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Effect of tamsulosin on iris vasculature and morphology

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Abstract

PURPOSE—To determine whether preoperative iris vasculature and morphology are altered in patients who have taken tamsulosin (Flomax).

SETTING—Academic multispecialty practice.

DESIGN—Case series.

METHODS—Patients with current or past tamsulosin use and age- and sex-matched control patients were included. Anterior segment optical coherence tomography (AS-OCT) and iris fluorescein angiography were performed to measure iris vasculature and thickness before cataract surgery. Data collected at surgery included pupil diameter, clinical signs of intraoperative floppy-iris syndrome, and surgical complications.

RESULTS—Tamsulosin was currently used by 16 patients and in the past by 4 patients; the control group comprised 10 patients. Pharmacologically dilated pupil diameter was significantly smaller preoperatively and immediately postoperatively in the tamsulosin group than in the control group ($P = .009$ and $P = .003$, respectively). There was a statistically significant decrease in pupil size intraoperatively in the tamsulosin group ($P = .05$) but not in the control group ($P = .3$). Iris-vasculature parameters, specifically time to first vessel fill and percentage of vessel fill on iris fluorescein angiography, were not significantly different between the 2 groups. The AS-OCT measurements of iris morphology were not statistically significantly different between the groups. No surgical complications occurred. No fluorescein dye leakage, staining, or other vascular anomalies were observed.

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There were no significant differences in iris vasculature by iris fluorescein angiography or in iris morphology by AS-OCT between patients who have used tamsulosin and those who have never used it.

CONCLUSIONS—Although there were differences in pupil measurements and intraoperative iris behavior between patients who had been on tamsulosin and control patients, there were no significant differences in iris vasculature on iris fluorescein angiography or in iris morphology on AS-OCT.

Intraoperative floppy-iris syndrome (IFIS) associated with the use of tamsulosin (Flomax), first described by Chang and Campbell in 2005,¹ is defined by iris billowing, prolapse, and progressive pupil constriction during cataract surgery. Since then, numerous reports have confirmed IFIS and its association with tamsulosin. There is a wide spectrum of clinical expression of this syndrome, with some patients showing signs in 1 eye only or having asymmetric involvement between fellow eyes.^{2,3} There are even reports of patients developing IFIS years after discontinuing tamsulosin.^{1,4}

The pathophysiology of IFIS is not well understood. Tamsulosin is an α_1 -adrenergic antagonist that is used to treat urinary retention from benign prostatic hypertrophy. It is believed that blocking α_1 -receptors on the smooth muscle of the prostate results in muscle relaxation and relief of bladder outflow obstruction. Alpha₁-adrenergic receptors are also found on the iris dilator muscle,^{5,6} and previous research has focused on the impact of tamsulosin use at this site. Recent studies^{7,8} suggest that iris dilator muscle thickness is reduced in individuals with a history of tamsulosin use. It has been hypothesized that blocking the α_1 -adrenergic receptors on the iris dilator muscle leads to disuse atrophy, impairing mydriasis and altering iris behavior during intraocular surgery.

A previously unaddressed potential mechanism for IFIS is the effect of α_1 -adrenergic antagonists on the iris blood vessels. A recent report describes the presence of the 1A subtype of α_1 -adrenergic receptors on the iris arterioles,⁹ and these receptors are known to play a role in vessel constriction.¹⁰ We hypothesize that chronic receptor blockade could lead to iris vascular dysregulation, subsequent secondary atrophy of the iris dilator muscle and, ultimately, the erratic iris behavior seen in IFIS. The current prospective case-control study was designed to determine whether there were measurable preoperative differences in the iris vasculature and iris morphology in eyes with tamsulosin use compared with those in matched controls. Iris fluorescein angiography was used to assess alterations in iris vasculature that could be secondary to vascular dysregulation, and anterior segment optical coherence tomography (AS-OCT) was used to assess for morphologic differences in iris structure.

PATIENTS AND METHODS

Institutional Review Board approval was obtained from the University of Michigan. All research in this study was compliant with the U.S. Health Insurance Portability and Accountability Act, and all research protocols adhered to the tenets of the Declaration of Helsinki. All study volunteers went through a complete informed consent process. This study was registered with the National Institutes of Health Clinical Trials.^A Patients were recruited from the pool of those scheduled to have cataract surgery at the W.K. Kellogg Eye Center, Ann Arbor, Michigan, USA.

Inclusion criterion for patients was current or past use of tamsulosin; control patients had never used tamsulosin. No patient in the study was previously or currently using any other α_1 -adrenergic antagonist medication. Exclusion criteria for all patients included a history of diabetes mellitus, systemic hypertension, glaucoma, pseudoexfoliation syndrome, previous ocular surgery, chronic use of medicated eyedrops, and other conditions deemed to have a possible effect on vasculature. The study was further limited to those with light-colored irides to allow optimum visualization of the iris vessels with iris fluorescein angiography.¹¹

A power calculation based on iris dilator muscle thicknesses measured by AS-OCT in a previous study⁸ indicated a sample size of 27 patients was needed for 80% power in a 2:1 study design.

Preoperative iris fluorescein angiography and AS-OCT were performed on all enrolled patients. Iris fluorescein angiography was performed with intravenous injection of sodium fluorescein dye (2 mL of 25% solution) and video image capture of the iris vasculature as the dye circulated. Images were captured using the Spectralis system (Heidelberg Engineering). The AS-OCT was performed using the Visante OCT system (Carl Zeiss Meditec AG) under standardized photopic lighting conditions.

Patients then had cataract surgery by 1 of 9 surgeons. The type of anesthesia and surgical technique were at the discretion of the operating surgeon. Surgeons were not masked to the status of patient use of tamsulosin. All patients received standardized preoperative dilation eyedrops of tropicamide 1.0%, phenylephrine 2.5%, and flurbiprofen. Use of adjunctive surgical measures (eg, intracameral epinephrine, pupil-expansion devices) was recorded. Pupil diameter was measured preoperatively in the surgery suite (before a surgical incision was created), and postoperatively (at the end of surgery but before use of miotic agents). The 3 clinical signs of IFIS (ie, iris billowing, iris prolapse, progressive pupil constriction) and surgical complications were recorded using a standardized form. Patients with any of these 3 clinical signs were designated as having IFIS. Patients with 2 or more of these signs were designated as having more severe IFIS.

Iris fluorescein angiography was used to assess the time to first dye appearance and the percentage of maximum iris vasculature filling. The time to first dye appearance was defined as the time stamp on the first fluorescein image in which dye could clearly be seen in the iris vasculature. Two independent observers subjectively identified the image of maximum fill as the fluorescein image in which the iris vasculature appeared most intense. From this image, the percentage of vessel fill per total iris area was calculated with Metamorph Microscopy automation and image-analysis software (Molecular Devices, LLC) using the procedure shown in Figure 1.

The AS-OCT images were analyzed using the software incorporated into the OCT system. The pupil diameter, anterior chamber depth (ACD), and iris thickness were measured from the horizontal AS-OCT image using the embedded caliper tool. The pupil diameter was measured as the distance between the edges of the pupil border. Anterior chamber depth was measured as the distance between the central posterior corneal surface and the anterior lens

surface. The iris sphincter muscle region was defined as 0.75 mm from the pupil border and the iris dilator muscle region as halfway between the pupil border and scleral spur previously described by Prata et al.⁸ The nasal and temporal iris thicknesses in each eye were averaged for analysis.

Study data were collected and managed using Research Electronic Data Capture electronic data capture tools (Redcap) hosted at the University of Michigan Medical School.¹² This secure web-based application was designed to support data capture for research studies and providing (1) an intuitive interface for validated data entry, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for importing data from external sources. Statistical analysis was performed using Excel 2010 software (Microsoft Corp.) and paired and unpaired *t* tests. A *P* value less than 0.05 was considered significant.

RESULTS

Thirty patients were recruited to exceed the calculated minimum sample size. Table 1 shows their demographic and surgical data. The study group comprised 16 patients (16 eyes) currently taking tamsulosin and 4 patients (4 eyes) who had used it in the past (range of use 6 weeks to 15 years). The control group comprised 10 patients (10 eyes). All patients were men, and mean age was similar in the 2 groups ($P = .28$). In the study group, some eyes had evidence of IFIS (iris billowing, iris prolapse, progressive pupil constriction) during surgery, with some having 2 or more signs (Table 1). All patients with the more severe IFIS (2 or more clinical manifestations of IFIS) were current users of tamsulosin. One patient (10%) in the control group had mild pupil constriction over the course of the surgery.

Most surgeries were performed under topical anesthesia, with 1 patient in each group having retrobulbar anesthesia. Nine study patients (45%) received topical phenylephrine 10% eyedrops or intracameral epinephrine; 2 control patients (20%) required additional pupil dilation treatments ($P = .18$). More than one third of patients in the study group required the use of an iris expansion device; none in the control group required this device ($P = .03$) (Table 1).

The mean pharmacologically dilated pupil diameter was significantly smaller in the study group than in the control group before (6.8 mm versus 7.7 mm) and immediately after (6.1 mm versus 7.5 mm) surgery ($P = .009$ and $P = .003$, respectively) (Figure 2). There was also a statistically significant decrease in pupil size over the course of surgery in the study group patients with tamsulosin use ($P = .05$), but not in the control group ($P = .34$). In the study group, preoperative pupil diameter did not correlate with duration of tamsulosin use or clinical manifestations of IFIS. No surgical complications occurred in any patient in this study.

Table 2 shows the iris fluorescein angiography results. The time to first vessel fill was not statistically significantly different between the control group and patients with any tamsulosin use, current tamsulosin use, or more severe IFIS ($P = .30$, $P = .38$, and $P = .22$, respectively). The percentage of iris vascular filling was also not statistically significantly

different between these groups ($P = .98$, $P = .94$, and $P = .76$, respectively). No fluorescein dye leakage, staining, or other iris vascular anomalies were observed in any patient.

The AS-OCT measurements of undilated pupil diameter under standardized lighting conditions were not statistically significantly different between control patients and patients with any tamsulosin use, current tamsulosin use, or more severe IFIS ($P = .35$, $P = .11$, and $P = .13$, respectively) (Table 3). The undilated pupil size on AS-OCT did not significantly correlate with the pharmacologically dilated pupil size measured clinically at the time of surgery. The iris thickness in the dilator muscle region and sphincter muscle region as well as the dilator muscle region to sphincter muscle region ratio were not statistically significantly different between the groups (all comparisons $P > .05$). There were also no statistically significant differences in ACD measurements between groups.

DISCUSSION

Since the initial report of IFIS in 2005,¹ there has been a great deal of interest in better understanding this condition to improve the safety of cataract surgery in patients taking tamsulosin. The pathophysiology of IFIS is poorly understood, and current research is predominantly focused on the direct effect of α_1 -adrenergic antagonists on the iris dilator muscle. This study used quantifiable preoperative diagnostic imaging techniques, iris fluorescein angiography, and AS-OCT to evaluate the iris vasculature and morphology to determine whether there were differences between those who have taken tamsulosin and those who have not.

Although we hypothesized that tamsulosin use may lead to dysregulation of the iris vessels, we were unable to detect differences in iris vasculature on iris fluorescein angiography between individuals who used tamsulosin and those who had not. We measured the percentage of iris vasculature fill as a surrogate for vascular dysregulation based on the hypothesis that chronic blockade of α_1 -adrenergic receptors on the iris vessels could lead to constriction and vessel “drop out.” Even a comparison of patients with more clinically evident IFIS showed no differences in iris fluorescein angiography findings. Iris vasculature is known to have interpersonal variability that makes it difficult to compare between groups.¹³ We used Metamorph, a sophisticated image analysis software, with a standardized protocol in an effort to reduce measurement bias. Even so, we did not detect significant differences in the iris fluorescein angiography images in our study group.

Although the results in this study did not support our hypothesis, the effect of tamsulosin on iris vasculature deserves further study because the specific mechanism of action of tamsulosin and other α_1 -adrenergic antagonist medications on the prostate in their primary use for treatment of benign prostatic hyperplasia is not fully understood. Although originally believed to work primarily by relaxation of the smooth muscle of the prostate, there is growing literature to indicate there are other contributing mechanisms, including possible direct effects on blood vessels of the prostate or urinary bladder.¹⁴ Similarly, the specific mechanism of action of tamsulosin on the iris is not fully understood; a laboratory study in pigmented rabbits found that tamsulosin and alfuzosin were less potent at blocking smooth-muscle contraction in the iris than in the prostate.¹⁵

The effect of tamsulosin on iris vasculature deserves further study. Ideally, it would be interesting to perform histopathologic analysis to compare iris blood vessels in patients who have been exposed to tamsulosin with those who have not, similar to histopathologic analyses in the literature that showed decreased iris dilator muscle thickness¹⁶ and cellular atrophy and pigment granule accumulation in the dilator muscle of patients with IFIS who had used a different α_1 -adrenergic antagonist medication.¹⁷

In this study, we also used AS-OCT to assess iris morphology, including iris thickness and pupil diameter. Although other studies using AS-OCT describe changes in iris thickness associated with tamsulosin use in patients with glaucoma,⁸ similar to Tufan et al.,¹⁸ we did not detect differences in iris thickness in this study. In contrast to the differences in pupil size seen by Tufan et al. on AS-OCT,¹⁸ in our study photopic pupil measurements by AS-OCT were not significantly different between patients who had taken tamsulosin and those who had not.

In contrast to the findings in a by Cooney et al.,¹⁹ our clinical measurements of pharmacologically dilated pupil size before surgery found significantly smaller pupils in patients who had used tamsulosin than in control patients. It is likely that our study used stronger pharmacologic pupil dilators because patients were being prepared for surgery rather than being dilated in the clinic. However, even in our study, preoperative pupil size was not directly associated with clinical manifestations of IFIS and thus provided no information that was predictive of intraoperative iris behavior.

Our hope was that preoperative assessment with iris fluorescein angiography and AS-OCT would allow us to preoperatively detect differences between patients who would or would not develop IFIS during cataract surgery. Not only would this improve our ability to identify individuals at high risk for developing IFIS, it could also improve our understanding of the iris changes caused by tamsulosin use. However, no such differences were detected in this study.

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Biography

Roni M. Shtein

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WHAT WAS KNOWN

- Patients who have taken tamsulosin are more likely to develop intraoperative IFIS.

WHAT THIS PAPER ADDS

- Preoperative pupil size was smaller and the change in pupil size over the course of cataract surgery was more marked in patients who have used tamsulosin.
- Preoperative imaging by iris fluorescein angiography and AS-OCT was not able to identify patients at higher risk for IFIS.

Figure 1.

Steps of the iris fluorescein angiography image analysis. *A*: Maximum iris vasculature dye fill is identified. *B*: The area from peripheral iris border to minor arterial circle is isolated. *C*: Statistical correction is performed to highlight iris vasculature and minimize background noise. *D*: The percentage of iris vasculature per total iris area is calculated.

Figure 2.
Pharmacologically dilated pupil diameter measurements.

Table 1

Demographic and cataract surgery data.

Parameter	Tamsulosin Group (n = 20)	Control Group (n = 10)	P Value
Mean age (y) $\pm$ SD	72.0 $\pm$ 7.8	68.0 $\pm$ 9.9	.28
Currently taking tamsulosin, n (%)	16 (80)	0	
Past use of tamsulosin, n (%)	4 (20)	0	
1 or more signs of IFIS, n (%)	15 (75)	1 (10)	.0008
2 or more signs of IFIS, n (%)	8 (40)	0	.02
Topical anesthesia only, n (%)	19 (95)	9 (90)	.60
Additional dilation medications used, n (%)	9 (45)	2 (20)	.18
Iris-expansion device used, n (%)	7 (35)	0	.03

IFIS = intraoperative floppy-iris syndrome

Table 2

Iris fluorescein angiography results.

Parameter	Mean $\pm$ SD			
	Controls (n = 10)	Any Tamsulosin Use (n = 20)	Current Tamsulosin Use (n = 16)	Two or More Signs of IFIS (n = 8)
Time to first vessel fill (s)	26.8 $\pm$ 5.4	32.3 $\pm$ 14.0	33.0 $\pm$ 15.8	31.1 $\pm$ 7.6
Iris vascular filling (%)	17.4 $\pm$ 5.7	17.3 $\pm$ 3.7	17.2 $\pm$ 3.7	18.0 $\pm$ 4.0

IFIS = intraoperative floppy-iris syndrome

P > .05 for all comparisons with controls

Table 3

Anterior segment OCT results.

Parameter	Controls (n = 10)	Any Tamsulosin Use (n = 20)	Current Tamsulosin Use (n = 16)	Two or More Signs of IFIS (n = 8)
Undilated pupil diameter (mm)	2.7 ± 0.8	2.5 ± 0.6	2.3 ± 0.4	2.3 ± 0.3
Anterior chamber depth (mm)	2.9 ± 0.7	2.8 ± 0.4	2.7 ± 0.4	2.8 ± 0.5
Iris thickness in DMR (mm)	0.53 ± 0.05	0.50 ± 0.06	0.50 ± 0.04	0.48 ± 0.05
Iris thickness in SMR (mm)	0.66 ± 0.07	0.59 ± 0.14	0.59 ± 0.15	0.62 ± 0.07
DMR/SMR ratio	0.80 ± 0.10	0.81 ± 0.10	0.80 ± 0.10	0.77 ± 0.11

DMR = iris dilator muscle region; IFIS = intraoperative floppy-iris syndrome; SMR = iris sphincter muscle region

P > .05 for all comparisons to controls