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MANAGING INTRAOPERATIVE FLOPPY IRIS SYNDROME WITH MALYUGIN PUPIL DILATOR¹

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ABSTRACT

Intraoperative floppy iris syndrome (IFIS) is a complication due to cataract surgery and has been linked to the use of systemic therapy with alpha-1 blocker drugs, especially tamsulosin. The appearance of its symptoms makes the cataract operation itself complicated in every step. The aim of this study was to demonstrate the efficacy of Malyugin pupillary dilator in dealing with IFIS symptoms. The study involved 40 untreated and 40 treated patients with Malyugin ring intraoperatively. In each patient the following parameters were evaluated: pre- and postoperative best corrected visual acuity (BCVA), intraoperative and postoperative pupillary diameter, as well as intraoperative and postoperative complications. Intraoperative and postoperative complications were significantly more prevalent in the untreated than in the treated group. This study suggests that Malyugin ring is effective in dealing with IFIS symptoms in patients undergoing tamsulosin therapy.

Key words: Intraoperative floppy iris syndrome, Malyugin ring, cataract, tamsulosin.

¹ original scientific paper

INTRODUCTION

Intraoperative floppy iris syndrome (IFIS) is an intraocular change which is linked with higher risk of complications during cataract surgery. Starting 15 years ago, when IFIS was described for the first time by Chang and Campbell¹, to the present day, it has kept the attention of cataract surgeons and it is a challenge to deal with its features. In order to recognize IFIS, the surgeon must know its clinical signs: the presence of flaccid iris, its prolapse through scleral intraoperative incisions, and progressive miosis of the eye's pupil despite the use of standard preoperative therapy.² The presence of these clinical signs obstructs the cataract surgery, leading to a higher incidence of complications.³

The occurrence of this syndrome is very often associated with the use of any drug from the group of alpha-1 blockers, but most often occurs with the use of the drug tamsulosin.⁴ Among the indications for tamsulosin therapy, its most common use is in the treatment of benign prostatic hyperplasia (BPH) in men. This disease occurs in about 50% of men aged 51 to 60 years, and in about 80% of men over the age of 80.⁵

PATIENTS AND METHOD

In this study, there are 80 eyes i.e 80 patients diagnosed with cataracts, all men, with systemic therapy with tamsulosin and without a medical history for another ophthalmic disease. To make the desired comparison, we divided the patients into two groups: the first group was our control group and included 40 patients in whom no mechanical pupillary dilator was used intraoperatively, and the second group included another 40 patients in whom Malyugin pupillary dilator was used intraoperatively.

Preoperatively, we informed all patients about the course, possible complications and the expected outcome of the cataract surgery. A complete ophthalmological examination, an internist examination, as well as a complete blood count test with sedimentation rate was performed in all patients. The complete ophthalmological examination included: determination of the best corrected visual acuity (BCVA) on the Snellen board with a SCHIN-NIPONN phoropter, measurement of intraocular pressure with a non-contact Huvitz tonometer, a detailed examination of the anterior segment with a spatula lamp (if the medium was transparent), as

well as a detailed examination of the posterior segment also with a split lamp, A-scan and/or B-scan with PIROP - Ophthalmic Scanner (A + B + CCT) and an OCT imaging with Cirrus HD OCT 4000 Zeiss (if the medium was transparent).

We used tropicamide (Mydriacyl 0.5%) preoperatively and intraoperatively lidocaine, hyalon 5 (viscoelastic), and adrenaline when the action of tropicamide was insufficient, to achieve the desired mydriasis of 6-7 mm.

We noted the pre- and intraoperative dimensions of the pupillary diameter. Preoperative pupillary dimensions were measured with Atlas 900 Zeiss, i.e. intraoperatively with Rosenbaum cards and Colvard pupilometer.

Phacoemulsification cataract surgery was performed with Zeiss OPMI Lumera operating microscope and Bausch Lomb Stellaris cataract surgery device.

We analyzed both intra and postoperative complications, the best corrected postoperative visual acuity according to the Snellen board, and postoperative intraocular pressure values.

There were performed two follow-ups, in 24 hours and in 30 days after cataract phacoemulsification surgery.

We used an unpaired Student t-test for statistical data analysis.

RESULTS

The preoperative dimensions of the pupillary diameter in the two examined groups were ranged from 2.5mm to 6.5mm, with an average of 5.23mm (Table 1).

Број на пациенти	Предоперативни димензии на пупиларен дијаметар								Вкупно
	2,5 mm	3.5 mm	4.0 mm	4.5 mm	5.0 mm	5.5 mm	6.0 mm	6.5 mm	
Група 1	1	3	3	5	9	9	8	2	40
Група 2	1	1	1	4	8	7	16	2	40
Вкупно	2	4	4	9	17	16	24	4	80

Table 1. Preoperative dimensions of pupillary diameter
Group 1: patients in whom Malyugin ring was not used
Group 2: patients in whom Malyugin ring was used intraoperatively

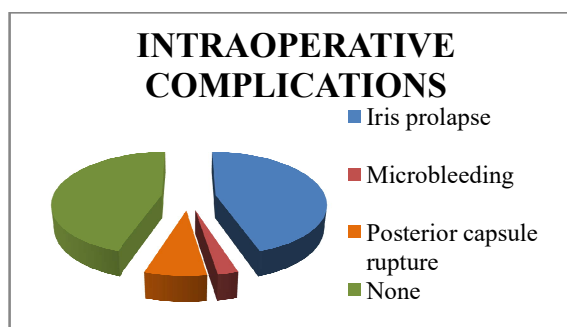
The intraoperative dimensions of the pupillary diameter in patients in the control group were ranged from 2.5 mm to 4.0 mm, with an average of 3.04 mm (Table 2).

Број на пациенти	Финални интраоперативни димензии на пупиларен дијаметар				Вкупно
	2,5 mm	3.0 mm	3.5 mm	4.0 mm	
Група 1	11	18	7	4	40
Група 2	10	21	5	4	40
Вкупно	21	39	12	8	80

Table 2. Final intraoperative dimensions of pupillary diameter

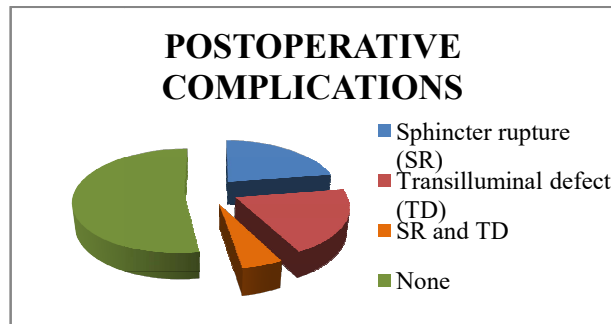
While in patients from the study group, in which Malyugin pupillary dilator was used intraoperatively, mydriasis of 6-7 mm was achieved after application of the dilator, which is crucial for the successful course of cataract surgery.

As a measure of the success of cataract surgery in patients was the occurrence of intra and postoperative complications, which were analyzed on two independent graphs in the control and study groups. The following intraoperative complications were noted in the control group: 18 patients had iris prolapse, 1 patient had microbleeding and 3 patients had a posterior capsule rupture as the most severe complication of cataract surgery (Graph 1).



Graph 1. Intraoperative complications in patients who were under tamsulosin therapy and mechanical dilators were not used while operating

The following postoperative complications were noted in the control group: 9 patients had a sphincter rupture, 8 patients had a transilluminal defect, while 2 patients had a sphincter rupture and a transilluminal defect combined (Graph 2).



Graph 2. Postoperative complications in patients who were under tamsulosin therapy and mechanical dilators were not used while operating

Contrary to the data obtained from patients in the control group, in patients in whom we used Malyugin pupillary dilator intraoperatively (the study group), there were no intraoperative complications. As postoperative complications, only 5 patients had a transilluminal defect, which occurred as a result of ring migration during its manipulation.

Preoperative best-corrected visual acuity values in patients in both groups ranged from 0.2 to 0.4, with an average of 0.3 according to the Snellen chart (Table 3).

The postoperative best corrected visual acuity of the operated eye in patients in the control group was on average 0.8, and in patients in the study group was 0.9 according to the Snellen board, indicating a small but insignificant decrease in vision in patients in the control group.

Intraocular pressure values in the first postoperative day in patients ranged from 16 to 24 mmHg, averaging 20.73 mmHg (Table 3).

There is no significant difference in BCVA preoperative values, preoperative pupil diameter dimensions and IOP values on the first postoperative day ($p > 0.05$). (Table 3)

		Age	BCVA (preop.)	BCVA (postop.)	IOP (first postop. day)	Preop. mydriasis	Intraop. mydriasis	Intraop. complications	Postop. complications
Group 1	Mean value	74.8	0.3	0.8	20.69	5.07	3.05	0.55	0.46
	Standard deviation	5.47	0.08	0.14	1.78	0.9	0.46	0.5	0.5
Group 2	Mean value	74.48	0.28	0.9	20.76	5.39	3.04	0	0.13
	Standard deviation	5.65	0.08	0.07	2.17	0.83	0.45	0	0.33
Student t-test (p value)		>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	<0.05	<0.05

BCVA (preoperative) - Preoperative best corrected visual acuity, BCVA (postoperative) - Postoperative best corrected visual acuity, Preop. mydriasis - preoperative dimensions of pupillary diameter; Intraop. mydriasis - final intraoperative dimensions of pupillary diameter; IOP - intraocular pressure in the first postoperative day.

Table 3. Statistical data processing, calculated standard deviation and Student t-test for patients from both groups

Figure 1 shows an already applied Malyugin ring.

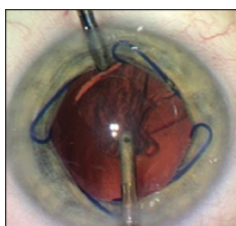


Figure 1. Applied Malyugin pupillary dilator

DISCUSSION

Intraoperative floppy iris syndrome (IFIS) is a clinical syndrome found in cataract surgery in patients receiving systemic therapy with alpha-1 blockers,

especially tamsulosin, which is used in treatment of benign prostatic hyperplasia. The expression of clinical symptoms in this syndrome is variable in different patients, and may even differ between the two eyes in the same patient. We distinguish three clinical forms of IFIS depending on the severity of the symptoms:⁶

- Mild form, where there is intraoperative mydriasis of 6mm or more, with minimal iris tremor;
- Moderate form, where there is a moderately dilated pupil intraoperatively and there is a moderate tendency of the iris to prolapse through surgical scleral incisions;
- Severe form, where there is progressive intraoperative miosis resistant to standard preoperative therapy for its prevention, and as a consequence more serious complications occur, such as rupture of the posterior capsule and prolapse of the vitreous in the anterior chamber.

Tamsulosin is the first licensed alpha-1 blocker (1997) to treat benign prostatic hyperplasia.⁷ Its main mechanism of action is relaxation of the smooth muscles of the prostate and bladder through selective inhibition of alpha-1 adrenoreceptors, but because these receptors are also present in large numbers in the iris dilator muscle, secondarily leads to the occurrence of IFIS.⁸ The exact pathophysiology of this syndrome is not fully understood. Equilibrium between pupillary constriction and dilatation occurs by default by interaction between alpha and beta-adrenergic receptors and the cholinergic system, with the alpha-1A adrenergic receptor being the most abundant receptor in the iris that mediates pupillary dilatation.^{9,10} In addition the alpha-1 receptor is the most common adrenergic receptor in the small arterioles of the iris, and although not completely confirmed, their inhibition results in changes in local blood flow that contribute to pathological changes in the iris.^{11,12} In one of the first studies, Prata and co-workers studied 27 patients treated with tamsulosin and 22 untreated patients as a control group using slit-lamp-adapted optical coherence tomography (SL-OCT). They observed a significant reduction in iris dilator muscle thickness in patients treated with tamsulosin ($P = 0.001$) compared with patients in the control group. In a recent study, with optical microscopy were examined 14 eyes removed after death of patients previously treated with tamsulosin and compared with samples taken from the eyes of untreated patients in a control group.¹⁴ Mean iris dilator muscle thickness was significant decreased in patients treated with tamsulosin compared with patients in the control group ($P = 0.004$), with no marked differences in iris stroma. Reduced myofibrils

and enlarged vacuoles have been observed on transmission electron microscopy (TEM), and such findings link iris dilator muscle atrophy to treatment with this alpha-blocker.¹⁴

Surprisingly, patients who received very small doses of tamsulosin were also at increased risk of developing IFIS. A study by Chang et al. showed that discontinuation of tamsulosin therapy 1 to 8 weeks before cataract surgery did not result in a change in the severity of IFIS symptoms, but resulted in greater mydriasis of the papilla at the onset of surgery.¹⁵ It has also been shown that even 1 year of discontinuation of tamsulosin does not prevent the development of IFIS.¹ There are studies showing that symptoms of IFIS may appear even after several years of discontinuation of tamsulosin therapy.¹⁶

In addition to understanding the pathophysiology of this syndrome, it is important to learn how to prevent and how to deal with the symptoms and consequences of IFIS. There are studies in which the authors have tried to replace tamsulosin with another alpha blocker preoperatively, but because the changes caused by tamsulosin are long-term, this attempt has proved unsuccessful.¹⁷ Several authors have tried to find a solution to this problem, such as Chadha V., Borooah S. and Tey A.¹⁸, then Chan DG. and Francis¹⁹, Gurbaxani A. and Packard R.²⁰, as well as Masket S. and Belani S.²¹, but unfortunately none of these proposals have proved effective enough. If the pupil is stretched with a spatula or a Kuglen hook, it can easily cause iris bleeding. Then the technique of applying the iris hooks in diamond configuration was presented, but even in this way the sphincter can rupture and the iris can bleed. Asia Pupil Expander recently introduced a new way of applying a square iris hook in the form of scissors, but the disadvantage is that two additional intraoperative incisions must be made to use this method.²²

In our study, we found that in patients who were under tamsulosin therapy and mechanical dilators were not used while operating were more likely to have complications, with the most severe complication being a posterior capsule rupture. One of the most common complications that greatly complicated cataract surgery was intraoperative iris prolapse, which was completely avoided in the treatment group in which Malyugin pupillary dilator was used.

Although intra and postoperative complications were observed in the control group, there was no difference in the postoperative results of BCVA in the two groups. IOP values showed no deviations in both groups.

Advantages of Malyugin pupillary dilator are:²³

1. It has a square shape, with 4 circular scrolls and 8 fixing points that allow an even circular opening of the pupil.
2. The dilator itself gently opens the iris thus eliminating the risk of damage. The latest version of the Malyugin dilator is made of 5.0 polypropylene.
3. The diameter of the dilator is from 6.25 to 7.0mm, i.e it can be applied through the main scleral incision of 2.0mm, so no additional intraoperative incisions are needed.
4. It is designed to have minimal contact with the iris during its application and extraction, i.e it is inserted and removed with a special injector.
5. The time of application and removal of the pupillary dilator is quite short.

CONCLUSION

Patients receiving systemic tamsulosin therapy are at risk of developing IFIS symptoms, which contribute to difficulties in performing cataract surgery with phacoemulsification, and thus increase the risk of intra and postoperative complications. However, in this study, there were no intraoperative or postoperative complications in patients with IFIS in whom Malyugin ring was applied. This study suggests that Malyugin ring is an effective method of preventing IFIS-related complications in patients using tamsulosin.

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