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Prostate drug associated with iris prolapse, miosis

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San Francisco—A drug commonly prescribed for older men suffering from prostate enlargement seems to cause a "floppy iris" that increases the risk of complications during cataract surgery.

What John R. Campbell, MD, identified less than a year ago as a "sporadic" problem led to a pair of parallel studies and an advisory by the American Society of Cata- ract and Refractive Surgery (ASCRS) warning ophthalmic surgeons of a new small pupil syndrome associated with tamsulosin hydrochloride (Flomax, Boehringer Ingelheim), the most frequently prescribed drug for benign prostatic hyperplasia (BPH). More than 9 million American men over age 50 are estimated to have BPH.

Dr. Campbell, an ophthalmologist in private practice in San Rafael, CA, and David F. Chang, MD, clinical professor, University of California, San Francisco, and in private practice in Los Altos, CA, have termed the condition "intraoperative floppy iris syndrome" (IFIS).

"We completed both a retrospective and a masked prospective study with more than 1,600 total patients," Dr. Chang said. "The incidence of IFIS in these combined studies was 2.3%—more than expected."

The drug, which was approved by the FDA on April 15, 1997, is a systemic alpha-1 antagonist medication that relaxes the smooth muscle in the bladder neck and prostate to allow more complete bladder emptying. Tamsulosin hydrochloride is highly specific for the alpha-1A receptor subtype that is in the prostate. Other alpha-1 blockers—terazosin (Hytrin, Abbott Laboratories) and doxazosin mesylate (Cardura, Pfizer)—are not as selective, and are more likely to cause the side effect of postural hypotension.

However, upon reviewing the pharmacologic literature, the doctors discovered that of the three known alpha-1 receptor subtypes (A, B, and D), the same alpha-1A receptor subtype also mediates contraction of the iris dilator smooth muscle. They believe that the drug relaxes this muscle, and that the loss of normal dilator muscle tone causes the iris stroma to billow and prolapse during cataract surgery.

Determining the cause Dr. Campbell was baffled by this "very vexing" cluster of cases and suspected a problem with his center's dilation procedures. Starting with the several recollected cases they had encountered, he and his staff reviewed office and surgery center records.

"We were tearing our hair out because at first it all seemed completely random," he said.

Then, a nurse was reviewing charts and discovered that all of the patients were taking tamsulosin hydrochloride, and they all were men.

"All of a sudden, the light bulb went on," Dr. Campbell said. "I was relieved when I called Dr. Chang, and he was interested enough to start an independent prospective study."

"Of my own patients with floppy irides that I could recall, some were taking tamsulosin hydrochloride, and some were not," Dr. Chang said. "I felt it was very important to do both a large retrospective study, and a masked prospective study to understand better the incidence and features of floppy iris cases, and what the possible causes were.

"Everyone has encountered these cases, but there were no descriptions in the literature," he said. "There could have been multiple factors involved, and a masked study was the only way to



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remove any bias with respect to tamsulosin hydrochloride."

Dr. Chang explained that the prospective study revealed three features common to all the IFIS cases: a billowing of the iris with normal irrigation currents; repeated prolapse to the phaco and side-port incisions; and progressive miosis that was not prevented by sphincterotomies or mechanical stretching of the pupil. While small pupils were common, some pupils dilated well preoperatively, only to constrict considerably during surgery.

Drs. Chang and Campbell advise surgeons with patients taking tamsulosin hydrochloride to have them stop taking the drug for 1 to 2 weeks prior to surgery. This does not seem to affect patients' BPH adversely, but does diminish the intensity of the iris problem, Dr. Campbell noted.

Dr. Chang feels that iris hooks or a pupil expansion ring are the best way to prevent iris prolapse and to keep the pupil dilated.

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