

## Intraoperative floppy iris syndrome in Indian population: A prospective study on incidence, risk factors, and impact on operative performance

Shilpa Goyal, Deepansh Dalela<sup>1</sup>, Neeraj Kumar Goyal<sup>1</sup>, Shobhit Chawla<sup>2</sup>, Rajat Dhesi<sup>2</sup>, Bela Kamboj<sup>2</sup>, Abha Dalela<sup>2</sup>

**Purpose:** The purpose of this study was to evaluate the incidence, risk factors, and impact of intraoperative floppy iris syndrome (IFIS) on surgical performance. **Materials and Methods:** Consecutive cataract surgeries from October 2010 to Feb 2011 (1003 eyes, 980 patients; 568 males, 412 females) were analyzed prospectively. Operating surgeon, masked about medication history, noted the intraoperative details. Cases were identified as IFIS or non-IFIS. Multivariate analysis was performed to find risk factors for IFIS. **Results:** Prevalence of tamsulosin use among men undergoing cataract surgery was 7.0% (41) with incidence of IFIS 4.78% (48). On multivariate analysis, hypertension (OR: 3.2, 95% confidence interval, 95% CI: 1.39-6.57;  $P = 0.005$ ), use of tamsulosin (OR: 133.32, 95% CI: 50.43-352.48;  $P < 0.0001$ ), or alfuzosin (OR: 9.36, 95% CI: 2.34-37.50;  $P = 0.002$ ) were the factors associated with IFIS. Among men taking tamsulosin ( $n = 41$ ) and alfuzosin ( $n = 28$ ), 68.3% and 16.6% developed IFIS, respectively. In subgroup analysis of men on tamsulosin, no factor added to the risk posed by tamsulosin. Seventeen of 944 eyes not exposed to any drug had IFIS (0.018%). On subgroup analysis, only risk factor for IFIS was hypertension (OR: 4.67, 95% CI: 1.63-13.35;  $P = 0.002$ ). Of 48 IFIS eyes, the surgeon observed increased difficulty in 57.1% (21) and additional measures were required in 9 eyes. Mean operative time was increased in IFIS eyes ( $11.68 \pm 3.46$  vs.  $10.01 \pm 0.22$  min;  $P = 0.001$ ). Surgical outcome was good in all cases. **Conclusion:** The prevalence of tamsulosin intake and IFIS incidence is higher in India. Current tamsulosin/alfuzosin use and hypertension are important risk factors. IFIS makes the surgery more difficult, significantly prolongs the operative time, and predisposes for other intraoperative complications. However, with appropriate management, final operative outcome is not affected.

**Key words:** Cataract, floppy iris syndrome, phacoemulsification, tamsulosin

Phacoemulsification is the modern state-of-art surgery used for restoration of vision in cataract patients. Pupillary dilatation and normal behavior of the iris is important for a successful cataract surgery. In 2005, Chang and Campbell described a novel entity called intraoperative floppy iris syndrome (IFIS) characterized by triad of flaccid iris stroma that undulates and billows in response to intraocular fluid currents, a propensity for the floppy iris stroma to prolapse toward the phacoemulsification and side-port incisions despite proper wound construction, and progressive intraoperative pupil constriction despite standard preventive preoperative pharmacologic measures.<sup>[1]</sup> All these condition are known to increase the difficulty level for the surgeon and the rate of complications.<sup>[1-5]</sup>

Various risk factors for IFIS have been described in the literature. Tamsulosin, a selective  $\alpha_1$ -adrenergic receptor antagonist, is a commonly prescribed drug for benign hyperplasia of prostate (BPH) and has been shown to have the strongest association with IFIS.<sup>[1-10]</sup> Patients on alfuzosin, another  $\alpha$ -blocker, showed a lesser risk for development of IFIS compared to tamsulosin.<sup>[9]</sup> Other drugs that predispose for IFIS include doxazosin, terazosin, finasteride, labetalol,

mianserin, chlorpromazine, donepezil, and other antipsychotic agents.<sup>[11-18]</sup> Systemic factors that have been implicated for IFIS predisposition include diabetes and hypertension.<sup>[19]</sup> In a recent meta-analysis, diabetes was not found to be a significant risk factor, whereas hypertension has been shown to be a risk factor for IFIS; however, the exact etiopathogenesis could not be explained in the presence of confounding factors such as medical history and treatment.<sup>[20,21]</sup> As pupillary behavior is proposed to be affected by the amount of pigment present in the iris, Friedman suggested that the color of iris may affect the behavior of iris during its dilatation.<sup>[8]</sup> Due to paucity of data regarding IFIS from South-east Asia, this study was planned on Indian population. The aim of the current study was to find the prevalence of  $\alpha$ -blocker use, incidence of IFIS, and identify the factors associated with IFIS in patients undergoing phacoemulsification cataract surgery in Indian population. In the current study, we also evaluated the effect of IFIS on operative performance.

### Materials and Methods

All the patients undergoing phacoemulsification cataract surgery at a single center, from October 2010 to March 2011 were included in this prospective study. The participants signed an informed consent explaining the study that was conducted in accordance with the Declaration of Helsinki principles. Pre-operative data noted for every patient included age, sex, detailed ophthalmological workup (grading of cataract, color of iris, intraocular pressure, fundus examination, and any other associated ocular disease), medical co-morbidities (diabetes, hypertension, and coronary heart disease), and use of any medications with its dose and duration (at least one month

#### Access this article online

##### Website:

www.ijo.in

##### DOI:

10.4103/0301-4738.141051

#### Quick Response Code:



Departments of Ophthalmology and <sup>1</sup>Urology, King George Medical University, Lucknow, <sup>2</sup>Eye-Q Super Specialty Eye Hospitals, Prakash Netra Kendra, Lucknow, Uttar Pradesh, India

**Correspondence to:** Dr. Neeraj Kumar Goyal, Room No. 204, Resident Hostel, King George's Medical University, Lucknow, Uttar Pradesh - 226 003, India. E-mail: neerajgoyal@yahoo.co.in

Manuscript received: 15.11.13; Revision accepted: 21.05.14

of intake was considered significant). A trained staff noted all the above-mentioned pre-operative data while the operating surgeon noted the operative details. Four senior surgeons with an experience of more than 5000 phaco-surgeries participated in the study and were masked regarding the use of any drugs by the patient in the preoperative period.

The standard preoperative regime used was topical flubiprofen (0.03% w/v) or nepafenac (0.1% w/v), two hours before surgery followed by pupillary dilatation using topical tropicamide (0.8%w/v) and phenylephrine (5%w/v). Oertli OS-3 (Switzerland) phaco machine was used for nucleus emulsification by the standard stop and chop technique.

At the end of the procedure, the surgeon recorded information regarding the intraoperative behavior of iris, such as meiosis, billowing, and prolapse. Measures taken to manage these issues such as use of iris hooks, Healon-5 (sodium hyaluronate 2.3%), and intracameral drugs were also noted. Any further intraoperative complication because of IFIS, any difficulty experienced by the surgeon to complete the surgery and prolongation of operative time were also recorded. For analytical purposes, each eye was given an IFIS score of 1, 2, or 3 depending upon the number of features of the syndrome as described by Cheung *et al.*<sup>[22]</sup>

#### Statistical analysis

The database was collected on a Microsoft Excel (Microsoft Corporation, Redmond, WA) spreadsheet and evaluated using SPSS software 15.0 version (SPSS, Inc., Chicago, IL). The results were presented in percentages and mean ( $\pm$ SD). The categorical/dichotomous variables were compared using Chi-square/Fisher exact test and continuous variables were compared using unpaired *t*-test. The odds ratio (OR) with its 95% confidence interval (CI) was calculated to find out the risk factors for IFIS. The univariate and multivariate analyses were carried out using binary logistic regression analysis. The multivariate analysis was performed using factors from the univariate analysis that achieved significance at the 0.05 level. A  $P < 0.05$  was considered significant.

## Results

A total of 1003 eyes of 980 patients with 568 males and 412 females were operated during the study period at the given center. The study group had 354 hypertensives (361 eyes), 265 diabetics (269 eyes), 41 patients on tamsulosin (0.4 mg), 18 on alfuzosin (10 mg), three on prazosin, and one each on dutasteride and finasteride. The demographic profile of the patients, medical co-morbidities, and other risk factors are summarized in Table 1.

#### Incidence of intraoperative floppy iris syndrome (IFIS)

IFIS was encountered in 48 cases (4.78%) in the study group (38 males, 10 were females; mean age  $61.06 \pm 11.50$  years). Distribution of affected eyes according IFIS score was 23 (score - 1), 22 (score - 2), and 3 (score - 3). Prevalence of tamsulosin use in men undergoing cataract surgery was 7.0% ( $n = 41$ ). Out of them, only 28 developed IFIS while three patients on alfuzosin ( $n = 18$ ), suffered from IFIS. The remaining 17 cases of IFIS were not on  $\alpha$ -blocker drug therapy. None of the patients on prazosin, dutasteride, or finasteride was noted to develop IFIS.

Table 1 summarizes the potential risk factors in both the eyes with IFIS and without IFIS. IFIS was significantly more frequent in men than in women ( $P = 0.003$ ), while age and color of the iris were not the significant predictors for syndrome ( $P > 0.05$ ). Hypertension was the only medical condition found to be significant predictor of IFIS ( $P < 0.0001$ ) while diabetes, coronary heart diseases, and cerebrovascular diseases were not significantly associated with IFIS ( $P > 0.05$ ). The use of  $\alpha$ -blocker drugs tamsulosin and alfuzosin were significantly associated with IFIS. Table 2 illustrates univariate and multivariate logistic regression analysis for the risk factors associated with IFIS. With 48 IFIS events, the multivariable model was limited to four risk factors found to be significantly associated with IFIS on univariate model at the 0.05 significance level. Multivariate analysis showed hypertension ( $P = 0.005$ ),

**Table 1: Patient demographics and risk factors**

Characteristics	Patients with IFIS ( $n=48$ )		Patients without IFIS ( $n=955$ )		P value
	Number	Percentage	Number	Percentage	
Age in years, mean $\pm$ SD	61.06 $\pm$ 11.5		60.85 $\pm$ 11.75		0.90
Gender					0.003*
Male	38	79.2	545	57.1	
Female	10	20.8	410	42.9	
Color of IRIS					0.08
Black	1	2.1	4	0.4	
Brown	7	14.6	275	28.8	
Dark brown	15	31.3	262	27.4	
Light brown	25	52.1	414	43.4	
Hypertension	31	64.6	330	34.6	<0.0001*
Coronary heart disease	6	12.5	60	6.3	0.09
Cerebrovascular accidents	1	2.1	3	0.3	0.06
Diabetes	18	37.5	251	26.3	0.09
Tamsulosin use	28	58.3	13	1.4	<0.0001*
Alfuzosin use	3	6.3	15	1.6	0.03*

\*Significant. IFIS: Intraoperative floppy iris syndrome

tamsulosin use ( $P < 0.0001$ ), and alfuzosin use ( $P = 0.002$ ) to be significantly associated with IFIS, while male gender was not a significant risk factor. The calculated unadjusted and adjusted odds ratio (OR) for tamsulosin and alfuzosin use and hypertension is shown in Table 2.

In the tamsulosin group [Table 3], 28 patients out of 41 were noted to develop IFIS while the remaining 13 had normal intraoperative course. The incidence of IFIS in this group was 68.3%. When IFIS eyes were compared with non-IFIS eyes in the tamsulosin group, the patient age, color of iris, and frequency of medical comorbidities including hypertension were comparable between the two groups ( $P > 0.05$ ). The duration of drug intake in cases that developed the syndrome ranged from two months to eight years. The mean duration of drug intake was  $23.11 \pm 23.42$  months for IFIS eyes as compared to  $28.62 \pm 32.88$  months for non-IFIS eyes ( $P = 0.86$ ). Similar to its incidence, the severity of IFIS as calculated by IFIS score was also not affected by the duration of drug intake ( $P > 0.05$ ).

Out of 18 men on alfuzosin therapy, three developed IFIS with incidence of 16.6%. The mean age of the patients taking alfuzosin was  $67.06 \pm 8.18$  years. The mean duration of drug intake was  $35.44 \pm 34.61$  months (range, 1-120 months). There were 17 eyes with IFIS that had not been exposed to  $\alpha$ -adrenergic blockers or other drugs known to cause IFIS [Table 4]. The mean age was  $60.47 \pm 13.01$  (range, 48-86 years) years in this group. On statistical analysis, the only significant risk factors for IFIS in these patients was found to be hypertension ( $P = 0.002$ ). Diabetes was not associated with an increased risk of IFIS ( $P > 0.05$ ).

#### Impact of IFIS on outcome of cataract surgery

In 21 out of the 48 IFIS cases (43.7%), the surgeon observed an increase in the difficulty level to perform the cataract surgery ( $P < 0.0001$ ). However, in nine cases no additional measures were required to overcome this difficulty whereas in 12 cases, additional measures were taken including use of intracameral epinephrine in five cases and Healon-5 in seven cases. However, the surgical outcome was satisfactory in all 21 cases. A statistically significant increase in the operative time was observed in IFIS eyes compared to non-IFIS eyes (mean operative time,  $11.68 \pm 3.46$  vs.  $10.01 \pm 0.22$  min;  $P = 0.001$ ). There was no case of posterior capsule rupture or vitreous loss due to IFIS. In the postoperative period, iris chafing was noted in two cases and iris incarceration of the wound was noted in one case. The overall incidence of operative complications due to IFIS was 6.25%, which was significantly higher in IFIS eyes than in non-IFIS eyes ( $P < 0.0001$ ).

## Discussion

IFIS is a known entity encountered during phacoemulsification cataract surgery, and after its initial report by Chang and Campbell in 2005,<sup>[1]</sup> published literature has confirmed its association with selective  $\alpha$ -1A adrenergic blockers.<sup>[3-5,20,21]</sup> Apart from  $\alpha$ -1 specific antagonists, IFIS is reported with a variety of other drugs including non specific  $\alpha$ - antagonist as well other drugs outside this category.<sup>[11-18]</sup> Specific  $\alpha$ -1A receptors are said to predominate in iris and prostate.<sup>[23-25]</sup> The high affinity and specificity of tamsulosin in these receptors accounts for highest incidence of IFIS in patients using this drug.<sup>[26]</sup>

To the best of our knowledge, this is the first study investigating the incidence and risk factors of IFIS in Indian

population and its effect on outcome of cataract surgery. Because both cataract disease and BPH are prevalent problems in aging men, it is important to analyze the evidence of the putative link between tamsulosin and IFIS. Practicing urologists, ophthalmologists, as well as primary care physicians need to be aware of this possible association.

In a database analysis of more than 96,000 men undergoing a cataract operation from Canada, 3.7% of patients had been treated with tamsulosin before cataract surgery.<sup>[27]</sup> In its first publication of tamsulosin-associated IFIS, Chang has reported a 3% prevalence of tamsulosin use by patients undergoing cataract surgery. However, in a study from United Kingdom, Cheung *et al.* reported the prevalence of tamsulosin use to be just 0.71% among men undergoing cataract surgery.<sup>[22]</sup> In a similar study from UK by Chadha *et al.*, only 1.2% of the study population was on tamsulosin.<sup>[28]</sup> Contrary to all these studies, in the current study, the prevalence of tamsulosin use was found to be much higher at 7.0% among men undergoing

**Table 2: Univariate and multivariate binary logistic regression analysis**

Variables	Unadjusted OR (95% CI), P value	Adjusted OR (95% CI), P value
Age	1.002 (0.98-1.03), 0.90	
Sex		
Male	2.90 (1.43-5.88), 0.003*	1.34 (0.29-1.79), 0.47
Female	Reference	Reference
Color of IRIS		
Black	Reference	
Brown	0.10 (0.01-1.03), 0.05	
Dark brown	0.23 (0.02-2.18), 0.20	
Light	0.24 (0.03-2.24), 0.21	
Hypertension		
Yes	3.45 (1.88-6.33), <0.0001*	3.02 (1.39-6.57), 0.005*
No	Reference	Reference
Coronary heart disease		
Yes	2.13 (0.87-5.21), 0.10	
No	Reference	
Cerebrovascular accidents		
Yes	6.75 (0.69-66.15), 0.10	
No	Reference	
Diabetes		
Yes	1.68 (0.92-3.07), 0.09	
No	Reference	
Tamsulosin		
Yes	101.45 (45.90-224.20), <0.0001*	133.32 (50.43-352.48), <0.0001*
No	Reference	Reference
Alfuzosin		
Yes	4.18 (1.17-14.95), 0.03*	9.36 (2.34-37.50), 0.002*
No	Reference	Reference

\*Significant

cataract surgery. As the actual prevalence of BPH in India is largely unknown, due to lack of large-scale screening database,<sup>[29]</sup> this high prevalence is probably explained by the fact that tamsulosin constitutes the most commonly prescribed  $\alpha$ -blocker for treatment of BPH in India.

The reported incidence of IFIS in literature varies across different countries ranging 0.9-3.7%.<sup>[20,27]</sup> In its initial report from US by Chang and Campbell, the overall incidence was 2.3%.<sup>[1]</sup> Another study by Neff *et al.* from US has shown an incidence of 3.7%.<sup>[20]</sup> Studies from UK have reported a lower overall incidence at 0.9-1.6%.<sup>[22,28,30]</sup> Similarly, Oshika found lower incidence of IFIS in the Japanese at 1.1%.<sup>[31]</sup> The overall incidence in the current study was 4.78%, which is much higher than global incidence. This higher incidence may be related to higher prevalence of tamsulosin use (as shown in current study) by Indian patients undergoing cataract surgery.

In the first ever report by Chang and Campbell,<sup>[1]</sup> the incidence of tamsulosin-associated IFIS was 63% and 94% in

retrospective and prospective series, respectively. In similar studies from Britain, incidence of tamsulosin-associated IFIS was 57.1% and 65%, respectively.<sup>[22,28]</sup> In the current study, the incidence of IFIS among tamsulosin users was 68.3%, which was comparable to the global incidence.

Blouin *et al.* from Canada, retrospectively studied the patients undergoing cataract surgery who were on tamsulosin or alfuzosin and found a much lower incidence of IFIS among alfuzosin users (15.4%) compared to tamsulosin users (86.4%).<sup>[3]</sup> Alfuzosin-associated IFIS incidence was comparable in the current study (16.6%). However, Altan *et al.* from Europe have reported a much higher incidence (60%) of IFIS among alfuzosin users with three of five patients developing IFIS.<sup>[32]</sup> None of the patients using Prazosin, dutasteride, or finasteride was noted to develop IFIS in the current study, although the number of patients on these drugs was too small to draw any conclusion.

The strongest cause of IFIS is the current or past use of tamsulosin and is well-proven in the literature. A recent

**Table 3: Risk factors for IFIS among patients on tamsulosin use**

Characteristics	Patients with IFIS (n=28)		Patients without IFIS (n=13)		OR (95% CI), P value
	No.	%	No.	%	
Age in years, mean±SD	61.86±11.16		59.85±10.50		0.59
Color of IRIS					
Black	0	0.0	0	0.0	
Brown	4	14.3	5	22.0	0.08
Dark brown	8	28.6	12	29.3	
Light	16	57.1	20	48.8	
Hypertension	18	64.3	5	38.5	2.88 (0.74-11.21), 0.12
Coronary heart disease	4	14.3	0	0.0	0.15
Cerebrovascular accidents	1	3.6	0	0.0	0.49
Diabetes	12	42.9	4	30.8	1.69 (0.42-6.81), 0.49
Duration of tamsulosin intake (months)	23.11±23.42		28.62±32.88		0.86

IFIS=Intraoperative floppy iris syndrome, SD: Standard deviation, CI: Confidence interval

**Table 4: Risk factors for IFIS among patients who were not on  $\alpha$ -blockers (tamsulosin or alfuzosin)**

Characteristics	Patients with IFIS (n=17)		Patients without IFIS (n=927)		OR (95% CI), P value
	No.	%	No.	%	
Age in years, mean±SD	60.47±13.01		60.88±11.80		0.88
Sex					
Male	7	41.2	517	55.8	0.55 (0.21-1.47), 0.23
Female	10	58.8	410	44.2	
Color of IRIS					0.10
Black	1	5.9	4	0.4	
Brown	5	29.4	263	28.4	
Dark brown	5	29.4	255	27.5	
Light brown	6	35.3	405	43.7	
Hypertension	12	70.6	315	34.0	4.67 (1.63-13.35), 0.002*
Coronary heart disease	0	0.0	58	6.3	0.28
Cerebrovascular accidents	0	0.0	3	0.3	0.81
Diabetes	5	29.4	241	26.0	1.18 (0.41-3.40), 0.75

IFIS: Intraoperative floppy iris syndrome, SD: Standard deviation, CI: Confidence interval

meta-analysis has described a pooled OR of 393 for current tamsulosin use and IFIS.<sup>[21]</sup> The adjusted OR for current tamsulosin use, on multivariate analysis was 133.3 (95% CI: 50.43-352.48;  $P < 0.0001$ ) compared to patients not using any  $\alpha$ -blocker drugs in the current study, signifying a very strong association between tamsulosin use and IFIS. This was higher compared to the findings of Neff *et al.* from US with adjusted OR being 18.8 for current tamsulosin use.<sup>[20]</sup> As alfuzosin is the second most commonly prescribed  $\alpha$ -blocker in India, it was evaluated as an independent risk factor for IFIS. The adjusted OR for alfuzosin use was 9.36 (95% CI: 2.34-37.50;  $P = 0.002$ ) in the current study. This was comparable to the meta-analysis by Chatziralli *et al.*,<sup>[21]</sup> having OR of 9.7 (95% CI: 2.0-48.7). Other major studies have not evaluated alfuzosin as an independent factor as it is an infrequently used drug. Chatziralli *et al.* found that OR for tamsulosin use was 40-fold higher than current alfuzosin use for developing IFIS. Similarly, Blouin *et al.*, have found OR of 32.2 for tamsulosin use compared to alfuzosin in their head to head comparison.<sup>[3]</sup> In the current study, although no direct comparison was done between tamsulosin and alfuzosin groups, tamsulosin was associated with much higher risk of IFIS. On standard dichotomous analysis, the 95% CI of tamsulosin did not overlap with confidence limit of alfuzosin, indicating the excess risk conferred by tamsulosin.

On univariate analysis, the male gender was found to be risk factors for IFIS but on multivariate analysis, it was not found to be statistically significant. However, Neff *et al.* found male gender to be at a higher risk of developing IFIS with calculated OR of 4.7 on multivariate analysis.<sup>[20]</sup> Hypertension was found to be a significant risk factor on multivariate analysis with adjusted OR being 3.0 (95% CI: 1.39-6.57;  $P = 0.005$ ), similar to the findings of Neff *et al.*, with calculated OR of 3.3. Prevalence of hypertension was higher among IFIS-eyes as compared to non-IFIS eyes (64.6% vs. 34.6%;  $P < 0.0001$ ). This was comparable to the findings of meta-analysis where hypertension was a significant risk factor with OR of 2.2. Diabetes and other chronic diseases like heart disease and cerebrovascular accidents were not found to be significant risk factors for IFIS as highlighted in some of the previous studies.<sup>[20,21]</sup>

In the current study, the incidence of IFIS among tamsulosin users was 68.3% while the remaining 13 eyes were noted to have normal intraoperative course. When these 13 patients were compared with 28 patients having IFIS, no statistical difference was noted between the two groups [Table 3]. No difference was observed between two groups with regard to the mean duration of tamsulosin use ( $P = 0.86$ ). One important finding was that among patients on tamsulosin use, those having a history of hypertension were not at higher risk as compared to normotensive patients, signifying that hypertension was not found to add to the risk posed by tamsulosin use.

There were 17 cases out of total 48 cases of IFIS (35.4%) who had not been exposed to any drug known to cause this syndrome. Therefore, the incidence of IFIS among patients not exposed to any  $\alpha$ -blocker was 1.8%, which was higher than the incidence reported by Chadha *et al.* for eyes not exposed to tamsulosin (17 of 1821 eyes; 0.93%).<sup>[28]</sup> Out of these 17 cases, 10 were females and seven were males. When these 17 eyes with IFIS were compared with 927 non-IFIS eyes [Table 4], the only significant factor in favor of IFIS was hypertension with calculated OR of 4.7 (95% CI: 1.63-13.35;  $P = 0.002$ ). The

prevalence of hypertension in IFIS eyes was 70.6% compared to 34.0% in non-IFIS eyes. No other systemic disease was associated with IFIS with comparable age and gender distribution between the two groups.

IFIS has long been known to be associated with increased operative difficulty and adverse events during phacoemulsification cataract surgery.<sup>[1,4,27]</sup> The reported rates of major complications in the initial studies were 7-12%.<sup>[1,2]</sup> However, with the growing understanding of IFIS and its management techniques, the complication rate has significantly reduced, in the contemporary literature, to as low as 0.6% for posterior capsular rupture (PCR) and vitreous loss in a multicenter study by Chang *et al.*<sup>[33]</sup> and to zero in a prospective study by Neff *et al.*<sup>[20]</sup> Similar results were seen in the current study with no case of PCR or vitreous loss being noted. As proposed by Casuccio *et al.*, preoperative assessment of pupillary dilation can help predicting IFIS.<sup>[34]</sup> Thus, measuring pupillary diameter after dilation as a routine preoperative protocol in all patients may improve surgical outcome. We encountered two cases of iris chafing and one case of iris incarceration in surgical wound; the overall complication rate in IFIS group being 6.25%, which was significantly higher than the non-IFIS group. Similar results have been reported in previous studies in literature.<sup>[3,4]</sup> It is a common opinion of most eye surgeons that IFIS increases the difficult level of the surgery,<sup>[4]</sup> which was also observed in our study. The current study also focused on the effect of IFIS on the average surgical time of phacoemulsification, which has not been studied in any of the published studies. A significant prolongation of the operative time was observed in IFIS eyes compared to non-IFIS eyes (mean operative time  $11.68 \pm 3.46$  vs.  $10.01 \pm 0.22$  min;  $P = 0.001$ ). It represented the statistically significant group mean difference with a range of prolongation being 0-20 min. The cases falling in the higher range, i.e. prolongation of surgical time nearing 20 min can have clinical significance also. The prolonged surgical duration can compromise the surgical outcome along with the other adverse effects of IFIS although no difference in surgical outcome was observed in the current study. The current study suffers with certain limitations in form of short duration, small sample size, inclusion of partial IFIS, and subjective assessment of IFIS and difficulty level by the surgeon. The one-month duration of tamsulosin use in the current study was taken arbitrarily, which might have reduced the IFIS incidence.

Our study highlights the behavior iris of in Indian eyes during phacoemulsification cataract surgery compared to the rest of the world. The prevalence of tamsulosin intake and thus IFIS incidence is much higher in this part of the world. The incidence of IFIS in the  $\alpha$ -blocker using population is comparable with the global scenario, and brown iris behaves in the same manner. The discreditation of IFIS should not be laid on the shoulders of  $\alpha$ -antagonist alone. Hypertension proves to be an important risk factor for IFIS although further studies are needed to investigate whether it is hypertension or some antihypertensive drugs that predispose to IFIS. IFIS increases the difficulty level for the surgeon to perform the surgery, significantly prolongs the operative time, and predisposes for other intraoperative complications. However, with increasing knowledge and appropriate management, final operative outcome is not compromised. Future studies are warranted to identify other potential risk factors and confirm our findings.

## References

- Chang DF, Campbell JR. Intraoperative floppy iris syndrome associated with tamsulosin. *J Cataract Refract Surg* 2005;31:664-73.
- Nguyen DQ, Sebastian RT, Kyle G. Surgeon's experiences of the intraoperative floppy-iris syndrome in the United Kingdom. *Eye (Lond)* 2007;21:443-4.
- Blouin MC, Blouin J, Perreault S, Lapointe A, Dragomir A. Intra-operative floppy iris syndrome associated with alpha1-adrenoreceptors: Comparison of tamsulosin and alfuzosin. *J Cataract Refract Surg* 2007;33:1227-34.
- Chang DF, Braga-Mele R, Mamalis N, Masket S, Miller KM, Nichamin LD, *et al.* ASCRS Cataract Clinical Committee. Clinical experience with intraoperative floppy-iris syndrome. Results of the 2008 ASCRS member survey. *J Cataract Refract Surg* 2008;34:1201-9.
- Lim LA, Frost A. Iris tears secondary to intraoperative floppy-iris syndrome associated with tamsulosin. *J Cataract Refract Surg* 2006;32:1777.
- Chang DF, Braga-Mele R, Mamalis N, Masket S, Miller KM, Nichamin LD, *et al.* ASCRS Cataract Clinical Committee. ASCRS White Paper: Clinical review of intraoperative floppy-iris syndrome. *J Cataract Refract Surg* 2008;34:2153-62.
- Leibovici D, Bar-Kana Y, Zadok D, Lindner A. Association between tamsulosin and intraoperative "floppy-iris" syndrome. *Isr Med Assoc J* 2009;11:45-9.
- Friedman AH. Tamsulosin and the intraoperative floppy iris syndrome. *JAMA* 2009;301:2044-5.
- Allen D, Packard R. Intraoperative floppy-iris syndrome associated with tamsulosin. *J Cataract Refract Surg* 2006;32:1899-900.
- Takmaz T, Can I. Clinical features, complications, and incidence of intraoperative floppy iris syndrome in patients taking tamsulosin. *Eur J Ophthalmol* 2007;17:909-13.
- Dhingra N, Rajkumar KN, Kumar V. Intraoperative floppy iris syndrome with doxazosin. *Eye (Lond)* 2007;21:678-9.
- Venkatesh R, Veena K, Gupta S, Ravindran RD. Intraoperative floppy iris syndrome associated with terazosin. *Indian J Ophthalmol* 2007;55:395-6.
- Issa SA, Dages E. Intraoperative floppy-iris syndrome and finasteride intake. *J Cataract Refract Surg* 2007;33:2142-3.
- Calotti F, Steen D. Labetalol causing intraoperative floppy-iris syndrome. *J Cataract Refract Surg* 2007;33:170-1.
- Ugarte M, Leong T, Rassam S, Kon CH. Intraoperative floppy-iris syndrome, alpha1-adrenergic antagonists, and chronic intake of mianserin: Is there an association? *J Cataract Refract Surg* 2007;33:170.
- Unal M, Yücel I, Tenlik A. Intraoperative floppy-iris syndrome associated with chronic use of chlorpromazine. *Eye (Lond)* 2007;21:1241-2.
- Papadopoulos R, Bachariou A. Intraoperative floppy-iris syndrome associated with chronic intake of donepezil. *J Cataract Refract Surg* 2007;33:1997-8.
- Pringle E, Packard R. Antipsychotic agent as an etiologic agent of IFIS. *J Cataract Refract Surg* 2005;31:2240-1.
- Schwinn DA, Afshari NA. alpha (1)-adrenergic receptor antagonists and the iris: New mechanistic insights into floppy iris syndrome. *Surv Ophthalmol* 2006;51:501-12.
- Neff KD, Sandoval HP, Fernández de Castro LE, Nowacki AS, Vroman DT, Solomon KD. Factors associated with intraoperative floppy iris syndrome. *Ophthalmology* 2009;116:658-63.
- Chatziralli IP, Sergentanis TN. Risk factors for intraoperative floppy iris syndrome: A meta-analysis. *Ophthalmology* 2011;118:730-5.
- Cheung CM, Awan MA, Sandramouli S. Prevalence and clinical findings of tamsulosin-associated intraoperative floppy-iris syndrome. *J Cataract Refract Surg* 2006;32:1336-9.
- Nakamura S, Taniguchi T, Suzufi F, Akagi Y, Muramatsu I. Evaluation of alpha1-adrenoreceptors in the rabbit iris: Pharmacological characterization and expression of mRNA. *Br J Pharmacol* 1999;127:1367-74.
- Suzuki F, Taniguchi T, Nakamura S, Akagi Y, Kubota C, Satoh M, *et al.* Distribution of alpha-1 adrenoreceptor subtypes in RNA and protein in rabbit eyes. *Br J Pharmacol* 2002;135:600-8.
- Ishikawa H, Miller DD, Patel PN. Comparison of post-junctional alpha-adrenoreceptors in iris dilator muscle of humans, and albino and pigmented rabbits. *Naunyn Schmiedebergs Arch Pharmacol* 1996;354:765-72.
- Palea S, Chang DF, Rekek M, Regnier A, Lluell P. Comparative effect of alfuzosin and tamsulosin on the contractile response of isolated rabbit prostatic and iris dilator smooth muscles; possible model for intraoperative floppy-iris syndrome. *J Cataract Refract Surg* 2008;34:489-96.
- Bell CM, Hatch WV, Fischer HD, Cernat G, Paterson JM, Gruneir A, *et al.* Association between tamsulosin and serious ophthalmic adverse events in older men following cataract surgery. *JAMA* 2009;301:1991-6.
- Chadha V, Borooah S, Tey A, Styles C, Singh J. Floppy iris behaviour during cataract surgery: Associations and variations. *Br J Ophthalmol* 2007;91:40-2.
- Bid HK, Konwar R, Singh V. Benign prostatic hyperplasia: Is it a growing public health concern for India? *Indian J Med Sci* 2008;62:373-4.
- Amin K, Fong K, Horgan SE. Incidence of intra-operative floppy iris syndrome in a U.K. district general hospital and implications for future workload. *Surgeon* 2008;6:207-9.
- Oshika T, Ohashi Y, Inamura M, Ohki K, Okamoto S, Koyama T, *et al.* Incidence of intraoperative floppy iris syndrome in patients on either systemic or topical alpha (1)-adrenoceptor antagonist. *Am J Ophthalmol* 2007;143:150-1.
- Altan-Yaycioglu R, Gedik S, Pelit A, Akova YA, Akman A. Clinical factors associated with floppy iris signs: A prospective study from two centers. *Ophthalmic Surg Lasers Imaging* 2009;40:232-8.
- Chang DF, Osher RH, Wang L, Koch DD. Prospective multicenter evaluation of cataract surgery in patients taking tamsulosin (Flomax). *Ophthalmology* 2007;114:957-64.
- Casuccio A, Cillino G, Pavone C, Spitale E, Cillino S. Pharmacologic pupil dilation as a predictive test for the risk for intraoperative floppy-iris syndrome. *J Cataract Refract Surg* 2011;37:1447-54.

**Cite this article as:** Goyal S, Dalela D, Goyal NK, Chawla S, Dhosi R, Kamboj B, *et al.* Intraoperative floppy iris syndrome in Indian population: A prospective study on incidence, risk factors, and impact on operative performance. *Indian J Ophthalmol* 2014;62:870-5.

**Source of Support:** Nil. **Conflict of Interest:** None declared.