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Scientific article

Experience of the anti-inflammatory eye drops Ivinak®-SOLOpharm use in patients after cataract surgery

© Yurii I. Pirogov[1, 2, 3], Fedor N. Rozhdestvenskiy[1, 2], Polina A. Dzitstsoeva[1, 4], Aleksandra Yu. Artiushenko[1, 5]

[1] City Hospital No. 26, Saint Petersburg, Russia;
[2] Medical Center, Admiralteyskiye verfi Ltd., Saint Petersburg, Russia;
[3] Saint Petersburg State University, Saint Petersburg, Russia;
[4] City Hospital No. 40, Polyclinic Department No. 68, Saint Petersburg, Russia;
[5] City Hospital No. 98, Saint Petersburg, Russia

BACKGROUND: The prevalence of inflammatory complications that occur after phacoemulsification remains an unsolved problem.

AIM: To analyze the results of the use of Ivinak®-SOLOpharm eye drops containing 0.09% bromfenac solution in the complex of anti-inflammatory therapy in patients after cataract surgery in comparison with similar drugs from other manufacturers.

MATERIALS AND METHODS: The study included 60 patients (60 eyes) with a diagnosis of "age-related cataract", who underwent phacoemulsification. All patients were divided into 2 groups: in the first group, patients used Ivinac eye drops 3 days before surgery and 20 days after it; in the second group, patients used another similar drug containing 0.09% bromfenac solution according to an identical scheme. All patients underwent visual acuity testing and keratopachimetry before and after surgery. On Day 4 and Day 20 after surgery, the degree of inflammatory reaction of the eye was assessed by the number of cells in the anterior chamber fluid, subjective signs of inflammation in patients, using the OSDI (Ocular Surface Disease Index) questionnaire.

RESULTS: When analyzing the obtained data, no statistically significant differences were found between the groups in terms of best corrected visual acuity, corneal thickness, number of cells in the anterior chamber fluid, and subjective symptoms of inflammation in patients.

CONCLUSIONS: Ivinak®-SOLOpharm has proven its effectiveness and safety in the perioperative prevention of inflammatory processes in phacoemulsification.

Keywords: phacoemulsification; inflammation; eye drops; bromfenac.

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Научная статья

Опыт применения глазных капель противовоспалительного препарата «Ивинак®-СОЛОфарм» у пациентов после хирургии катаракты

© Ю.И. Пирогов[1, 2, 3], Ф.Н. Рождественский[1, 2], П.А. Дзиццоева[1, 4], А.Ю. Артюшенко[1, 5]

[1] Городская больница № 26, Санкт-Петербург, Россия;
[2] Медицинский центр АО «Адмиралтейские верфи», Санкт-Петербург, Россия;
[3] Санкт-Петербургский государственный университет, Санкт-Петербург, Россия;
[4] Городская больница № 40, Поликлиническое отделение № 68, Санкт-Петербург, Россия;
[5] Городская поликлиника № 98, Санкт-Петербург, Россия

Актуальность. Остаётся нерешённой проблемой частота осложнений воспалительного характера, возникающих после факоэмульсификации катаракты.

Цель — провести анализ результатов применения глазных капель «Ивинак®-СОЛОфарм», содержащих 0,09 % раствор бромфенака, в комплексе противовоспалительной терапии у пациентов после хирургии катаракты в сравнении с аналогичными препаратами других фирм производителей.

Материалы и методы. В исследование было включено 60 пациентов (60 глаз) с диагнозом «возрастная катаракта», которым была выполнена факоэмульсификация катаракты. Все пациенты были разделены на 2 группы: в первой группе пациенты применяли глазные капли «Ивинак®-СОЛОфарм» 3 дня до операции и 20 дней после; во второй группе — другой аналогичный препарат, содержащий 0,09 % раствор бромфенака, по идентичной схеме. Всем пациентам до и после операции проводили визометрию и кератопахиметрию. На 4-е и 20-е сутки после операции оценивали степень воспалительной реакции глаза по количеству клеток во влаге передней камеры, субъективные признаки воспаления у пациентов, с помощью опросника OSDI (Ocular Surface Disease Index — Индекс заболеваний поверхности глаз).

Результаты. При анализе полученных данных статистически значимого различия между группами по максимальной корригированной остроте зрения, толщине роговицы, количеству клеток во влаге передней камеры глаза, субъективным ощущениям пациентов выявлено не было. Ивинак доказал эффективность и безопасность в периоперационной профилактике воспалительных процессов при факоэмульсификаци катаракты.

Выводы. Ивинак®-СОЛОфарм доказал эффективность и безопасность в периоперационной профилактике воспалительных процессов при факоэмульсификации катаракты.

Ключевые слова: факоэмульсификация; воспаление; глазные капли; бромфенак.

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ЭКО•ВЕКТОР

BACKGROUND

Cataract phacoemulsification is currently the most popular ophthalmic surgery worldwide. Continuous improvement of a surgical technology has positioned this technique among most predictable and advanced ones [1]. However, the incidence of inflammatory complications that occur in 5–15% of the cases after this surgery remains an unresolved problem. This means that visual functions decrease, and the terms of postoperative rehabilitation increase. The smooth course of the postoperative period is largely determined by the efficiency of a medical support after the surgery [2]. Therefore, studying the effect of various new drugs and treatment regimens aimed at preventing such complications is very important [3].

To this day, a combination of non-steroidal anti-inflammatory drugs, steroids, and antibiotics is the best option for a standard postoperative management of patients [4].

Bromfenac is a non-steroidal anti-inflammatory drug that relieves all signs of inflammation caused by surgical trauma during cataract surgery. Bromfenac is safe, and it is well tolerated. According to many researchers, the efficiency of bromfenac is higher, and the incidence of side effects is lower than that of other drugs in this group [5].

Ivinak®-SOLOpharm is a new ophthalmic solution with bromfenac as the active ingredient. The advantages of the medication include low content of the preservative – benzalkonium chloride (0.001%), presence of hydroxypropyl betadex among excipients, as well as convenient original bottle with the strike-stop.

The study aimed to analyze the results of the use of Ivinak®-SOLOpharm eye drops containing 0.09% bromfenac solution in the complex of anti-inflammatory therapy in patients after cataract surgery, in comparison with similar drugs produced by other manufacturers.

MATERIALS AND METHODS

This study, carried out at the city hospital No. 26, St. Petersburg, included 60 patients (60 eyes), aged 60–85 years, diagnosed with an age-related cataract. The gender distribution was 10 men and 50 women. Exclusion criteria were the absence of history of uveitis and diabetes mellitus, as well as of disorders of the anterior and posterior eye segments, which could increase the risk of cystoid macular edema. All patients underwent cataract surgery by phacoemulsification with intraocular lens implantation. All surgeries were performed through a temporal corneal incision 2.2 mm wide using the Visalis surgical unit (Zeiss, Germany). Acrysof intraocular lenses were implanted. During the procedure, BSS and DisCoVisc viscoelastic were used intraocularly. All included in this study patients were distributed into two groups depending on the postoperative treatment regimen. Instillations of eye drops of 0.5% solution of levofloxacin q.i.d., and non-steroidal anti-inflammatory drug Ivinak®-SOLOpharm b.i.d. were prescribed to the group 1 patients (30 eyes) for three days before surgery. In the postoperative period from the Day 1, the regimen of instillations changed (0.5% solution of levofloxacin 6X/day; 0.1% dexamethasone solution q. i.d. until the Day 10 after surgery). Two instillations of Ivinak per day were used until the Day 20 after surgery, and then discontinued. The group 2 included patients (30 eyes) who received a similar medication containing 0.09% bromfenac solution, according to an identical treatment regimen instead of Ivinak eye drops.

All patients underwent visual acuity testing without correction and with best correction, tonometry, biomicroscopy of the anterior segment of the eye, according to the standard follow-up protocol. In addition, before the surgery, on Day 4 and Day 20 after surgery, the corneal thickness was measured, and the degree of the ocular inflammatory reaction was objectively assessed by a number of cells in the anterior chamber fluid. Cells in the anterior chamber fluid were counted in the thinnest light beam passing within the optical zone of the media. Patients' subjective feelings of discomfort were studied using the Ocular Surface Disease Index (OSDI) questionnaire. The results obtained were statistically processed using the GraphPadPrism 8 program.

RESULTS

The mean best corrected visual acuity (BCVA) in the groups preoperatively (Table 1) was approximately the same (0.19 ± 0.16 and 0.20 ± 0.15, respectively). On Day 4 and Day 20 after surgery, the BCVA of the group 1 patients was slightly higher than that of the group 2 patients. However, statistically significant difference was not found by analyzing the data obtained ($p > 0.05$).

When analyzing keratopachymetry results (Table 2), an increase in the corneal thickness (on average by the 41 and 42 μm, respectively) was revealed in both groups in the early postoperative period, due to postoperative subclinical corneal edema (a statistically significant difference between the index before a surgery and that on the Day 4 after surgery, $p < 0.05$). By the Day 20 after surgery, in both groups of patients, the corneal thickness almost returned to preoperative values ($p < 0.05$), remaining on average 10.03 and 10.00 μm more than that before the surgery, respectively. There was no statistically significant difference between the keratopachymetry data of patients before surgery and on the Day 20 after surgery ($p > 0.05$).

When investigating subjective sensations of patients using the OSDI questionnaire (Table 3), it was found that in the early postoperative period (on the Day 4 after surgery), patients of both groups noted moderate complaints associated, as expected, with the procedure, namely a feeling of dust in the eye, increased light sensitivity, soreness, tearing, blurred vision, difficulty in reading or watching TV, slight discomfort when going outside in windy weather, etc. OSDI scores in the groups were almost equal (20.63 and 21.67 points, respectively). When interviewing patients on the Day 20 after surgery, the number of similar complaints of patients decreased in both

Table 1. Comparative dynamics of the Best Corrected Visual Acuity of patients in the groups
Таблица 1. Сравнительная динамика максимальной корригированной остроты зрения пациентов в группах

Stages	Group 1	Group 2
Before surgery	0.19 ± 0.16	0.20 ± 0.15
Day 4 after surgery	0.84 ± 0.24	0.75 ± 0.28
Day 20 after surgery	0.94 ± 0.15	0.83 ± 0.22

Table 2. Comparative dynamics of corneal pachymetry (μm) of patients in groups
Таблица 2. Сравнительная динамика кератопахиметрии (мкм) пациентов в группах

Stages	Group 1	Group 2
Before surgery	556.8 ± 29.87	545.4 ± 33.14
Day 4 after surgery	598.8 ± 68.52	587.9 ± 64.28
Day 20 after surgery	566.8 ± 32.97	555.4 ± 34.30

Table 3. Comparative dynamics of the severity of subjective discomfort in patients, according to the OSDI questionnaire score (in points)
Таблица 3. Сравнительная динамика выраженности субъективного дискомфорта пациентов по опроснику OSDI (баллы)

Stages	Group 1	Group 2
Day 4 after surgery	20.63 ± 12.91	21.67 ± 13.72
Day 20 after surgery	10.69 ± 5.558	13.61 ± 8.017

groups. At the same time, according to the analysis results, the satisfaction of patients treated with Ivinak was slightly higher than that in the control group (10.69 and 13.61 points, respectively), mainly due to a decrease in the number of complaints about the feeling of dust in the eye, tearing, and blurred vision. No statistically significant difference was found between the groups ($p > 0.05$).

During the examination on the Day 4 after surgery, cells in the anterior chamber fluid were detected in four patients from the group treated with Ivinak, and in six patients from the control group, as well as in small amount (⩽6 cells per field of view) in all cases. On the Day 20 after surgery, cells in the anterior chamber fluid were not detected in any of both groups' patients.

DISCUSSION

Eye drops of the non-steroidal anti-inflammatory drug Ivinak®-SOLOpharm, containing 0.09% bromfenac solution, have demonstrated their efficiency, comparable to that of already available on the Russian market eye drops, in preventing inflammation and relieving discomfort in patients during the postoperative period. This is proven by the examination results (the number of cells in the anterior chamber fluid, keratopachymetry data) and by subjective sensations of patients according to the OSDI questionnaire. It could be assumed that the presence in the composition of the medication of the auxiliary substance hydroxypropyl betadex from the class of cyclodextrins, which increases solubility and bioavailability of the active substance molecules, as well as lower concentration of the preservative benzalkonium chloride (0.001% vs. 0.005%), in comparison with some analogs, contribute to the rapid relief of discomfort in patients after phacoemulsification [6]. Ivinak is supplied with a strike-stop, which makes it easier for patients to use this medication, and as a result, increases patients' compliance.

CONCLUSIONS

1. In comparison with already available on the Russian market drugs, Ivinak®-SOLOpharm showed a comparable efficacy in the perioperative prevention of inflammatory processes in patients who underwent cataract phacoemulsification with intraocular lens implantation.

2. Eye drops Ivinak®-SOLOpharm are well tolerated and safe to use. During the study, patients did not reveal any case of side effects, poor tolerance, or allergic reactions to the drug.

3. Significant advantages over analogs are lower concentrations of preservative, and hydroxypropyl betadex in the composition of Ivinak®-SOLOpharm eye drops, as well as the vial with the strike-stop, so that the drug is used easily and safely.

4. It seems appropriate to recommend the use of the drug Ivinak®-SOLOpharm in a general ophthalmic surgical practice.

ADDITIONAL INFORMATION

Author contributions. All the authors confirm that their authorship complies with the international ICMJE criteria (all the authors have made a significant contribution to the development of the concept, research, and preparation of the article, read and approved the final version before its publication).

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

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AUTHORS' INFO

Yurii I. Pirogov, ophthalmologist;
address: 2 Kostyushko, Saint Petersburg, 196247, Russia;
ORCID: https://orcid.org/0000-0002-8791-5400;
e-mail: visus1@yandex.ru

Fedor N. Rozhdestvenskiy, ophthalmologist;
e-mail: fedor_keyer@mail.ru

Polina A. Dzitstsoeva, ophthalmologist;
e-mail: poli93@mail.ru

Aleksandra Yu. Artiushenko, ophthalmologist;
e-mail: bovykina@gmail.com

ОБ АВТОРАХ

***Юрий Иванович Пирогов,** врач-офтальмолог;
адрес: Россия, 196247, Санкт-Петербург, ул. Костюшко, д. 2;
ORCID: https://orcid.org/0000-0002-8791-5400;
e-mail: visus1@yandex.ru

Федор Николаевич Рождественский, врач-офтальмолог;
e-mail: fedor_keyer@mail.ru

Полина Аркадьевна Дзиццоева, врач-офтальмолог;
e-mail: poli93@mail.ru

Александра Юрьевна Артюшенко, врач-офтальмолог;
e-mail: bovykina@gmail.com

* Corresponding author / Автор, ответственный за переписку