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Evaluation of retinal thickness and of pseudophakic cystoid macular edema incidence in patients with primary open-angle glaucoma treated with prostaglandin analogues

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BACKGROUND: Cataract is often associated with primary glaucoma. Prostaglandin analogues use is considered to be a risk factor for pseudophakic cystoid macular edema.

PURPOSE: To evaluate the effect of prostaglandin analogues and non-steroidal anti-inflammatory medications on the central retinal thickness and the incidence of pseudophakic cystoid macular edema after phacoemulsification with intraocular lens implantation in patients with primary open-angle glaucoma.

MATERIALS AND METHODS: 91 patients were enrolled in the study. The first and the second main groups included 22 patients (22 eyes) each. All patients in main groups had glaucoma and were treated with prostaglandin analogues. 47 patients (57 eyes) without glaucoma were included in the control group. After phacoemulsification, patients from all groups were treated with topical antibiotics and steroids. Patients in the main second and in the control groups received also non-steroidal anti-inflammatory drops. The retinal thickness was measured by optical coherence tomography 2 weeks, 2 months and 6 months after surgery.

RESULTS: After surgery, the foveal thickness in patients of the first and the second groups increased, but returned to the preoperative level after 6 and 2 months, respectively. The foveal thickness in the control group decreased after surgery, and it increased gradually but did not achieve the preoperative values.

CONCLUSION: Prostaglandin analogues use after phacoemulsification with intraocular lens implantation does not affect the incidence of pseudophakic cystoid macular edema. Prescribing non-steroidal anti-inflammatory drops after the surgery helps achieving more rapid normalization of the central retinal thickness.

Keywords: retinal thickness; fovea; phacoemulsification; primary open-angle glaucoma; prostaglandin analogues; pseudophakic cystoid macular edema; non-steroidal anti-inflammatory drops; optical coherence tomography.

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Оценка толщины сетчатки и частоты развития псевдофакичного кистозного макулярного отёка у больных первичной открытоугольной глаукомой, получающих аналоги простагландинов

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Цель. Оценить влияние аналогов простагландинов и нестероидных противовоспалительных препаратов на толщину фовеолярной сетчатки и развитие псевдофакичного кистозного макулярного отёка после факоэмульсификации с имплантацией интраокулярной линзы у больных первичной открытоугольной глаукомой.

Материалы и методы. В исследование включен 91 пациент. В первую и вторую основные группы вошли по 22 человека (22 глаза), получающие аналоги простагландинов. Контрольную группу составили 47 пациентов (57 глаз) без сопутствующей глаукомы. Исследуемые всех групп получали после операции кортикостероиды и антибиотики, пациенты второй основной и контрольной групп также получали нестероидные противовоспалительные препараты. Методом оптической когерентной томографии оценивали толщину центральной зоны сетчатки до и через 2 нед., 2 и 6 мес. после операции.

Результаты. Толщина сетчатки в фовеа после факоэмульсификации в основных группах была увеличена и вернулась к исходным значениям через 6 мес. в первой группе и через 2 мес. во второй, в контрольной группе — через 2 нед. после операции была ниже дооперационных значений, затем постепенно возрастала, но не достигла исходного уровня.

Заключение. У прооперированных нами пациентов, получающих аналоги простагландинов, после факоэмульсификации с имплантацией интраокулярной линзы псевдофакичный кистозный макулярный отёк не выявлен. Применение нестероидных противовоспалительных препаратов в послеоперационном периоде стабилизирует толщину сетчатки и способствует восстановлению её нормальной толщины.

Ключевые слова: толщина сетчатки; фовеа; факоэмульсификация; первичная открытоугольная глаукома; аналоги простагландинов; псевдофакичный кистозный макулярный отёк; нестероидные противовоспалительные средства; оптическая когерентная томография.

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INTRODUCTION

Surgical procedure is known to be currently the only effective treatment for cataracts. One of the significant complications after cataract extraction is pseudophakic cystoid macular edema (PCME), which is a common cause of painless decrease in visual function in the postoperative period.

CME is defined as the accumulation of fluid in the outer plexiform layer and the inner nuclear layer, as well as edema of the Mueller cells of the retina. CME consists in local expansion of the extracellular space of the retina (sometimes related with the intracellular space) in the macular region [1]. Depending on the cause and mechanism of occurrence, there are diabetic ME (DME), postocclusive CME, postoperative or pseudophakic (artiphakic) CME, and CME in presence of concomitant inflammatory diseases (uveitis). In our study, only PCME is considered.

Despite the fact that PCME was first identified 40 years ago, the pathogenesis is still not fully understood [2–6]. The risk factors of PCME, on the other hand, are well-known. PCME is caused by a disorder of the blood-retinal barrier and/or vitreomacular traction in complicated surgery [7, 8]. In surgical trauma, the iris can produce inflammatory mediators (mainly prostaglandins), which disrupt the blood-retinal barrier, increasing vascular permeability in postoperative inflammation [9–11].

The risk factors for the development of PCME include the following:

1) Type of surgical intervention or type of surgical access [8, 12]:

- Intracapsular extraction – 7–24% [7];
- Extracapsular extraction – 2–6.7% [13];
- Phacoemulsification (PE) – up to 0.1%–2% [14];

2) Intraoperative factors:

- Radiation intensity of the operating microscope [15];
- Power and duration of ultrasound and/or different types and models of phacoemulsifiers [16];

3) Intraoperative complications [6] (rupture of the posterior capsule, vitreous prolapse, retention of the lens masses and traction of the vitreous [10, 11, 17]);

4) Severity of inflammation in the anterior segment.

As a rule, CME occurs 4–12 weeks after surgery [10, 11, 17].

In 14%–77% of cases, cataract occurs in combination with glaucoma, and more than 50% of patients with primary open-angle glaucoma (POAG) follow the IOP-lowering drug regimen [18]. Prostaglandin analogs (PGA) are widely used not only as monotherapy, but also in combination treatment. The literature presents data on the correlation between the use of PGA and CME. In early studies, it was shown that PCME is associated with the topical application of latanoprost in POAG patients [19–21]. According to some authors, PGA may be a risk factor that increases the probability of PCME [22–24]. There is also a theory that the preservative, not the active ingredient of PGA, is the major cause of CME [19]. Some researchers believe that retinal thickening after PE in POAG patients on the background of PGA therapy may be caused by PGA disrupting the blood-aqueous barrier of the pseudophakic eye [25–27]. Despite the large number of published works focused on this problem, the question on the safety of PGA use in the preoperative and postoperative periods of PE with intraocular lens (IOL) implantation in POAG patients has not yet been resolved. Due to the increase in the state of the art for performing PE, surgical trauma and inflammatory response in the postoperative period were significantly reduced, and intraoperative complications were minimized. On the other hand, in clinical practice in the postoperative period for the prevention of CME, non-steroidal anti-inflammatory drugs (NSAIDs) are widely used to inhibit the synthesis of prostaglandins [19].

Optical coherence tomography (OCT) is a non-contact, non-invasive examination for obtaining high-resolution biomicroscopic imaging. With the development of OCT, fluorescein angiography has been replaced as the leading method for CME diagnosis [28, 29].

The study aimed to assess, based on OCT data, the effect of PGA and NSAIDs on the foveal retinal thickness after PE with IOL implantation and the incidence of PCME in the postoperative period in POAG patients.

MATERIALS AND METHODS

The study included 91 patients (101 eyes) with cataracts, who were admitted for surgical treatment at the St. Petersburg city multi-field hospital No. 2 from March 2018 to October 2020. The follow-up period was 6 months. Forty-four patients (44 eyes) had cataracts with POAG and received IOP-lowering monotherapy with PGA. These patients were distributed into two main groups. The main group 1 included 22 patients (22 eyes) aged 61–87 years (mean age 74.4 ± 7.4 years), to whom standard instillations (antibiotics and glucocorticoids) were prescribed in the postoperative period; the main group 2 included 22 patients (22 eyes) aged from 54 to 88 years (mean age 73.4 ± 9.3 years), to whom antibiotics, glucocorticoids, and NSAIDs were prescribed in the postoperative period. The control group consisted of 47 patients (57 eyes) aged 53–84 years (mean age 70.8 ± 8.3 years) who had cataracts but no POAG, and in the postoperative period, instillations of an antibiotics, glucocorticoids, and NSAIDs were prescribed to them.

Patient inclusion criteria:

- POAG stages I–III compensated with PGA monotherapy;
- Various stages of uncomplicated cataract;

• Without intraoperative complications (posterior capsule rupture, vitreous prolapse, remnants of lens masses, trauma to the iris, etc.).

Exclusion criteria:

• Concomitant systemic conditions, such as diabetes mellitus and rheumatoid diseases;

• Concomitant ocular conditions (uveitis, "wet" age-related macular degeneration, macular hole, secondary glaucoma, vascular diseases of the retina, vitreomacular traction syndrome and refractive amblyopia);

• History of eye surgeries and trauma.

Diagnosis of cataract and POAG was performed based on complaints, medical history, and analysis of the results of instrumental examinations. Before and after PE, all patients were subjected to standard ophthalmological examinations, including auto-refractometry, visual acuity testing, gonioscopy, tonometry, perimetry, biomicroscopy, and ophthalmoscopy; additional examinations included OCT performed on the RTVue-100 device (Optovue, USA).

Patients of the main group constantly used one of the PGA drugs or prostamides (latanoprost, travoprost, tafluprost, or bimatoprost). Intraocular pressure was measured using an ICare TA01i tonometer (Finland). The dynamics of glaucoma stabilization was assessed using static (threshold) automated perimetry using the Pericom perimeter. The examination of retinal and the analysis of the data based on the Retina thickness map protocol (the retina thickness in the 1-mm zone) were performed using an RTVue-100 optical coherence tomograph (Optovue, USA). The study was performed before surgery, after 2 weeks, 2 months, and 6 months after the surgery.

All patients underwent standard PE with implantation of various IOL models using an Infiniti phacoemulsifier (Alcon, USA) by the same experienced surgeon. At the end of surgery, the ultrasonic, temporal, and hydrodynamic parameters of the PE were recorded. All surgical procedures were performed without intraoperative complications.

In the postoperative period, all subjects received treatment according to the following schemes. Patients in main group 1 received PGA q. d. at bedtime. After surgery, they received levofloxacin 0.5% q.i.d. for 2 weeks and dexamethasone 0.1% for 4 weeks tapering the dose from q.i.d. to q.d. In the group 2, additional nepafenac 0.1% was prescribed t.i.d. for 4 weeks. The control group had a similar regimen of postoperative treatment.

Statistical processing of the material was performed using the IBM SPSS Statistics Subscription software, the mean value and standard deviation were calculated, and the differences between the groups were determined according to OCT data before and after surgery by one-way analysis of variance. Differences between the results of measurements before and at different times after surgery in each group were determined using the Student's *t*-test. Pearson's correlation analysis was used to assess the correlation between PE parameters and retinal thickness.

RESULTS

All patients were examined before surgery and after 2 weeks, 2 months, and 6 months after it.

Next day after the surgery, biomicroscopy revealed that all patients had a moderate mixed redness of the eyeball, the cornea was transparent or there was mild keratopathy, anterior chamber fluid had minor opalescence ("+"/"++"), the pupil reaction to light was retained, and the IOL was in the correct position. The posterior capsule was intact and transparent. After the surgery, high visual functions were registered in all patients (Table 1). Intraocular pressure in patients was normalized throughout the follow-up period (Table 2).

All patients underwent OCT using an RTVue-100 device (Optovue, USA) before and after surgery; the results the retinal thickness measurements are presented in Table 3. The dynamics of thickness changes of the foveolar retina at different times is presented in Fig. 1 and Fig. 2.

The numerical data in our study were shown to have a normal distribution and uniform variance using Kolmogorov–Smirnov test and variance analysis. For all the results obtained, a multiple comparison was performed (LSD and Bonferroni test).

Based on the results of the foveal retinal thickness evaluation, no statistically significant differences were

Table 1. Visual acuity in groups, *M* ± *SD* (*n* = 101)

Таблица 1. Острота зрения в группах сравнения, *M* ± *SD* (*n* = 101)

Group	Before surgery	After surgery		
		after 2 weeks	after 2 months	after 6 months
I (*n* = 22)	0.1 ± 0.1	0.8 ± 0.2	0.8 ± 0.2	0.9 ± 0.1
II (*n* = 22)	0.3 ± 0.1	0.8 ± 0.2	0.9 ± 0.2	0.9 ± 0.1
Control (*n* = 57)	0.3 ± 0.2	0.9 ± 0.1	0.9 ± 0.1	0.9 ± 0.1

revealed between the groups before and 2 weeks and 2 months after the surgery ($p > 0.05$); 6 months after surgery, there was a statistically significant difference between the group 2 and the control group ($p < 0.05$).

Statistically significant differences were found between the preoperative data on the retinal thickness in the fovea and the results at different times after the surgery in each group ($p < 0.001$).

The surgery duration did not have significant differences between the groups, although there were differences in the spent cumulative energy of ultrasound and aspirated balanced salt solution ($p < 0.05$) (Table 4). Moreover, these intraoperative factors (spent cumulative ultrasound energy, balanced salt solution, and surgery duration) did not correlate with changes in retinal thickness in the foveal area.

Table 2. IOP by ICare in groups, *M* ± *SD* (*n* = 101)

Таблица 2. Параметры внутриглазного давления по ICare в группах сравнения, *M* ± *SD* (*n* = 101)

Group	Before surgery, mmHg	After surgery, mmHg		
		after 2 weeks	after 2 months	after 6 months
I (*n* = 22)	15.0 ± 2.5	15.7 ± 3.7	13.0 ± 2.1	13.7 ± 3.8
II (*n* = 22)	15.4 ± 1.9	16.9 ± 4.8	15.0 ± 2.4	12.8 ± 3.4
Control (*n* = 57)	15.3 ± 3.8	14.5 ± 3.5	13.0 ± 3.2	13.1 ± 34

Table 3. Foveal thickness in groups, *M* ± *SD* (*n* = 101)

Таблица 3. Толщина сетчатки в фовеа в группах сравнения, *M* ± *SD* (*n* = 101)

Group	Before surgery, μm	After surgery, μm		
		after 2 weeks	after 2 months	after 6 months
I (*n* = 22)	250.2 ± 18.0	253.1 ± 25.8	258.0 ± 22.7	258.7 ± 13.6
II (*n* = 22)	248.1 ± 22.5	251.0 ± 21.9	250.2 ± 17.3	241.3 ± 14.6
Control (*n* = 57)	266.0 ± 1.4	251.0 ± 1.4	255.0 ± 7.1	258.3 ± 16.6

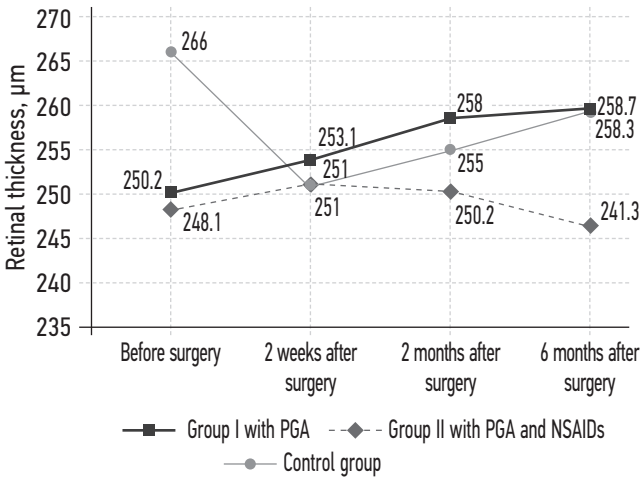

Fig. 1. Dynamics of foveal thickness at different follow-up periods in groups

Рис. 1. Динамика толщины сетчатки в фовеа в различные сроки наблюдения в группах сравнения

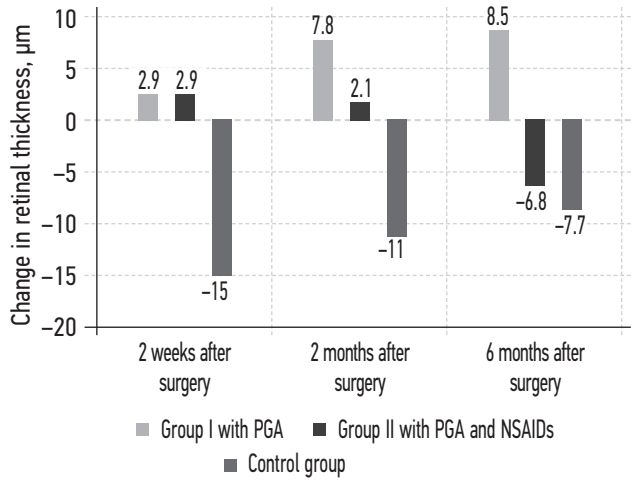

Fig. 2. Dynamics of the difference from the initial level of foveal thickness at different follow-up periods of observation in groups

Рис. 2. Динамика отличия от исходного уровня центральной толщины сетчатки в различные сроки наблюдения в группах сравнения

Table 4. Parameters of phacoemulsification in groups, *M* ± *SD* (*n* = 101)
Таблица 4. Параметры факоэмульсификации в группах сравнения, *M* ± *SD* (*n* = 101)

Group	Cumulative energy used, kJ	Balanced irrigation solution, ml	Surgery duration, min
I (*n* = 22)	15.1 ± 7.3	63.2 ± 15.1	7.5 ± 1.6
II (*n* = 22)	8.1 ± 4.3	55.3 ± 15.0	6.8 ± 1.9
Control (*n* = 57)	9.9 ± 7.7	51.8 ± 12.4	7.1 ± 2.3

DISCUSSION

There were no patients participating in the study who had systemic and/or ocular diseases that increased the probability of CME. In addition, there were no intraoperative or postoperative complications. In the course of the study, no patient with PCME was identified. Many studies have revealed that after PE in patients using PGA, the probability of developing PCME does not increase [18, 30, 31].

The results of our study reveal that according to the OCT data of the one-millimeter central zone of the retina, the parameters of its thickness in patients of the group 1 increased gradually after the surgery, and these were +2.9 microns after 2 weeks, 0.01% of the initial level; +7.8 microns after 2 months, 0.03% of the initial level; +8.5 microns after 6 months, 0.03% of the initial level (Tables 4, 5, Figs. 1, 2). Our data support the conclusions of the study by S. Yu. Astakhov et al. [18], who found that in patients receiving IOP-lowering therapy after PE for 6 months, the retinal thickness increases, and returns to its initial values by the end of the year one after surgery. In 2008, a study was performed in which NSAIDs were not used in the postoperative period, while the retinal thickness in the fovea area after PE increased in all groups after 8 weeks, but in POAG patients using IOP-lowering medications, the thickening of the retina was two times higher than in patients without POAG [27].

Patients of the groups 1 and 2 were characterized by minor increase in the central retinal thickness 2 weeks after the surgery (+2.9 microns, 0.01% of the initial level). However, in the group 2, receiving NSAID instillations, the restoration of the initial retinal thickness began earlier (after 2 months) and took less time (less than 6 months, Tables 4, 5, Figs. 1, 2).

Many studies have focused at changes in the retinal thickness after PE of uncomplicated cataract, with the prescription of antibacterial and steroid therapy after surgery. Within 6 months, the increase in the central thickness of the retina varied (from 17.33 to 23.68 μm) within the normal range [32, 33]. However, H. Ching et al. [34] obtained opposite results in the form of a decrease in the retinal thickness in the foveal area after PE after 2, 4, and 8 weeks (–14, –9, and –13 μm, respectively). They suggested that this may be due to an error in OCT measurements due to lens opacity and restoration of the transparency of optical media after surgery. A similar effect of retinal thickness decrease was obtained in the control group. It should be borne in mind that the effect of restoring the transparency of optical media on the result of the retinal OCT can lead to underestimation of its real thickening in other groups.

A number of studies have demonstrated that in patients with uncomplicated cataracts using NSAIDs instillations, the central retinal thickness maximally increased (up to 10.2 μm) in the postoperative period at 12 weeks and 3 months after surgery, and did not return to the initial level within 6 months [35–37]. The authors of these studies believe that in the postoperative period, the use of NSAIDs slowed down the rate of retinal thickening. In our study, the central retinal thickness in patients of the control group decreased 2 weeks after surgery (–15 μm, 0.05% of the initial level), then gradually returned to the initial level, but did not reach it, as the average difference from the initial level was –11 μm after 2 months, and –7.7 μm after 6 months (Tables 4, 5, Figs. 1, 2).

There are many reports focused on the prescription of NSAIDs for the prevention and treatment of CME [16, 38], but the question of the additional benefits of NSAIDs when using steroid instillations after PE of uncomplicated

Table 5. Mean change of foveal thickness at different follow-up periods, *M* ± *SD* (*n* = 101)
Таблица 5. Среднее изменение толщины сетчатки в фовеа в различные сроки наблюдения, *M* ± *SD* (*n* = 101)

Group	Before surgery, μm	After surgery, μm		
		after 2 weeks	after 2 months	after 6 months
I (*n* = 22)	250.2 ± 18.0	2.9 ± 7.8	7.8 ± 4.7	8.5 ± 4.4
II (*n* = 22)	248.1 ± 22.5	2.9 ± 0.6	2.1 ± 5.2	–6.8 ± 7.9
Control (*n* = 57)	266.0 ± 1.4	–15 ± 0	–11 ± 5.7	–7.7 ± 15.2

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cataract for the prevention of CME has long remained open. However, in 2018, the PREMED study proved the efficiency of 0.09% bromfenac for the prevention of CME [39].

In the course of our investigation, it was proven that instillation of NSAIDs after PE of uncomplicated cataract in patients receiving PGA accelerates the return to the initial thickness of the retina.

The use of eye drops with NSAIDs in the postoperative period can reduce the effect of retinal thickening and accelerate its return to the initial level.

In case of successful PE of uncomplicated cataract in the absence of systemic and local factors that increase the probability of CME, the use of NSAIDs in the form of eye drops in the postoperative period is not obligatory even with the use of PGA.

CONCLUSION

In POAG patients receiving PGA after PE with IOL implantation for 6 months, no PCME was detected.

ADDITIONAL INFORMATION

Conflict of interest. The authors declare no conflict of interest.

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