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Information Statement

Cataract Patients Being Prescribed Tamsulosin (Flomax®) and other alpha-blockers

Recommendations

The American Academy of Ophthalmology (Academy) and the American Society of Cataract and Refractive Surgery (ASCRS) recommend that patients taking alpha-blockers to treat prostate enlargement or other conditions inform their ophthalmologist about these medications before undergoing eye surgery. Prior to being started on this class of drugs, patients with cataracts should be informed that alpha-blockers, in general, and Flomax, in particular, may increase the difficulty of cataract surgery.

Background

Tamsulosin (Flomax®) is the most commonly prescribed drug for prostate enlargement, or benign prostatic hyperplasia (BPH). By relaxing muscles in the enlarged prostate and facilitating more complete emptying of the bladder, Flomax decreases the need to urinate during the middle of the night. Other drugs in this alpha-blocker class include terazosin (formerly Hytrin®), doxazosin (Cardura®), alfuzosin (Uroxatral®), and silodosin (Rapaflo®). Alpha-blockers may be prescribed for urinary retention in women and are also used to treat hypertension. Flomax and Rapaflo are considered “selective” alpha-blockers,¹ because their drug effects are more selective for, and therefore more limited to, the prostate and iris. The other drugs in this group are called “non-selective” alpha-blockers.

The effect of Flomax on cataract surgery

In 2005, investigators reported a new problem that occurs during cataract surgery in patients using alpha-blockers, such as Flomax.² They called the condition Intraoperative Floppy Iris Syndrome (IFIS).

The iris, the part of the eye that gives it its color, opens and closes in response to varying light levels. Because the iris is located in front of

the cataract, the pupil (opening in the iris) must be widely dilated to perform the surgery. A large pupil is obtained, in part, by using dilating drops that stimulate the iris dilator muscle. Alpha-blockers, such as Flomax, block this iris muscle, leading to poor dilation and sometimes causing the pupil to suddenly constrict during surgery. Alpha-blockers, such as Flomax, do not cause other vision or eye health problems.

Following the publication of these findings, and after receiving corroborative reports from other ophthalmologists, the U.S. Food and Drug Administration (FDA) instituted a new label warning in 2005 for Flomax and other alpha-blocker drugs that reads: "The patient's ophthalmologist should be prepared for possible modifications to their surgical technique."

Additional studies have confirmed the following clinical features of IFIS.

1. Other alpha-blockers besides Flomax can cause IFIS, but several studies suggest that IFIS is more likely to occur with the "selective" alpha-blocker Flomax compared to the other "non-selective" alpha-blockers.²⁻⁷ There are no data yet on IFIS with Rapaflo, the newest alpha-blocker to be FDA approved, but which, like Flomax, is pharmacologically "selective" for the iris and prostate tissue.
2. Discontinuing these drugs prior to cataract surgery does not necessarily help.^{2,4} In a large national survey conducted in 2008, nearly 3 out of 4 cataract surgeons reported encountering IFIS in patients who had stopped (but previously taken) alpha-blockers.⁸ Only 11% of ophthalmologists routinely ask their patients to stop alpha-blockers prior to cataract surgery.
3. IFIS increases the difficulty and risk of cataract surgery, particularly if the ophthalmologist did not know that the patient was taking alpha-blockers.⁸ Knowing that the patient is taking alpha-blockers, different eye surgical techniques and modifications help to achieve excellent outcomes, should IFIS occur. In one study, a group of experienced surgeons achieved excellent results and a very low complication rate by using these special surgical techniques.⁴ For this reason, patients already taking alpha blockers need not avoid or delay cataract surgery if it is recommended by their ophthalmologist.
4. 5-alpha reductase inhibitors, the other major class of drugs to treat BPH, do not appear to cause IFIS to any significant degree.⁷ This class of drugs includes dutasteride (Avodart®) and

finasteride (generic, but includes Proscar®). However, Saw Palmetto, an herbal alternative to alpha-blocker therapy, can produce a mild form of IFIS.

New study of cataract complication risk with Flomax

Bell et al reported in May 2009 on a large population-based study from Ontario, Canada that found a higher rate of postoperative complications in cataract patients who were taking Flomax⁹. The study looked at all men over age 66 in that province undergoing cataract extraction between 2002 and 2007 (n=96,128) and found that 3.7% had recently taken Flomax, compared to 7.7% who had recently taken other alpha-blockers. A total of 284 (0.3%) patients required extra procedures for complications within 14 days postoperatively. Analyzing this group, the investigators determined that taking Flomax made patients 2.3 times more likely to develop these postoperative complications than those who were not exposed to the drug preoperatively. However, they did not find that the risk was increased when non-selective alpha-blockers, such as terazosin (Hytrin®), doxazosin (Cardura®), or alfuzosin (Uroxatral®), were taken.

Advice for Patients

Flomax and other alpha-blockers increase the difficulty of cataract surgery, particularly if the ophthalmologist does not know that the patient is taking or has been taking these medications. The risk appears to be higher in patients taking Flomax than in patients taking non-selective alpha-blockers, as reported by Bell et al (2009)⁹ and others.²⁻⁷ Therefore, it is important that patients inform their ophthalmologist whether they are currently taking alpha-blockers, such as Flomax, or did so in the past. However, patients should not decide on their own to discontinue their alpha-blockers without first discussing this with the prescribing physician. Before being started on an alpha-blocker medication for the first time, patients who already have cataracts should understand that these drugs can complicate cataract surgery later on. For this reason, they may want to discuss the risks and the timing of their operation with their ophthalmologist performing cataract surgery. The ophthalmologist performing the cataract surgery can advise a patient how much risk the alpha-blocker medication poses for his or her surgery, and whether stopping, delaying or avoiding the drug is advisable.

Summary

Recent scientific evidence supports an association between alpha-blocker drugs, particularly Flomax, and increased postoperative risks for patients undergoing cataract surgery. Therefore, ophthalmologists, primary care physicians, urologists and patients should all be aware of the difficulties that these drugs may pose for cataract surgery. The overall risk of serious cataract surgical complications is low, and when the ophthalmologist is informed of the patient's history of alpha-blocker use, the success rate of cataract surgery remains very high.

Approved by: American Society of Cataract and Refractive Surgery, June 2009
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