



# One-day postoperative intraocular pressure spikes after phacoemulsification cataract surgery in patients taking tamsulosin

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**PURPOSE:** To evaluate the relationship between 1-day postoperative intraocular pressure (IOP) after phacoemulsification cataract surgery and tamsulosin use.

**SETTING:** University of Colorado Health Eye Center, Aurora, Colorado, USA.

**DESIGN:** Retrospective cohort study.

**METHODS:** Registry data from men who had cataract surgery were used. Patients taking tamsulosin at the time of surgery were included as cases, while patients with no history of tamsulosin use were used as controls. The primary outcome was a 1-day postoperative IOP spike defined as an IOP increase greater than 10 mm Hg compared with baseline or a 1-day postoperative IOP of 30 mm Hg or higher. General estimating equations were used for analysis.

**RESULTS:** The study comprised 584 men (864 eyes). An IOP increase greater than 10 mm Hg or IOP 30 mm Hg or higher after cataract surgery occurred in 12.4% and 9.3%, respectively, of eyes in the tamsulosin group versus 4.4% and 2.1%, respectively, in the control group (all  $P = .001$ ). After adjusting for significant covariates, patients on tamsulosin were 2.6 times (95% confidence interval [CI], 1.2–5.7;  $P = .01$ ) and 3.8 (95% CI, 1.3–10.9;  $P = .01$ ) more likely to have a 1-day postoperative IOP increase greater than 10 mm Hg or a 1-day postoperative IOP of 30 mm Hg or higher.

**CONCLUSION:** Patients on tamsulosin had an increased risk of a 1-day postoperative IOP spike after cataract surgery, showing the importance of identifying patients on tamsulosin preoperatively to better manage and potentially mitigate IOP spikes.

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Tamsulosin has been available in the United States for the treatment of benign prostatic hypertrophy since 1996. Tamsulosin is an alpha-1 adrenergic ( $\alpha_{1A}$ ) receptor antagonist that improves lower urinary tract flow by relaxing the smooth muscle in the prostate and bladder neck.<sup>1</sup>

Within a few years of the introduction of the drug, systemic effects on similar receptors located in the smooth dilator muscle of the iris were noticed in patients having phacoemulsification cataract surgery. This was comprehensively described by Chang and Campbell in 2005<sup>2</sup> as intraoperative floppy-iris

syndrome (IFIS) and further explored by others.<sup>3–11</sup> Several investigators<sup>2,12–15</sup> also described other intraoperative and postoperative complications of cataract surgery in patients taking tamsulosin at the time of surgery; these include posterior capsule rupture, vitreous loss, rebound uveitis, cystoid macular edema, retinal detachment, lost lens or lens fragments, and endophthalmitis. Moreover, it was estimated that patients with a history of tamsulosin use were 2.3 times more likely to have an adverse event after cataract surgery than patients without a history of tamsulosin use.<sup>13</sup>

The long-term effects of transient intraocular pressure (IOP) spikes on healthy eyes is unclear; however, risks include intraocular pain, ischemic optic neuropathy, corneal edema, and in patients with glaucoma, progressive visual field loss.<sup>16–34</sup> Chang and Campbell<sup>2</sup> and Chang et al.<sup>12</sup> described an elevated 1-day postoperative IOP in patients using tamsulosin; however, a formal study of this adverse outcome has yet to be performed.

The purpose of this study was to evaluate the relationship between 1-day postoperative IOP spikes and tamsulosin in a cohort of men who were using tamsulosin at the time of cataract surgery. We hypothesized that patients taking tamsulosin preoperatively would have an increased risk of 1-day postoperative IOP spikes.

## PATIENTS AND METHODS

This retrospective cohort study was approved by the Colorado Multiple Institutional Review Board. The University of Colorado Health Eye Center's Cataract Outcomes Registry was used to identify patients for inclusion in this study. In brief, every patient who has cataract surgery has a comprehensive review of his or her medical record. The registry includes data on demographic information, medical history, preoperative medication history, intraoperative and postoperative complications, and preoperative and postoperative eye examinations. The data are collected for up to 8 months postoperatively. This review is performed by a group of data abstractors trained specifically in the abstraction of information related to cataract surgery. Fifteen percent of the records receive a secondary review by 2 of the authors (J.R.S., L.K.S.) to ensure there is no misclassification of the exposures or outcomes. The data are also presented to the Cataract Outcomes Oversight Committee on a quarterly basis.

## Inclusion and Exclusion Criteria

The study included patients who had phacoemulsification cataract surgery with intraocular lens (IOL) implantation in 2014 and the first half of 2015. For this study, the records of the following were excluded: women, patients who had cataract surgery combined with another surgical procedure, patients with a traumatic cataract, patients who did not have

IOP measured 1 day postoperatively, and patients younger than 18 years. Some eyes were excluded based on multiple criteria. Information from patients who had both unilateral and bilateral cataract surgery was included, and the proper statistical methods to account for the intereye correlation were used.

## Outcome Measures

The primary outcome of the study was the 1-day postoperative IOP measured using Goldmann applanation tonometry (Haag-Streit Diagnostics). This was collected as a continuous variable. An IOP spike was categorized as (1) a 1-day postoperative IOP increase of more than 10 mm Hg compared with the patient's most recent IOP measurement before surgery and (2) a 1-day postoperative IOP 30 mm Hg or higher. The primary exposure was use of tamsulosin preoperatively. Other risk factors included in the analysis were a history of glaucoma, diabetes, age, and smoking status. Information on the use of a pupil expansion device, typically a Malyugin ring, (Microsurgical Technology) or iris hooks during surgery, was also specifically included.

## Statistical Analysis

Chi-square tests and independent *t* tests were used for patient-level categorical variables and continuous variables, respectively, to determine whether there were differences associated with tamsulosin use at the time of surgery. Odds ratios were used to estimate relative risks because the outcome is rare. Variables found to be statistically significant ( $P < .05$ ) in the univariate analysis were included in the full model examining the relationship of tamsulosin and other variables with an elevated 1-day postoperative IOP. Logistic regression and generalized estimating equations (GENMOD<sup>®</sup>) were used with an independent working correlation structure to account for the presence of a correlation between eyes in patients who had bilateral cataract surgery. A sensitivity analysis compared the full model including the covariate's age, the use of a pupil expansion device, and smoking status against the parsimonious model. Statistical analyses were performed using SAS software (version 9.4, SAS Institute, Inc.).

## RESULTS

In 2014 and the first half of 2015, 1692 patients (2595 eyes) had phacoemulsification cataract surgery with IOL implantation. Excluded were 1485 women, 377 patients who had cataract surgery combined with another surgical procedure, 18 patients with a traumatic cataract, 131 patients who did not have IOP measured 1 day postoperatively, and 10 patients younger than 18 years. The final analytic dataset contained information on 584 men and 864 eyes.

Table 1A and Table 1B show the overall characteristics of the cohort. Patients on tamsulosin at the time of surgery were significantly older and more likely to be former or current smokers than patients not on tamsulosin (Table 2A). A Malyugin ring was more frequently used in eyes of patients who were on tamsulosin before surgery (Table 2B). Iris hooks were used in

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