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## FDA adds warning to tamsulosin labeling

### New information meant to alert patients and physicians about risks with cataract surgery

Publish date: Jan 1, 2006  
 By: Cheryl Guttman

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**Chicago**—This past October, the FDA issued a labeling change for the drug tamsulosin HCl (Flomax, Boehringer Ingelheim) warning of the possibility of intraoperative floppy iris syndrome (IFIS), stating "The patient's ophthalmologist should be prepared for possible modifications to their surgical technique."

That labeling change comes as the result of the astute observations and studies conducted by John R. Campbell, MD, and David F. Chang, MD, who postulated there was a connection between IFIS and tamsulosin and then confirmed that association in retrospective and prospective clinical trials.

Dr. Chang did not indicate any financial interest in any of the products mentioned. Phone: 650/948-9123 E-mail: dceye@earthlink.net

Tamsulosin, an alpha-1 blocker, is the most commonly prescribed medication for treating benign prostatic hyperplasia (BPH). By relaxing the smooth muscle in the bladder neck and prostate, the patient's urinary outflow symptoms are improved. Boehringer Ingelheim, the manufacturer, also sent a "dear doctor" letter to every ophthalmologist, urologist, and primary-care physician notifying them about IFIS.

#### Patients at risk

"Awareness of this new syndrome and identification of patients at risk is important because it allows surgeons to undertake appropriate small-pupil management strategies," explained Dr. Chang. "IFIS has been associated with a high rate of posterior capsule rupture when the surgeon did not anticipate it. Now, by eliciting a history of alpha-blocker use, cataract surgeons can predict in advance when this problem may occur," said Dr. Chang, clinical professor at the University of California, San Francisco. Dr. Chang spoke about IFIS in the Spotlight on Cataract Surgery 2005 session held during the annual meeting of the American Academy of Ophthalmology in Chicago.

The condition is characterized by the clinical triad of billowing and floppiness of the iris in response to normal irrigation currents in the anterior chamber, repeated iris prolapse to the incisions, and progressive miosis. In many cases, the pupil dilates poorly preoperatively.

Dr. Chang credited Dr. Campbell with first suspecting tamsulosin as a cause for IFIS. To investigate that link further, Dr. Campbell undertook a retrospective study reviewing cataract surgery cases that he and his partner had performed during the previous year. In reviewing the operative reports for 706 eyes (511 patients), a floppy iris was identified as occurring in 16 eyes (2.3%) of 10 (2.0%) patients, all of whom were taking tamsulosin. Another six patients were found to have been taking tamsulosin without any mention of floppy iris in the operative report. Other systemic alpha-1 blockers, including terazosin HCl (Hytrin, Abbott), doxazosin mesylate (Cardura, Pfizer), and prazosin HCl (Minipres, Pfizer), were being used by 11 patients, but none of them were recorded as having a floppy iris.

#### Characterizing the syndrome

In his attempt to characterize the features, incidence, and causes of IFIS, Dr. Chang undertook a prospective study of 900 consecutive eyes of 741 cataract patients whom he operated on while being masked to each individual's medication history. In that series, IFIS also occurred in

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about 2% of cases whether considering the number of eyes (21/900; 2.3%) or patients (16/741; 2.2%). Of the 16 affected patients, 15 were found to have a history of current or prior tamsulosin use. Among the 725 patients who did not manifest IFIS, none had a history of tamsulosin treatment.

Importantly, a relatively high risk for posterior capsule (PC) rupture was also identified. In Dr. Campbell's study, the PC rupture rate was 12.5% among the 16 cases of IFIS. No posterior capsular ruptures occurred in Dr. Chang's series, but he noted that two of the patients with IFIS had a history of PC rupture in the fellow eye operated on previously at another center. Drs. Chang and Campbell's companion studies were published in the April 2005 issue of the *Journal of Cataract and Refractive Surgery* [Chang DF, Campbell JR. Intraoperative floppy iris syndrome associated with tamsulosin (Flomax). *J Cataract Refract Surg* 2005;31:664-673].

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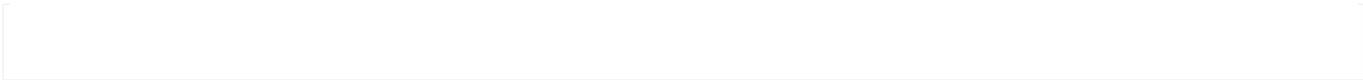
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