Resident-Performed Phacoemulsification Surgery in Tamsulosin-Treated Patients

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Objectives: To compare intraoperative complication rates and visual outcomes for patients treated and not treated with tamsulosin hydrochloride who underwent resident-performed phacoemulsification, and to determine whether the recognition of intraoperative floppy iris syndrome (IFIS) in 2005 affected the subsequent complication rates for tamsulosin-treated patients.

Methods: This comparative retrospective cohort study included 101 tamsulosin-treated eyes and 404 non–tamsulosin-treated eyes from January 1, 1998, to August 31, 2008. Main outcome measures were major and minor complication rates and postoperative best-corrected visual acuity. Complication rates were compared between August 11, 1999, to December 31, 2005, and January 1, 2006, to September 3, 2008, for both tamsulosin-treated and non–tamsulosin-treated eyes.

Results: The major complication rates were 3.0% for tamsulosin-treated eyes and 8.9% for non–tamsulosin-treated eyes (P = .08), while the minor complication rates were 24.8% and 12.1%, respectively (P = .002). Both groups had an equal likelihood of attaining better than 20/40 postoperative visual acuities (82.2% vs 82.9%, respectively; P = .85). Frequency of major complications between tamsulosin-treated and non–tamsulosin-treated eyes was 6.0% vs 15.8%, respectively (P = .09), from August 11, 1999, to December 31, 2005, compared with 0.0% vs 2.0%, respectively (P > .99), from January 1, 2006, to September 3, 2008.

Conclusions: Differences in the major complication rates for tamsulosin-treated and non–tamsulosin-treated eyes were not significant, whereas tamsulosin exposure was associated with a significant increase in minor complications. Both groups had similar, good postoperative visual outcomes. After 2005, a reduction in major complications was seen in both groups, attributed to programmatic changes in surgical education. Recognition of intraoperative floppy iris syndrome did not impart a significant additional protective effect in preventing major complications.

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STUDY POPULATION

Medical records from patients who underwent resident-performed phacoemulsification cataract surgery at the San Francisco Veterans Affairs Medical Center between January 1, 1998, and August 31, 2008, were retrospectively reviewed. Resident surgeons perform nearly all cataract extraction procedures at the San Francisco Veterans Affairs Medical Center. The starting date was chosen because tamsulosin achieved US Food and Drug Administration approval on April 15, 1997. The study had institutional review board approval and complied with the Health Insurance Portability and Accountability Act and the tenets of the Declaration of Helsinki (1996).

CASE SELECTION

Tamsulosin-treated cases were identified through pharmacy records and by Current Procedural Terminology codes for phacoemulsification. Inclusion criteria were the following: (1) patients undergoing resident-performed phacoemulsification, (2) any current or past tamsulosin use within 3 years of surgery, and (3) adequate documentation in the medical record consisting of a preoperative history, ophthalmic examination results, and intraoperative note. A 3-year cutoff was used because IFIS was reported in a patient who had discontinued tamsulosin more than 3 years before surgery. Exclusion criteria for tamsulosin cases were the following: (1) planned extracapsular cataract extractions, (2) combined surgical cases (eg, phacoemulsification and trabeculectomy), and (3) tamsulosin use more than 3 years before surgery. Potentially challenging surgical cases (eg, pseudoexfoliation syndrome) were not excluded.

Patients without history of tamsulosin use were randomly selected from a list of patients identified by Current Procedural Terminology codes for phacoemulsification. We identified 4 non–tamsulosin-treated cases that took place within 15 days of each tamsulosin case. Inclusion and exclusion criteria were the same for both groups with the exception that non–tamsulosin-treated cases could have no suspected or confirmed history of tamsulosin use. The tamsulosin-treated and comparison groups did not exclude patients using α-blockers other than tamsulosin preoperatively.

IFIS MANAGEMENT

Starting in May 2007, 2 years after IFIS had been described in the literature, residents at the San Francisco Veterans Affairs Medical Center began using pharmacologic agents (preoperative topical atropine sulfate and/or intraoperative intracameral epinephrine) in tamsulosin-treated cases to attempt to reduce IFIS incidence.

DATA COLLECTION AND CLASSIFICATION

The following patient data were collected from the medical record: age, sex, laterality, preoperative and postoperative best-corrected visual acuity (BCVA), potential of challenging features (eg, mature cataract, zonular weakness), surgery date, resident’s month of training, complication type, and reoperation date and type. Preoperative and intraoperative management strategies were also recorded (eg, iris hooks, topical atropine, 1%, and/or intracameral epinephrine, 1:2500 bolus). History of any α1-AR antagonist use was determined from ophthalmology, anesthesia, pharmacy, urology, and primary care records. In cases of inadequate follow-up data, we searched electronic records from remote Veterans Affairs sites and archived medical records.

Major complications were defined as any of the following conditions occurring within 90 days postoperatively: capsular tear with vitreous loss, corneal wound burn, Descemet membrane detachment requiring reoperation, suprachoroidal or new vitreous hemorrhage, endophthalmitis, or reoperation. Minor complications were defined as iris abnormalities (transillumination defects, stromal atrophy, or irregular pupil) documented within 90 days postoperatively, intraoperative iris prolapse, iridodialysis, failure of continuous curvilinear capsulorhexis, capsular tear or zonular dialysis without vitreous loss, or any intraocular lens problem not requiring reoperation.

Preoperative BCVA was determined from the most recent preoperative manifest refraction. We defined postoperative BCVA as the BCVA documented within 90 days postoperatively. No cases were excluded owing to comorbid ocular pathologic findings that limited visual acuity.

STATISTICAL ANALYSIS

Data were tabulated in an Excel spreadsheet (Microsoft Corp, Redmond, Washington) and analyzed using the R software package version 2.8.1 for Macintosh (The R Foundation for Statistical Computing, http://www.r-project.org).

Percentages, means, and 95% confidence intervals (CIs) were calculated to describe baseline characteristics of the tamsulosin-treated and non–tamsulosin-treated groups. The groups were compared using a 2-sample t test for continuous variables and a Fisher exact test for categorical variables.

Rates and 95% CIs of major and minor complications were calculated for the tamsulosin-treated and non–tamsulosin-treated groups. Univariate analyses compared complication rates between the 2 groups and compared complication rates with and without iris hook use. All univariate analyses were performed using clustered logistic regressions, which took into account both matching of 4 non–tamsulosin-treated cases around each tamsulosin-treated case according to time and the contribution of 2 eyes from some patients in the study. A multivariate logistic regression analysis was performed controlling for significant differences in baseline characteristics (age, sex, and mature cataracts) between the tamsulosin-treated and non–tamsulosin-treated groups and for factors that could influence surgical outcomes (potential zonular pathologic findings and preoperative BCVA). Multivariate logistic regressions controlled for time and tamsulosin use to determine whether awareness of IFIS after 2005 resulted in decreased complication rates.

Univariate clustered logistic regressions were performed on the subset of tamsulosin-treated cases (n = 101) to determine whether iris hooks or pharmacologic agents (atropine and/or epinephrine) affected the major complication risk. Multivariate logistic regressions controlled for age, preoperative BCVA, mature cataracts, and potential zonular pathologic findings.

We explored the effect of other (nontamsulosin) α1-AR antagonists on complication rates. On the subset of non–tamsulosin-treated eyes (n = 404), we used univariate clustered logistic regressions to compare complication rates between (1) eyes with and without exposure to other α1-AR antagonists, and (2) eyes exposed to tamsulosin only and those exposed to neither tamsulosin nor other α1-AR antagonists. These analyses were repeated using a multivariate logistic regression controlling for age, sex, preoperative BCVA, potential zonular pathologic findings, and mature cataracts.

Visual acuities were converted from Snellen to logMAR notation for statistical analyses. We assigned the following logMAR
visual acuity values: finger counting = 1.7, hand motions = 1.8, light perception = 1.9, and no light perception = 2.0.26 LogMAR values were converted back to Snellen notation for reporting in the article. The percentages of tamsulosin-treated eyes and non–tamsulosin-treated eyes in both treated groups (3.0% vs 8.9%, respectively) in univariate analyses. The multivariate analysis produced similar results in which there was no disproportionate reduction in major complications for tamsulosin-treated eyes compared with non–tamsulosin-treated eyes (P > .99) between 2005 and earlier vs after 2005.

RESULTS

BASELINE CHARACTERISTICS

The study included 101 eyes of 77 tamsulosin-treated patients and 404 eyes of 384 non–tamsulosin-treated patients. The baseline characteristics of patients are summarized in Table 1.

Within the study period from January 1, 1998, to August 31, 2008, there was a trend toward an increasing percentage of phacoemulsification performed in patients with current or past tamsulosin use, ranging from no tamsulosin-treated cases in 1998 to 9.0% of all cases in 2007 (Figure). Most operations were performed by third-year residents under direct attending supervision.

INTRAOPERATIVE COMPLICATIONS

The major complication rate did not differ significantly between the tamsulosin-treated and non–tamsulosin-treated groups (3.0% vs 8.9%, respectively) in univariate (P = .08) or multivariate (P = .08) analyses. Minor complications were significantly more common in tamsulosin-treated eyes than in non–tamsulosin-treated eyes in both univariate (P = .002) and multivariate (P = .001) analyses. Minor complications did not predict major complications (P = .49). Table 2 lists the major and minor complication subtypes seen in both groups. Minor complications in tamsulosin-treated eyes consisted mostly of iris prolapse and iris abnormalities.

IFIS AWARENESS AFTER 2005

There was a significant decrease in major complications after 2005 in both tamsulosin-treated and non–tamsulosin-treated eyes (P < .001). However, there was no significant difference in major complication rates between tamsulosin-treated and non–tamsulosin-treated eyes from August 1, 1999, to December 31, 2005 (6.0% vs 15.8%, respectively; P = .09), or from January 1, 2006, to September 3, 2008 (0.0% vs 2.0%, respectively; P > .99), in univariate analyses. The multivariate analysis produced similar results in which there was no disproportionate reduction in major complications for tamsulosin-treated eyes compared with non–tamsulosin-treated eyes (P > .99) between 2005 and earlier vs after 2005.

MANAGEMENT STRATEGIES

Iris Hooks

Iris hooks were used in 12 of 101 tamsulosin-treated eyes (11.9%) and 19 of 404 non–tamsulosin-treated eyes (4.7%) due to inadequate intraoperative mydriasis (P = .01). Hooks

Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Tamsulosin-Treated Group</th>
<th>Non–Tamsulosin-Treated Group</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes, No.</td>
<td>101</td>
<td>404</td>
<td></td>
</tr>
<tr>
<td>Patients, No.</td>
<td>77</td>
<td>384</td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>78.0 (76.6-79.4)</td>
<td>71.5 (70.5-72.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Male, No. (%)</td>
<td>101 (100.0)</td>
<td>385 (95.3)</td>
<td>.02</td>
</tr>
<tr>
<td>Right eye, No. (%)</td>
<td>52 (51.5)</td>
<td>210 (52.0)</td>
<td>.99</td>
</tr>
<tr>
<td>Preoperative BCVA, mean (95% CI)</td>
<td>20/58</td>
<td>20/65</td>
<td>.15</td>
</tr>
<tr>
<td>Resident experience, mean (95% CI), mo</td>
<td>27.8 (26.5-29.0)</td>
<td>28.5 (27.9-29.1)</td>
<td>.17</td>
</tr>
<tr>
<td>Mature cataract, No. (%)</td>
<td>8 (7.9)</td>
<td>6 (1.5)</td>
<td>.002</td>
</tr>
<tr>
<td>Potential zonular pathologic finding, No. (%)</td>
<td>5 (5.0)</td>
<td>21 (5.2)</td>
<td>&gt;.99</td>
</tr>
</tbody>
</table>

Abbreviations: BCVA, best-corrected visual acuity; CI, confidence interval.

Table 2. Subtypes of Intraoperative Complication in Eyes of Tamsulosin-Treated and Non–Tamsulosin-Treated Patients

<table>
<thead>
<tr>
<th>Complication</th>
<th>Tamsulosin-Treated Group (n=101)</th>
<th>Non–Tamsulosin-Treated Group (n=404)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major a</td>
<td>3 (3.0)</td>
<td>36 (8.9)</td>
</tr>
<tr>
<td>Vitreous loss</td>
<td>1 (1.0)</td>
<td>33 (8.2)</td>
</tr>
<tr>
<td>Reoperation within 90 d</td>
<td>1 (1.0)</td>
<td>7 (1.7)</td>
</tr>
<tr>
<td>Descemet membrane detachment</td>
<td>1 (1.0)</td>
<td>0</td>
</tr>
<tr>
<td>Suprachoroidal hemorrhage</td>
<td>0</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Minor a</td>
<td>25 (24.8)</td>
<td>49 (12.1)</td>
</tr>
<tr>
<td>Iris abnormalities</td>
<td>19 (18.9)</td>
<td>35 (8.7)</td>
</tr>
<tr>
<td>Iris prolapse</td>
<td>11 (10.9)</td>
<td>13 (3.2)</td>
</tr>
<tr>
<td>Capsular tear</td>
<td>2 (2.0)</td>
<td>9 (2.2)</td>
</tr>
<tr>
<td>Failure of curvilinear capsulorrhexis</td>
<td>2 (2.0)</td>
<td>6 (1.5)</td>
</tr>
<tr>
<td>Iridodialysis</td>
<td>0</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Intraocular lens problem</td>
<td>1 (1.0)</td>
<td>4 (1.0)</td>
</tr>
<tr>
<td>Zonular dialysis</td>
<td>0</td>
<td>1 (0.2)</td>
</tr>
</tbody>
</table>

a The sum of the complication subtypes exceeds the total major or minor complication events because some cases involved more than 1 complication.

Figure. Percentage of all phacoemulsification operations from January 1, 1998, to August 31, 2008, occurring in eyes of patients with a history of tamsulosin use.
Atropine and Epinephrine

Twenty-one of 101 tamsulosin-treated eyes (20.8%) received preoperative atropine eyedrops and/or intraoperative intracameral epinephrine. Of the treated eyes, 3 received only preoperative atropine, 2 received only intracameral epinephrine, and 16 received combined therapy. There were no major complications in the treatment group and 3 (3.8%) in the no-treatment group (P > .99). Minor complications occurred in 5 cases (23.8%) in the treatment group vs 20 cases (25.0%) in the no-treatment group (P = .91). Multivariate analyses yielded similar results.

Exposure to Other α1-AR Antagonists

In the subset of 404 non–tamsulosin-treated eyes, 116 eyes (28.7%) were in patients who had a preoperative history of other α1-AR antagonist use, while 288 eyes (71.3%) were in patients who had no preoperative history of other α1-AR antagonist use. In comparing preoperative α1-AR antagonist exposure with no α1-AR antagonist exposure, the rates of major (10.3% vs 8.3%, respectively; P = .55) and minor (12.9% vs 11.8%, respectively; P = .75) complications were similar.

To examine the effect of tamsulosin exposure alone on complication rates, we excluded from the analysis 52 eyes of tamsulosin-treated patients and 116 eyes of non–tamsulosin-treated patients who had any preoperative history of other α1-AR antagonist use. The major complication rates in tamsulosin-treated eyes (n = 49) and non–α1-AR antagonist–treated eyes (n = 288) were similar (2.0% vs 8.3%, respectively; P = .18), whereas the minor complication rate for tamsulosin-treated eyes was significantly higher than for non–α1-AR antagonist–treated eyes (28.6% vs 11.8%, respectively; P = .002). Multivariate analyses produced similar results.

VISUAL ACUITY

Postoperative BCVA data were available for 99 of 101 tamsulosin-treated eyes (98.0%) and for 396 of 404 non–tamsulosin-treated eyes (98.0%). The mean postoperative BCVA was 20/28 (95% CI, 20/26-20/31) in the tamsulosin-treated group and 20/27 (95% CI, 20/26-20/28) in the non–tamsulosin-treated group (P = .32). The percentages of eyes achieving better than 20/40 postoperative BCVA were 82.2% and 82.9% in the tamsulosin-treated and non–tamsulosin-treated groups, respectively (P = .85).

Owing to the additional challenges an inexperienced surgeon may face when encountering IFIS, we sought to determine whether residents performing phacoemulsification on eyes of tamsulosin-treated patients might experience high complication rates and unsatisfactory postoperative visual outcomes. Although we expected a high major complication rate for residents operating on tamsulosin-treated patients, the major complication rate in our study was only 3.0%, which was within the ranges reported for resident surgery in the general population25,27-31 and for surgery performed by expert surgeons on tamsulosin-treated patients.1,3,5,7,9,14,23 Non–tamsulosin-treated patients actually showed a trend toward a higher major complication rate compared with tamsulosin-treated patients (8.9% vs 3.0%, respectively; P = .08), even after controlling for multiple potential confounders. Owing to the very low rate of major complications in the study overall, we believe this finding most likely occurred due to chance alone. However, it is possible that residents aware of early intraoperative signs of IFIS (even before the syndrome was described in 2005) may have proceeded with more caution, thus avoiding major complications.

We investigated postoperative visual outcomes in eyes of tamsulosin-treated and non–tamsulosin-treated patients. To avoid bias, our study included eyes with preexisting or unrelated ocular comorbidities in both groups. The percentage of eyes achieving better than 20/40 postoperative BCVA was similar for both groups. Other studies on resident-performed phacoemulsification in the general population have reported 77% to 98% of patients achieving postoperative BCVA of 20/40 or better, which is similar to our results.27,28,31-33

We expected the major complication rate for tamsulosin-treated eyes to be lower after 2005 compared with 2005 and earlier due to increasing awareness of IFIS. We found that major complications after 2005 were dramatically reduced for both tamsulosin-treated and non–tamsulosin-treated eyes alike; there was no additional protective effect after 2005 for tamsulosin-treated eyes. This observation was likely due to programmatic changes that coincidentally took place in the same year, benefiting all patients in reducing the overall complication risk. These programmatic changes have previously been described and included changes in case assignment, increased phacoemulsification training, improved preoperative identification of patients receiving tamsulosin, and education regarding IFIS management.25 Although our study was not powered to show that IFIS awareness further reduced complication risk, it is good practice for residents to preoperatively identify tamsulosin-treated patients, giving consideration to the use of iris expansion devices, atropine and epinephrine, and/or cohesive viscoelastics.11,12,31-36

Minor complications occurred at a significantly higher rate in tamsulosin-treated eyes than in non–tamsulosin-treated eyes and were driven by the predominance of iris prolapse and iris abnormalities. This finding was expected owing to our inclusion of iris prolapse and iris defects in the definition of minor complication. These were surrogate measures of IFIS, which could not have been evaluated directly in our study because of its retrospective nature; half of the tamsulosin-treated cases in this study occurred prior to the initial description of IFIS in 2005.3

Iris hook use is one strategy to achieve additional intraoperative mydriasis. We found a higher rate of iris hook use among tamsulosin-treated eyes than among non–tamsulosin-treated eyes, suggesting that active management strategies were used for preoperative or intraop-
operative pupillary miosis, likely without awareness of IFIS in some patients. We did not find a protective effect of iris hooks on the major complication rate in the tamsulosin-treated subset of patients owing to the low complication rate and small sample of tamsulosin-treated eyes in which iris hooks were used (n = 12). Although Blouin et al found a slight trend toward fewer complications in patients with IFIS who had iris hook use vs no iris hook use, their study was also underpowered to detect a significant risk reduction with iris hooks based on widely overlapping CIs.

Studies evaluating the efficacy of preoperative topical atropine, intraoperative administration of intracameral epinephrine, or a combination of both have reported mixed results in preventing IFIS. Pharmacologic management of IFIS was not used in our residency program until May 2007; hence, only 20.8% of tamsulosin-treated eyes in our study received atropine and/or epinephrine. While we found no major complications in the atropine- or epinephrine-treated group, the sample size and low number of major complications overall limited our ability to detect any statistical effect of a particular management strategy.

Because history of \(\alpha_1\)-AR antagonist use has been shown to significantly increase IFIS risk, we explored whether other \(\alpha_1\)-AR antagonist use may increase the risk of intraoperative complications. In the subset of non–tamsulosin-treated eyes, there was no significant effect of other \(\alpha_1\)-AR antagonist use on complication rates. While our findings are consistent with the results of the study by Bell et al., Miyamoto et al reported increased complication risk in patients receiving other \(\alpha_1\)-AR antagonists. Exclusion of patients receiving other \(\alpha_1\)-AR antagonists would have resulted in the disproportionate exclusion of patients with benign prostatic hyperplasia from our study population of mostly older male veterans. To remove the effect other \(\alpha_1\)-AR antagonists may have on our analyses, we compared tamsulosin-treated and non–tamsulosin-treated eyes after statistically excluding eyes with any preoperative history of other \(\alpha_1\)-AR antagonist use. Exclusion of these cases did not alter the conclusions regarding the effects of tamsulosin on complication rates, suggesting that our analyses were minimally affected by the inclusion of patients who received other \(\alpha_1\)-AR antagonists. Other studies have found the incidence of IFIS to be higher among patients receiving tamsulosin compared with nontamsulosin \(\alpha_1\)-AR antagonists. This observation is supported by our data because minor complications in tamsulosin-treated eyes (24.8%) occurred more frequently than in eyes exposed to other \(\alpha_1\)-AR antagonists (12.9%) or in eyes with no prior \(\alpha_1\)-AR antagonist exposure (11.8%).

There were several limitations to our study. First, our interest in complication rates prior to 2005 necessitated a retrospective study design, making it more difficult to control for potential confounders. Second, we included cases undergoing phacoemulsification performed by multiple residents at various stages of the learning curve in order to obtain a sufficient number of cases for analysis. However, we attempted to control for the potential confounding effects of time and resident experience by matching non–tamsulosin-treated cases to tamsulosin-treated cases based on timing of surgery. While most residents who operated on the tamsulosin-treated cases also operated on the 4 matched non–tamsulosin-treated cases, some operations on non–tamsulosin-treated cases were performed by a different resident who had rotated onto the service during the 15-day window. Resident experience was similar in tamsulosin-treated and non–tamsulosin-treated cases (Table 1). The small number of major complications also reduced our power to detect a difference in complication rates between tamsulosin-exposure groups. Our results, however, suggest that programmatic changes at our institution had a dominant effect over any tamsulosin effect on reducing complications.

In summary, we found a low major complication rate (3.0%) for resident-performed phacoemulsification in tamsulosin-treated patients, which was similar to the rate for non–tamsulosin-treated patients and comparable to rates reported in the literature for expert surgeons. Postoperative visual outcomes between eyes of tamsulosin-treated and non–tamsulosin-treated patients were similar. Residency programmatic changes in 2005 reduced major complication risk in all patients undergoing phacoemulsification at our institution regardless of tamsulosin exposure. We believe that with proper instruction and supervision, resident surgeons can operate on tamsulosin-treated patients, achieving low rates of major complications and good postoperative visual outcomes.

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REFERENCES


