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ABSTRACT

of the dissertation for the degree of Doctor of Philosophy

PECULIARITIES OF THE USE OF PROSTOGLANDIN ANALOGUES IN PRIMARY OPEN-ANGLE GLAUCOMA PATIENTS DURING THE PERIOPERATIVE PERIOD FOLLOWING PHACOEMULSIFICATION

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GENERAL DESCRIPTION OF THE WORK

Relevance and the degree of the study of the theme. In Azerbaijan, as elsewhere in the world, glaucoma and cataracts, and more than often their combined manifestation occupy a leading place among the nosological group of eye diseases[1]. Achieving normal intraocular pressure levels is currently a crucial prerequisite for cataract surgery in patients with primary open-angle glaucoma (POAG). For this purpose, drugs that lower the intraocular pressure (IOP) are used. The drugs of choice in the prescription of the treatment scheme are such F2a prostoglandin analogues (PGAs) as travoprost, latanoprost, and Tafluprost. These drugs have the advantage of the persistent hypotensive effect, and the convenience of the instillation schedule. In addition, they have relatively fewer contraindications, local and systemic side effects. However, different authors express conflicting opinions concerning the safety of these drugs used in the patients with concomitant cataract and POAG in the perioperative period. These differing opinions are due to the fact that being the mediators of inflammation, prostoglandins may cause vasodilation, increase the permeability of the vessels and the development of exudations[2]. The main side effect of PGAs, according to certain authors, is Cystoid Macular Edema (CME)[3]. They think that the main factor contributing to the development of ME after Phaco is the biological activity mechanism of PGAs, specifically their proinflammatory action. Such suthors claim that prostaglandins, which interfere with the hematoretinal barrier's permeability, play a role in the development of cystoid ME following cataract extraction[4]. But there are at least as many

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[1] Гасанов Д.В., Касимов Э.М. Отдаленные результаты факоканалопластики при далеко зашедшей псевдоэксфолиативной глаукоме и катаракте // Вестник офтальмологии, – 2018. № 3(134), – с. 28-34.

[2] Miyake K., Ibaraki, N. Prostaglandins and Cystoid Macular Edema // Survey of Ophthalmology, 2002. August; 47(1). – p. S203-S218.

[3] Иошин И.Э. Послеоперационный или артифакичный (псевдофакичный) макулярный отек // Российский офтальмологический журнал, – 2020. №13 (4), – с. 64-69.

[4] Holló, G. Cystoid macular edema related to cataract surgery and topical prostaglandin analogs: Mechanism, diagnosis, and management / G. Holló, T. Aung,

scientists and practitioners that do not support this opinion[5]. They believe that, given the history of PGAs use in Phaco procedures, the risk of ME is linked to concurrent eye conditions like uveitis, artiphakia, chronic diabetes, high blood pressure, surgical injuries, etc.; in other words, it is related to the patient's condition and the surgeon's qualifications. They also think that PGAs typically cannot pass through the hematoretinal barrier[6].

These contradicting findings demonstrate how intricate and multifaceted are PGAs' mechanisms of action are on the eye's structures. A number of hypotheses have been put up in recent years to explain the mechanism of ME formation against the background of PGA instillation. One of the widely supported hypotheses is the effects of PGAs on the macular vascular system. It is thought that PGAs can enhance the capillary permeability and dilate blood vessels, which increases the penetration of fluid and proteins into macular tissues and causes ME[7]. Another hypothesis states that PGAs may directly affect blood vessel endothelium and retinal cells, resulting in metabolic or inflammatory alterations that impair the barrier functions of macular tissues and exacerbate edema [4]. The third idea states that PGAs can raise intraocular fluid levels, which will put more strain on the macula's arteries and promote the growth of CME.

However, it is worth noting that the precise mechanism of ME development against the backdrop of PGA instillations, cannot be explained by current assumptions. More research is necessary to more

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L.B. Cantor [et al.] // Survey of Ophthalmology, – 2020. September-October; 65(5). – p. 496-512.

[5] Hernstadt D., Hernstadt, D., Husain R. Effect of prostaglandin analogue use on the development of cystoid macular edema after phacoemulsification using STROBE statement methodology // Journal of Cataract & Refractive Surgery, – 2017. April 43(4). – p. 564-569.

[6] Fakhraie G. Cystoid macular edema with prostaglandin analogue use after uneventful cataract surgery in glaucoma patients // G. Fakhraie, M. Mirghorbani, L. Jay Katz [et al.] // Journal of Cataract & Refractive Surgery, – 2019. October 45 (10). – p. 1436-1445.

[7] Zhang Q. The role of retinal glial cells and related factors in macular edema [electronic resource] /Q. Zhang, S. Qi, J. You [et al.] // Biochemical and Biophysical Research Communications, – 2024. February, 695. – 149415.

precisely ascertain their influence on ME development and to create the strategies to prevent or minimize complications[8].

Therefore, the issue of examining how PGAs affect the course of the postoperative period still remains relevant for clinical practice in order to create a cohesive approach to perioperative patient care.

The object Studies. The objects of the clinical studies were the 80 patients of the Badam Medical Center and the Brizol Eye Clinic with concomitant cataract and POAG and 69 the experimental animals - chinchilla rabbits.

Study design: prospective, comparative clinical and experimental studies carried out using clinical, instrumental, biochemical, morphological and statistical study techniques.

All clinical and experimental research was carried out with thepermission of Local Ethics Committee of Azerbaijan Medical University.

The purpose of the Study. Experimental and clinical study of pathogenetic mechanisms of cystoid macular edema development under the impact of topical prostaglandins following the phacoemulsification in the patients with primary glaucoma.

Study objectives.

1. To study in a comparative aspect the effects of antihypertensive agents Tafluprost and a fixed combination drug containing brinzolamide 1% and timolol maliate 0.5%on IOP, visual acuity, conjunctival redness, and the Tyndall effect in the patients with concomitant cataract and POAG during perioperative use.

2. To study in a comparative aspect the effects of Tafluprost and a fixed combination drug containing brinzolamide 1% and timolol maliate 0.5%on the CME development risk in the patients following the Phaco.

3. To create an experimental glaucoma model and to study the hypotensive efficacy of Tafluprost and a fixed combination drug containing brinzolamide 1% and timolol maliate 0.5% in a comparative

[8] Иошин И.Э., Толчинская А.И., Багиров А.М. Влияние факоэмульсификации двухсторонней катаракты при различных интервалах между операциями на состояние макулярной области сетчатки // Вестник офтальмологии, – 2019. № 135(3), – 90-98.

aspect.

4. To create an autoimmune uveitis model against the experimental glaucoma model and to determine the immune status markers in the blood of the animals sensitized by normal horse serum (NHS) and with developed uveitis.

5. To study in a comparative aspect the morphofunctional alterations in the rabbit retina's vascular system in experimental models developed against the background of the treatment with tafluprost and to determine the role played by hypotenzive agents in the development of macular edema (ME) in experimental animals.

6. Based on the study results, to develope the recommendations for the efficient hypotensive therapy of the patients with POAG undergoing Phaco both during pre- and postoperative periods.

The main provisions of the dissertation submitted for defense:

1. Tafluprost used perioperatively in the patients with concomitant cataract and POAG does not cause a statistically significant increase in macular thickness (based on OCT data) or an increase in the probability of CME development, nor does it lead to other side effects (decreased VA, Tyndall effect).

2. Animals with experimental glaucoma and uveitis undergoing hypotensive treatment with different drugs experience morpho-functional alterations in the retinal vascular system against the backdrop of ophthalmotonus. However, Tafluprost does not significantly increase the risk of developing ME. Experimentally modeled postoperative inflammation, increases the risk of ME and is its major cause. Under these conditions, Tafluprost further increases the risk of ME development.

3. In the animals sensitized by NHS, Tafluprost increases the risk of ME development by 58.3% ($p>0,05$). Consequently, it is recommended ro take into consideration the presence of autoimmune diseases along with other concomitant diseases when prescribing Tafluprost to patients with concomitant cataract and POAG.

Scientific novelty of the Study.

– A model of autoimmune uveitis was developed against the background of experimental glaucoma and morphofunctional

alterations caused by this pathology in the retina of the eye have been studied.

– In the experiment, the pathogenetic mechanism of ME development was studied against the background of the use of PGAs along with the identification of the factors influencing the risk of ME development.

– An increased risk of developing ME was revealed in animals with experimental glaucoma on the background of increased immune status and the use of PGAs.

– A comparative statistical assessment of the risk of developing CME is made against the background of the use of various hypotensive drugs in glaucoma patients after phacoemulsification.

Scientific and practical significance of the study.

– The experimental study's findings will have theoretical implications for the basic understanding of the mechanisms behind the development of ME brought on by PGA drugs.

– Methodological guidelines for the perioperative use of PGAs in cases of phacoemulsification in patients with POAG will be developed based on the study's findings.

– The results of the study are used in perioperative treatment of patients with combined POAG and cataracts.

– An answer to the controversial question of clinical ophthalmology is provided: Should the treatment with PGAs be cancelled in the patients with POAG or not?. The STUDY findings prove that, treatment with PGAs do not necessarily need to be stopped in a typical, straightforward postoperative scenario; however, considering the experimental data, the treatment with PGAs should be stopped against the background of intraoperative or postoperative complications, and inflammation.

Approbation and implementation of the study results. The main provisions of the dissertation have been presented at the following conferences**:** AMU "Təbabətin aktual problemləri – 2020" international scientific -practical congress, Baku, 2020, AMU "Təbabətin aktual problemləri – 2022" international scientific - practical congress, Baku, 2022, II international scientific and practical conference «modern science: experience, traditions,

innovations», Berlin, Germany, 2023, European society of cornea and ocular surface disease specialists, Paris, France, 2019; 2023 ASCRS ASOA Annual Meeting, San Diego, USA, 2023 et al.

The initial discussion of the work took place at the interdepartmental meeting at the Azerbaijan Medical University (12/26/2024, protocol No. 1) and at the Scientific Seminar of the Dissertation Council FD1.03, operating on the basis of the National Center of Ophthalmology named after Academician Zarifa Aliyeva (04/16/2025, protocol No. 7).

The main content of the dissertation has been reported in 8 magazine articles in the editions recommended by the Supreme Attestation Commission, as well as in 6 abstracts.

The results of the study were implemented in the Teaching Surgery Clinic of Azerbaijan Medical University, in the Ophthalmology Department of the Badam Medical Center, and in the Ophthalmology Department of the Clinical Hospital of the Presidential Administration of the Russian Federation.

The name of the organization where the work was carried out. The work was performed at the Department of Ophthalmology, at the Research Centre of Azerbaijan Medical University, at the "Badam" Medical Center and "Briz L" Eye Clinic, Baku.

Volume and structure of the dissertation. The dissertation contains 169 pages of computer text and includes an introduction, literature review, study materials and methods, two chapters on the study itself, results, conclusions, practical recommendations, bibliography, and abbreviations. The work is documented in 15 tables, illustrated with 17 graphs and 14 figures.

STUDY MATERIALS AND METHODS

Clinical studies covered the results of data analysis of 80 patients. In order to ensure the objectivity of the results, the presence of uncomplicated, mature and immature stage, age-related concomitant cataract and POAG stages I to III was chosen as the criterion for including the patients in the study. The control group consisted of the patients with uncomplicated, early and immature age-related cataracts

without concomitant POAG. Since the literature indicates that these conditions increase the risk of developing cystic postoperative ME in patients with POAG during phacoemulsification, the patients with retinal vein occlusion, diabetic retinopathy, uveitis, vitreomacular traction, epiretinal membrane, aphakia, capsulectomy, and vitreous loss as a result of intraoperative complications were excluded from the studies.

All patients (with the exception of the control group) included in the studies received appropriate medications a week before cataract phacoemulsification and in the postoperative period to maintain targeted IOP levels.

We chose Tafluprost as a PGA preparation without preservatives in light of the findings of several authors stating that benzalkonium chloride, caused an inflammatory reaction[9].

As a drug from the beta-adrenergic blockers +carbonic anhydrase inhibitor group, we used a fixed combination drug containing brinzolamide 1% and timolol maliate 0.5%– comparison drug (CD).

Additionally, all patients received standard instillation scheme for one month following the surgery, comprising fluoroquinolone solution as an antibacterial agent, steroid medications (dexamethasone), and a nonsteroidal anti-inflammatory drug (NSAID).

Instillation of NSAIDs into the operated eye continued for 6 weeks after the surgery.

According to the Study purposes and objectives, the patients were divided into 4 groups: Control group 1, consisting of 18 patients (of which OD – 7 (38.9%), OS – 11 (61.1%)) who did not receive any agents to reduce IOP; Group 2, consisting of 37 patients (of which OD – 15 (40.5%), OS- 22 (59.5%)), instilled with Tafluprost; Group 3 – 15 patients (of which OD – 6 (40.0%), OS – 9 (60.0%)), instilled with CD; Group 4 – 10 patients (of which OD – 5 (50.0%), OS – 5 (50.0%)) who received both Tafluprost and CD. The mean age of the patients included in the study was 69.4±1.1 (42-91) years. Of these, 29 subjects were men (36.3%) and 51 subjects were women (63.7%). It should be noted that

[9] Hommer, A. Effect of changing from preserved prostaglandins to preservative-free tafluprost in patients with glaucoma on tear film thickness / A. Hommer, D. Schmidl, M. Kromus [et al.] // Eur. J. Ophthalmol., – 2018. Jul; 28(4). – p. 385-392.

the mean age of patients within the groups did not differ much (P_h=0.594), where in the 1st group it was 70.6±2.1, in the 2nd – 70.3±1.8, in the 3rd – 67.7±3.2, and in the 4th – 67.7±3.2. And as age is one of the key variables that affect the development of ME, this is significant for the validity of the study findings and the interpretation of the findings.

Study methods: Anamnestic, Pre- and postoperative instrumental examinations: visometry, refractometry, tonometry, biomicroscopy, biomicroscopy of the posterior segment. Honioskopy, USI, Perymertry, Endothelial biomicroscopy, Optical Coherence Tomography (OCT).

Experimental studies were conducted on 69 chinchilla rabbits weighing from 2,800 to 3,000 kg. All experimental animals were maintained with Directive 2010/63/EU of the European Parliament and Council of the European Union On the protection of animals used for scientific purposes, dated September 22, 2010.

The experiments were carried out in two rounds: in the first round, glaucoma was modeled in animals, and the hypotensive effect of Tafluprost and CD investigated.

During the II round, uveitis was modeled in the animals against the background of ocular hypertension. The animals underwent ophthalmological examination of the retina, and measurement of intraocular pressure (IOP) with the use of a manual ophthalmoscope. Blood for immunological testing and for determination of the leukocytes, neutrophils, and lymphocytes count was drawn from the ear vein. Following the completion of the experiment, the eyeballs of the animals were enucleated under anesthesia, and micropreparations were prepared for morphological studies of the eye retina, for reviewing the state of the vascular bed, and the presence of ME.

Glaucoma modeling. The glaucoma model was created by administering one drop of 0,1% dexamethasone solution to each rabbit eye for 30 days. The long modeling time was chosen taking into account the fact, that persistent, irreversible glaucoma-related changes start to take place with prolonged use of steroids[10], while cataract also is

[10] Mechelen, R. Animal models and drug candidates for use in glaucoma filtration surgery: A systematic review / Ralph J.S. van Mechelen, Jarno E.J. Wolters, Christian J.F. Bertens [et al.] // Experimental Eye Research, – 2022, Apr; 217. – 108972.

developed along with glaucoma, which serves the stated Study purpose. The model obtained this way is similar to human iatrogenic glaucoma in many aspects, such as morphology and clinical features[11].

Uveitis modeling. The uveitis model was developed as follows[12]: to sensitize the animals, they were first subcutaneously injected with 5 ml of NHS, followed by another, intramuscular injection of 1 ml of NHS. 9 days after the last injection, 0.07 ml shocking dose of NHS was administered intravitreally into the right eye. The left eye was used as a control. Clinical presentation of uveitis started 3 days after the administration of the shocking dose in the right eye.

Normal, fluid horse serum was used for modeling, i.e. for the cultivation of microorganisms (in conformity with ТУ 21.20.21-094-20401675-2020 specifications, 100 ml vials, Microgen, Russia, Moscow.

Study methods:

The IOP levels were measured with a portable Tono-Pen X pneumotonometer (Reichert, USA).

An ophthalmological examination of the anterior segment of the eye. Retina was carried out using a Welch Allyn portable ophthalmoscope (USA, Dealmed

Blood tests. 1) The immunological studies of CIC, immunoglobulins (Ig), and lymphocytes in the blood were carried out using an enzymatic colorimetric approach on an FP-9019 analyzer (made in Finland), while the complement components were determined based on hemolytic activity. 2) The laboratory studies of the leukocytes, lymphocytes, and neutrophils counts were carried out on an Auto Hematology Analyzer Ratyo RT-7600. 3) Morphological studies.

The fixation of the collected material (eyeballs) for morphological studies was carried out using a standard procedure**.** The resulting paraffin blocks were then cut into 4-micron-thick serial sections, stained

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[11] Онуфрийчук, О.Н. Экспериментальные модели глаукомы / О.Н.Онуфрийчук, И.Р.Газизова, А.В.Куроедов [и др.] // Российский офтальмологический журнал, – 2021. № 14(4), – с. 164-171.

[12] Аксенова, С. В. Сравнительная оценка двух методов моделирования аутоиммунного увеита / С. В. Аксенова, Н. А. Пятаев, М. В. Малькина [и др.] // Вестник Мордовского университета, – 2017. № 3 (27), – с. 428-439.

using the conventional hematoxylin-eosin technique, and examined under a SCOP microscope (Netherlands) capable of a x 400 magnification, automatically taking the pictures of enlarged section patterns.

Morphometry was carried out using method of G.G.Avtandilov[13]. For this purpose, an eyepiece graticule and a screw eyepiece micrometer mounted to the microscope.

Statistical study. Nonparametric U (Mann-Whitney), F-Fisher, χ^2 (Chi-Square) – Pearson, H-test (Kruskal-Wallis), F-test, using the programs MS Excel and SPSS.

RESULTS AND DISCUSSION

Clinical studies

All study participants had ophthalmotonus assessed both prior to and at the appropriate dates following the surgery. The results of the tests are presented in table 1 below, where it can be seen that the ophthalmotonus of all 80 patients in the preoperative period was within the reference standards.

On the next day following the Phaco surgery, the average IOP value of the patients increased slightly (by 3.3%) and remained within the reference values in all groups (P_f=0.484 and P_h=0.485). In subsequent periods, the determined IOP values in the groups were also within the reference values.

Visometry before the surgery in all groups revealed a low VA index, undergoing a sharp increase after the surgery.

The difference in the average HP values within and between the groups did not reach statistical significance at any examination date: P=0.147 before surgery and P_h=0.282, one day after – at P=0,461 and P_h=0,500, on the 7th day – at P=0,817 and P_h=0,695, one month after – at P=0,817 and P_h=0,695, 3 months after – at P=0,909 and P_h=0,784.

Visual acuity correction was performed in 31 patients: in I group – 10, II group – 12, III group – 6, IV group – 3 patients.

[13] Автандилов, Г.Г. Морфометрия в патологии / Г.Г.Автандилов. – Москва: Медицина, – 2002. – 304 с.

Table 1.

Dynamics of ophthalmotonus tests among the patients with concomitant POAG and cataract carried out during the perioperative period

Dates	Groups	Amt	IOT				
			M±m	Min	Max	P_f	P_h
Before the Phaco	1	18	18,1±0,9	12	25	0.075	0.336
	2	37	17,5±0,4	11	24		
	3	15	21,2±2,2	10	42		
	4	10	18,3±0,9	14	22		
	Total	80	18,4±0,5	10	42		
1 day after the Phaco	1	18	18,7±1,4	10	38	0.484	0.485
	2	37	18,8±0,6	11	29		
	3	15	20,7±1,8	12	37		
	4	10	17,6±1,6	10	27		
	Total	80	19,0±0,6	10	38		
7 day after the Phaco	1	18	17,4±0,9	11	24	0.828	0.872
	2	37	17,4±0,5	10	22		
	3	14	17,9±1,2	11	25		
	4	10	18,5±1,1	13	25		
	Total	79	17,6±0,4	10	25		
1 month after the Phaco	1	18	16,4±1,0	8	24	0.736	0.834
	2	37	16,9±0,4	11	22		
	3	15	17,9±1,4	10	35		
	4	10	17,1±0,8	12	20		
	Total	80	17,0±0,4	8	35		
3 month after the Phaco	1	17	15,9±0,8	10	22	0.459	0.417
	2	37	16,3±0,4	12	21		
	3	14	17,3±0,7	13	22		
	4	10	16,9±,5	14	19		
	Total	78	16,5±0,3	10	22		

Contrary to some authors' beliefs that PGAs may act as an inflammatory mediator to amplify the harmful effects of ultrasound on the corneal, iris, ciliary body, and retinal epithelium during Phaco, an analysis of the acquired data in the context of scientific literature indicates that Tafluprost, a medication from the PGA group, did not

result in impaired VA[14].

Palpebral conjunctiva is a very sensitive organ and, with irritation and inflammation, may become hyperemic, edematous, reddened due to the dilation and congestion of the vessels. There are 3 degrees (table 2) of conjunctival redness (conjunctival vascular injection): I grade – no redness, II grade – moderate redness, III grade – severe redness[15].

The results of the conujunctival hyperemia degree tests of the patients in the perioperative period are presented in table 2 below, where it is seen that both before the surgery and in the postoperative periods, the number of patients in the Tafluprost instillation group with redness of the conjunctiva, and especially in terms of the severity of redness (grade 2) was higher than in other groups.

The biomicroophthalmoscopy revealed the Tyndall effect in various groups with varying degrees of severity. The SUN nomenclature (Standardization of Uveitis Nomenclature) identifies the following grades of Tyndall effect intensity: 0 – none; 1^+ – 6-15 cells; 2^+ – 16-25 cells; 3^+ 26-50 cells; 4^+ – >50 cells.

The recorded grades of intensity of the Tyndall effect among the patients throughout the study was from 0 to 3.The results are presented in Table 3 below.

As can be seen from the data shown in table 3, the transparency of the ocular media was compromised in 100% of patients prior to surgery, making it impossible to determine the Tyndall effect. First day after surgery, 100% of patients have demonstrated varying degrees of the Tyndall effect, which was caused by an operational trauma. However, the degree of its intensity varied. Thus, among the patients who did not receive hypotensive drugs, the Tyndall effect of I grade was observed in 22.2%, and II grade – in 77.8% of the patients.

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[14] Young Cho, S. Twenty-four-hour efficacy of preservative-free tafluprost for open-angle glaucoma patients, assessed by home intraocular pressure (Icare-ONE) and blood-pressure monitoring / Soon Young Cho, Yong Yeon Kim, Chungkwon Yoo [et al.] // Jpn J Ophthalmol., – 2016. Jan; 60(1). – p. 27-34.

[15] Ogawa Y. International Chronic Ocular Graft-vs-Host-Disease (GVHD) Consensus Group: Proposed Diagnostic Criteria for Chronic GVHD (Part I) / Y. Ogawa, S.K.Kim, R. Dana [et al.]// Sci Rep. 2013. Dec; 3. – p. 3419.

Table 2.

Severity of conjunctival hyperemia among the study groups

Degree of conjunctival hyperemia		Groups					Chi-Square Tests Compared to I gr.	
		1	2	3	4	Total	χ^2	Sig.
Before the surgery	not	94.4%	67.6%	80.0%	90.0%	78.8%	6.185	0.103
	I	5.6%	32.4%	20.0%	10.0%	21.3%		
	II	0.0%	0.0%	0.0%	0.0%	0.0%		
	III	0.0%	0.0%	0.0%	0.0%	0.0%		
After 1 day	not	72.2%	27.0%	26.7%	20.0%	36.3%	16.890	0.010
	I	27.8%	51.4%	66.7%	70.0%	51.2%		
	II	0.0%	21.6%	6.7%	10.0%	12.5%		
	III	0.0%	0.0%	0.0%	0.0%	0.0%		
After 7 days	not	88.9%	73.0%	71.4%	90.0%	78.5%	7.402	0.285
	I	11.1%	27.0%	21.4%	10.0%	20.3%		
	II	0.0%	0.0%	7.1%	0.0%	1.3%		
	III	0.0%	0.0%	0.0%	0.0%	0.0%		
After 1 month	not	94.4%	97.3%	93.3%	100.0%	96.3%	1.018	0. 797
	I	5.6%	2.7%	6.7%	0.0%	3.8%		
	II	0.0%	0.0%	0.0%	0.0%	0.0%		
	III	0.0%	0.0%	0.0%	0.0%	0.0%		
After 3 month	not	94.1%	78.4%	92.9%	90.0%	85.9%	3.374	0.337
	I	5.9%	21.6%	7.1%	10.0%	14.1%		
	II	0.0%	0.0%	0.0%	0.0%	0.0%		
	III	0.0%	0.0%	0.0%	0.0%	0.0%		

The situation with the patients in other groups getting different drugs to lower IOP was essentially the same: Tyndall effect of I grade was not observed, while nearly all patients demonstrated II grade, and only 8.1% of patients receiving Tafluprost experienced III grade. The difference between the study groups and the control group (patients not receiving IOP-lowering drugs) was statistically confirmed (p=0.007). This implies that the patients with POAG are experiencing the most active development of the inflammatory process, albeit the degree of this process is independent of instilled IOP-lowering drugs. The intensity of the inflammation process decreases in all groups during the following periods, and no patient has a Tyndall effect three months after the surgery.

Table 3.
Intensity of the Tyndall effect the among the study groups

Tyndall effect		Groups					Chi-Square Tests	
		1	2	3	4	Total	Compared to I gr.	
							χ2	Sig.
Before the surgery	not	100%	100%	100%	100%	100%		
After 1 day	not	0.0%	0.0%	0.0%	0.0%	0.0%	17.834	0.007
	I	22.2%	0.0%	0.0%	0.0%	5.0%		
	II	77.8%	91.9%	100%	100%	91.3%		
	III	0.0%	8.1%	0.0%	0.0%	3.8%		
After 7 days	not	5.6%	0.0%	0.0%	0.0%	1.3%	8.110	0.230
	I	94.4%	100%	92.9%	100%	97.5%		
	II	0.0%	0.0%	7.1%	0.0%	1.3%		
	III	0.0%	0.0%	0.0%	0.0%	0.0%		
After 1 month	not	94.4%	100%	100%	100%	98.8%	3.488	0.322
	I	5.6%	0.0%	0.0%	0.0%	1.3%		
	II	0.0%	0.0%	0.0%	0.0%	0.0%		
	III	0.0%	0.0%	0.0%	0.0%	0.0%		
After 3 months	not	100%	100%	100%	100%	100%		

The macular part of the eye retina has its own specific structure that promotes the accumulation of the vascular exudates in the intercellular space, this process may be exacerbated due to the inflammatory response, provoked by PGAs[16]. The OCT examination of the macular part of the eye reveals the changes in the macula structure, which may be conditionally divided into the following parts: central (central) with a layer thickness of 220-284 μm; upper (superior) with a layer thickness of 296-347 μm; lower (inferior) with a layer thickness of 293-337 μm; nasal, with a layer thickness of 296-348 μm; temporal,

[16] Sharma, N. Targeting the role of angiogenesis, inflammation and oxidative stress in pathogenesis of glaucoma: Strategic nanotechnology-based drug delivery approaches / Neelam Sharma, Neha Tiwary, Sukhbir Singh [et al.] // Basic and Clinical Angiogenesis, - 2024. - p. 349-380.

with a layer thickness of 265-344 μm. The results of our study are presented in table 4 below. The analysis of the data revealed that macular thickness (MT) was within normal limits in all groups prior to the surgery, and that observed variations in MT in different segments during the postoperative phase were also within normal limits. Thus, 94.4% of patients in group 1 displayed a minor, within-normal range, shift in MT on the 7th day following the Phaco, particularly in the central (1.3%) and upper (1.4%) parts. Only 1 patient (5.6%) had MT thickness of 338.0 μm in the lower part, which exceeds the upper normal level by 1.0 μm.

Table 4.

The results of macular thickness measurements during the perioperative period

Exam. Dates	Part	Macular thickness (μm)				Statistical value	
		Group 1	Group 2	Group 3	Group 4	P_f	P_h
Before the Phaco	Central	245.4±7.8	239.1±4.1	245.4±8.6	235.5±17.5	0.824	0.708
	Nasal	306.3±6.1	300.3±6.5	308.4±7.2	317.0±19.0	0.704	0.729
	Temporal	299.9±7.7	304.6±4.7	295.6±6.4	304.5±20.5	0.793	0.771
	Superior	310.2±5.7	310.6±4.3	304.8±7.1	315.5±16.5	0.847	0.846
	Inferior	304.5±6.4	308.4±3.6	306.1±5.5	313.5±20.5	0.888	0.933
on day 7 after Phaco	Central	242.2±6.8	244.1±3.7	248.5±5.6	243.3±5.7	0.899	0.609
	Nasal	303.2±4.5	301.1±4.0	309.6±4.3	296.0±11.8	0.567	0.697
	Temporal	297.4±4.7	302.1±3.0	293.3±8.1	299.8±6.8	0.614	0.643
	Superior	306.0±4.3	308.8±2.9	308.4±4.5	314.3±5.4	0.691	0.701
	Inferior	303.1±4.5	306.8±2.5	308.8±3.2	305.7±6.2	0.775	0.611
1 month after Phaco	Central	243.8±5.5	253.4±4.4	251.1±5.3	249.0±5.6	0.579	0.694
	Nasal	306.9±4.8	308.6±4.3	313.6±3.7	317.3±5.0	0.577	0.633
	Temporal	301.4±4.9	305.8±3.0	304.2±3.7	305.0±6.8	0.873	0.809
	Superior	308.9±3.9	313.0±2.9	313.5±4.2	317.5±5.7	0.642	0.587
	Inferior	302.8±7.2	310.8±2.6	313.6±2.8	309.9±7.2	0.442	0.694
3 months after Phaco	Central	255.6±7.0	252.3±3.5	252.0±5.8	252.1±5.5	0.959	0.964
	Nasal	312.5±4.9	316.0±3.8	317.8±4.1	321.2±5.2	0.743	0.753
	Temporal	309.8±4.1	310.0±2.9	304.7±4.1	308.9±6.8	0.805	0.640
	Superior	314.4±4.3	316.0±2.9	312.0±5.1	319.6±5.7	0.766	0.774
	Inferior	318.8±6.5	314.6±2.5	315.2±3.9	313.7±6.7	0.878	0.982

One month after the Phaco, 88.9% of patients had MT in all 5 parts within the normal range, and there was a slightly greater MT, mostly pronounced in the temporal part (1.3%). Two patients (11.1%) had MT greater by 3,0 μm than the upper normal level: one of them had

thicker macula in the central part, and the other in the lower part. Three months after the surgery, in one patient, MT in the central part exceeded the upper normal level by 39.0 μm, and in the other patient, the lower part – by 11.0 μm.

On day seven following the Phaco, 97.2% of patients in group 2 showed a minor, statistically insignificant change in MT, with the thickness of the central portion increasing by 2.09% and the remaining portions decreasing. All other markers, however, stayed within the normal range. One patient (2.8%) had its MT reaching 324.0 μm in the central part, which exceeds the upper normal level by 40.0 μm.

All patients experienced a slight, statistically inconclusive rise of MT one month following the Phaco, with the increase being more pronounced in the central part (3.8%). 89.2% of patients (33 patients), had MT in all 5 parts determined within the normal range.

In four patients (10.8%), MT was greater than the upper normal level: in 3 patients in the central part (increased on the 7th day, the macular thickness of 1 patient continued to grow and already reached 330.0 μm, which is 46.0 μm higher than the upper normal level (female, 86 years old), the other had MT of 300 μm, which is 16.0 μm higher than the upper normal level (male, 73 years old), the third had MT of 330.0 μm, which is 46.0 μm higher than the upper normal level (female, 74 years old). 1 patient (female, 74 years old), had the nasal MT exceeding the upper normal level by 35.0 μm, reaching 383.0 μm.

After 3 months, 94.6% of patients had all MT measurements within the normal range. 2 patients (11.8%) had MT higher than upper normal levels: in one case, MT in the central part increased dynamically from day 7 and exceeded the upper normal levels by 48 μm by the end of the 3rd month (female, 86 years old). One month following surgery, another patient, a female, aged 74, had a thickening in the nasal part of the macula. By the end of three months, this thickening increased and exceeded the upper normal level by 42 μm.

The group 3 had no patients experiencing macular thickening above the upper normal level at the end of the experiment.

In group 4, all MT measurements had changed throughout the postoperative period in 90% of the patients by the end of the studies, but were within the normal range, and only one patient (10%, female, 48

years old) had MT in the lower part exceeding the upper normal level by 3 μm. Comparing the positive outcome results (Diagram 1), we can see that 100% of the patients treated with CD , 94.6% of patients treated with Tafluprost, 90% of patients treated with Tafluprost + CD , and 88.2% of the patients not receiving IOP lowering drugs did not demonstrate a pathological MT three months following the Phaco. The difference in the values between the groups is not statistically significant (P>0.05). This finding allows us to assume that Tafluprost, a drug belonging to PGA group, has no impact on the rise in MT during the perioperative use.

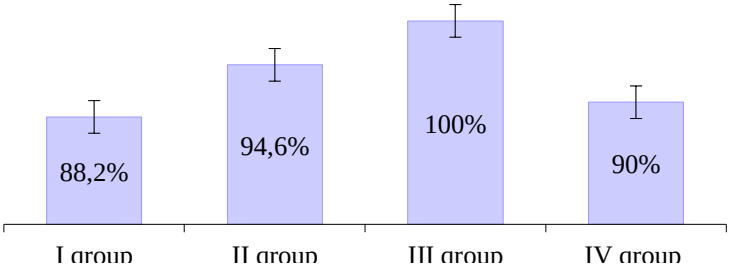

Diagram 1. Number of the patients with concomitant cataract and POAG three months after Phaco having the macular thickness values measured within the normal range (%), with percentage errors indicated.

We can conclude that Tafluprost, as a PGA, does not cause statistically significantly more undesirable side effects, such as decreased VA, the Tyndall effect, and macular thickening, which are summarized in table 5. More than that, Tafluprost reduced IOP more effectively, but also caused more pronounced redness of the conjunctiva. The age of the patients having an increase in macular thickness in 80% of the cases was over 75 years, and 80% of these patients were females.

The statistical analysis of acquired data carried out using Pearson's Chi-square and Kruskal-Wallis H-test for the calculation of the risks related to the use of Tafluprost revealed that the risk factor for the development of such pathologies as Tyndall effect, thickening of macula is the Phaco surgery itself rather than PGA drugs. Thus, there is no statistically proving evidence of the risk of pathological macular thickening due to Tafluprost use in the central part (P=0.712), nasal part

(P=0.387), temporal part (P=0.712), upper part (P=0.637), or lower part (P=0.856).

Table 5.
Clinical and functional indicators of the perioperative use of Tafluprost and a comparison medication in the patients with concomitant cataract and POAG 3 months after the Phaco

Groups	Measured values				
	IOP	VA	No conjunctival hyperemia present	No Tyndall effect present	Macular thickness is within the normal range
I	15.9±0.8	0.913	94.1%	100%	88.2%
II	16.3±0.4	0.889	78.4%	100%	94.6%
III	17.3±0.7	0.907	92.9%	100%	100%
IV	16.9±.5	0.91	90.0%	100%	90%
P	>0.05	>0.05		>0.05	>0.05

Consequently, Tafluprost does not increase the risk of developing ME, according to the results of clinical studies.

Experimental studies

Animal models of glaucoma were used in the first round to examine the efficacy of the study drugs. The glaucoma model was created through instilling 0.1% dexamethasone solution into the eyes of the animals. By day 30, all rabbits had achieved a steady, raised intraocular pressure of 30-31 mm Hg. The studied hypotensive drugs, i.e. Tafluprost and CD reduced IOP down to the reference range. The result of the experiment demonstrated that the drugs have comparable effects. Both drugs reduced IOP down to reference values throughout the whole period of experimental observations. That being said, with Tafluprost the reference values were reached in 10 days, while for CD this took 20 days. Taking into consideration the convenience of the use of Tafluprost, it may be recommended as the most convenient and efficient in terms of the reduction of ocular hypertension.

The second round involved the use of NHS to imitate autoimmune uveitis in animals with ocular hypertension, and the changes were examined against the background of Tafluprost and CD usage. Animal

eyes undergo an inflammatory process when uveitis is modeled similarly, which results in pathomorphological changes that are close to the inflammatory changes seen with Phaco. As the results of the experiment demonstrated, the next day after the right eyes of sensitized Group 2 animals were instilled with a shocking dosage of NHS, uveitis began to manifest clinically. On the third day, the condition grew worse and reached a pronounced severity level. These manifestations, evidencing a pathology development, included corneal opacities in all animals (100%), corneal edema (100%), and precipitates (50%), clouding (62.5%) of the anterior chamber; hypopion (25%); single synechias (43.75%), multiple sinechias (12.5%); pupil occlusion (6.25%); vasodilation, edema on the iris (18.75%); and vitritis (62.5%). Leukocyte counts rose by 95.9% ($P<0.001$) and 90.8% ($P<0.001$) in the blood of both NHS-sensitized animals and uveitis-developing animals, while neutrophil counts fell by 22% ($P=0.417$) and 105.8% ($P<0.001$) accordingly. The overall hemolytic ability of the complement decreased in both samples by 84.4% ($P<0.001$), while the CIC content fell down by 99.1% ($P<0.001$) and 96.9% ($P<0,001$ accordingly. At the same time, there was an 120.5% ($P<0.001$) and 116.8% ($P<0.001$) increase in T-lymphocyte content in the second and third samples, and 93.0% ($P<0,001$) increase in B-lymphocyte content in both samples. The IgE blood levels increased more actively. The IgE concentration rose 5.3 times ($P<0.001$) in the second sample and 6.5 times ($P<0.001$) in the third sample.

The results of the micromorphological studies enabled us to visualize and quantify the alterations in the retina of the eye (Fig. 1-2).

The vascular system of the eye retina experiences pathological changes with persistent ocular hypertension, according to our comparison of the results of microscopy of the sections and morphometry. In particular, the microcirculatory network suffers, with its total area decreasing by 2.2% ($P=0.178$) and the lumen of medium-diameter arteries increasing by 1.4% ($P=0.68$).

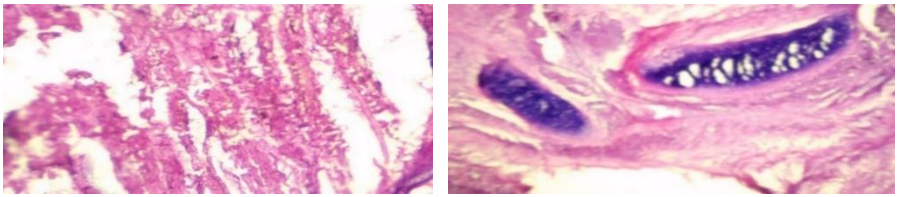

Figure 1 Microscopic section of the rabbit eye retina against the background of the uveitis + Tafluprost model. Hematoxylin and eosin staining. Magnification: ×400

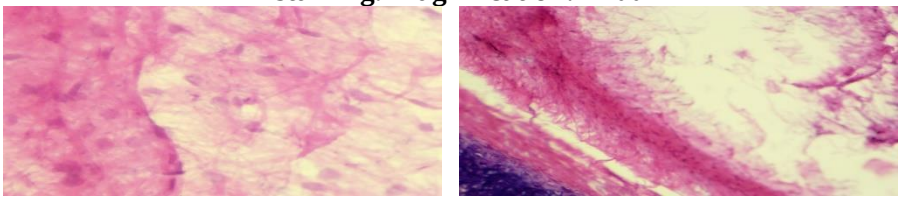

Figure 2. Figure 2 Microscopic section of the rabbit eye retina against the background of NHS sensitization + Tafluprost (left eye). Hematoxylin and eosin staining. Magnification: ×400

There are more noticeable alterations in the retinal vascular bed with sensitization and a developed model of uveitis, particularly in the diameter of functional capillaries, which rose by 12.9% (P=0.022) and capillary diameter Tafluprost deteriorated the vascular bed in the uveitis model and reduced the number of functional capillaries, but it also led to a statistically significantly increase in their diameter (P=0.02).

An ophthalmological examination of the fundus revealed that the macula of all 6 rabbits' (12 eyes) was intact (table 6).

ME was seen in 16.7% of animal eyes against the background of glaucoma model at P=0,699 (Mann-Whitney test), in 16.7% – against the background of sensitization (P=0,699), and in 83.3% – against the uveitis background (P=0.015).

The instillation of CD and Tafluprost against the background of sensitization led to ME in 25% (P=0,491) and 75% (P=0,020) of the animals accordingly. The instillation of CD and Tafluprost against the background of uveitis led to ME in 75% (P=0.020) and 100% (P=0.001) of the animals accordingly.

Table 6.

Macular edema in the eyes of rabbits detected during the examination of the fundus with a manual ophthalmoscope

Groups	No ME present		ME present	
	Count	Column N %	Count	Column N %
Group 1	6	100.0%	0	0.0%
Group 2	5	83.3%	1	16.7%
Group 3	5	83.3%	1	16.7%
Group 4	1	16.7%	5	83.3%
Group 5	6	75.0%	2	25.0%
Group 6	2	25.0%	6	75.0%
Group 7	2	25.0%	6	75.0%
Group 8	0	0.0%	8	100.0%

A comparative analysis (diaq. 2-4) clearly showed the severity of ME in experimental animals. Most ME is observed in animals with uveitis (83.3%) (diaq. 2). Against the background of experimental glaucoma, the use of drugs did not increase the number of MEs (diaqram 3)

Against the background of sensitization, ME increased to 75% with the use of Tafluprost. (diaq. 3). And against the background of experimental uveitis, MO was observed in 100% of animals (diaq. 4).

As the results show, not only the inflammatory process in the eyes, but also overall body sensitization increases the probability of the development of ME.

Thus, against the background of experimental autoimmune uveitis mimicking the postoperative inflammatory process, the risk of developing ME is very high, and Tafluprost increases the risk of ME development even more. Sensitization of the organism with NHS also increases the risk of ME development against the background of Tafluprost usage. That being said, the sensitization of rabbits by NHS against the background of an experimental glaucoma model does not affect the risk of ME development, with this probability not being statistically confirmed (P=1.000). The use of Tafluprost against the background of the glaucoma model also did not increase the risk of ME development.

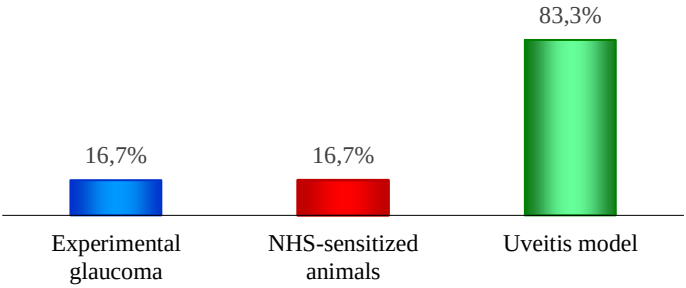

Diagram 2. The percentage of experimental animals with macular edema as opposed to those with intact indicators

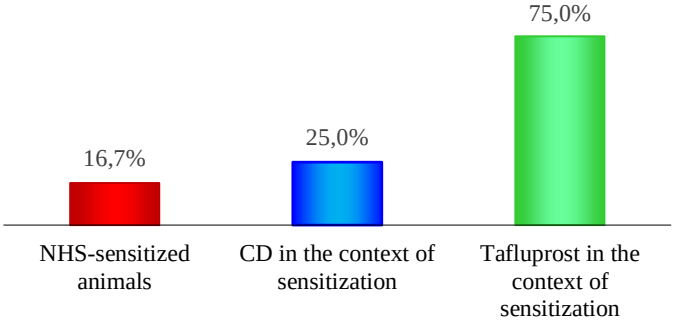

Diagram 3. The occurrence of retinal edema in the experimental animals following the treatment with antihypertensive agents against the background of the sensitization with NHS (CD – comparison drug - a fixed combination drug containing brinzolamide 1% and timolol maliate 0.5%)

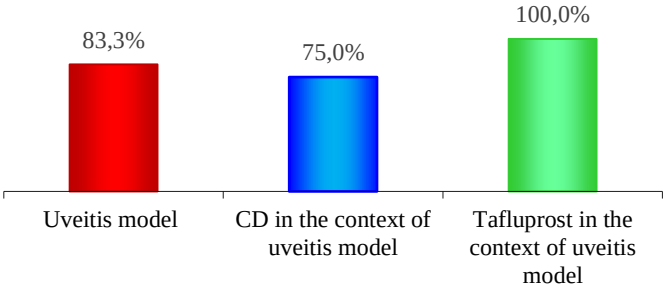

Diagram 4. The occurrence of retinal edema in the experimental animals following the treatment with antihypertensive agents against the background of experimental uveitis model (as compared to intact values) (CD – comparison drug - a fixed combination drug containing brinzolamide 1% and timolol maliate 0.5%)

CONCLUSIONS

1. The study on a representative group of patients (80 patients) yielded the following clinical and functional characteristics: Following surgery, all groups' corrected visual acuity improved. The difference between the indicators of the groups was not statistically significant (P=0.909 and P_h=0.784). Over the whole course of the study, the level of ophthalmotonus in every group stayed within the reference levels. Prior to surgery, 5.6% of patients in group 1 (who did not receive topical therapy), 32.4% of patients in group 2 (who received tafluprost), 20% of patients in group 3 (who received CD), and 10% of patients in group 4 (who received a fixed combination of tafluprost + CD) had I degree conjunctival hyperemia. By the end of the study, I degree hyperemia was observed in group 1 in 5.9% of patients, 21.6% of patients in group 2, 7.1% of patients in group 3, and 10% of patients in group 4 [5]. Tyndall effect of I degree was noted one day after surgery onlyin group 1 in 22.2% of patients, grade 2 in group 1 in 77.8%, In the 2nd group in 91.9%, in the 3rd and 4th groups in 100% of patients.II degree was observed only in group 2 in 8.1 of patients. It subsequently decreases in all groups almost simultaneously and equally (P=0.230), which can be regarded as the absence of a significant effect of the IOP-lowering drugs on the severity of the inflammatory process. No Tyndall effectr was observed in 100% of patients by the end of the study.

2. Depending on the observation groups, the type of structural alterations (increase in macular thickness) observed after three months differs: pathological abnormalities were observed in 11.8% of group 1, 0.6% of group 2, 0% of group 3, and 10% of group 4. However, there was no confirmation of the intergroup statistical difference (P>0.05) [6].

3. Tafluprost reduces IOP in the steroid experimental glaucoma model with satisfactory results.In the same time, IOP, which rose in the model to 30.2 (30-31) mm Hg with tafluprost instillation, fell by 38.74% after 20 days reaching 19.5 (18-19) mm Hg (P=0.04) and stayed within the reference values in the following periods (30 days) (p=0.002). On day 20, the IOP of animals given a fixed comination of 1% brinzolamide and 0.5% timolol malate dropped by 24.8% to 22.7 (22-24) mmHg (p=0.004), and on day 30, it dropped by 37.4% (p=0.002) to 18.9 (18-20) mmHg [9]. Taking into consideration the convenience of the use of

tafluprost, it may be recommended as the most convenient and efficient in terms of the reduction of ophthalmotonus.

4. The model of autoimmune uveitis developed using NHS against the backdrop of ocular hypertension is an appropriate technique for researching the alterations in the retinal vascular system, which create additional pathogenic grounds for ME development risk. Every animal in the resulting model displayed uveitis as a clinical symptom along with related pathomorphological alterations. The total number of leukocytes, neutrophils, and immunological markers rose in animal blood against the background of sensitization and subsequent uveitis [10].

5. Against the background of the glaucoma model, histological sections showed the progressive development of destructive changes in the retina, damage to the retinal nerve fiber layer and ganglion cells, hydrodynamics, with an increase in the content of intraocular fluid, and microcirculation disorders in animals. The overall area of the microcirculatory network of the animal retina was 2.2% (P=0.178) smaller than that of intact parameters, according to the morphometric analyses of the retinal vascular bed. In the uveitis model against the background of ocular hypertension, hydrodynamic disorders increased, the permeability of the retinal vessels increased both in the center and on the periphery. The use of tafluprost increases the vascular permeability, while the comparison medication does not have any impact in this regard. At the same time, tafluprost significantly increased the diameter of the vessels – by 15.9% (P=0.002). Remaining parameters like macular thickness CD, total area of medium-diameter arteries was changed almost in all animals, though these changes were not statistically significant. [1,11]. While the inflammatory process in the eyes and body sensitization raise the chance of getting ME, POAG does not raise the risk of developing ME in intact eyes or against the background of experimental glaucoma in this experiment [11].

6. It is advised not to stop the instillation of tafluprost in order to maintain a safe level of intraocular pressure as the studies' findings indicate that it does not cause pathological changes in patients who do not have surgical complications or concurrent systemic diseases.

PRACTICAL RECOMMENDATIONS

1. It is recommended to continue with the original hypotensive regimenwith APG in patients with concomitant POAG and cataract following uncomplicated phacoemulsification, taking into account the degree of ophthalmotonus, and the efficacy and safety of PGA.

2. The role of the immune status and inflammatory markers in raising the risk of developing CME in clinical studies must be investigated in light of the experimental data acquired in this study in order to prevent an increased risk of developing CME following a FE surgery with the perioperative prescription of Tafluprost.

3. The outcomes of the experimental studies can be utilized by medical university students, physicians, and other healthcare professionals.

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ABBREVIATIONS

AA – Area of the Arteries
CIC – Circulating Immune Complexes
CME – Cystoid Macular Edema
CME– Cystoid Macular Edema
DA – Diameter of the Arteries
DFC – Diameter of Functional Capillaries
FC – Functional Capillaries
HRB – Hematoretinal Barrier
IgE – immunoglobulin E
IOP – Intraocular Pressure
ME – Macular Edema
MN – Microcirculatory Network
MT – Macular Thickness
NHS – Normal Horse Serum
PGAs – Analogues of Prostaglandins
Phaco – Phacoemulsification of Cataracts
POAG – Primary Open-Angle Glaucoma

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