Retinal Complications Follow Use of Compounded Medication for “Dropless” Cataract Surgery

The American Society of Cataract and Refractive Surgery and the American Academy of Ophthalmology are aware of two separate outbreaks of acute retinal toxicity after intravitreal injection of compounded triamcinolone-moxifloxacin not produced by Imprimis. We suggest that ophthalmologists exercise caution and due diligence when obtaining this medication from a new compounding source.

These outbreaks occurred at two different Dallas surgery centers that obtained this formulation from the same Dallas compounding pharmacy, Guardian Pharmacy Services.

The more-recent outbreak occurred following cataract surgeries performed in February 2017. The affected patients presented with variable, but frequently severe vision loss, and OCT abnormalities of the ellipsoid layer of the macula. Because of its analogy to toxic anterior segment syndrome (TASS), we are referring to this complication as toxic posterior segment syndrome (TPSS).

We have learned that about 50 patients have been affected in these two separate clusters. We have been unable to confirm, and are not aware of any other cases of TPSS in the United States. However, the Dallas compounding pharmacy in question may have used a formulation protocol provided by a national organization of compounding pharmacies to other pharmacies. Therefore, unrecognized or unreported cases might exist from other compounding pharmacies.

The national 503B certified outsourcing facility, Imprimis Pharmaceuticals Inc., has patented a triamcinolone-moxifloxacin formulation with the trademarked name Tri-Moxi. This drug is compounded for intravitreal injection following cataract surgery. Surgery incorporating a combination antibiotic-steroid intravitreal injection in order to reduce the need for topical postoperative medication is sometimes referred to as “dropless” cataract surgery. According to Imprimis, no cases of TPSS have been reported in association with its proprietary Tri-Moxi compounded product.

Because Tri-Moxi is a proprietary product, other compounding pharmacies (such as Guardian) must devise their own methodology to compound their version of triamcinolone-moxifloxacin for intravitreal injection following cataract surgery. There is no FDA-approved formulation of this drug combination for ophthalmic use.
Investigations into the etiology and clinical course of these TPSS cases are ongoing. We encourage any ophthalmologists with knowledge of other possible TPSS cases associated with compounded intravitreal triamcinolone-moxifloxacin to report these to the ASCRS TASS Registry.

Until more conclusive information is known, ophthalmologists should exercise caution and due diligence when obtaining intravitreal triamcinolone-moxifloxacin from a new compounding source and carefully monitor patients. Compounders classified as 503B by the FDA (known as outsourcing facilities) meet more stringent regulatory requirements than traditional compounding pharmacies classified by the FDA as 503A.

If you have questions, please contact Nancey McCann at nmccann@ascrs.org.

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