

Continuing Medical Education:

Risk factors for intraoperative floppy iris syndrome: a prospective study

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Learning objectives

Upon completion of this activity, participants will be able to:

1. Distinguish the prevalence of intraoperative floppy iris syndrome in patients undergoing phacoemulsification cataract surgery and demographic and comorbidity risk factors, based on a prospective study.
2. Determine the association of α -blocker use with the risk for intraoperative floppy iris syndrome.
3. Identify other medications associated with the risk for intraoperative floppy iris syndrome.

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Risk factors for intraoperative floppy iris syndrome: a prospective study

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Abstract

Purpose To evaluate risk factors for intraoperative floppy iris syndrome (IFIS) in patients undergoing phacoemulsification. **Methods** Participants in the study were 1274 consecutive patients, who underwent routine phacoemulsification cataract surgery. The following data were recorded and evaluated as possible risk factors: ophthalmological conditions, axial length of the eye, socio-demographic features, clinical data (hypertension and diabetes mellitus), medications being taken at the time of surgery, and duration of their intake. Cases were characterized intraoperatively as IFIS and non-IFIS. Univariate and multivariate logistic regression analysis were performed. **Results** IFIS was observed in 63/1274 eyes (4.9%, 95% CI: 3.9–6.7%). Current use of tamsulosin, alfuzosin, terazosin, benzodiazepines, quetiapine, and finasteride, as well as hypertension, were all independently associated with IFIS. Significant associations were noted for male sex, rivastigmine, and short axial length, which did not reach significance at the multivariate analysis. Duration of α -blockers intake was not found to be associated with IFIS. **Conclusion** Apart from the well-established associations with α -blockers, this prospective study points to benzodiazepines, quetiapine, finasteride, and hypertension as potential risk factors for IFIS. Short axial length and rivastigmine were significantly associated with IFIS only at the univariate analysis.

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Introduction

Intraoperative floppy iris syndrome (IFIS) was first described by Chang and Campbell¹ in 2005, being defined by flaccid iris stroma leading to fluttering and billowing of the iris, tendency of

iris prolapse through the surgical incisions and progressive intraoperative pupil constriction. IFIS can be characterized as complete, when all the three features are present or incomplete, when even one feature is missing.^{1–4} It is very important for physicians and especially ophthalmologists to be aware of IFIS, as it may lead to complications, such as posterior capsular rupture, loss of vitreous, iris prolapse, iris stroma atrophy, capsulorhexis tear, and anterior chamber hemorrhage, due to restricted surgical field secondary to miosis.^{3,5}

Previous studies have reported an association between IFIS and intake of α -blockers, which are commonly used for the treatment of benign prostatic hyperplasia. Specifically, IFIS was independently associated with tamsulosin,^{1,6–10} doxazosin,^{2,9,11} terazosin,¹² alfuzosin,^{8,10,13} silodosin,¹⁴ or labetalol, a selective α - and β -blocker.¹⁵ Interestingly, a meta-analysis of the risk factors for IFIS demonstrated a hierarchy in the magnitude of the associations between the various α -blockers and IFIS.¹⁶ The pooled odds ratio (OR) for IFIS after tamsulosin use was nearly 40-fold higher than that of alfuzosin, which was the second α -blocker in order of effect size, in line with Chang *et al*,¹⁷ who also found that severe IFIS was statistically more likely with tamsulosin than with alfuzosin. Terazosin exhibited a comparable pooled OR as alfuzosin in the meta-analysis by Chatziralli and Sergentanis,¹⁶ whereas the effect of doxazosin was rather faint.

Furthermore, several reports have been published, suggesting an association between IFIS and finasteride,^{9,18,19} mianserin,²⁰ antipsychotic agents,²¹ chlorpromazine,^{22,23} donepezil,²⁴ quetiapine,^{9,25} imipramine,²⁶ risperidone,²⁷ duloxetine,²⁸ warfarin,²⁹ aspirin,²³ losartan,²³ and metformin.²³ Apart from potential association with the intake of various medications, IFIS has been also noted in patients with hypertension.^{10,16,30} However, most of the published studies examining risk factors for IFIS

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are retrospective. In addition, as the awareness about IFIS becomes larger, the syndrome is more likely to be detected and various risk factors will be confirmed. In light of the above, the purpose of our prospective study was to investigate possible risk factors for IFIS, encompassing ophthalmological conditions, sociodemographic, and clinical data, as well as medications being taken at the time of surgery.

Materials and methods

Participants in our study were 1274 consecutive Caucasian patients, who underwent cataract surgery in our department. The study was in accordance with the tenets of Helsinki Declaration and was approved by the Institutional Review Board, whereas written informed consent was obtained from the patients before enrollment into the study.

After adequate dilation with tropicamide 0.5% (tropixal and demo) and phenylephrine hydrochloride 5% (phenylephrine and cooper) drops, a routine phaco-emulsification with intraocular lens implantation was performed in all patients, using Alcon Infiniti (Alcon, TX, USA). Intracameral alpha agonists were not administered. At the time of surgery, all eyes were characterized by the surgeon as IFIS or non-IFIS using the criteria of Chang and Campbell.¹ In some cases, the characteristic triad was not present, but there were one or two of the characteristics and the syndrome was designated as incomplete IFIS.

The following data were recorded: presence of IFIS, sociodemographic features (age and gender), clinical data (hypertension and diabetes mellitus), ophthalmological conditions (pseudoexfoliation, glaucoma and retinal disorders), axial length of the eye, smoking, and medications being taken at the time of surgery. To consider 'current use' of a medication as meaningful, at least 1 month of intake should have been documented. In addition, duration of each medication intake was recorded. It is worthy to note that an independent doctor (different from the surgeon in each case) has collected the data concerning the potential risk factors for IFIS, so as to avoid observation bias.

Statistical analysis was performed using SPSS 22.0 statistical software (SPSS Inc, Chicago, IL, USA). IFIS was treated as a dichotomous variable (0 = no IFIS, 1 = IFIS). The association between IFIS and possible risk factors was examined by means of univariate and multivariate analysis (multivariate logistic regression). At the univariate analysis, the associations between IFIS and possible risk factors were evaluated with χ^2 -test, Fisher's exact test, and Mann-Whitney-Wilcoxon test for independent samples, as appropriate. At the multivariate logistic regression, IFIS was treated as the dependent variable and the variables found significant at the univariate analysis were examined as independent variables. Statistical significance was defined as $P < 0.05$.

Results

IFIS was observed in 63/1274 eyes (4.9%, 95% CI: 3.9–6.7%). Among 63 cases, 41 presented complete IFIS and 22 incomplete. Table 1 shows the demographic and clinical data of our study sample. Male sex, short axial length, hypertension, α -blocker use (tamsulosin, alfuzosin, and terazosin), benzodiazepine use, finasteride use, quetiapine use, and rivastigmine use were associated with IFIS. On the other hand, no significant associations were observed regarding age, diabetes mellitus, pseudoexfoliation, glaucoma, retinal disorders, and warfarin or aspirin use. In addition, duration of intake of any significantly associated medication was not found to be associated with IFIS ($P > 0.05$ for all medications).

Table 2 presents the results of the multivariate analysis. Hypertension and the use of tamsulosin, alfuzosin, terazosin, benzodiazepines, finasteride, and quetiapine were all independently associated with IFIS, as reflected upon the mutually adjusted ORs. Male sex, short axial length, and rivastigmine lost their significance at the multivariate approach.

Discussion

The principal message of this prospective study was that apart from the well-established association between IFIS and α -blockers, other medications, that is, benzodiazepines, finasteride, and quetiapine, as well as hypertension, were significantly associated with IFIS.

Table 1 Demographic and clinical data of our study sample

	Non-IFIS group (n = 1211)	IFIS group (n = 63)	P-value
	Mean \pm SD		
Age (years)	71.8 \pm 9.2	73.3 \pm 6.1	0.219 ^a
Axial length (mm)	23.7 \pm 1.4	22.3 \pm 1.8	0.027^a
	N (%)		
Male sex	642 (53.0)	47 (74.6)	<0.001^b
Hypertension	812 (67.1)	51 (81.0)	0.031^b
Diabetes mellitus	184 (15.2)	11 (17.5)	0.592 ^b
Pseudoexfoliation	233 (19.2)	13 (20.6)	0.745 ^c
Glaucoma	127 (10.5)	8 (12.7)	0.531 ^c
Retinal disorders	153 (12.6)	6 (9.5)	0.561 ^c
Tamsulosin use	117 (9.7)	18 (28.6)	<0.001^c
Alfuzosin use	109 (9.0)	12 (19.0)	0.014^c
Terazosin use	49 (4.0)	6 (9.5)	0.050^c
Benzodiazepine use	103 (8.5)	11 (17.5)	0.023^c
Finasteride use	59 (4.9)	8 (12.7)	0.015^c
Rivastigmine use	3 (0.2)	2 (3.2)	0.022^c
Quetiapine use	8 (0.7)	3 (4.8)	0.014^c
Warfarin/aspirin use	265 (21.9)	19 (30.2)	0.123 ^c

Abbreviations: IFIS, intraoperative floppy iris syndrome; SD, standard deviation. ^aP-value derived from Mann-Whitney-Wilcoxon test for independent samples. ^bP-value derived from χ^2 -test. ^cP-value derived from Fisher's exact test. Bold cells denote statistical significance.

Table 2 Variables retained in the multivariate logistic regression analysis with their respective odds ratios

Variable	Category or increment	Odds ratio (95% confidence interval)	P-value
Gender	Male <i>vs</i> female	2.23 (1.65–4.12)	0.217
Hypertension	Yes <i>vs</i> no	19.4 (15.2–28.8)	<0.001
Tamsulosin use	Yes <i>vs</i> no	3125.0 (287.3–35 991.1)	<0.001
Alfuzosin use	Yes <i>vs</i> no	788.9 (73.4–5145.2)	<0.001
Terazosin use	Yes <i>vs</i> no	512.3 (51.9–2281.3)	<0.001
Benzodiazepine use	Yes <i>vs</i> no	823.8 (259.3–3935.9)	<0.001
Finasteride use	Yes <i>vs</i> no	338.2 (30.6–3733.8)	<0.001
Quetiapine use	Yes <i>vs</i> no	177.3 (121.9–855.1)	<0.001
Rivastigmine use	Yes <i>vs</i> no	5.94 (3.33–6.12)	0.129
Axial length	0.1 mm increase	0.68 (0.43–0.89)	0.085

Bold cells denote statistical significance.

Our results confirm the findings of previous studies and isolated case reports.^{6,10–19,23,25,30,31}

It is worthy to mention that tamsulosin was found to be the most significant factor independently associated with IFIS. Noticeably, the OR for tamsulosin was significantly higher than that regarding alfuzosin or terazosin. This could be possibly explained based on a rabbit experimental model, postulating the existence of a hypothetical additional receptor besides the α_1 -receptor with relevance to iris dilator muscle, which may exhibit higher affinity for tamsulosin.³²

Another interesting finding of our study was the positive association between benzodiazepine use and IFIS, which confirmed the results of our previous retrospective study in a different population.⁹ The mechanism by which benzodiazepines were associated with IFIS remains elusive, although we hypothesized that a biochemical link may exist. In fact, it has been shown that benzodiazepine receptors are present in various regions of the eye, including the ciliary body and specifically the iris, as well as in the retina and optic nerve.³³

Concerning finasteride, the evidence in the literature is relatively low, as there is only a retrospective study and two case reports dealing with the association between finasteride and IFIS.^{9,18,19} It should be noted that in all these cases, the patients had never received tamsulosin or other α -blocker, suggesting that the effect of finasteride seems independent. The underlying mechanism remains unknown; therefore, experimental studies are needed to confirm this finding.

Regarding quetiapine, our results are in line with the existing scarce data from previous case reports and retrospective studies.^{9,25} Interestingly, the observation on quetiapine, which is an antipsychotic agent, can be analogous to that of chlorpromazine, attributing the effects of both medications to α_1 -adrenergic antagonism.^{22,34} Moreover, hypertension was another positively associated factor with IFIS, a finding that has been also

emerged at previous studies³¹ and our previous meta-analysis on the field.¹⁶

Of note, duration of any of the medications was not found to be associated with IFIS. In fact, the onset of IFIS following α -blockers use and its discontinuation before cataract surgery remains controversial. It has been shown that IFIS cannot be prevented by cessation of the α -blocker and that it has been described even shortly after α -blocker intake, suggesting that potential irreversible structural changes occur on the iris muscle after α -blockers use.³⁵ However, there is lack of large studies to confirm or not this finding.

In conclusion, this study confirms the association of α -blockers with IFIS and additionally points to benzodiazepine, finasteride, and quetiapine use, as well as to hypertension as potential risk factors for IFIS. Caution is also advised for patients receiving rivastigmine or those with short axial length concerning their elevated risk for IFIS. It is important for ophthalmologists to know whether a patient has increased risk for IFIS, so as to prevent potential complications and inform appropriately the patient preoperatively.

Summary

What was known before

- IFIS has been definitely associated with the use of α -blockers (tamsulosin, alfuzosin, terazosin, and doxazosin) in previous studies.
- Few prospective studies have examined other medications and risk factors for IFIS.

What this study adds

- Our study points to benzodiazepines, quetiapine, finasteride use, as well as hypertension as risk factors for IFIS.
- Rivastigmine use and short axial length should be also taken into account before cataract operation, as there is elevated risk for IFIS.

Conflict of interest

The authors declare no conflict of interest.

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Risk factors for intraoperative floppy iris syndrome: a prospective study

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- Your patient is a 72-year-old man undergoing phacoemulsification cataract surgery. According to the prospective study by Chatziralli and colleagues, which of the following statements about the prevalence of intraoperative floppy iris syndrome (IFIS) in patients undergoing phacoemulsification cataract surgery regarding demographic and comorbidity risk factors is *correct*?
 - Prevalence of IFIS was 10.3% (incomplete in three-quarters of operated eyes)
 - Female sex and older age were associated with an increased risk for IFIS
 - Short axial length was associated with a significantly increased risk for IFIS in multivariate analysis
 - Hypertension was independently associated with IFIS, but diabetes mellitus, pseudoexfoliation, glaucoma, and retinal disorders were not
- According to the prospective study by Chatziralli and colleagues, which of the following statements about the association of α -blocker use with the risk for IFIS is *correct*?
 - Alfuzosin use was the most significant factor independently associated with IFIS
 - The odds ratio for terazosin was significantly higher than for alfuzosin or tamsulosin
 - IFIS has been described even shortly after α -blocker intake, suggesting that potential irreversible structural changes may occur on the iris muscle after α -blocker use
 - Duration of α -blocker use was significantly associated with IFIS

- According to the prospective study by Chatziralli and colleagues, which of the following statements about other medications associated with the risk for IFIS would *most* likely be correct?
 - Quetiapine use was independently associated with IFIS
 - Finasteride use was not independently associated with IFIS
 - Benzodiazepine use was not independently associated with IFIS
 - Warfarin and aspirin use were each independently associated with IFIS

Activity evaluation

- The activity supported the learning objectives.

Strongly disagree				Strongly agree
1	2	3	4	5
- The material was organized clearly for learning to occur.

Strongly disagree				Strongly agree
1	2	3	4	5
- The content learned from this activity will impact my practice.

Strongly disagree				Strongly agree
1	2	3	4	5
- The activity was presented objectively and free of commercial bias.

Strongly disagree				Strongly agree
1	2	3	4	5