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Medical Societies Issues Advisory to Patients Taking Prostate Medications

Fairfax, VA – The American Society of Cataract and Refractive Surgery (ASCRS), the American Academy of Ophthalmology (Academy) and the American Urological Association (AUA) today advised patients taking certain drugs to treat prostate enlargement to inform their eye surgeon about these medications before undergoing eye surgery. These drugs can potentially cause complications during cataract surgery. However, preliminary results of a new study found that these patients can still have successful surgery if their surgeon knows they are taking or have taken these drugs and alters the surgical technique.

Advisory

Tamsulosin (Flomax®) is the most commonly prescribed drug for prostate enlargement, or benign prostatic hyperplasia (BPH). By facilitating more complete emptying of the bladder, Flomax decreases the need to urinate during the middle of the night. However, Flomax and other similar systemic drugs called alpha-blockers can potentially cause difficulty during cataract surgery, particularly if the eye surgeon has not been forewarned. For this reason, ASCRS, the Academy and AUA advise patients who are taking or have taken alpha-blocker prostate drugs such as Flomax, to inform their ophthalmologist before surgery. Other drugs in this alpha-blocker class include, terazosin (Hytrin®), doxazosin (Cardura®), and alfuzosin (Uroxatral®). The alpha-blocker drugs are all regarded as being safe and effective for the treatment of urinary symptoms due to prostate enlargement without harming the eyes.

The effect of Flomax® on cataract surgery:

In 2005, David F. Chang, MD, and John R. Campbell, MD, completed both a retrospective and a prospective study of 1,600 patients and identified a new problem that occurs during cataract surgery in patients using Flomax. 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 in order to perform the surgery. A large pupil is obtained by using dilating drops that stimulate the iris dilator muscle. Chang and Campbell found that Flomax appears to block this iris muscle, leading to troublesome behavior of the iris during eye surgery. The iris tends to be floppy and the pupil may suddenly constrict during the middle of surgery. If the iris problems are not anticipated or prevented, there is an increased risk of having surgical complications. Interestingly, they still found IFIS in some patients who had been off the medication for two years. “Flomax does not affect vision or eye health,” Dr. Chang said. “But it impairs the dilator muscle in the iris, and during cataract surgery the pupil needs to stay dilated.”

Following the publication of Chang and Campbell’s findings, and after receiving corroborative reports from other ophthalmologists, the U.S. Food and Drug Administration (FDA) instituted a new label warning for Flomax and other alpha-blocker drugs that reads: “The patient’s ophthalmologist should be prepared for possible modifications to their surgical technique.” In 2005, frequent discussion among ophthalmic surgeons of problems posed by patients on Flomax resulted in the formation of an ASCRS task force, chaired by Dr. Chang, which developed recommendations for surgical techniques to be used during cataract surgery on patients taking Flomax or other alpha-blockers. The Academy will be including this information in its evidenced-based Preferred Practice Pattern® guide (PPPs) for cataract care. These PPP guides are followed by ophthalmologists worldwide.

Multi-center study of cataract surgery in Flomax patients

To assess the effectiveness of these techniques, a large multi-center trial was undertaken at 10 centers around the country. More than 160 cataract surgeries were performed on patients taking Flomax using these modified techniques. Dr. Chang reported the preliminary results at the recent ASCRS Annual Symposium in San Francisco. The study demonstrated that if the surgeon knew about the Flomax use in advance, and if the modified surgical techniques were used, the surgical success rate was excellent and the complication rate was not increased in comparison to surgery on non-Flomax patients. Final results of the study will be presented at the Academy’s Annual Meeting in November.

Several important conclusions can be drawn from this study, according to Dr. Chang. “Although the drug can make cataract surgery more difficult, if the surgeon knows in advance that the patient is or has taken Flomax or another alpha-blocker drug, then appropriate techniques can be used that provide excellent results,” he said. **“Flomax is an excellent prostate medication, and there is no need for patients to avoid it or stop taking it out of concern over eye problems. However, the key is for patients to inform their ophthalmologist when they are taking this or any other prostate drugs prior to eye surgery.** This is not something that you would ordinarily think to tell your eye doctor.”

Background

Cataracts and prostate enlargement are both very common age-related conditions. In men, enlargement of the prostate typically begins around age 55. The condition prevents

complete emptying of the bladder, which in turn increases the frequency of urination. Urologists treat prostate enlargement through the use of drugs and, if needed, surgery. Alpha-blockers, such as Flomax, relax muscles in the enlarged prostate in order to improve urinary outflow. This decreases the need to urinate as frequently and allows men to sleep uninterrupted for longer periods.

Cataracts are a progressive clouding of the lens of the eye and are the most common age-related cause of worsening vision. Ophthalmologists treat cataracts by surgically removing the cloudy natural lens and replacing it with a clear artificial lens implant.

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The American Society of Cataract and Refractive Surgery is an international educational and scientific organization whose 9,100 member ophthalmologists specialize in cataract and refractive surgery. The American Society of Ophthalmic Administrators, with over 2,000 members, represents ophthalmic practice professionals who specialize in reimbursement, marketing, and business management. For more information, visit our website, www.ascrs.org.

The American Academy of Ophthalmology is the voice of ophthalmologists and their patients in Washington, D.C., and is the world's largest organization of eye physicians and surgeons with more than 29,000 members. www.aao.org.