BROMFENAC 0.09% OPHTHALMIC SOLUTION FOR POSTOPERATIVE PAIN AND OCULAR DISCOMFORT AFTER CATARACT SURGERY WITH PHACOEMULSIFICATION

Jana Simova, Mladena Radeva, Dimitar Grupchev, Christina Grupcheva

Department of Ophthalmology and Visual Sciences, Faculty of Medicine, Medical University of Varna

РЕЗЮМЕ

Цел: Да се изследват ефектите на бромфенак 0.09% (Bromfenac 0.09%) за очно приложение при лечение на боля и други очни симптоми след операция на катаракта.

Материали и методи: Проследени са 51 пациенти (61 очи), планирани за операция за отстраняване на катаракта чрез факоемулсификация. Те са случайно разпределени в две групи: в едната получават стандардната постоперативна локална терапия, а в другата е добавен бромфенак 0.09%. Всички пациенти попълват въпросници, касаещи локална болезненост и други очни симптоми, предоперативно и при три следоперативни визити. Резултатите са обработени чрез SPSS (v22.0) и поради липсата на нормално разпределение, данните са анализирани чрез методите на непараметричен анализ. Променливите са представени с техните медианни стойности, а нулевата хипотеза е тествана при доверителен интервал от 95% (CI=95%).

Резултати: В деня след операцията 80.8% от тестовата група дават оценка за зрението си “много добро” и “отлично”, докато 68.6 % от контролната са маркирали „добро” или по-висока. Средната субективна оценка за качеството на зрението е значимо по-висока за тестовата група в сравнение с контролната. Тази тенденция се запазва през цялата края на месеца, но разликата не е статистически значима. В деня след операцията 92.3% от тестовата група и 88.6% от контролната смятат зрението си за стабилно през повечето или през цялото време (p=0.05).

Заключение: Bromfenac 0.09% очни капки, в допълнение към стандартното постоперативно лечение, оказва добър ефективен и съществен облекчаване на постоперативния дискомфорт след неусложнена факоемулсификация, но и за по-бързото постигане на стабилна рефракция и зрелост функция след операция на катаракта. Успешният резултат не се ограничава само до добре извършена, неусложнена процедура за отстраняване на помътнената леща, въпреки леко опълчения и епизодически състояние функция на мазнините. Следващият важен аспект по отношение на бромфенак 0.09% е бележителноността на белезите, които може да допринесе за постигането на тази цел, освен ако не се допълнил добър риск.

Ключови думи: операция на катаракта, факоемулсификация, НСПВС, проследяване, възстановяване
ABSTRACT

Aim: The aim of this article is to study the effect of bromfenac 0.09% ocular solution on postoperative pain and other ocular symptoms after cataract surgery.

Methods: Sixty-one eyes of 51 patients undergoing uneventful cataract surgery with phacoemulsification technique were randomized to tobramycin 3 mg/mL-dexamethasone 1 mg/mL ophthalmic solution or with the adjunct of bromfenac 0.09% ophthalmic solution. All patients completed a questionnaire about pain and other ocular symptoms at baseline and at 3 postoperative visits. Statistical analysis was performed using SPSS statistics software package (v22.0) for Windows (IBM SPSS Inc., Chicago, IL.). On account of lack of normal distribution, a nonparametric analysis was conducted. Variables were compared by their medians and the null hypothesis was tested with a confidence level of 95% (CI=95%).

Results: On the first postoperative day 68.6% of controls assessed their vision as ‘good’ or better, while in the test group 80.8% chose ‘very good’ and ‘excellent’ from the questionnaire. A week later, the mean rank proportion remaining similar by the end of the follow-up period, the difference was not found to be statistically significant. On day 1, 88.6% of the control group and 92.3% of the treatment group stated that their vision was stable always or most of the time (p=0.05).

Conclusion: Bromfenac 0.09% ophthalmic solution in addition to standard postoperative topical treatment showed to be effective not only in alleviating ocular discomfort after uneventful cataract surgery, but in faster achievement of stability of refraction and overall visual function. The successful surgical outcome is not restricted only to a well-performed safe cataract removal, leading to the optimal refractive and visual result, it is also of significant importance to provide a painless, comfortable and satisfying postoperative period for the patient. This means that every therapeutic option, which can contribute to achieving this goal should be considered as long as it poses no risk.

Keywords: cataract surgery, phacoemulsification, NSAIDs, follow-up study, recovery

INTRODUCTION

Cataract, characterized by opacification of the crystalline lens, can markedly restrict the routine activities of patients, such as reading, writing, walking and eventually reduce the quality of life (1–3). Cataract is the leading cause of avoidable blindness worldwide (4–6). Despite some recent advances in the field of potential drug treatments, surgery is still acknowledged to be the most effective treatment option (7–10). Cataract surgery is one of the most frequently performed procedures (11–18). The successful surgical outcome is not defined solely by the safe removal of the opaque lens, but the essential goal is achievement of the best visual and refractive result with maximal postoperative comfort for the patient (19–23). The modern cataract surgery with phacoemulsification is considered a minor procedure with an uneventful and pain-free recovery period. However, there are few published studies focusing on the subjective complaints of patients and the reported data are conflicting (24). For instance, some publications reveal that up to 90% of the patients had postoperative ocular symptoms (25,26), whereas other studies announce that only a minority of the patients had any complaints (27,28). Ocular symptoms after cataract surgery could be related to the visual function: light sensitivity and unstable vision, or could concern physical sensation like pain, foreign body sensation, itching, burning, etc. A review of the published articles did not identify any studies where the primary outcome measure is the subjective assessment of patients after an uneventful cataract surgery. For that reason, we performed a prospective study in which the main goal was to evaluate...
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MATERIALS AND METHODS

Fifty-one adult patients with senile cataract, scheduled for surgery, were included in the current study. They underwent uneventful cataract surgery with phacoemulsification and IOL implantation, performed by the same experienced surgeon. A standardized technique, using corneoscleral tunnel incision, under local anesthesia was performed. No routine postoperative pain medication was prescribed, but patients were allowed to take paracetamol or metamizole if needed. Postoperative aftercare instructions were given according to the normal protocol of the hospital. After surgery a sterile eye patch was placed over the operated eye for 24 hours and taken off only for administration of the medication drops. The patients were randomly distributed into two groups. The first group (control group) received standard postoperative treatment, which included combined topical formulation antibiotic and steroid (tobramycin 3 mg/mL-dexamethasone 1 mg/mL, Tobradex, Alcon) 5 to 7 times during the first 24 hours and then 5 times a day for 30 days. The second group (test group) received topical nonsteroidal anti-inflammatory drug (Bromfenac 0.09%, Yellox, Croma-Pharma GmbH) along with the standard postoperative topical treatment, two times a day for one month. The study consisted of four visits, excluding the cataract surgery visit: baseline visit, on the day prior to surgery, and 3 postoperative visits. All patients were examined on the first day after surgery in order to rule out any early postoperative complications and to assess immediate postoperative visual outcome. The next visits were scheduled for the 7th and 30th day after surgery. All enrolled subjects gave written consent after receiving verbal information.

The data were collected using questionnaire, which was completed at baseline, 1 day, 1 week and 1 month after surgery. The questionnaire included questions concerning visual function and ocular sensation. Patients could rate their vision and vision stability using a five-point scale, where 2 = worst/very bad and 6 = best/excellent. Similar scale was used to assess light sensitivity, ocular discomfort (itching, burning, foreign body sensation) and pain, where 2 = worst/very bad and 6 = best/excellent. Safety and tolerability

None of the patients in the study had any adverse effects or complications from the medications used, which required their discontinuation.
me притеснява. Въпросништата се подробно разяснени на пациентите, а при нужда получават допълнително информация.
Резултатите са обработени чрез SPSS statistics software package (v22.0) for Windows (IBM SPSS Inc., Chicago, IL) и поради липса на нормално разпределение, данните са анализирани чрез метотите на непараметричен анализ. Всички променливи са представени с тежните медианни стойности, а нулевата хипотеза е тествана при доверителен интервал от 95% (CI=95%).

Безопасност и толерантност
При никого от пациентите не се установиха странични ефекти или усложнения във връзка с прилагането на медикамент, което да наложи преустановяването му.

РЕЗУЛТАТИ
Проследени са 51 пациента (61 очи): 23 мъже и 28 жени на възраст между 53 и 87 години (средно 72 год.). В първата група попадат 30 пациенти (35 очи) на възраст между 55 и 87 години (средно 73.89 год.), от които 13 жени и 17 мъже. Във втората група има 21 пациенти (26 очи) между 53 и 80 години (средно 67 год.), 9 са мъже и 12 жени. Данните, получени от анкетите, са анализирани и разделени в следните категории: зрение, стабилност на зрението, фотофобия, очен дискомфорт и болка.

RESULTS
In total, 61 eyes of 51 patients (23 men and 28 women, aged between 53 and 87 years (mean 72) were included in the present study. In the first group there were 35 eyes of 30 patients aged between 55 and 87 years (mean 73.89), of which 13 women and 17 men. The second group consisted of 26 eyes of 21 patients, aged between 53 and 80 years (mean 67), 9 of which were men and 12 women. The data collected from the questionnaire was analyzed and divided into the following categories: vision, vision stability, light sensitivity, ocular discomfort, and ocular pain.

Vision
At baseline, in 69.2% of the cases in the test group, vision was rated as ‘unsatisfying’ (‘poor’ or ‘very poor’), as opposed to 51.4% from the control group. On the first postoperative day in the test group, 80.8% chose ‘very good’ and ‘excellent’ from the questionnaire, while 68.6 % of controls assessed their vision as ‘good’ or ‘better’. A week later, the mean rank for vision was significantly higher for the treatment group compared to the control group and despite the proportion remaining similar by the end of the follow-up period, the difference was not found to be statistically significant (Kruskal Wallis test; \( p_{7th\ day} = 0.014, p_{30th\ day} = 0.08 \)).

The differences in the subjective assessment of patients’ vision could be explained by the disparity between best corrected distance visual acuity (BCVA) of the groups at baseline and the following visits. However, the Mann-Whitney U test did not
**Vision**

Preoperatively in 69.2% of cases from the test group and 51.4% from the control group were able to assess their vision as either “unsatisfactory” (poor” and “very poor”). After surgery, 80.8% of patients in the test group and 68.6% of patients in the control group were able to mark themselves “good” or “very good”. The average subjective visual quality rating for vision was significantly higher for the test group than the control group. Despite this trend, there was no statistically significant difference between the groups (Kruskal Wallis test; p<0.014, p<0.08).

Differences in ratings between the two groups may be explained by differences in average visual acuity (VA) in both groups prior to surgery and after surgery. However, nonparametric analysis (Mann-Whitney U test) did not reveal a statistically significant difference in VA distribution across groups on the first day after surgery (p<0.05).

**Vision Stability**

A total of 38.5% from the test group and 11.4% of controls reported unstable vision preoperatively. The positive ranks for stability of vision were comparable (p=0.531). On day 1, 92.3% of the treatment group and 88.6% of the control group stated their vision was stable all the time or most of the time. Small percentages of both groups complained their vision was unstable. Almost all of the patients in both groups had stable vision by the 30th postoperative day. According to the performed nonparametric analysis (Mann-Whitney U test) the difference in distribution across groups was statistically significant only on the first day after surgery (p=0.05).

<table>
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<td>30th day</td>
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**Table 1. BCVA measured at the four visits**

**Fig. 2. Subjective assessment (questionnaire-based) of visual stability of cataract patients.**

A) preoperatively; B) 1st day; C) 7th day; D) 30th day.
от тестовата група и 88.6% от контролната смятат зрението си за стабилно през повечето или през цялото време. Само малка част от пациентите от гвеме групи имат оплаквания от нестабилно зрение. Почти всички от пациентите споделят, че зрението им е стабилно винаги или през повечето време при последния постоперативен преглед. Според проведен непараметричен сравнителен анализ (Mann-Whitney U test) разликите в разпределението на отговорите между двете групи са статистически значими само през първия ден след операцията (p=0.05).

Фотофобия
При първия постоперативен преглед в 58% от тестовите случаи и в 54% от контролните пациенти имат оплаквания от фотофобия. Данните от седмия ден показват висока част от пациентите в 57% и 68% от случаите, а броят на месеца процентите са съответно 75% и 83%. Не се открива статистически значима разлика в разпределението на отговорите между гвеме групи при никой от визитите.

Light Sensitivity
A total of 58% of the cases among the test subjects and 54% of the controls reported no light sensitivity 24 hours after surgery. The results at the end of the first postoperative week showed 57% and 68% of the cases experienced no disturbance by the light, and by the end of the follow-up period the percentage was 75% and 83%, respectively. A statistically significant difference in the distribution of answers across groups was not found at any visit.

Ocular Discomfort
Various sensations and disturbances can be described as discomfort. Patients were asked about burning sensation, itching, foreign body sensation, dryness, etc. and the incidence of these was analyzed. On the first postoperative day, in 39% of the test group cases, patients had no troublesome sensations and the percentage rose to 70.8% by the end of the first week. For comparison, for the control group, lack of ocular discomfort of the described modalities was noted in 27% of the cases at day 1 and in 54% at day 7. At the last visit in 84% and 68% of the cases, respectively, the patients had no complaints whatsoever. There was no statistically significant difference between the two groups at any time.
Patients were asked about ocular pain, intensity, occurrence and duration. Interpretation of collected data showed that no significant pain was reported in any of the groups during the postoperative period. Moreover, there was no noteworthy difference between the results of the two groups: in approximately 75% of the cases on the first postoperative day and 92% at the end of the first week, patients did not experience any pain, and by the last follow-up visit all patients were pain-free.

**DISCUSSION**

Recording and objectification of subjective awareness and perception is a difficult task, since different approaches are needed for assessment of pain and other sensations. Moreover, patients undergoing cataract surgery are elderly individuals, who have different severity levels of dry eye and other ocular symptoms.

The anti-inflammatory effectiveness of topical nonsteroidal anti-inflammatory drugs (NSAIDs) (bromfenac 0.09% in particular) after ocular surgery has already been proved, as well as its pain-relieving effect during the postoperative period (27,29–33). Most of the studies are concentrated on documentation of the decrease of inflammation response in the anterior chamber.
ОБСЪЖДАНЕ
Обектноизмереното и документираното на субективната оценка и перцепция е сложна задача, тъй като са нужно размична подходи за определение на болката и възрастите други усещания. Допълнително затрупване възвикава от факта, че повечето пациенти с катаракта са във възрастни хора с различни степени на сухо око и други възрастови обусловени очни съвършения.

Противо-възпалителното действие на локалните НСПВС (в частност bromfenac 0.09%) след очна хирургия са добре известни, както и аналгетичният им ефект през постоперативния период (27,29–33). Повечето изследвания са насочени към демонстрирането на потискарането на възпалителния отговор в предна камера (ПК), а ефективността при облекчаването на болката е само допълнение (30,31,34,35). Целта на настоящото проучване е да се установи дали bromfenac 0.09% повлиява субективната оценка на пациентите за качествеността на зрението им, фотофобията, очния дискомфорт и болката след неусложнена фациохисуфакция и дали благоприятстват повишаването на качествеността на жилот през ранния постоперативен период.

В проучване от 2014 година (36) се посочва връзка между морфометричните изменения в роговицата и хирургично-преразглеждане на астигматизма след операция в ПК, а ефективността при облекчаването на болката е само допълнение (30,31,34,35). Целта на настоящото проучване е да се установи дали bromfenac 0.09% повлиява субективната оценка на пациентите за качествеността на зрението им, фотофобията, очния дискомфорт и болката след неусложнена фациохисуфакция и дали благоприятстват повишаването на качествеността на жилот през ранния постоперативен период.

Възможно предимство на добавянето на топични НСПВС е съкращаване на времето за възстановяване (39). Възможно предимство на добавянето на топични НСПВС е съкращаване на времето за възстановяване (39). Възможно предимство на добавянето на топични НСПВС е съкращаване на времето за възстановяване (39). Възможно предимство на добавянето на топични НСПВС е съкращаване на времето за възстановяване (39). Възможно предимство на добавянето на топични НСПВС е съкращаване на времето за възстановяване (39).
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REFERENCES


This additionally complicates the objective assessment and is a possible explanation for the widely varying reported results.

CONCLUSION

Bromfenac 0.09% ophthalmic solution, added to the standard postoperative topical treatment, showed to be effective not only in alleviating ocular discomfort after uneventful cataract surgery, but in faster achieving stability of refraction and overall visual function. The successful surgical outcome is not restricted only to a well performed safe cataract removal, leading to the optimal refractive and visual result, it is also of significant importance to provide a painless, comfortable and satisfying postoperative period for the patient. This means that every therapeutic option, which can contribute to achieving this aim should be embraced as long as it poses no risk.

REFERENCES


