jointly sponsored by The Dulaney Foundation and *Retina Today*. Supported by an educational grant from Allergan Inc.

STATEMENT OF NEED

Although noninfectious intermediate and posterior uveitis are thought to be relatively uncommon, the Northern California Epidemiology of Uveitis Study (n = 731 898), which is the largest population-based uveitis study that has been performed in the United States, showed the incidence of uveitis to be approximately 3 times that of previous estimates.[1] This study showed the annual incidence of noninfectious intermediate and posterior uveitis to be 52.4 per 100 000 person-years and a period prevalence of 115.3 per 100 000 persons.

The symptoms of noninfectious intermediate uveitis include sudden painless vision loss or vision decrease with appearance of floaters.[2] In noninfectious posterior uveitis, the symptoms range from a decrease in visual acuity with floaters to retinal detachment and optic nerve inflammation.[2] Untreated uveitis may result in long-term vision-threatening complications.[3]

Macular edema is a common problem in patients with uveitis, often limiting visual potential. Optical coherence tomography studies demonstrate that macular edema is more common in these patients than previously thought, even in patients with anterior nongranulomatous uveitis.[4-5] It precludes good vision even after the uveitis is apparently in remission, for reasons that include retinal pigment epithelial (RPE) dysfunction, vitreomacular traction, and epiretinal membrane formation; finally, inflammatory cytokines themselves can lead to increased vascular permeability, leading to macular edema.

The treatment options for noninfectious intermediate and posterior uveitis include off-label use of corticosteroids and anti-VEGF agents, but currently, the only 2 US Food and Drug Administration-approved local treatments for noninfectious intermediate and posterior uveitis are the intravitreal fluocinolone acetonide 0.59 mg implant (Retisert, Bausch + Lomb) and the dexamethasone 0.7 mg intravitreal implant (Ozurdex, Allergan Inc).

The clinical trial for the fluocinolone acetonide 0.59 mg implant evaluated 278 patients over the course of 34 weeks after implantation with the implant. Patients were randomized to receive either a 0.59 mg implant or a 2.1 mg implant. The implant was shown at all doses to significantly reduce the rate of uveitis recurrence and to stabilize vision in 87% of implanted eyes.[6] The most common side effects were increased intraocular pressure (IOP) and cataract progression.

The HURON trial[7] was to evaluate the safety and efficacy of 2 doses of the dexamethasone intravitreal implant for the treatment of noninfectious intermediate or posterior uveitis. The primary outcome measure in this trial was the proportion of patients with a vitreous haze score of 0 at week 8. Additional outcome measures were vitreous haze through week 26, best corrected visual acuity, adverse events, IOP, and biomicroscopy/ophthalmoscopy.

The results of the trial showed that a single dexamethasone intravitreal implant was significantly more effective than sham at eliminating vitreous haze. At the primary endpoint of week 8, approximately 4 times more eyes treated with the dexamethasone implant 0.7 mg had complete resolution of vitreous haze compared with sham. Treatment with the dexamethasone intravitreal implant also led to a significant improvement in BCVA by week 3 that persisted through week 26. In regard to safety, IOP increases were relatively low in the treatment groups. There was no statistically significant difference in rate of cataract surgery between treatment groups and sham at 6 months.

Other forms of local therapy include periocular (subconjunctival or sub-Tenon) and intravitreal injections. Sub-Tenon triamcinolone injections are commonly used to treat uveitic cystoid macular edema. Risks include glaucoma, cataract, and rare cases of scleral perforation with or without retinal detachment. A typical regimen is to use triamcinolone acetonide 40 mgs (1 mL) in the sub-Tenon space. Intravitreal injections of triamcinolone acetonide 2 mg to 10 mg can be considered if periocular injections are ineffective. The risk of glaucoma and cataract are greater with intravitreal injections. The use of preservative-free triamcinolone reduces the risk of sterile endophthalmitis. In 2011, the results of the Multicenter Uveitis Steroid Trial were released.[8] This study randomized patients with noninfectious intermediate, posterior, and panuveitis to local therapy with the fluocinolone implant or systemic therapy with corticosteroids and/or immunosuppressive drugs. In both treatment groups, vision improved over 2 years, with neither approach showing a statistically significant benefit over the other. Not surprisingly, the risk of glaucoma and cataract was greater in the implant group, and systemic side effects were greater in the systemic therapy group, although these side effects were usually mild and reversible. The results of the study suggested that the choice of therapy should be dictated by the individual patient's particular circumstances and preferences.

Retina specialists who treat noninfectious intermediate and posterior uveitis face a growing number of treatment options, requiring physicians and their staff to identify, learn about, and implement these newer treatments in a seamless manner. As the US population continues to age and the incidence of vascular and metabolic disorders associated with retinal diseases also increases, clinicians will need to recognize the importance of implementing treatment regimens that maximize efficacy, minimize patient burdens, and help patients manage their disease.

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TARGET AUDIENCE

This certified CME activity is designed for retina specialists and general ophthalmologists involved in the management of retinal disease.

LEARNING OBJECTIVES

Upon completion of this activity, the participant should be able to:

- Understand the new data available on treatments for noninfectious intermediate and posterior uveitis and how to apply this information in monotherapy and combination therapy treatment schemes.
- Discuss the effective administration of intravitreal injections.
- Differentiate steroids and systemic treatments for posterior segment inflammation and their effects in the treatment of macular edema and inflammation.
- Treat various forms of macular edema and inflammation, based on assessment of patient need, the latest developments in the medical literature, and insights from case-based learning.

ACCREDITATION AND DESIGNATION

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FACULTY CREDENTIALS

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FACULTY/STAFF DISCLOSURE DECLARATIONS

Dr. Albini states that he is a consultant for Allergan Inc, Bausch + Lomb, and Eleven Biotherapeutics.

Cheryl Cavanaugh, director of operations, The Dulaney Foundation; Brianna Falcone, *Retina Today*; Michelle Dalton, writer; and David Friess, reviewer, have no financial relationships with commercial interests.

The Management of Posterior Noninfectious Uveitis

BY THOMAS ALBINI, MD

When a patient presents with uveitis, it is important to determine whether it is infectious or noninfectious. This is achieved with a thorough clinical examination, acquisition of a complete medical history, and appropriate ancillary tests including blood screens. First, the location of the inflammation must be determined and systemic conditions that may be contributing factors identified. A complete medical history should include any medications or treatments that the patient is currently receiving for any systemic conditions or the inflammation itself. Once the medical history has been established, a targeted review of symptoms and clinical examination should be performed to determine whether the inflammation is associated with an undiagnosed condition. Infectious uveitis is typically treated with targeted antimicrobials and, in some cases, antimicrobials in conjunction with steroids.

Fundus fluorescein angiography, indocyanine green angiography, ultrasonography, optical coherence tomography, and appropriate laboratory testing are typically part of a complete assessment of posterior segment uveitis.

Noninfectious uveitis in the anterior segment is treated with steroid eye drops, most commonly prednisolone acetate or difluprednate (Durezol, Alcon).

For posterior noninfectious uveitis, a local approach can be taken using intravitreal or periocular steroid injection. Alternatively, a sustained-release approach can be employed with either the fluocinolone acetonide 0.59 mg implant (Retisert, Bausch + Lomb) or the dexamethasone 0.7 mg implant (Ozurdex, Allergan Inc).

Another mode of treatment is systemic steroids for the first 2 months followed by a systemic steroid-sparing agent such as methotrexate or mycophenolate. The other classes of drugs that are used for posterior noninfectious uveitis include TNF inhibitors, such as adalimumab, infliximab, etanercept, and golimumab, and alkylating agents such as cyclophosphamide and chlorambucil. Drugs that are used off-label to treat posterior segment noninfectious uveitis include cyclosporine A, tacrolimus, sirolimus, azathioprine, methotrexate, and mycophenolate.

WHICH IS BETTER: LOCAL OR SYSTEMIC TREATMENT?

The National Eye Institute (NEI)-funded Multicenter Uveitis Steroid Treatment (MUST) trial compared the efficacy and safety of local vs systemic treatments for severe forms of uveitis including intermediate, posterior, and panuveitis over a 2-year time period.[1] The study randomized patients (n=255) to either high doses of oral corticosteroids for 1 to 4 weeks after which the doses were lowered, in some cases with adjunctive immunosuppressive therapies, or to implantation with the fluocinolone acetonide 0.59 mg intravitreal implant, which has a duration of approximately 30 months.[2]

The average visual acuity improvement over 2 years for patients in both the implant and systemic treatment groups was +6.0 and +3.2 letters, respectively. Although the vision gains in the implant group were slightly higher, the difference was not statistically significant ($P = .16$). The implant ranked slightly higher in improvement of vision-related quality of life scales also, but again, the difference was not significant.

In regard to safety, patients in the implant group had a higher risk of cataract formation ($P < .0001$), increased intraocular pressure (IOP [$P < .0001$]), and glaucoma ($P = .0008$). Patients in the systemic treatment group had an increased need for prescription therapy to manage infection ($P = .34$), but none of these patients had long-term complications.

The conclusions of the study were that there was no significant difference in efficacy, although there were increased ocular complications when using the fluocinolone implant for noninfectious uveitis. Despite these safety concerns, the overall conclusion was that either approach is reasonable depending on the patient's individual situations and responses to therapy.

DEXAMETHASONE INTRAVITREAL IMPLANT

The dexamethasone intravitreal implant is the most recent addition to local treatment for posterior noninfectious uveitis. Dexamethasone is a multifactorial corticosteroid and, although we do not know all the ways that steroids work, we do know they work quickly by binding steroid receptors in the cytoplasm and then by altering DNA expression in the cell nucleus. Corticosteroids are potent inhibitors of leukocyte migration and decrease capillary permeability. Dexamethasone blocks the effector arm of the immune response and effectively and quickly decreases inflammation.

Dexamethasone is 5 times more potent than triamcinolone acetonide[3] but has a short half-life in the eye; hence the rationale for a sustained-delivery system. The duration of sustained release is shorter than with the fluocinolone acetonide implant because fluocinolone has 1/24 the solubility of dexamethasone, allowing the longer duration (30 months vs 6 months).

The HURON study evaluated 2 doses (0.35 mg and 0.70 mg) of dexamethasone intravitreal implant vs sham for the treatment of intermediate or posterior noninfectious uveitis.[4] Patients (n=229) were evenly randomized to treatment in the 26-week trial. The main outcome measure was vitreous haze score of 0 at week 8.

Forty-seven percent of eyes that received the 0.70-mg dexamethasone implant achieved a vitreous haze score of 0 at week 8 compared with 36% of patients with the 0.35-mg implant and 12% with sham, a statistically significant difference. This effect persisted to week 26.

In regard to visual acuity, significantly more eyes in both of the implant groups had improved vision by 15 or more letters. The difference in increased IOP between all 3 groups was not significant, nor was cataract formation.

Based on these data showing that the dexamethasone implant significantly improved visual acuity and reduced inflammation with a relatively good safety profile, the implant was approved by the US Food and Drug Administration for the treatment of noninfectious uveitis affecting the posterior segment of the eye.

DEXAMETHSONE IMPLANT VS FLUOCINOLONE IMPLANT

A recent comparative case series evaluated the efficacy and safety of the fluocinolone acetonide implant compared with the dexamethasone intravitreal implant.[5] In this case series (n=27), patients received either the fluocinolone acetonide implant (n=16) or the dexamethasone intravitreal implant (n=11). Most of the patients included in this study had panuveitis, and follow-up ranged from 6 months to 2 years.

At the conclusion of this study, there were no significant differences seen in visual acuity or inflammation scores between the 2 groups, nor was there any significant difference in recurrence rates. Reimplantation was 5 times more likely in the patients who received the dexamethasone implant, but this was most likely directly related to the shorter duration and the length of the study.

In regard to safety, 44% of patients with the fluocinolone acetonide implant required additional glaucoma medications, surgery, or laser, compared with no patients who received the dexamethasone implant. All patients in the fluocinolone acetonide implant group progressed to cataract and required surgery, compared with 50% of patients in the dexamethasone implant group.

The authors concluded that the 2 implants were equivalent in their ability to prevent recurrence of noninfectious uveitis, improve visual acuity, and reduce inflammation, but that the side effect profile was more favorable for the dexamethasone intravitreal implant.

CLINICAL IMPRESSIONS OF THE DEXAMETHASONE INTRAVITREAL IMPLANT

I use the dexamethasone intravitreal implant in patients who have mild to moderate intermediate or posterior segment uveitis, such as retinal vasculitis, either as monotherapy or in conjunction with systemic treatment. For instance, if a patient is taking a systemic antimetabolite and still has some degree of vascular leakage, rather than adding cyclosporine A, I inject the dexamethasone intravitreal implant.

Using the dexamethasone intravitreal implant allows me to avoid anterior migration of drug and provides a longer duration of action, with more steady intravitreal concentrations.

My clinical impression, although anecdotal, has been that IOP rises are more controlled with the dexamethasone intravitreal implant than they have been with triamcinolone acetonide. I also am able to cut the number of required injections in half with the implant vs triamcinolone acetonide. In general, I have achieved good, sustained immunosuppression with the dexamethasone implant. I have performed approximately 100 injections of the implant with good patient tolerance and satisfaction.

THE INJECTION PROCESS

When counseling patients on what to expect during the injection process, I tell them that the needle for the dexamethasone intravitreal implant is larger than what I would use for injecting bolus steroids or anti-VEGF, and so they might feel pressure when I am injecting. Many patients do not even notice the difference.

I approach the injection very much the same way that I would a standard 32-gauge intravitreal injection. I place a lidocaine pledget on the surface of the eye for a few minutes, and then I place the lid speculum and instill povidone-iodine. I then perform a subconjunctival lidocaine injection with a 32-gauge needle and put in another drop of povidone-iodine. I displace the conjunctiva with a cotton-tipped swab and approach the eye with the injector needle at a fairly low angle—10º to 30º—and perform a 2-step beveled incision through the conjunctiva and the slcera. I usually have the patient look in a superonasal direction and administer the injection inferotemporally.

To inject the implant, I find that, if I push on the back end of the plunger all at once, the implant goes in more smoothly. I avoid pressing on the plunger too gently, because this can result in the implant getting caught up in the injector.

I roll a cotton-tipped swab over the wound as I withdraw the injector to help seal the wound. Finally, I use an indirect ophthalmoscope to ensure that the implant is in the eye. I then remove the lid speculum, rinse the eye, and have my technician check the IOP to be sure it rises above 8 mm Hg.

Postinjection, I usually give patients gentamicin or trimethoprim/polymyxin to be used 3 times a day for 3 days.

TIPS FOR INJECTION

My advice for physicians who are new to injecting the dexamethasone intravitreal implant is to approach it much like a standard intravitreal injection. If a physician does not have experience with small-gauge surgery, I would definitely recommend a wet lab so that he or she can practice the beveled injection. For a vitreoretinal surgeon, however, the injection is fairly straightforward.

I also recommend using a smaller 32-gauge needle for the subconjunctival lidocaine.

SUMMARY

It is important to choose treatment for noninfectious posterior uveitis based on individual patients' needs. It is certainly advantageous to have so many treatment options, both local and systemic, that can be used alone or in combination with 1 another. As we gain more experience and follow-up with the newer treatments that have become available, our outcomes are certain to improve, because we can now better match the best therapy for each individual with uveitis. ■

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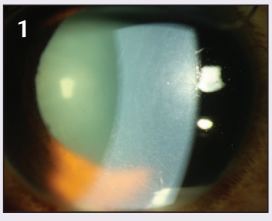
CASE REPORT

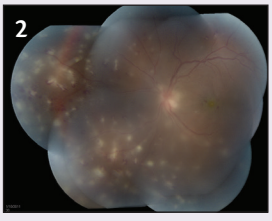
A 27-year old black man presented with painful oral ulcers, bilateral panuveitis, shifting hypopyon in the right eye (OD; Figure 1), no view to the fundus from fulminant vitritis OD, and multifocal hemorrhagic retinitis in the left eye (OS; Figure 2).

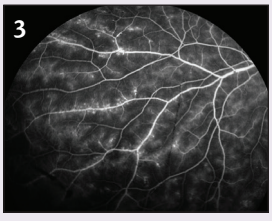
After a 2-month oral prednisone taper and 4 months of 150 mg azathioprine daily, vision was 20/60 OD and 20/20 OS. A late frame of fluorescein angiography (FA) of the inferotemporal periphery showed persistent vascular leakage (Figure 3), and optical coherence tomography (OCT) showed mild macular edema OD (Figure 4). The inflammation had completely resolved OS.

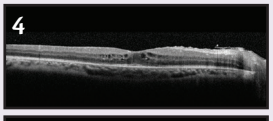
The dexamethasone intravitreal implant was injected OD, and azathioprine was continued. Three months later, FA shows persistent but much improved vascular leakage (Figure 5) and complete resolution of macular edema on OCT (Figure 6). The visual acuity was 20/30 OD.

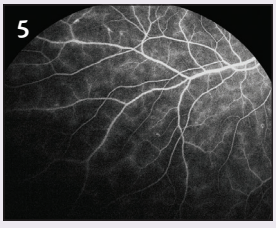
Take-home point: Disease was completely controlled in 1 eye with systemic medication. The active eye was improved significantly with the dexamethasone intravitreal implant as an alternative to increasing azathioprine dose or adding additional immunosuppressants.











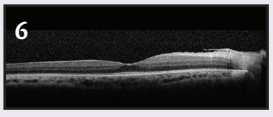


Figure 1. Shifting hypopyon OD.
Figure 2. Multifocal hemorrhagic retinitis OS.
Figure 3. Persistent vascular leakage OD in the inferotemporal periphery on FA.
Figure 4. OCT shows mild macular edema OD.
Figure 5. FA shows improved vascular leakage OD.
Figure 6. OCT shows complete resolution of macular edema OD.

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CME QUESTIONS

1. Dexamethasone is ___ times more potent than triamcinolone acetonide.

a. 3
b. 7
c. 5
d. 2
e. None of the above

2. The conclusions of the MUST study include which of the following?

a. The fluocinolone acetonide 0.59 mg implant is as safe as systemic therapy for noninfectious uveitis.
b. Systemic therapy for noninfectious uveitis has more local side effects than the fluocinolone acetonide 0.59 mg implant.
c. The fluocinolone acetonide 0.59 mg implant has more ocular side effects than systemic therapy for noninfectious uveitis.
d. All of the above

3. A comparative case study found the side effect profile more favorable for which?

a. The fluocinolone acetonide 0.59 mg implant
b. The dexamethasone 0.7 mg implant
c. The 2 were comparable

4. Which are appropriate tests for evaluating patients who present with suspected posterior uveitis?

a. Fundus fluorescein angiography
b. Indocyanine green angiography
c. Ultrasonography
d. Optical coherence tomography
e. All of the above

5. In the HURON study, significantly more eyes in the implant groups gained how many letters of vision?

a. 10
b. 0
c. 30
d. 15
e. None of the above

Did the program meet the following educational objectives?	Agree	Neutral	Disagree
Understand the new data available on treatments for noninfectious intermediate and posterior uveitis and how to apply this information in monotherapy and combination therapy treatment schemes	_____	_____	_____
Discuss the effective administration of intravitreal injections	_____	_____	_____
Differentiate steroids and systemic treatments for posterior segment inflammation and their effects in the treatment of macular edema and inflammation	_____	_____	_____
Treat various forms of macular edema and inflammation, based on assessment of patient need, latest developments in medical literature and insights from case-based learning	_____	_____	_____

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Rate your knowledge/skill level prior to participating in this course: **5 = High, 1 = Low**_____

Rate your knowledge/skill level after participating in this course: **5 = High, 1 = Low** _____

Would you recommend this program to a colleague? ❒ Yes ❒ No

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If yes, please specify. We will contact you by email in 1 to 2 months to see if you have made this change.

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If no, please identify the barriers to change.

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Please list any additional topics you would like to have covered in future Dulaney Foundation CME activities or other suggestions or comments.

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